Ground Rules for Consideration of Proposals by the GEAC as per the good practices in environmental regulation adopted by MoEF.

The Ministry of Environment & Forests has formulated procedural guidelines to streamline the working of the regulatory bodies constituted by the Ministry. In this context a document on "Good Practices in Environmental Regulations" has been prepared. These guidelines would be applicable to the functioning of the GEAC.

As per these guidelines a number of checks and counter checks have been put in place to ensure that the regulator adopts the operational guidelines for observations of good practices in environmental regulations. Accordingly, to ensure transparency in the decision making process a set of information such as Ground Rules, Name of the Chair/ Co-Chair/ Vice Chair, Standing time table of the Committee, Agenda for the next meeting, Status of Pending Projects etc. are to be posted on the MoEF web-page. Information for applicants seeking approval of GEAC are enumerated below

1.0 A brief note on the Biosafety Regulatory Framework in India.

1.1 The Ministry of Environment & Forests (MoEF), has notified the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells 1989 under the Environment (Protection) Act, 1986, These rules and regulations cover the areas of research as well as large scale applications of GMOs and products made therefrom throughout India. The rules also cover the application of hazardous microorganisms, which may not be genetically modified. Hazardous microorganisms include those, which are pathogenic to animals as well as plants. The rules cover activities involving manufacture, use, import, export, storage and research. The target substances covered are, besides the hazardous natural microorganisms, all genetically engineered organisms including microorganisms, plants and animals.

1.2 These rules also define the competent authorities and composition of such authorities for handling of various aspects of the rules. Presently there are six competent authorities that is, Recombinant DNA Advisory Committee (RDAC), Institutional Biosafety Committees (IBSC), Review Committee on Genetic Manipulation (RCGM), Genetic Engineering Approval Committee (GEAC), State Biotechnology Coordination Committee (SBCC) and the District Level Committee (DLC). The RCGM established under the Department of Biotechnology (DBT) supervises and accords approval for research activities including small-scale field trials/pre-clinical trials, whereas approvals for large-scale releases and commercialization of GMOs are given by the GEAC, established under the Ministry of Environment and Forests. The SBCC's and DLC's have a major role in monitoring. The Rules also mandate that every institution engaged in GMO research establish an IBSC to oversee such activities and to interface with the RCGM in regulating it.
The 'Rules 1989' have been supplemented by technical guidelines with a view to address various biosafety concerns. The various guidelines issued by DBT include:

- Recombinant DNA guidelines, 1990
- Revised guidelines for research in transgenic plants & guidelines for toxicity and allergenicity evaluation of transgenic seeds, plants and plant parts, 1998
- Guidelines for generating pre-clinical and clinical date for rDNA based vaccines, diagnostics and other biologicals, 1999.

A copy of the 'Rules 1989' and the Biosafety Guidelines are annexed.

2.0 Rules for Consideration of the Proposal

2.1 All new proposals received in the Ministry 30 days prior to the GEAC meeting would be placed for consideration of the GEAC in the next GEAC meeting, which is scheduled every 2nd Wednesday of the month in the Ministry of Environment & Forests. In case the information is not received within the prescribed time limit, the proposal would be considered in the subsequent GEAC meeting.

2.2 In reconsideration cases, the requisite information sought by the Committee should be submitted 15 days prior to the next GEAC meeting for it's consideration in the meeting; in case the information is not received within the prescribed time limit, the proposal would be considered in the subsequent GEAC meeting.

2.3 The requisite information required for consideration of the application by the GEAC include:

a. The Project Proponent should submit their request through an application as per the prescribed GEAC proforma.
b. The request for approval of large-scale trials of transgenic crops should be accompanied by RCGM and MEC recommendation.
c. The request for commercial cultivation of transgenic crops should include data on large-scale trials and ICAR trials and recommendation of MEC.
d. In case of Pharma products, the request for Phase-III clinical trials should be accompanied by recommendation of RCGM.
e. The request for manufacture and marketing of pharma products should include details of containment facilities and clinical trials and recommendation of RCGM on the containment facilities.
f. The request for import and marketing of Pharma products should include detailed information on the trials conducted in the country of origin and approvals obtained.

2.4 The application and other requisite information should be submitted in both hard copy as well as electronic copy to the Member Secretary GEAC. Subsequently a copy of the same should be made available to the members of the GEAC.

2.5 The request for import of transgenic seeds/ genetically engineered microorganisms for the purpose of research activities should be submitted to RCGM as per the prescribed DBT proforma.

3.0 Schedule of GEAC Meeting

3.1 The GEAC Meeting would be held every 2nd Wednesday of the month at 10.30 am in Paryavaran Bhavan, CGO Complex, Lodhi Road, New Delhi- 110003. In case the 2nd Wednesday is a holiday, the GEAC meeting would be held the following day.

3.2 The agenda for the meeting would be displayed on the MoEF website 15 days prior to the next GEAC Meeting.

3.3 All Project Proponents would be given an opportunity for a personal hearing. The project proponents who wish to present their case may be present in the Ministry on the date of the meeting.

3.4 Decisions taken in the GEAC meeting would be displayed on MoEF website within 5 working days after the GEAC meeting.

3.5 Status of pending projects and reasons for pendency would be updated every 15 days.

4.0 Chairman /Co- Chairman of the GEAC is as follows:

1. Mr. Suresh Chandra **Chairman**
Special Secretary,
Ministry of Environment & Forests
Paryavaran Bhavan
CGO Complex, Lodhi Road
New Delhi -110003

2. Dr. Amit Ghosh **Co- Chairman**
Co-Chairman GEAC & Former Director
Institute of Microbial Technology (IMTech),
Sector 39,A
Chandigarh – 160 036

All application/communication regarding GEAC approval may be addressed to Chairman GEAC.

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