

BIOSAFETY GUIDELINES

(RDAC, RCGM, GEAC, IBSC, SBCC, DLC)

In India, the manufacture, import, research and release of Genetically Engineered Organisms (GEOs), as well as products made by the use of such organisms are governed by The Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms, Genetically Engineered Organisms or Cells, (commonly referred to as “Rules 1989) notified by the Ministry of Environment, Forest and Climate Change (MoEF& CC), on December 5, 1989, under the Environment (Protection) Act 1986.

The Rules 1989 are broad in scope and covers the area of research as well as large-scale handling of hazardous microorganisms, GE organisms or cells and products thereof. In order to implement the Rules in the entire country, six competent authorities and roles have been notified under the Rules 1989.

Competent Authorities under Rules 1989

Competent Authorities	Role
Recombinant DNA Advisory Committee (RDAC)	Advisory
Genetic Engineering Appraisal Committee (GEAC)	Regulatory/ Approval
Review Committee on Genetic Manipulation (RCGM)	
Institutional Biosafety Committee (IBSC)	
State Biotechnology Coordination Committee (SBCC)	Monitoring
District Level Committee (DLC)	

Recombinant DNA Advisory Committee (RDAC)

This Committee is set up and functions in the Department of Biotechnology with a role to;

- i. Review developments in Biotechnology at national and international levels.
- ii. Shall recommend suitable and appropriate safety regulations for India in recombinant research, use and applications from time to time.
- iii. Evolve long-term policy for research and development in Recombinant DNA research.

Review Committee on Genetic Manipulation (RCGM)

This Committee shall function from the Department of Biotechnology to monitor the safety related aspect in respect of on-going research projects or activities involving hazardous microorganisms, GE organisms and cells and products thereof. The RCGM shall include representatives of (a) Department 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. RCGM may appoint sub groups to assist RCGM on matters related to risk(s) assessment, in reviewing of existing and preparing new guidelines.

RCGM shall bring out Manuals of guidelines specifying procedure for regulatory process with respect to activities involving GE organisms in research use as well as industrial & environmental applications with a view to ensure human health and environmental safety. All ongoing research projects involving hazardous microorganisms, GE organisms or cells and products thereof shall be reviewed to ensure that adequate precautions and containment conditions are being met.

RCGM shall lay down procedures restricting or prohibiting production, sale, importation and use of such hazardous microorganisms, GE organisms or cells.

TERMS OF REFERENCE (TOR) OF RCGM

As per the Rules for the manufacture, use, import, export & storage of hazardous microorganisms, genetically engineered organisms or cells, 1989 notified under the Environment (Protection) Act, 1986 and as amended from time to time, the Review Committee on Genetic Manipulation (RCGM) shall function in the Department of Biotechnology (DBT).

1. RCGM shall monitor the safety related aspects in respect of ongoing recombinant DNA (r-DNA) projects and activities involving Genetically Engineered (GE) organisms/hazardous microorganisms. All ongoing projects including high risk category and confined field experiments shall be reviewed by RCGM to ensure that adequate precautions and containment conditions are complied with as per the Guidelines and Standard Operating Procedures (SOPs) issued by DBT from time to time.
2. The RCGM shall lay down procedures restricting or prohibiting production, sale, importation and use of such GE organisms or products thereof for research and applications as mentioned in the schedule of Rules, 1989.
3. RCGM shall bring out manuals and guidelines specifying procedure for regulatory processes with respect to activities involving GE organisms in research, use and application including industry with a view to ensure safety to human, animal, and environment health.
4. The RCGM would issue the clearance letters/permits for import or exchange of genes, DNA fragments, vectors, plasmids, cosmids, etiologic agents and transgenic organisms

or germplasm(s) including transformed calli, seeds, plants and plant parts for research use only. It will also take note of all such commercially available agents which are acquired from commercial sources through Institutional Biosafety Committee (IBSC).

5. The RCGM shall be the regulatory body for receiving and reviewing the applications to conduct confined field trials (such as event selection trials, Biosafety Research Level I trials (BRL-I), pollen flow studies or any other trial involving GE organisms) and recommend appropriate studies to be conducted for data generation for biosafety assessment as per clause 4, as per the decision of the Genetic Engineering Approval Committee (GEAC) for its authorization.
6. The RCGM, on case-by-case basis, can authorize applicants to use bioreactors to produce sufficient material/end-products of GE organisms required for conducting pre-clinical studies and other relevant data generation including the use of capacity over and above as specified by Recombinant DNA Safety Guidelines, 1990. It will authorize to produce sufficient quantities of GE organism/plant product(s) for generating safety data in appropriate animals as per National and International Guidelines, as appropriate on case-by-case basis.
7. The RCGM, if required, call generate, examine or invite the research projects, proposals for capacity building and training courses in biosafety, creation of information systems/data banks in electronic media, websites etc. for financial support and recommend the same to DBT for furthering the cause of generating specific biosafety data related to use of GMOs and strengthening infrastructure facilities & dissemination of information on biosafety rules, regulations and guidelines in the country.
8. The RCGM may also invite, induct or appoint special experts in their individual capacities on a case-by-case basis.
9. The RCGM may constitute subgroups of its members or subcommittees involving experts for specific functions or seek advice on specific matters from other external experts.
10. The RCGM or its constituted subgroups/subcommittees may visit periodically the experimental sites where r-DNA projects and activities involving GE organisms/hazardous microorganisms are being pursued to ensure that adequate safety measures have been taken as per the guidelines and compliance of SOPs.
11. The RCGM shall maintain the classified/confidential business information provided by the applicants as confidential.
12. The RCGM shall function for a period of three years from the date of notification.

13. The RCGM shall meet once in a month or as and when required.
14. The members of RCGM shall be paid TA/DA and honorarium as per the Government of India rules as applicable from time to time.

Institutional Biosafety Committee (IBSC)

This Committee shall be constituted by all institutions handling hazardous microorganisms and/or GE organisms. The Committee will be the nodal point for implementation of the biosafety guidelines and for the interactions within the institution. The Committee shall comprise of the Head of the Institution, Scientists engaged in the recombinant DNA work, a medical doctor and a nominee of the Department of Biotechnology. Institutions handling risk-inherent microorganisms or GE organisms shall prepare, with the assistance of the Institutional Biosafety Committee (IBSC), on-site emergency plan and update from time to time according to the manuals/guidelines of the RCGM and make available copies to the District Level Committee/State Biotechnology Co-ordination Committee and the Genetic Engineering Appraisal Committee.

The constitution, composition, role and functions, information for compliance requirements, processes to be followed while dealing with hazardous microorganisms, GE organisms or cells and product thereof in line with Rules 1989 is described in “Guidelines and Handbook for Institutional Biosafety Committee”. Adherence to the guideline shall be binding for all IBSCs.

Genetic Engineering Appraisal Committee (GEAC)

Genetic Engineering Appraisal Committee (GEAC) [formerly known as Genetic Engineering Approval Committee (GEAC) name changed through Gazette notification, G.S.R No. 613 dated 16th July 2010], has been established under the Ministry of Environment, Forest and Climate Change (MoEF&CC). The major functions of GEAC as prescribed in the Rules 1989 are:

- i. To appraise activities involving large scale use of hazardous microorganisms GE organisms or cells in research and industrial production from the environmental angle.
- ii. To appraise proposals relating to release of GE organisms and products into the environment including experimental field trials.
- iii. The committee or any persons authorized by it has powers to take punitive action under the Environment (Protection) Act, 1986.

Submission of applications to GEAC, information on current composition, meeting deliberations etc. is available at [here](#).

State Biotechnology Co-ordination Committee (SBCC)

The State Biotechnology Co-ordination Committee (SBCC) is a monitoring committee at State level. It shall have powers:

- i. To inspect, investigate and to take punitive action in case of violations of statutory provisions through the State Pollution Control Board (SPCB) or the Directorate of Health etc.
- ii. To review periodically the safety and control measures established at various institutions handling GE organisms.
- iii. To act as a nodal agency at the State level to assess the damage, if any, due to the release of GE organisms and to take on-site control measures.

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 authorized in this behalf shall visit the installation engaged in activity involving hazardous microorganisms, GE organisms or cells, and , formulate information chart, find out hazards and risk(s) associated with each of these installations and coordinate activities with a view to meet any emergency. They shall also prepare an off-site emergency plan. The District Level Committee shall regularly submit its report to the SBCC/ GEAC.
