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(Marine)
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Unit V

Institutional Biosafety Committees

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Syllabus

- **Biosaftey:**

  Purpose, Scope, Terminology, Constitution of IBSC, Tenure of IBSC, Composition, Procedure of Registration, Role of IBSC in approval, Functions, IBSC meetings, Conflict of interest, Confidentiality, Reporting requirement, IBSC records, Persons responsible for compliance, Addressing noncompliance, Training, Laboratory inspections, Security of GMOs / LMOs / rDNA materials, Disposal.

Introduction

- By manipulating the genetic material
- Many novel experiments and applications
- Biological experiments
- Work involving pathogenic microorganism
- Countries – safety guidelines / regulations
- Considering possible risks
- Last few years genetic manipulation – lab to market
- Govt. Research Institution, Universities, R&D labs
- Plant, animals, tissue culture, cell lines - generation of vaccine
- Diagnostics, Biofertilisers, Biocides, Fertility

- Biotechnology safety guidelines - not one time exercise
- Guidelines covers - genetically engineered organism
- Revision – committee/sub committee – 4 times/year
- Current guidelines –other countries
- Updation - experts, academics, agencies, Industry, Ministry

In India GMOs & Products

Rules for the manufacture, use/import/export and storage of hazardous microorganisms/genetically engineered organisms or cells, 1989

Who?

MoEF, DBT, Min. Sci & tech and State Govt through 6 component authorities

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

Purpose /Objectives

To provide guidance to organisations that have Institutional Biosafety Committees (IBSCs)

Rules for the manufacture, use / import / export and storage of hazardous microorganisms / genetically engineered organisms or cells, 1989

Environmental Protection act (1986)

- IBSC - to conduct onsite evaluation, assessment and monitoring .
- The decisions taken by the next higher (DBT, MoEF) committee i.e., Review Committee on Genetic Manipulation (RCGM).
- The investigators with the approval of IBSC.
- Compliance with the Rules, 1989,
- Recombinant DNA (rDNA) Safety

Scope

- Guidelines describe the constitution, composition, role and functions of IBSCs.

- The guidelines provide information for compliance requirements by IBSCs and processes to be followed while dealing with genetically modified organisms (GMOs) / living modified organisms (LMOs) and rDNA materials in line with Rules, 1989 and guidelines issued by DBT from time to time.

Terminology

- Biosafety officer
- Containment
- DBT
- GEAC – Genetic Engineering Appraisal Committee
- Head – VC, CEO, MD
- IBSC
- Principal Investigator
- rDNA
- Regulatory Authority

In India, GMOs and products thereof are regulated as per the "Rules for the manufacture, use/import/export and storage of hazardous microorganisms/ genetically engineered organisms or cells, 1989" (commonly referred as Rules, 1989) notified by the Ministry of Environment and Forests (MoEF), Government of India under the Environment (Protection) Act (1986). These rules are implemented by MoEF, the Department of Biotechnology (DBT), Ministry of Science and Technology and the State Governments through the six competent authorities notified under the Rules which are as follows:

- Recombinant DNA Advisory Committee (RDAC)
- Institutional Biosafety Committee (IBSC)
- Review Committee on Genetic Manipulation (RCGM)
- Genetic Engineering Appraisal Committee (GEAC)
- State Biotechnology Coordination Committee (SBCC)
- District Level Committee (DLC).

Constitution of IBSC

- Any organisation, which undertakes research, shall establish an IBSC to ensure that all activities conducted comply with Rules 1989 and various guidelines issued by DBT from time to time.

- The IBSC shall be registered with DBT.

Tenure of IBSC

- Each IBSC shall be registered for a period of three years.
- The registration needs to be renewed after every three years.
- The request for renewal must be submitted 60 days in advance before the expiry of the tenure of IBSC.

Composition

- Chair person – Head, senior, experienced rDNA
- Scientists 3 or more - Appointed by the head (3 yrs-Minimum) – Annually reviewed by Head
- Biosafety officer – Medical qualification – rDNA, member of IBSC , knowledge containment
- A nominee of DBT – From DBT – link between DBT IBSC
- Changes – to be informed HEAD, IBSC, DBT
- Consultant

Procedure of Registration / Renewal

Registration

Member, application to institution, Biodata

DBT Evaluation – Notification to IBSC chairman

Renewal

Similar

Role of IBSC in approval

- Research activities related to rDNA technology
- Research activities related to transgenic plants
- Large scale trials and production
- Import and transfer / shipment

Research activities related to rDNA technology

- IBSC has to review all recombinant research carried out by an organisation depending upon the category of experiments,
- IBSC can simply note the information provided by PI, give permission before start of the experiments or forward it to RCGM for approval as per the Recombinant DNA Safety Guidelines, 1990 of DBT.
- Different levels of containment have been prescribed for different categories of rDNA experiments in the Guidelines.
- IBSC should allow genetic engineering activity on classified organisms only at places where such work can be performed as per Guidelines and containment facilities.
- Provision of suitable safe storage facility of donor, vectors, recipients and other materials involved in experimental work should be made and may be subject to inspection for accountability on biosafety.

Research activities related to transgenic plants

- Revised Guidelines for Research in Transgenic Plant, 1998 by DBT
- DNA fragments that are non pathogenic to human and animals are used for genetic transformation of plants.
- Permission provided by IBSC but the decision of the IBSC needs to be intimated to the RCGM before execution of the experiment and RCGM would put this information on record.
- High risk experiments where the escape of transgenic traits into the open environment could cause significant alterations in the biosphere.
- Such experiments could be conducted only after clearance from RCGM and notified by DBT

Large scale trials and production

- Conduct of field trials and large scale production, IBSC has to verify the information being forwarded to RCGM and GEAC in terms of physical containment conditions, categorization in terms of risk assessment etc., as further reviews by these regulatory committees depends on the review of the IBSC on the submissions made.

- IBSC has to recommend emergency plan in case of large-scale operations, as and when required, which would be then approved by competent authorities i.e. RCGM and GEAC. Emergency plan shall include methods and procedures for handling large volumes of cultures and organisms for production, transport, storage or disposal etc.

Import and transfer/shipment

- The interstate transfer/shipment of indigenous etiological agents, diagnostic specimens and biological products need clearance of IBSC and is subject to appropriate packaging, labeling and shipping requirements.
- The import permits of regulated materials for research and specifying conditions under which the agent or vector is shipped, handled and use are issued by RCGM while large scale imports regulated material for environmental and industrial use are regulated by GEAC.
- In case of plants, the import is routed through the Director, National Bureau of Plant Genetic Resources (NBPGR) on the basis of the import permit issued by the RCGM Secretariat, based on recommendations of the RCGM. However, all these proposals need to be submitted by the Pis through their IBSCs.

Functions

- IBSC
- Chairperson
- Member Secretary
- Biosafety officer
- Principal Investigator
- DBT nominee

IBSC

- Review and clearance of project
- Tailoring biosafety programme to the level of risk assessment.
- Assess and monitor the research facilities, procedures and experts involved
- Inform the Principal Investigator about IBSC review, approval or rejection of their projects
- Ensure that the information provided in the application form is correct and complete.
- Provide guidance to Principal Investigator on the issues related to biosafety
- Assess field experiments to ensure that the proposed risk assessment, risk management and emergency plan are sufficient.
- Review the emergency plan

- Review and report to the Head of the organisation and to Member Secretary,
- In addition, the Chairperson, Member Secretary, Biosafety Officer and DBT nominee of IBSC have specific functions.
- Further the Principal Investigator(s) of the project(s) have significant role to play in complying with he regulatory framework.

Chair person

- The Chairperson should preside over the IBSC meetings
- The Chairperson of IBSC may designate a member of the IBSC to serve as Acting Chair in his/her long term absence.
- Ensure that the facilities at the organisation are sufficient to meet the containment levels
- Regular meetings of IBSC are held to review recombinant research projects in the organisation and open discussion - views of external members as well DBT nominee are recorded sincerely.
- Provide leadership and support that laboratory personnel receive appropriate training prior to the initiation of research projects.

Member Secretary

- The Member Secretary shall be responsible for all reporting and communication with respect to functioning of IBSC in an organisation
- Maintain documents, agenda, minutes of meetings and other related papers for proper record keeping
- Organising meetings and provide technical advice to Principal Investigator about safety procedure and containment facility.

Biosafety Officer

- Act as a focal point for compliance with rDNA safety guidelines, good lab practices, biological containment etc
- Ensure that measures are in place to prevent the accidental escape of regulated GMOs/LMOs and rDNA materials.
- Undertake periodic laboratory inspections.
- Assist Investigator in developing emergency plans for containment and clean up accidental spills; investigates and reviews recombinant DNA lab accident
- A report from the officer may form part of the IBSCs annual report.

Principal Investigator

- To make an initial determination of the required levels of physical and biological containment in accordance with the stipulated guidelines.
- To submit the initial research protocol and any subsequent changes (such as changes in the source of DNA or host vector system) to the IBSC for review and approval.
- To ensure that no work is initiated until the research project has been approved by the IBSC and has met all requirements of DBT guidelines.
- To communicate with IBSC throughout the conduct of the project.
- To ensure safe conduct of the rDNA experiments in his laboratory.

- To make available the protocols that describe the potential biohazards and the precautions to be taken to all laboratory staff.
- To instruct laboratory staff about the practices and techniques required to ensure safety, and the procedures for dealing with accidents including the reasons and provisions for any precautionary medical practices advised or requested.
- To supervise the performance of the laboratory staff to ensure that the required safety practices and techniques are employed.
- To undertake corrective measures promptly for any work errors and conditions that may result in the release of recombinant DNA materials.

DBT Nominee

- The IBSC has been constituted as per the norms.
- The stipulated rDNA Safety Guidelines are strictly followed in the organisation/institution.
- The IBSC meets regularly, at least twice in a year to review the ongoing activities and provides annual reports to RCGM in the prescribed proforma.
- All the activities are within the purview of the guidelines and in the knowledge of RCGM.
- The DBT nominee is also expected to guide the IBSC on biosafety issues.

IBSC meetings

- Regular meetings
- Emergency meetings

- Documents to be reviewed
- Attendance and Quorum
- Minutes of IBSC meetings

Regular meetings

- At least twice in a year to review and approve the rDNA projects in an organisation.
- It is important that the Chairperson and Member Secretary ensure that regular meetings take place.
- More than two meetings may be held as per requirement of the projects.

The IBSC members are expected to look into the following aspects during the meetings:

- Action taken on the decisions of earlier IBSC meetings.
- Assessment of work elements and approval as per risk category of organism involved.
- Evaluation of projects and direction for submission to appropriate agencies for statutory approvals.
- Inspection of containment facilities, unit process areas, greenhouses etc. and preparation of reports for regulatory agencies.
- Review the medical reports of employees
- Examining and recommending procedures and other approval requirements.

Emergency meetings

- The Chairperson may call an emergency meeting of the IBSC to address any urgent issues such as non-compliance or unexpected events involving GMOs/ LMOs/ rDNA materials in an organisation.

Documents to be reviewed

- Prior to the regular meeting, each member should be sent a copy of the documents to be reviewed at the meeting, in addition to other information to be discussed.

- The prescribed formats for information on projects to the IBSC and RCGM should be used appropriately.

Attendance and Quorum

- Attendance of members at IBSC meetings is mandatory.
- Members who are unable to attend the meeting should inform the Chairperson, IBSC and provide a written summary of their review and any comments to the IBSC.
- It is mandatory to provide the duly signed attendance sheet as part of IBSC minutes, while submitting the minutes of IBSC meeting to the Member Secretary, RCGM.

- At least 50% of the IBSC members along with DBT nominee must be present to conduct the meeting. The final approval or disapproval of non-exempt projects of GMOs/LMOs/rDNA materials requires a majority vote by IBSC members and DBT nominee.

- If a quorum is lost at any time during the meeting, the meeting should be adjourned and no further action should be taken by the IBSC until a quorum is re-established or a new meeting is appropriately convened.

Minutes of IBSC meetings

- Attendance of members and invitees, if any
- IBSC's review and decisions on all applications considered in the meeting including modifications to project proposals, if any.
- Remarks on suitability of facilities with respect to containment requirements after inspection of GMOs/LMOs/rDNA facilities and suggestions, if any.
- Signatures of the Chairperson and DBT nominee is compulsory otherwise minutes will be treated as an invalid.
- The minutes should clearly indicate about discussions and decisions taken during the meeting.

Conflict of interest

- IBSC members who have a conflict of interest in a project should not be present during the IBSC's initial or project extension review deliberations on the project.
- This might be their own proposal, or a proposal in which they are co investigators, or in which they or a family member has a financial interest.
- Minutes should record the information on such members who have declared a conflict of interest.

Confidentiality

- All members including DBT nominee and external experts are expected to maintain confidentially of the proposals and other related information made available to them for review, reference or discussion and not divulge any confidential or Intellectual Property (IP) or commercial business information (CBI) of an applicant/organisation/institute acquired as a result of review of such proposals and subsequent discussions.

- IBSC members are also expected to respect the confidential nature of the opinions expressed by other IBSC members or invited experts during discussions in the meetings or provided in written form and not divulge to any person, press or media.

- If desired, IBSCs can sign a confidentiality agreement with the members including DBT nominee and/or external experts so as to ensure confidentiality of applications, issues and other matters placed before an IBSC.

Reporting Requirements

- **Submission of Annual reports**

  31 January –prescribed proforma

- **Information for biosafety websites**

  Two regulatory websites set up by DBT

  Biosafety Regulatory Website (http://dbtbiosafety.nic.in)
  Information about contact address, composition and agenda and minutes of meetings – updated – web id – accounts – member secretary

  Indian GMO Research Information System (IGMORIS)
  Website (http://www.igmoris.nic.in)
  Two years once –updates / change in system

- **Reporting for incidents and spills**

  Incidents, accidents and illnesses, equipment failure
  PI is responsible for reporting - IBSC Chairperson – 24 hrs
  Incident Reporting to RCGM - 48 hours - Chairman sign
  Submitted to Member Secretary, RCGM, DBT, New Delhi – 110 003

IBSC records

- Approved and duly signed minutes of IBSC meetings including attendance sheets.
- Annual report of all ongoing rDNA projects.
- Information about the projects approved by IBSC and related enclosures / attachments.
- Applications forwarded to RCGM or GEAC
- Other documents such as statements regarding conflict of interest, confidentiality agreements with DBT nominee and/ external experts etc.

Persons responsible for compliance

- Responsibility - **Head of the organisation** and **PI**

  Head of the Organisation

  Responsible for compliance with Rules, 1989

  Other related regulations regarding rDNA research

  Safe conduct of activities

- **Principal Investigator**

  Comply with the appropriate research guidelines and laws related to biosafety and is accountable to the Head and IBSC .

  Laboratory Personnel (Technician, Technologist, Student, Post-doctorate)

Laboratory personnel must

- Follow all safety guidelines and establish good laboratory practices. Work within the assigned biological safety containment level as recommended by the PI.
- Immediately notify the PI or BSO of any health condition that may be due to their work in the laboratory or any health condition that may be compromised prior to the initiation of a research project (i.e. pregnancy, immunosuppression).
- Follow all practices and procedures as provided by the PI and BSO, and ensure strict compliance with all required biosafety regulations and guidelines.
- Report problems, procedural mistakes, spills, etc. to the PI, and if necessary to the BSO, as soon as they occur.
- Report to the PI, BSO or IBSC on non-compliance of biosafety guidelines or policies.

Addressing noncompliance

- **Noncompliance by Principal Investigator (PI)/ Organisation**

  Suspension of the use of GMOs / LMOs / rDNA materials.

  Cessation of the approval for use of the GMOs / LMOs / rDNA materials.

  Confiscation and /or destruction of the GMOs / LMOs / rDNA materials.

  Any other action necessary to protect the public and/or the organisation,

  Including suspending the relevant research activity.

  Reporting to the RCGM.

- **Noncompliance by IBSCs**

  The registration of an IBSC can be cancelled by DBT in case IBSC does not comply with stipulated guidelines, including reporting requirements. If annual report of an IBSC is not received for two consecutive years, the registration will automatically laps and the organisation shall have to re-initiate the process of registration of its IBSC.

Training

- **Training of IBSC Members**

  Initial mandatory - refresher training on biosafety
  Familiarise - rDNA guidelines and related regulations
  Refresher training on any changes to national guidelines
  Organised by IBSC with commitment from the organisation
  Responsibility Chairperson to arrange for providing this training

- **Training of Laboratory Personnel**

  General biosafety training - organised by the organisation
  Individual researchers – report – training under gone
  Laboratory training - Based on incidents

Laboratory inspections

- The IBSC will inspect laboratories using checklists
- Inspection reports should be maintained
- For routine inspections - relevant authorised personnel
- IBSC members, representatives and officers

Security of GMOs/LMOs/rDNA materials

- Authorised access and proper storage of biological materials
- The PI and all associated personnel - controlling
- Access to biological materials – authorised personnel
- The PI, depending on the risk group of GMOs/ LMOs and rDNA materials, should develop a plan to protect the security
- Additional locks for laboratories, chain-of-custody forms- log book
- Routine cleaning, maintenance and repairs
- Restricting unauthorised persons
- Addressing loss of keys
- Passwords & secured information

Disposal

- IBSC may review the disposal methods as potentially hazardous biological materials and GMOs / LMOs / rDNA materials are to be considered as "regulated waste" and should be disposed of in a manner consistent with rDNA safety guidelines and other stipulated guidelines issued from time to time.