# REGULATORY FRAMEWORK FOR GMOs IN INDIA

Project Coordinating and Monitoring Unit (PCMU)
Ministry of Environment & Forests

In association with
Biotech Consortium India Limited

2007

Compiled by :

Dr. Manoranjan Hota
Project Coordinator & Additional Director
MoEF

Dr. Vibha Ahuja
Deputy General Manager, BCIL
Biotech Consortium India Limited



Published 2006
Reprinted 2007

Soft copy available on
http://www.envfor.nic.in/divisions/csurv/biosafety/default.htm

Printed by Marshall Advertising Co.

## Contents

**G. BALACHANDHRAN**
**JOINT SECRETARY**
E-mail: gb-mef@nic.in
Tel: 011-24362551
Fax: 011-24360894

भारत सरकार
पर्यावरण एवं वन मंत्रालय
GOVERNMENT OF INDIA
MINISTRY OF ENVIRONMENT & FORESTS

## FOREWORD

Biosafety capacity building is of strategic importance particularly in view of increasing development and commercialization of genetically modified organisms and products thereof. The adoption and implementation of the Cartagena Protocol on Biosafety also requires significantly enhanced capacity among concerned stakeholders.Biosafety capacity building needs to be science-based, acknowledging the importance of achieving a balance between agricultural productivity and competitiveness and environmental concerns.

The GEF-World Bank capacity building project on biosafety,being implemented by Ministry of Environment and Forests is focussed on institutional strengthening, information dissemination and training. As part of the project activities, a Biosafety Information Kit has been prepared to provide basic information on GMOs, Regulatory Framework in India and Cartagena Protocol on Biosafety with an objective to serve as a knowledge support for various stakeholders. The CD provided in the kit contains full texts of the relevant rules and regulations and other useful information for ready reference. The Biosafety Information kit has been compiled by Dr. Manoranjan Hota, Additional Director, MoEF and Dr. Vibha Ahuja, Deputy General Manager, Biotech Consortium India Limited.

I am pleased to note that the kit has been widely circulated across the country and greatly appreciated by all concerned stakeholders.The information in the three books and the CD has now been updated and the complete kit reprinted. I.hope that this kit will help in further strengthening our efforts for information sharing and creating awareness among various stakeholders.

(G. BALACHANDHRAN)

# REGULATORY FRAMEWORK FOR GMOs IN INDIA

## INTRODUCTION

Biosafety concerns have led to the development of regulatory regimes in various countries for research, testing, safe use and handling of GMOs and products thereof. An overview of the regulatory framework in India governing GMOs and their applications particularly in agriculture is given below:

## RULES FOR GMOs

Ministry of Environment & Forests, Government of India notified the rules and procedures for the manufacture, import, use, research and release of GMOs as well as products made by the use of such organisms on December 5, 1989 under the Environment (Protection) Act, 1986 (EPA) (Annex). These rules and regulations, commonly referred as Rules 1989 cover areas of research as well as large scale applications of GMOs and its products. These Rules are implemented by the Ministry of Environment & Forests and the Department of Biotechnology, Government of India. Six Competent Authorities and their composition have been notified under these Rules which are as follows:

i. Recombinant DNA Advisory Committee (RDAC)
ii. Institutional Biosafety Committees (IBSC)
iii. Review Committee on Genetic Manipulation (RCGM)
iv. Genetic Engineering Approval Committee (GEAC)
v. State Biosafety Coordination Committees (SBCC)
vi. District Level Committees (DLC).

While the RDAC is of advisory in function, the IBSC, RCGM, and GEAC are of regulatory function, SBCC and DLC are for monitoring purposes.

(i) **Recombinant DNA Advisory Committee (RDAC):** This committee constituted by the Department of Biotechnology takes note of developments in biotechnology at national and international levels. The RDAC recommendations include, from time to time, the technologies/processes suitable for implementation for upholding the safety regulations in research and applications of GMOs and products thereof. This Committee prepared the Recombinant DNA Biosafety Guidelines in 1990, which was adopted by the Government for conducting research and handling of GMOs in India.

(ii) **Institutional Biosafety Committee (IBSC):** It is necessary that each institution intending to carry out research activities involving genetic manipulation of microorganisms, plants or animals should constitute the IBSC. All the IBSCs, inter alia, need to have one nominee from the DBT. The IBSC is the nodal point for interaction within the institution for implementation of the guidelines. The main activities of IBSCs are:

- To note and to approve r-DNA work.
- To ensure adherence of r-DNA safety guidelines of government.
- To prepare emergency plan according to guidelines.
- To recommend to RCGM about category III risk or above experiments and to seek RCGM's approval.
- To inform DLC and SBCC as well as GEAC about the experiments where ever needed.
- To act as nodal point for interaction with statutory bodies.
- To ensure experimentation at designated locations, taking into account approved protocols.

(iii) **Review Committee on Genetic Manipulation (RCGM):** The RCGM functions as a body under the Department of Biotechnology and has the following functions:

- To bring out manuals of guidelines specifying producers for regulatory process on GMOs in research, use and applications including industry with a view to ensure environmental safety.
- To review all on going r-DNA projects involving high risk category and controlled field experiments.
- To lay down producers for restriction or prohibition, production, sale, import & use of GMOs both for research and applications.
- To permit experiments with category III risks and above with appropriate containment.
- To authorize imports of GMOs/ transgenes for research purposes.
- To authorize field experiments in 20 acres in multi-locations in one crop season with up to one acre at one site.
- To generate relevant data on transgenic materials in appropriate systems.

- To undertake visits of sites of experimental facilities periodically, where projects with biohazard potentials are being pursued and also at a time prior to the commencement of the activity to ensure that adequate safety measures are taken as per the guidelines.

(iv) **Genetic Engineering Approval Committee (GEAC):** Genetic Engineering Approval Committee (GEAC) functions as a body under the Ministry of Environment and Forests and is responsible for approval of activities involving large scale use of hazardous microorganisms and recombinant products in research and industrial production from the environment angle. GEAC, *inter alia*, has the following functions:

- To permit the use of GMOs and products thereof for commercial applications.
- To adopt producers for restriction or prohibition, production, sale, import & use of GMOs both for research and applications under Environment (Protection)Act, 1986..
- To authorize large-scale production and release of GMOs and products thereof into the environment.
- To authorize agencies or persons to have powers to take punitive actions under the under Environment (Protection)Act, 1986.

(v) **State Biotechnology Coordination Committee (SBCC):** SBCC is constituted in each State where research and applications of GMOs are contemplated. SBCC is headed by the Chief Secretary of the State and has the following functions:

- Powers to inspect, investigate and to take punitive action in case of violations of statutory provisions through the State Pollution Control Board or the Directorate of Health etc.
- To review periodically the safety and control measures in various institutions handling GMOs.
- To act as nodal agency at State level to assess the damage, if any, due to release of GMOs and to take on site control measures.
- The Committee coordinates the activities related to GMOs in the State with the Central Ministries. This committee also nominates State Government representatives in the activities requiring field inspection of activities concerning GMOs.

(vi) **District Level Committee (DLC):** This Committee, constituted at the district level, is considered to be smallest authoritative unit to monitor the safety regulations in installations

engaged in the use of GMOs in research and applications. The DLC is headed by the District Collector who can induct representatives from State agencies to enable smooth functioning and inspection of the installations with a view to ensure the implementation of safety guidelines while handling GMOs, under the Indian EPA. Its functions are:

- ❖ To monitor the safety regulations in installations.
- ❖ Has powers to inspect, investigate and report to the SBCC or the GEAC about compliance or non compliance of r-DNA guidelines or violations under EPA.
- ❖ To act as nodal agency at District level to assess the damage, if any, due to release of GMOs and to take on site control measures.

In addition, Monitoring and Evaluation Committee set up by RCGM visits field trial sites and recommends safe and agronomically viable transgenic crops to RCGM/GEAC.

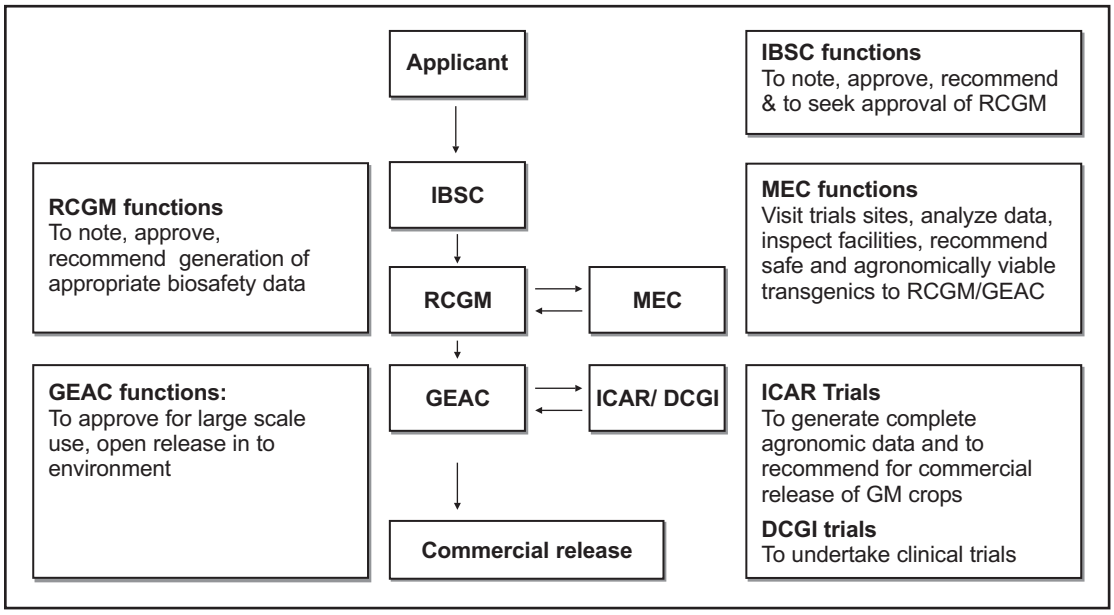
The notification orders compliance of the safeguards through voluntary as well as regulatory approach and any violation and non-compliance including non-reporting of the activity in this area would attract punitive actions provided under the EPA.

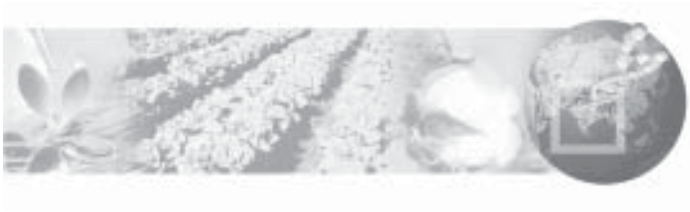
The approvals and prohibitions under Rules 1989 are summarized below:

- No person shall import, export, transport, manufacture, process, use or sell any GMOs, substances or cells except with the approval of the GEAC.
- Use of pathogenic organisms or GMOs or cells for research purpose shall be allowed under the Notification, 1989 of the EPA, 1986.
- Any person operating or using GMOs for scale up or pilot operations shall have to obtain permission from GEAC.
- For purpose of education, experiments on GMOs IBSC can look after, as per the guidelines of the Government of India.
- Deliberate or unintentional release of GMOs not allowed.
- Production in which GMOs are generated or used shall not be commenced except with the approval of GEAC
- GEAC supervises the implementation of rules and guidelines.
- GEAC carries out supervision through SBCC, DLC or any authorized person.

- If orders are not complied, SBCC/DLC may take suitable measures at the expenses of the person who is responsible.
- In case of immediate interventions to prevent any damage, SBCC and DLC can take suitable measures and the expenses incurred will be recovered from the person responsible.
- 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:
    i. Any new information on harmful effects of GMOs.
    ii. GMOs cause such damage to the environment as could not be envisaged when approval was given.
    iii. Non-compliance of any conditions stipulated by GEAC.

To summarize, under Rules, 1989, IBSC, RCGM and GEAC are involved in approval process of LMOs/GMOs and SBCC and DLC have monitoring functions. The procedures involved in the approval of GMOs in India are summarized below:





## RECOMBINANT DNA GUIDELINES, 1990

With the advancement of research work initiated in biotechnology in the country by various Indian institutions and industry, Department of Biotechnology had formulated Recombinant DNA Guidelines in 1990. These guidelines were further revised in 1994. The revised guidelines includes 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 issues relating to genetic engineering of human embryo, use of embryos and fetuses in research and human germ line, and gene therapy areas have not been considered while framing the guidelines.

The research activities have been classified into three categories based on the level of the associated risk. Accordingly, the requirement for the approval of competent authority is envisaged. Category I activities include those experiments involving self cloning using strains and also inter-species cloning belonging to organism in the same exchanger group which are exempt for the purpose of intimation and approval of Competent Authority. Category II activities which require prior intimation of Competent Authority and include experiments falling under containment levels II, III and IV (details of each containment level provided separately in the guidelines). Category III activities that require review and approval of competent authority before commencement include experiments involving toxin gene cloning, cloning of genes for vaccine production, and other experiments as mentioned in the guidelines. 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. The guidelines enumerate the concept of physical and biological containment and the principles of good laboratory practices. For containment facilities and biosafety practices, recommendations of the WHO laboratory safety manual on genetic engineering techniques involving microorganisms of different risk groups have been incorporated therein.

For large scale experiments, the guidelines categorize experiments beyond 20 liters capacity for research and industrial purposes as large-scale experiments/operations. In case of plants, this limits is beyond 20 acres area. The guideline gives principles of occupational safety and hygiene for large-scale practice and containment. Safety criteria have also been defined in the guidelines. Physical containment conditions that should be ensured for large-scale experiments and production have been specified in the guidelines.

The guidelines require the interested party to evaluate GMOs for potential risk prior to application

in agriculture and environment i.e properties of the organism, possible interaction with other disease causing agents and the infected wild plant species. An independent review of potential risks should be conducted on a case-to-case basis.

Details of the guidelines may be seen at www.dbtbiosafety.nic.in

## REVISED GUIDELINES FOR RESEARCH IN TRANSGENIC PLANTS, 1998

In 1998, DBT brought out separate guidelines for carrying out research in transgenic plants called the "Revised Guidelines for Research in Transgenic Plants". These also include the guidelines for toxicity and allergenicity of transgenic seeds, plants and plant parts.

These guidelines cover areas of recombinant DNA research on plants including the development of transgenic plants and their growth in soil for molecular and field evaluation. The guidelines also deal with import and shipment of genetically modified plants of research use.

The genetic engineering experiments on plants have been grouped under three categories. Category I includes routine cloning of defined genes, defined non-coding stretches of DNA and open reading frames in defined genes in *E.coli* or other bacterial/fungal hosts which are generally considered as safe to human, animals and plants. The category II experiments include experiments carried out in lab and green house/net house using defined DNA fragments non-pathogenic to human and animals for genetic transformation of plants, both model species and crop species. Category III includes experiments having high risk where the escape of transgenic traits into the open environment could cause significant alterations in the biosphere, the ecosystem, plants and animals by dispersing new genetic traits the effects of which cannot be judged precisely. Further this also includes experiments conducted in green house and open field conditions having risks mentioned above.

To monitor over a period of time, the impact of transgenic plants on the environment, a special Monitoring cum Evaluation Committee (MEC) has been set up by the RCGM. The committee undertakes field visits at the experimental sites and suggests remedial measures to adjust the trial design, if required, based on the on-the-spot situation. This committee also collects and reviews the information on the comparative agronomic advantages of the transgenic plants and advises the RCGM on the risks and benefits from the use of transgenic plants put into evaluation.

The guidelines include complete design of a contained green house suitable for conducting

research with transgenic plants. Besides, it provides the basis for generating food safety information on transgenic plants and plant parts.

Deatils of the guidelines may be seen at www.dbtbiosafety.nic.in

## SEED POLICY, 2002

Seed Policy, 2002, has a separate section (No. 6) on transgenic plant varieties which states that all genetically engineered crops/varieties will be tested for environment and biosafety before their commercial release as per the regulations and guidelines under the EPA, 1986. Seeds of transgenic plant varieties for research purposes will be imported only through the National Bureau of Plant Genetic Resources (NBPGR) as per the EPA, 1986. Transgenic crops/varieties will be tested to determine their agronomic value for at least two seasons under the All India Coordinated Project Trials of ICAR, in coordination with the tests for environment and bio-safety clearance as per the EPA before any variety is commercially released. Once the transgenic plant variety is commercially released, its seed will be registered and marketed in the country as per the provisions of the Seeds Act. The performance of the commercially released variety in the field will be monitored for at least 3 to 5 years by the Ministry of Agriculture and State Departments of Agriculture.

It has also been mentioned that transgenic varieties can be protected under the Plant Varieties & Farmers Rights Protection (PVP) legislation in the same manner as non-transgenic varieties after their release for commercial cultivation.

## THE FOOD SAFETY AND STANDARDS ACT, 2006

The Ministry of Food Processing Industries has introduced "The Food Safety and Standards Act, 2006" which seeks to consolidate the laws relating to food and establish the "Food Safety and Standards Authority of India". This step has been taken keeping in view the fact that presently eight ministries are administering food laws in diverse ways, which has been found to be not conducive to the growth of the food processing industry.

The "Food Safety and Standards Authority of India" would facilitate scientific standards for food articles and regulate their manufacture, storage, distribution, sale and import to ensure the availability of safe and wholesome food for human consumption. The authority will consist of members from various ministries, and representatives from State Governments, the food industry, consumer organisations and even farmers' organisations. Scientific committees

and panels will assist it in fixing standards, while a Central Advisory Committee will prioritise the work.

The enforcement of the legislation will be through the State Commissioner for Food Safety and Panchayati Raj/municipal bodies. The Food Act not only incorporates the salient provisions of the Prevention of Food Adulteration (PFA) Act, but is also based on international legislations, instrumentalities and Codex Alimentaries Commission (related to food safety norms).

The Food Authority will regulate the limits on the usage of food additives, crop contaminants, pesticide residues, heavy metals, processing aids, myco-toxins, antibiotics and pharmacological active substances.

It will formulate mechanisms and guidelines for the accreditation of bodies engaged in the certification of a food safety management system for the food business. It will also set up food labelling standards, including claims on health, nutrition and special dietary uses. The Act seeks to regulate nutraceuticals and dietary supplements. It has stressed on proper labelling and has said that information should not be misleading. Imposing restrictions on advertising, it specifies, "No advertisement shall be made of any food, which is misleading or contravenous to the provisions of this Act." The Act has imposed safeguards on imports of food products. No person shall be allowed to import unsafe, misbranded or sub-standard food and importing would require a license. Stringent penalties have also been included in the Act.

The Act also moots the establishment of a Food Safety Appellate Tribunal to hear the appeals of disputed parties.

The "genetically modified food" has been defined in the Act 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.

There is a provision for a separate scientific panel on genetically modified organisms. No person shall manufacture, process, export, import or sell genetically modified articles of food, organic foods, functional foods, neutraceuticals, health supplements etc. except in accordance with the regulations made there for under this Act.

Acts/Orders which would stand repealed on commencement of this Act, include the Prevention

of Food Adulteration Act 1954, and few other orders relating to food include orders issued under the Essential Commodities Act, 1955.

Details may be seen at www.mofpi.nic.in

## PLANT QUARANTINE ORDER, 2003

The provisions of Plant Quarantine (Regulation of Import into India) Order 2003, which came into force from April 1, 2004, are also applicable to import of transgenic seeds. The issuance of import permit of transgenic material is extremely important from the point of view of their potential impact on environment and on agriculture in the country. National Bureau of Plant Genetic Resources (NBPGR) has been designated as the Competent Authority to issue import permits for import of seeds by public and private sector agencies for research purposes after getting permission from DBT and MoEF as the case may be under Rules 1989..

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. These two documents must accompany with every seed/ plant consignment imported from abroad. NBPGR has been authorized to issue Import Permit on the basis of import permission from DBT and receive imported materials from custom authorities for its quarantine inspection and clearance on a prescribed application form. The Import Permit is valid for six months. the indentor, before obtaining import permit, should furnish all information on safety point of view and provide an undertaking as well as certificate from the supplier in accordance with paras 4 and 5 of the permission accorded by the DBT. The details of paras 4 and 5 are given below.

**Para No.4**

- No transgenic material is permitted for experimentation in open environment without prior authorisation from the Government of India.
- Full account of transgenic plants raised from the imported seeds is to be kept in a bound book, which should he available for inspection by the authority in case such a need arises.
- All transgenic materials prescribed by he indentors may be available for inspection, whenever required.
- All the unwanted transgenic materials may be destroyed by burning after the experiments are conducted.

- All precautions would be taken to prevent the escape of the genetic material into the open environment and shall follow the Recombinant DNA Safety Guidelines of the Government of India.

**Para No.5**

- The supplier of the transgenic material shall certify that the transgenic has the genes as has been described in the permission.
- The supplier shall also certify that these transgenic materials do not contain any embryogenesis deactivator gene sequence.

The second mandatory requirement is that of Phytosanitary Certificate which is to be issued by the National Plant Protection Agency of the donor country.

All indents for import of transgenics are registered for assigning the case number and then forwarded to the Plant Quarantine (PQ) Division without opening the parcel alongwith duly filled Import Quarantine (IQ) form for detailed quarantine inspection and clearance. After clearance from PQ Division. the Samples are first arranged taxonomically indicating their genus, species. common name and cultivar name etc. for national accessioning in the national record. Each introduction/ accession is assigned an EC (Exotic Collection) number which remains unchanged with information like name and address of donors, characteristics of the germplasm, relevant references. date of arrival, condition of the material and distribution of the materials. All assembled healthy plant material is regularly transmitted to various researchers to make use of these valuable genetic resources.

Details may be seen at www.plantquorantineindia.org.

## REGULATION FOR IMPORT OF GM PRODUCTS UNDER FOREIGN TRADE POLICY (2006-07)

On 7th April 2006, the Ministry of Commerce and Industry through Director General of Foreign Trade (DGFT) has notified new regulation for import of GM products by amending Schedule - I (Imports) of the ITC(HS) Classifications of Export and Import Items, 2004-09 under the Foreign Trade Policy (2004-09) to be effective from 1st April 2006. As a result of this notification, following items relevant to GMOs have been inserted in Chapter 1A : General Notes regarding Import Policy:

"18. Import of Genetically Modified Food, Feed, Genetically Modified Organism (GMOs) and Living Modified Organisms (LMOs) will be subject to the following conditions:

(a) 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.

(b) 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).

(c) 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 Bio-Technology. In case the Companies / Institutes use these Genetically Modified material for commercial purposes, approval of GEAC is also required.

(d) 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.

As a result of these changes, all applications for bulk import of GM food, feed, raw or processed or any ingredient of food, food additives or any food product that contains GM materials will now be approved by GEAC. It is now mandatory on the part of importers to get approval from GEAC prior to import of GM products such as GM Soya oil. Further all the GM products/ ingredients have to carry a declaration stating that the product is Genetically Modified at the time of import.

## NATIONAL ENVIRONMENT POLICY, 2006

MoEF has released the Draft Environment Policy in December 2004. The actions proposed in the policy include reviewing of the regulatory processes for LMOs so that all relevant scientific knowledge is taken into account, and ecological, health, and economic concerns are adequately addressed. Periodically review of the National Bio-safety guidelines and Bio-safety Operations Manual has been suggested to ensure that these are based on current scientific knowledge and ensuring the conservation of bio-diversity and human health when dealing with LMOs in transboundary movement in a manner consistent with the Multilateral Bio-safety Protocol.

The policy lays major emphasis on environmental awareness, education and information which is essential not only to harmonize patterns of individual behaviour with the requirements of environmental conservation but would also minimize the demands placed on the monitoring and enforcement regimes; in fact, large-scale non-compliance would simply overwhelm any feasible regulatory machinery.

The suggested actions would include mainstreaming scientifically valid environment content in the curricula of formal education, at primary, secondary, tertiary, and professional levels, focusing on the content appropriate at each stage, and without increasing the course load overall. Special mid-career training programmes may be conducted for groups with special responsibilities, e.g. the judiciary, policy makers, legislators, industrial managers, city and regional planners, voluntary and community based organizations, etc. It is proposed to prepare and implement a strategy for enhancing environmental awareness among the general public, and special groups, by professional production and airing of information products through diverse media catering to the different target groups. The production, as well as dissemination may involve public, private, and voluntary agencies.

Details may be seen at www.envfor.nic.in

## TASK FORCE ON APPLICATION OF AGRICULTURAL BIOTECHNOLOGY (2005)

Ministry of Agriculture had set up a Task Force under the chairmanship of Prof. M.S. Swaminathan, Chairman, MSSRF to formulate a draft long-term policy on applications of biotechnology in agriculture and suggest modifications in the existing administrative and procedural arrangements for the approval of GM crops. The report covered issues related to biotechnology applications in agriculture, animal husbandry and fishery sectors. It has been suggested that transgenic approach should be considered as complimentary and resorted to when other options to achieve the desired objectives are either not available or not feasible. There is a need to priortise and reor atters relating to agricultural biotechnology, the task force report has indicated that an effective communication strategy must be developed and a cohesive mechanism established to ensure that messages are consistent with National policy on agricultural biotechnology and also that all target groups are reached. Education and development communication must receive high priority. Field research may be required to ensure that the concerns of various groups of population are understood and addressed to see that the messages are evidence based, simple and effective.

The issues in regard to the release of GM crops are not understood correctly owing to the lack of information on this subject even amongst the otherwise well-informed members of the public. An information campaign needs to be conducted to generate public awareness on the benefits and risks associated with biotechnology and the social, ethical, economic, scientific, environmental and health issues which are addressed by regulatory bodies before allowing the cultivation of GM crops.

Active cooperation of various scientific organizations/institutions/ universities/NGOs may be sought to generate public awareness in the country on the following specific aspects of agricultural biotechnology:

- Concept of plant breeding, pressures on modern plant breeding and the need for novel genetic enhancement strategies
- Introduction to genetic engineering technology
- The benefits, risks and constraints of agricultural biotechnology
- Current status of national and global GM crops and other biotechnological applications in agriculture
- Risk assessment procedures (regulatory mechanisms) for environmental and food safety, and related legislations
- Social, economic, ethical, scientific, environmental and health issues which are addressed by regulatory bodies before allowing release of GM crops.
- Current GM products under evaluation in India under biosafety, VCU and other regulatory trials
- Community and Farmers' Rights and benefit sharing related to agro-biotechnological applications

Post-release monitoring and management of GM crops and their products, such as insect resistance management, transgene stability at the farm level, use of transgenic diagnostic kits, and maintenance of transgenic seed quality, should be organized with effective involvement of State Level and District Level Coordination Committees of the existing transgenic biosafety evaluation and management mechanism.

Details may be seen at www.agricoop.nic.in

## DRAFT NATIONAL BIOTECHNOLOGY DEVELOPMENT STRATEGY (2005)

DBT has brought out a National Biotechnology Development Strategy in 2005 which covers regulatory mechanisms as well. The policy indicates that it has to be ensured that research and application in biotechnology is guided by a process of decision-making that safeguards both human health and the environment with adherence to the highest ethical standards.

Choices are required to be made that reflect an adequate balance between benefit, safety, access and the interest of consumers and farmers. It is also important that biotechnology products that are required for social and economic good are produced speedily and at the lowest cost. It stresses on a scientific, rigorous, transparent, efficient, predictable, and consistent regulatory mechanism for biosafety evaluation and release system/protocol for achieving these multiple goals. Strategic actions include the implementation.

(i) It is proposed to set up an inter-ministerial group chaired by a reputed scientist to address anomalies and issues that arise in regulation from time to time. The mandate of the committee should be to vet any changes in policies, procedures, protocols by departments dealing with regulation in biotech products and processes; resolve issues emanating from the overlapping/conflicting rules in various acts related to regulation of biotechnology activities in research and development, import, export, releases etc. and to review guidelines, protocols, standard operating procedures and ensure their dissemination to all stakeholders from time to time.

(ii) It is proposed to establish a competent single National Biotechnology Regulatory Authority with separate divisions for agriculture products/transgenic crops, pharmaceuticals/drugs and industrial products; and transgenic food/feed and transgenic animals/aqua culture. The authority is to be governed by an independent administrative structure with common chairman. The inter-ministerial group will evolve suitable proposals for consideration of the government.

(iii) A centre for in-service training of all professionals, irrespective of their location, engaged in the regulatory process to be established by the Department of Biotechnology in close collaboration with other concerned departments and institutions.

(iv) All existing guidelines are to be updated and made consistent with the recommendations of the Swaminathan and Mashelkar committees in 2005. New guidelines on transgenic

research and product/process development in animal, aqua culture, food, phyto-pharma and environmental application to be put in place in 2005 by the concerned ministries/ departments

(v) As an interim measure, a special regulatory cell will be created by the DBT to build capacity in the country for scientific risk assessment, monitoring and management, to foster international linkages, support biosafety research; to obtain and review feedback from different stakeholders and provide support to industry and R&D institutions. This cell will only have a promotional and catalytic role

Regarding public communication and participation proposed strategic actions include providing credible information based on scientific data, training media personnel through Institutes of Mass Communication, colleges of journalism and others and capacity building among extension personnel in agricultural, fisheries, veterinary and medical sectors.

Involvement of *Panchayati Raj* institutions in the process of analysis and understanding the risks and benefits associated with GMOs has been suggested as they will be playing an important role in the local level management of bio-diversity, access to benefit sharing etc.

Awareness generation among undergraduate and post-graduate students in universities, colleges etc on issues related to biosafety and promoting a genetic literacy movement within government and public schools through 50 genome club nature clubs each year are some of other recommendations.

It has been proposed to create a media resource network to facilitate access to information and empower policy makers by participation in regular training programs.

Details may be seen at www.dbtindia.nic.in

## TASK FORCE ON R-PHARMA

To streamline the regulatory process in respect of the r-Pharma Sector under the Rules, 1989, the MoEF had constituted a Task Force on Recombinant Pharma Sector under the Chairmanship of Dr R A Mashelkar, Director General, CSIR. The mandate of the Task Force was to review the current framework and recommend a transparent and streamlined regulatory mechanism and process for the use of Living Modified Organisms (LMOs) in the pharmaceutical industry during the various stages of R & D, testing, manufacture and import of LMOs as drugs.

The recommendations and procedures outlined by the Task Force have been adopted by the Government of India and shall be in force from 1st April 2006 and shall be applicable in respect of recombinant Pharma products under Rules 1989.

As per the report, the product where the end product is a LMO has the potential for propagating/ replicating in the environment and therefore needs a higher level of regulation as compared to products derived from LMOs where the end product is not a LMO. Further the magnitude and probability of environmental risk depends on the extent of use of LMOs within the R&D and production units. In case of imports this risk is not there especially in cases of import of therapeutic proteins in finished form. Further taking into consideration the regulatory objectives of RCGM, GEAC and DCGI and the risks involved in the use of LMOs during the research & product development, manufacture and import from the environmental angle, the Task Force has rationalized the regulatory procedure for five categories.

a. Indigenous product development, manufacture and marketing of pharmaceutical products derived from LMOs but the end product is not a LMO

b. Indigenous product development, manufacture and marketing of pharmaceutical products where the end product is a LMO

c. Import and marketing of LMOs as Drugs/Pharmaceuticals in finished formulations where the end product is a LMO

d. Import and marketing of LMOs as Drugs/Pharmaceuticals in bulk for making finished formulation where the end product is a LMO

e. Import and marketing of products derived from LMOs as Drugs/Pharmaceuticals in bulk and/or finished formulations where the end product is not a LMO.

Detailed report is available at http:// www.envfor.nic.in

## REPORT OF THE SUB-COMMITTEE ON Bt COTTON AND RELATED ISSUES, 2006

The Ministry of Environment & Forests, Government of India had constituted a sub-committee on Bt cotton under the Chairmanship of Dr C. D. Mayee, Chairman ASRB, and Co-Chair GEAC, to look into the existing processes, protocols and other related issues and give recomendations for retionalization of the same.

The committee analyzed the constraints in the current regulatory framework such as a case-by-case approval, which follows extensive testing under RCGM/GEAC/ICAR trials even if the hybrid contains a gene/event cleared from biosafety angle, limited parameters being conducted while selecting hybrids, non planting of refugia and issues regarding affordable prices.

Major recommendations of the commitee are as follows:

a) The committee recommends 'an event based approval system' i.e., extensive biosafety and agronomic testing not necessary for approved gene/event.
b) Due consideration for the agronomic value of the hybrid should be given.
c) For sale/commercialization of any transgenic hybrids/varieties testing by ICAR is anot mandatory for an approved event that has been declared bio-safe and being cultivated extensively.
d) Involvement of the SAUs and State Agriculture Department to monitor the performace of the agricultural crops in their jurisdiction.
e) Need to strengthen the enforcement mechanism, dissseminate information regarding the field trials and enhance the awareness and extension work at the field level.
f) Responsibility of both pre and post release monitoring should be entrusted to the State Agricultural University (SAU) under the direct supervision of Director of Research and Director of Agriculture Extension respectively of each SAU.
g) To review alternatives with respect to refugia, IRM practice, IPM strategy, appropriate packaging practice etc.
h) While considering the parameters for deciding the superiority of the hybrids it may be compared with the released non-Bt hybrids check of respective group viz., early/medium/late and the candidate checks may be declared from time to time. For judging fiber quality of a hybrid, CIRCOT guidelines/norms should be followed.
i) Other recommendations are related to issues such as strengthening the enforcement mechanism to address various issues reported by the NGOs, permission for LST/Commercial release based on agro-climate conditions rather than the zonal concept as recommended by ICAR and rationalization of Biosafety studies with a view to promote the development of transgenic crops from public institutions.

Detailed information of the sub-committee report may be seen at http://www.envfor.nic.in

## NOTIFICATIONS ON QUALITY CONTROL OF GM CROPS

Various notifications have been issued by Ministry of Environment and forests and Ministry of agriculture to ensure the seed quality of GM crops particularly Bt cotton as detailed below:

1) **MoEF Notifications for Quality Control in Transgenic Seeds**

As the Seeds Act, 1966 does not cover trnsgenic seeds, there were difficulties faced by State Department of Agriculture in the quality enforcement of the Bt cotton seeds. The Department of Agriculture and Cooperation, Ministry of Agriculture, therefore, had requested the Ministry of Environment and Firests to notify the Seed Inspectors under Section 13 pf the Seeds Act and Section 12 of the Seeds (Control) Order to draw the seed samples of transgenic seeds as mentioned under Section 10 of the Environment (Protection) Act, 1986. Ministry of Environment & Forests in consultation with Ministry of Law & Justice has issues six Gazette Notifications (G.S.R. 584 (E) to 589(E) dated September 1, 2006) wherein Seeds Inspectors have been given adequate power to draw seed samples of transgenic seeds for the purpose of quality control and to get it tested in the notified seed testing laboratories and prosecute in case of spurious Bt cotton seeds. With the promulgation of the said notifications, the seed law enforcement agencies are empowered to take necessary punitive action against the offenders.

ii) **Referral Laboratory for Bt Cotton**

Ministry of Agriculture has issued a Notification on November 12, 2003 nominating Central Institute of Cotton Research (CICR) to act as a referral laboratory for ascertaining the presence or absence of cry1Ac gene in cotton seeds for the whole of India.

iii) **Purity of Bt Cotton Seeds**

In addition to the above, Seeds Division has issued minimum limits of purity in respect of Bt cotton seeds as 90% (Bt. Protein-toxin) under Section 6 of the Seeds Act, 1966 in the Gazette Notification issued vide SO No. 1567 (E) dated 5th November, 2005.

Annex

**MINISTRY OF ENVIRONMENT & FORESTS**

**NOTIFICATION**

**New Delhi, the 5th December, 1989**

## RULES FOR THE MANUFACTURE, USE/IMPORT/EXPORT AND STORAGE OF HAZARDOUS MICRO ORGANISMS/ GENETICALLY ENGINEERED ORGANISMS OR CELLS

**(To be notified under the EP Act, 1986)**

G.S.R. 1037 (E).- In exercise of the powers conferred by sections 6,8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) and with a view to protecting the environment, nature and health, in connection with the application of gene technology and micro-organisms, the Central Government hereby makes the following rules, namely:-

### 1. SHORT TITLE, EXTENT AND COMMENCEMENT

(1) These rules may be called the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous micro-organisms/Geneti-cally engineered organisms or cells.

(2) These rules shall come into operation on the date to be notified for this purpose in the Official Gazette.

### 2. APPLICATION

(1) These rules are applicable to the manufacture, import and storage of micro-organisms and Gene-Technological products.

(2) These rules shall apply to genetically engineered organisms/micro-organisms and cells and correspondingly to any substances and products and food stuffs, etc., of which such cells, organisms or tissues hereof form part.

(3) These rules shall also apply to new gene technologies apart from those referred to in clauses (ii) and (iv) of rule 3 and these rules shall apply to organisms /micro-organisms and cells generated by the utilisation of such ether gene-technologies and to substances and products of which such organism and cells form part.

(1) These rules shall be applicable in the following specific cases:

(a) sale, offers for sale, storage for the purpose of sale, offers and any kind of handling over with or without a considera-tion:

(b) exportation and importation of genetically engineered cells or organisms:

(c) production, manufacturing, processing, storage, import, drawing off, packaging and repackaging of the Genetically Engi-neered Products:

(d) production, manufacture etc. of drugs and pharmaceuticals and food stuffs distilleries and tanneries, etc. Which make use of micro-organisms/ genetically engineered microorganisms one way or the other.

(4) These rules shall be applicable to the whole of India.

## 3. DEFINITIONS

In these rules unless the context requires.

(i) "Biotechnology" means the application of scientific and engineering principles to the processing of materials by biologi-cal agents to produce goods and services;

(ii) "Cell hybridisation" means the formation of live cells with new combinations of genetic material through the fusion of two or more cells by means of methods which do not occur naturally;

(iii) "Gene Technology" means the application of the gene tech-nique called genetic engineering, include selfcloning and dele-tion as well as cell hybridisation;

(iv) "Genetic engineering" means the technique by which herita-ble material, which does not usually occur or will not occur naturally in the organism or cell concerned, generated outside the organism or the cell is inserted into said cell or organism. It shall also mean the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material;

(v) "microorganisms" shall include all the bacteria, viruses, fungi, mycoplasma, cell lines, algae, protodoans and nematotes indicated in the schedule and those that have not been presently know to exist in the country or not have been discovered so far.

## 4. COMPETENT AUTHORITIES

(1) **Recombinant DNA Advisory Commit-tee (RDAC):** This committee shall review developments in Biotechnology at national and international levels and shall recommend suitable and appropriate safety regulations for India in recombinant research, use and applications from time to time. The Committee shall function in the Department of Biotechnology.

(2) **Review Committee on Genetic Manipulation (RCGM):** This committee shall function in the Department of Biotechnology to monitor the safety related aspects in respect of on-going research projects and activities involving genetically engineered organisms/hazardous microorganisms. The Review Committee on Genetic Manipulation shall include representatives of (a) Depart-ment of Biotechnology (b) Indian Council of Medical Research (c) Indian Council of Agricultural Research (d) Council of Scientific and Industrial Research (e) other experts in their individual capacity. Review Committee on Genetic Manipulation may appoint sub groups.

It shall bring out Manuals of guidelines specifying procedure for regulatory process with respect to activities involving geneti-cally engineered organisms in research, use and applications including industry with a view to ensure environmental safety. All ongoing projects involving high risk category and controlled field experiments shall be reviewed to ensure that adequate precautions and containment conditions are followed as per the guidelines.

The Review Committee on Genetic Manipulation shall lay down procedures restricting or prohibiting production, sale, importa-tion and use of such genetically engineered organism of cells as are mentioned in the Schedule.

(3) **Institutional Biosafety Committee (IBSC):** This committee shall be constituted by an occupier or any person including research institutions handling microorganism/genetical-ly engineered organisms. The committee shall comprise the Head of the Institution,

Scientists engaged in DNA work, a medical expert and a nominee of the Department of Biotechnology. The occupier or any person including research institutions handling microorganisms/genetically engineered organisms shall prepare, with the assistance of the Institutional Biosafety Committee (IBSC) an uptodate on site emergency plan according to the manu-als/guidelines of the RCGM and make available copies to the District Level Committee/State Biotechnology Co-ordination Committee and the Genetic Engineering Approval Committee.

(4) **Genetic Engineering Approval Committee (GEAC):** This committee shall function as a body under the Department of Environment, Forest and Wildlife for approval of activities involving large scale use of hazardous microorganisms and recom-binants in research and industrial production from the environ-mental angle. The Committee shall also be responsible for ap-proval of proposals relating to release of genetically engineered organisms and products into the environment including experimen-tal field trials.

The composition of the Committee shall be

(i) Chairman-Additional Secretary, Department of Environment, Forests and Wild life Co-Chairman-Representative of Department of Bio-technology

(ii) Members: Representative of concerned Agencies and Depart-ments, namely, Ministry of Industrial Development, Department of Biotechnology and the Department of Atomic Energy:

(iii) Expert members: Director General Indian Council of Agri-cultural Research, Director General-Indian Council of Medical Research, Director General-Council of Scientific and Industrial 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.

(iv) Member Secretary: An official of the Department or Envi-ronment, Forest and Wild life.

The committee may co-opt other members/experts as necessary.

The committee or any person/s authorised by it shall have powers to take punitive action under the Environment (Protection) Act.

**State Biotechnology Co-Ordination Committee (SBCC):** There shall be a State Biotechnology Coordination Committee in the States wherever necessary. It shall have powers to inspect, investigate and take punitive action in case or violations of statutory provisions through the Nodal Department and the State Pollution Control Board/Directorate of Health/Medical Services. The Committee shall review periodically the safety and control measures in the various industries/institutions handling geneti-cally engineered Organisms/Hazardous microorganisms. The composi-tion of the Coordination Committee shall be:

(i) Chief Secretary - Chairman

(ii) Secretary, Department of Environment - Member Secretary

(iii) Secretary, Department of Health - Member

(iv) Secretary, Department of Agriculture - Member

(v) Secretary, Department of Industries and Commerce - Member

(vi) Secretary, Department of Forests - Member

(vii) Secretary, Department of Public works/Chief Engineer, Department of Public Health Engineering - Member

(viii) State microbiologists and Pathologists - Member

(ix) Chairman of State Pollution Control Board

The Committee may co-opt other members/experts as necessary.

**District Level Committee (DLC):** There shall be a District Level Biotechnology Committee (DLC) in the districts wherever necessary under the District Collectors to monitor the safety regulations in installations engaged in the use of genetically modified organisms/hazardous microorganisms and its applications in the environment.

The District Level Committee/or any other person/s authorised in this behalf shall visit the installation engaged in activity involving genetically engineered organisms, hazardous microorgan-isms, formulate information chart, find out hazards and risks associated with each of these installations and coordinate activ-ities with a view to meeting any emergency. The District Level Committee shall regularly submit its report to the State Biotech-nology Co-ordination Committee/Genetic Engineering Approval Committee. The District level Committee shall comprise of:

(i) District Collector - Chairman

(ii) Factory Inspector - Member

(iii) A representative of the Pollution Control Board - Member

(iv) Chief Medical Officer (District Health Officer) – Member (Convenor)

(v) District Agricultural Officer - Member

(vi) A representative of the Public Health Engineering Department - Member

(vii) District Microbiologists pathologist (Technical expert) - Member

(viii) Commissioner Municipal Corporation - Member

The Committee may co-opt other member/s/experts as necessary.

## 5. CLASSIFICATION OF MICROORGANISMS OR GENETICALLY ENGINEERED PRODUCT

(i) For the purpose of these rules, microorganisms or genetically engineered organisms, products or cells shall be dealt with under two major heads; animal pathogens and plant pests and these shall be classified in the manner specified in the Schedule.

(ii) If any of the microorganism, genetically engineered organism or cell falls within the limits of more than one risk class as specified in the Schedule, it shall be deemed to belong exclusively to the last in number of such classes.

## 6. MICROORGANISMS LAID DOWN IN THE SCHEDULE ARE DIVIDED INTO THE FOLLOWING

(i) Bacterial agents:

(ii) Fungal Agents:

(iii) Parasitic Agents

(iv) Viral, Rickettsial and Chlamydial Agents:

(v) Special Category

## 7. APPROVAL AND PROHIBITIONS

(1) No person shall import, export, transport, manufacture, process, use or sell any hazard-ous microorganisms or genetically engineered organisms/substances or cells except with the approval of the Genetic Engineering Approval Committee.

(2) Use of pathogenic microorganism or any genetically engi-neered 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.

(3) The Genetic Engineering Approval Committee shall give direc-tions 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, hospi-tals and other areas including prohibition of such discharges and laying down measures to be taken to prevent such discharges.

(4) Any person operating or using genetically engineered organ-ism 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.

(5) Certain experiments for the purpose of education within the field of gene technology or microorganism may be carried out outside the laboratories and laboratory areas mentioned in sub-rule (2) and will be looked after by the Institutional Biosafety Committee.

## 8. PRODUCTION

Production in which genetically engineered organisms or cells or micro-organism are generated or used shall not be commenced except with the consent of Genetic Engineering Approval Committee with respect of discharge of genetically engineered organisms or cells into the environment. This shall also apply to production taking place in connection with develop-ment, testing and experiments where such production, etc, is not subject to rule 7.

## 9. DELIBERATE OR UNINTENTIONAL RELEASE

(1) Deliberate or unintentional release of genetically engineered organisms/hazard-ous microorganisms or cells, including deliberate release for the purpose of experiment shall not be allowed.

Note: Deliberate release shall mean any intentional transfer of genetically engineered organisms/hazardous microorganisms or cells to the environment or nature, irrespective of the way in which it is done:

(2) The Genetic Engineering Approval Committee may in special cases give approval of deliberate release.

## 10. PERMISSION AND APPROVAL FOR CERTAIN SUBSTANCES

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

**11. PERMISSION AND APPROVAL FOR FOOD STUFFS**

Food stuffs, ingredients in food stuffs and additives including processing aids containing or consisting of genetically engi-neered organisms or cells, shall not be produced, sold, imported or used except with the approval of the Genetic Engineering Approval Committee.

**12. GUIDELINES**

(1) Any person who applies for approval under rules 8-11 shall, as determined by the Genetic Engineering Ap-proval Committee submit information and make examinations or cause examinations to be made to elucidate the case, including examinations according to specific directions and at specific laboratories. He shall also make available an on-site emergency plan to GEAC before obtaining the approval. If the authority makes examination itself, it may order the applicant to defray the expenses incurred by it in so doing.

(2) Any person to whom an approval has been granted under rules 8-11 above shall notify the Genetic Engineering Approval Commit-tee of any change in or addition to the information already submitted.

**13. GRANT OF APPROVAL**

(1) In connection with the granting of approval under rules 8 to 11 above, terms and conditions shall be stipulated, including terms and conditions as to the control to be excercised by the applicant, supervision, restriction on use, the layout of the enterprise and as to the submission of information to the State Biotechnology Co-ordination Committee or to the District Level Committee

(2) All approvals of the Genetic Engineering Approval Committee shall be for a specified period not exceeding four years at the first instance renewable for 2 years at a time. The Genetic Engineering Approval Committee shall have powers to revoke such approval in the following situations:

(a) If there is any new information as to the harmful effects of the genetically engineered organisms or cells.

(b) If the genetically engineered organisms or cells cause such damage to the environment, nature or health as could not be envisaged when the approval was given, or

(c) Non compliance of any condition stipulated by Genetic Engi-neering Approval Committee.

**14. SUPERVISION**

(1) The Genetic Engineering Approval Committee may supervise the implementation of the terms and conditions laid down in connection with the approvals accorded by it.

(2) The Genetic Engineering Approval Committee may carryout this supervision through the State Biotechnology Coordination Commit-tee or the State Pollution Control Boards/ District Level Commit-tee or through any person authorised in this behalf.

**15. PENALTIES**

(1) If an order is not complied with, the District Level Committee or State Biotechnology Co-ordination Committee may take measures at the expenses of the person who is responsible.

(2) In cases where immediate interventions is required in order to prevent any damage to the environment, nature or health, the District level Committee or State Biotechnology

Coordination Committee may take the necessary steps without issuing any orders or notice. The expenses incurred for this purpose will be repay-able by the person responsible for such damage.

(3) The State Biotechnology Co-ordination Committee /District Level Committee may take samples for a more detailed examination of organisms and cells.

(4) The State Biotechnology Co-ordination Committee/District Level Committee shall be competent to ask for assistance from any other Government authority to carry out its instructions.

**16. RESPONSIBILITY TO NOTIFY INTERRUPTIONS OR ACCIDENTS**

(1) Any person who under rule 7-11 is responsible for conditions or arrangements shall immediately notify the District Level Commit-tee \State Biotechnology Co-ordination Committee and the state medical officer of any interruption of operations or accidents that may lead to discharges of genetically engineered organisms or cells which may be harmful to the environment, nature or health or involve any danger thereto.

(2) Any notice given under sub-rule (1) above shall not lessen the duty of the person who is responsible to try effectively to minimise or prevent the effects of interruptions of operations of accidents.

**17. PREPARATION OF OFF-SITE EMERGENCY PLAN BY THE DLC**

(1) It shall be the duty of the DLC to prepare an off-site emergency plan detailing how emergencies relating to a possible major accident at a site will be dealt with and in preparing the plan, the DLC shall consult the occupier and such other person as it may deem necessary.

(2) For the purpose of enabling the DLC to prepare the emergency plan required under sub-rule(I), the occupier shall provide the DLC with such information relating to the handling of hazardous microorganisms/genetically engineered organisms under his control as the DLC may require including the nature, extent and likely off-site affects of a possible major accident and the DLC shall provide the occupier with any information from the off-side emergency plan which relates to his duties under rule 16.

**18. INSPECTIONS AND INFORMATIONS REGARDING FINANCE**

(1) The State Biotechnology Co-ordination Committee or the Genetic Engi-neering Approval Committee/the DLC or any person with special knowledge duly authorised by the State Biotechnology Co-Ordina-tion Committee or the Genetic Engineering Approval Committee or the DLC where it is deemed necessary, at any time on due produc-tion if identity be admitted to public as well as to private premises and localities for the purpose of carrying out supervi-sion.

(2) Any person who is responsible for activities subject to rules 7-11 above shall at the request of District level Committee or State Biotechnology Coordination Committee or the GEAC submit all such information including information relating to financial conditions and accounts, as is essential to the authority's administration under these rules. He shall also allow supervi-sion or inspection by the Authorities or persons indicated in sub-rule(I).

(3) The Genetic Engineering Approval Committee may fix fees to cover, in whole or in part, the expenses incurred by the authorities in connection with approvals, examinations, supervi-sion and control.

**19. APPEAL**

(1) Any person aggrieved by a decision made by Genetic Engineering Approval Committee/ State Biotechnology Co-ordination Committee in pursuance of these rules may within thirty days from the date on which the decision is communicated to him, prefer an appeal to such authority as may be appointed by Ministry of Environment and Forests provided that the appellate authority may entertain the appeal after the expiry of the said period of thirty days if such authority is satisfied that the appellant was prevented by sufficient cause from filing the appeal in time.

**20. EXEMPTION**

The Ministry of Environment and Forests shall, wherever necessary, exempt an occupier handling a particular microorganism/genetically engineered organism from rule 7-11.

**A. ANIMAL AND HUMAN PATHOGENS**

Schedule

BACTERIAL

**Risk Group II**

- Acinetobacter calcoacetieus
- Actinobacillus-all species except A mallei, which is in Risk Group III
- Aeromonoas hydrophila
- Arizona hinshawii-all serotypes
- Bacillus anthracis
- Bordetella all species
- Borrelia recurrentis.B.Vincenti
- Campylobacter fetus
- Camphylobacter jejuni, Chalamydia psittaci
- Cheamydia trachomatics
- Clostridium chauvoei, Cl.difficile Cl/fallax. Cl haemolyticum Q.histolyticum, CI novyi (CI,Pefringes) Cl.speticum, Cl.sordelli
- Corynebacterium diptheriae, C.equi, C. haemolyticum, C.Pseudotu-berculosis, C.pyogenes, C.renale
- Diplococcus (Streptococcus) pneumoniae
- Edwardsiila tarda
- Erysipelothix insidiosa
- Escherichia Coli-all enteropathogenic serotypes, enterotoxigenic
- Haemophilus ducrevi, H.influenzae, H. pneumoniae
- Herellea vaginicola
- Klebsiella-all species and all serotypes
- Legionlla pneumophila
- Letionella
- Leptospira interrogans-all serotypes reported in India
- Listeria, all species
- Mima polymorpha
- Moraxella-all species
- Mycobacteria-all species including Mycobacterium avium
- M.Bovis M.tuberculosis, M.Leprae
- Mycoplasma-all species except M.Mycoides and M.angalactiae
- Meosseroc gonorrhoea,N. Leprae
- Mycoplasma-all species except M.Mycoides and M.angalactiae
- Neisseric gonorrhoea,N. meningitis
- Pasteurella-all species except those listed in Risk Group III
- Salmonella-all species and all setotypes
- Shigella-all species and all serotypes
- Sphaerophorgs necrophorus
- Staphylococcus aureus
- Streptobacillus moniliformis
- Streptococcus pneumoniae
- Streptococcus pyogenes.S.equi
- Streptomyces madurae,s.pelleteri, s.somaliensis
- Treponema carateum, T.pallidam and T.pettenue
- Vibrio foetus V.comma including biotype EI Top and
- V. parahemolyticus
- Vibrio cholerae

**Risk Group III:**

- Actinobacillus mallei
- Bartonella-all species
- Brucella-all species
- Clostridium botulium Cl.tetani
- Francisella tularensis
- Mycobacterium avium,. M.bovis, M.tuberculosis,m.leprae

- Pasteurella multocida type B("buffalo" and other foreign viru-lent strains)
- Pseudomonas pseudomallai
- Yersinia pestis

**FUNGAL**

**Risk Group II**

- Actinomycetes (including Nocardia SP, Actinomyces species and Arachina propinica)
- Aspergillus fumigatus
- Blastomyces dermatitis
- Cryptococcus neoformans C. fersiminosos
- Epidermophyton madurella, microsporon
- Paracoccidiodes brasiliensis
- Sporothrix
- Trichoderma
- Trichophyton

**Risk Group III**

- Coccidioides immitis
- Histoplasma capulatum
- Histoplasma capsulatum var duboiss

**PARASITIC**

**Risk Group II**

- Entahoeba histolytica
- Leishmania species
- Naegleria gruberia
- Plasmodium theilera, *P. babesia, P. falcoparum*
- Plasmodium babesia
- Schistosoma
- Toxoplasma gondii
- Toxocana canis
- Trichinella spiralis
- Trichomanas
- Trypanosoma cruzi

**Risk Group III**

- Schisistosoma mansoni

**VIRAL RICKETTSIAL AND CHALMYDIAL**
**Risk Group II**

- Adenoviruses - Human all types
- Avian loukosis
- Cache Valley virus
- CELO (avian adenovirus)
- Coxsackie A and B viruses
- Corona viruses
- Cytomegalo viruses
- Dengue virus, when used for transmission experiments
- Echo viruses - all types
- Encephalomyocarditis virus (EMC)
- Flanders virus
- Hart Part virus
- Hepatitis - associated antigen material - hepatitis A and B viruses, non A and non B, HDV
- Herpes viruses - except herpesviruses simiae (monkey B virus) which is in Risk Group IV.
- Infectious Bovine Rhinotraechitis virus (IBR)
- Infectious Bursal diseases of poultry and Infectious Bronchitus
- Infectious Laryngotraechitis (ILT)
- Influenza virus - all types, except A PR 834 which is in Risk Group I
- Langat virus Leucosis Complex
- Lymphogranuloma venereum agent
- Marek's Disease virus
- Measles virus
- Mumps virus
- Newcastle disease virus (other than licenced strain for vaccine use)
- Parainfluenza viruses - all type except

parainfluenza virus 3, SF4 strain, which is in Risk Group I.

- Polio viruses - all types, wild and attenuated
- Poxviruses - all types except Alastrim, monkey pox, sheep pox and white pox, which depending on experiments are in Risk Group III or IV.
- Rabies virus - all strains except rabies stret virus, which should be classified in Risk Group III when inoculated into cornivores
- Reoviruses - all types
- Respiratory syncytial virus
- Rhinoviruses - all types
- Rinderpest (other than vaccine strain in use)
- Rubella virus
- Stimian viruses - all types except herpeavirus simlae (Monkey Virus) which is in Risk Group IV.
- Simian virus 40 -
- Ad 7 SV 40 (defective)
- Sindbis virus
- Tensaw virus
- Turlock virus
- Vaccinia virus
- Varicella virus
- Vole rickettsia
- Yellow fever virus, 17D vaccine strain

**Risk Group III**

- African House Sickness (attenuated strain except animal passage)
- Alastrim, monkey pox and whitepox, when used in vitro
- Arboviruses - All strains except those in Risk Group II and IV.
- Blue tongue virus (only serotypes reported in India)
- Ebola fever virus
- Feline Leukemia Epstein-Barr virus
- Feline sarcoma
- Foot and Mouth Disease virus (all serotypes and sutbypes)
- Gibbon Ape Lymphosarcoma
- Herpesvirus ateles
- Herpesvirus saimiri
- Herpes simplex 2
- HIV-I & HIV-2 and strains of SIV
- Infectious Equine Anaemia
- Lymphocytic choriomeningitis virus (LCM)
- Monkey pox, when used in vitro
- Nen-defective Adeno-2 SV-40 hybrids
- Psittacosis-ornithosis-trachoma group of agents
- Pseudorabies virus
- Rabies street virus, when used inoculations of carnivores
- Rickettsia-all species except Vole rickettsia and Coxiell burnetti when used for vector transmission or animal inoculation experiments
- Sheep pox (field strain)
- Swine Fever virus
- Vesicular stomatitis virus
- Woolly monkey Fibrosarcoma
- Yaba pox virus

**Risk Group IV**

- Alastrim, monkeypox, whitepox, when used for transmission or animal inoculation experiments
- Hemorrhagic fever agents, including Crimean hemorrhagic fever (congo)
- Korean hemorrhagic fever and others as yet undefined
- Herpes virus simlae (monkey B virus)
- Tick-borne encephalitis virus complex,

including - Russian

- Spring Summer Encephalitis, Kyasanur Forest Diseast, omsk hemorrhagic fever and Central European encephalitis viruses.

**SPECIAL CATEGORY**

**BACTERIAL**

- Contagious Equine Metritis (H. equigenitalis)
- Pestis petit de ruminantium

**VIRAL RICKETTSIAL AND CHLAMYDIAL**

- African Horse Sickness virus (serotypes not reported in India and challenge strains)
- African Swine Fever
- Bat rabies virus
- Blue tongue virus (serotypes not reported in India)
- Exoitic FMD virus types and sub-types
- Junin and Machupo viruses
- Lassa virus
- Marburg virus
- Murrey valley encephalitis virus
- Rift Valley Fever virus
- Smallpox virus - Archieval storage and propagation Swine Vesicular Disease
- Veneseulan equine encephalitis virus - epidemic strains
- Western Equine encephalitis virus Yellow fever virus - Wild strain
- Other Arboviruses causing epizootics and so far not recorded in India

**B. PLANT PESTS**

Any living stage (including active and dormant forms) of insects, mites nematodes, slugs, snails, bacteria, fungi, proto-zoa, other parsitic plants or reproductive parts thereof: vi-ruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants are considered plant pests.

Organisms belonging to all lower Taxa contained within the group listed are also included.

1. **Viruses:**

All viroids

All bacterial, fungal, algal, plant, insect and nematode viruses; special care should be take for:

(i) Geminiviruses,

(ii) Caulimoviruses,

(iii) Nuclear Polyhedrosis viruses,

(iv) Granulosis viruses, and

(v) Cytoplasmic polyhedrosis viruses.

2. **Bacteria:**

***Family Pseudomonadaceae***

Genus Pseudomonas

Genus Xanthomonas

Genus Azotobacter

***Family Rhizobiaceae***

Genus Rhizobium/Azorhizobium

Genus Bradyrhizobium

Genus Agrobacterium

Genus Phyllobacterium

Genus Erwinia

Genus Enterobacter

Genus Klebzieller

***Family Spirollacea***

Genus Azospirillum

Genus Acquspirillum

Genus Oceonospirillum

***Family Streptomycetaceae***

Genue Streptomyces

Genue Nocardia

***Family Actinomycetaceae***

Genue Actinomyces

***Coryneform Group***

Genus Clavibacter

Genus Arthrobacter

Genus Curtobacterium

Genus Bdellovibro

***Family Rickettsiaceae***

Rickettsial-like organisms associated with insect diseases

Gram-negative phloem-limited bacteria associated with plant diseases

Gram-negative xylem-limited bacteria associated with plant diseases

Cyanobacteria - All members of blue-green algae

Mollicutes

Family Spiroplasmataceae

Mycoplama-like organisma associated with plant diseases

Mycoplasma-like organisms associated with insect diseases

***Algae***

Family Chlorophyceae

Family Euglenophyceae

Family Pyrophyceae

Family Chrysophyceae

Family Phaephyceae

Family Rhodophyceae

***Fungi***

Family Plasmodiophoraceae

Family Chytridiaceae

Family Olpidiopsidaceae

Family Synchytriaceae

Family Catenariaceae

Family Coelomomycetaceae

Family Saprolegniaceae

Family Zoopagaceae

Family Albuginaceae

Family Peronosporaceae

Family Pythiaceae

Family Mucoraceae

Family Choanephoraceae

Family Mortiercllaceae

Family Endogonaceae

Family Syncephalastraceae

Family Dimargaritaceae

Family Kickxellaceae

Family Saksenaeaceae

Family Entomophthoraceae

Family Ecerinaceae

Family Taphrinaceae

Family Endomycetaceae

Family Saceharomycetaceae

Family Eurotiaceae

Family Gymnoascaceae

Family Aseophaeriaceae

Family Onygenaceae

Family Microascaceae

Family Protomycetaceae

Family Elsinoeaceae

Family Myriangiaceae

Family Dothidiaceae
Family Chaetothyriaceae
Family Parmulariaceae
Family Phillipsiellaceae
Family Hysteriaceae
Family Pleosporaceae
Family Melamomataceae
Family Ophiostomataceae
Family Aseosphaeriaceae
Family Erysiphaceae
Family Meliolaceae
Family Xylariaceae
Family Diaporthaceae
Family Hypoereaceae
Family Clavicipataceae
Family Phacidiaceae
Family Ascocorticiaceae
Family Hemiphacidiaceae
Family Dermataceae
Family Sclerotiniaceae
Family Cyttariaceae
Family Helosiaceae
Family Sarcostomataceae
Family Sarcoscyphaceae
Family Auricolariaceae
Family Ceratobasidiaceae
Family Corticiaceae
Family Hymenochaetaceae
Family Echinodintiaceae
Family Eistuliniaceae
Family Clavariaceae
Family Polyporaceae
Family Tricholomattaceae
Family Ustilaginaceae
Family Sporobolomycetaceae
Family Uredinaceae
Family Agaricaceae
Family Graphiolaceae
Family Pucciniaceae
Family Melampsoraceae
Family Gandodermataceae
Family Labonlbeniaceae
Family Sphaeropsidaceae
Family Melabconiaceae
Family Tuberculariaceae
Family Dematiaceae
Family Moniliaceae
Family Aganomucetaceae

***Parasitic Weeds***

Family Balanophoraceae-parasitic species
Family Cuscutaceae-parasitic species
Family Ttydonoraceae-parasitic species
Family Lauraceae-parasitic species Genus Cassytha
Family Lennoaceae-parasitic species
Family Loranthaceae-parasitic species
Family Myzodendraceae-parasitic species
Family Olacaceae-parasitic species
Family Orobanchaceae-parasitic species
Family Rafflesiaceae-parasitic species
Family Santalaceae-parasitic species
Family Scrophulariaceae-parasitic species

***Protozoa***

Genus Phytomonas

And all protozoa associated with insect diseases.

***Nematodes***

Family Anguinidae

Family Belonolaimidae
Fmaily Caloosiidae
Family Criconematidae
Family Dolichodoridae
Family Fergusobiidae
Family Hemicycliophoridae
Family Heteroderidae
Family Hoplolaimidae
Family Meloidogynidae
Family Neotylenchidac
Family Nothotylenchidae
Family Paratylenchidae
Family Pratylenchidae
Family Tylenchidae
Family Tylenchulidae
Family Aphelenchoidiae
Family Longidoridae
Family Trichodoridae

*Mollusca*

Superfamily Planorbacea
Superfamily Achatinacea
Superfamily Arionacea
Superfamily Limacacea
Superfamily Helicacea
Superfamily Veronicellacea

*Arthropoda*

Superfamily Ascoidea
Superfamily Dermanyssoidea
Superfamily Erjophyoidea
Superfamily Tetranychoidea
Superfamily Eupodoidea
Superfamily Tydeoidea
Superfamily Erythraenoidea
Superfamily Trombidioidea
Superfamily Hydryphantoidea
Superfamily Tarasonemoidea
Superfamily Pyemotoidea
Superfamily Hemisarcoptoidea
Superfamily Acaroidea
Order Polydesmida
Family Sminthoridae
Family Forfieulidae
Order Isoptera
Order Thysanoptera
Family Acrididea
Family Gryllidae
Family Gryllacrididae
Faily Gryllotalpidae
Family Phasmatidae
Family Ronaleidae
Family Tettigoniidae
Family Tetragidae
Family Thaumastocoridae
Superfamily Piesmatoidea
Superfamily Lygacoidea
Superfamily Idiostoloidea
Superfamily Careoidea
Superfamily Pentatomoidea
Superfamily Pyrrhocoroidea
Superfamily Tingoidea
Superfamily Miroidea
Order Homoptera
Family Anobiidae
Family Apionidae
Family Anthribidae
Family Bostrichidae
Family Brentidae

Family Bruchidae
Family Buprestodae
Family Byturidae
Family Cantharidae
Family Carabidae
Family Ceambycidae
Family Chrysomelidae
Family Coecinellidae
Family Curculionidae
Family Dermestidae
Family Elalteridae
Family Hydrophilidae
Family Lyctidae
Family Meloidae
Family Mordellidae
Family Platypodidae
Family Scarabaeldae
Family Scolytidae
Family Selbytidae
Order Lepidoptera
Family Agromyzidae
Family Anthomiidae
Family Cecidomiidae
Family Chioropidae
Family Ephydridae
Family Lonchaeidae
Family Muscidae
Family Otitidae
Family Syrphidae
Family Tephritidae
Family Tipulidae
Family Apidae
Family Caphidae
Family Chalcidae
Family Cynipidae
Family Eurytomidae
Family Formicidae
Family Psilidae
Family Sircidae
Family Tenthredinidae
Family Torymidae
Family Xyloiopidae and

Also unclassified organisms and/or organisms whose classification is unknown and all other organisms associated with plant and insect diseases.