Mini Review Article

Bio Safety Regulatory Agencies in India

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Abstract

The IBC's primary objective is to safeguard protection of personnel, the general public, and the environment. Institutional Biosafety Committees (IBCs) are the cornerstone of institutional oversight of recombinant DNA research. To meet this goal, the IBC imposes requirements for safe laboratory and biological safety practices; reviews and approves policies, procedures, training, programs and facilities pursuant to the safe use of biological agents, other biological materials, and toxins. The IBC is responsible for reviewing and approving those research and teaching activities conducted by faculty, staff, students, and/or visiting scientists on Cornell property, and/or under the control of Cornell faculty, staff or students, that involve the use of biohazardous materials including regulated animal and plant pathogens, biological toxins, and recombinant or synthetic nucleic acid molecules. The Institutional Biosafety Committee (IBSC) is a statutory committee of an organisation undertaking r-DNA activities, constituted as per provisions of Rules, 1989 and chaired by the Head of the organisation or his designate.

***Keywords*:** Institutional Biosafety Committee, recombinant DNA, Department of Biotechnology, National institute of Health

Introduction

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 (Draft: National Biotechnology Regulatory Bill, 2008) through the six competent authorities notified under the Rules which are as follows:

(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).

DBT has formulated various biosafety guidelines for research involving GMOs that include Recombinant DNA safety guidelines, 1990, revised in 1994, Guidelines for carrying out research in transgenic plants, 1998 and Guidelines for preclinical and clinical evaluation of rDNA vaccines, diagnostics and other biologicals. The purpose of these guidelines is to provide guidance to organisations that have Institutional Biosafety Committees (IBSCs, 2011) or intend to set up an IBSC in compliance with "Rules for the manufacture, use/import/export and storage of hazardous microorganisms/ genetically engineered organisms or cells, 1989" (hereinafter referred as Rules, 1989) notified by the Ministry of Environment and Forests (MoEF), Government of India under the Environment (Protection) Act, 1986 (Notification No. G.S.R. 1198(E) dated 12-11-86 published in the Gazette of India No. 525 dated 12-11-86). These 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. Federal Guidelines established by the National Institute of Health, require that institutions conducting or sponsoring research using recombinant or synthetic nucleic acid molecules covered by the NIH Guidelines, be responsible for ensuring that the research is conducted in full conformity with the provisions

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of the *NIH Guidelines*. In order to fulfill this responsibility Cornell University has established an Institutional Biosafety Committee (IBC), charged with oversight responsibilities for all research related activities involving recombinant or synthetic nucleic acid molecules and other biohazardous materials(The NIH Guidelines-Appendix E1-3). The IBC's primary objective is to safeguard protection of personnel, the general public, and the environment. To meet this goal, the IBC imposes requirements for safe laboratory and biological safety practices; reviews and approves policies, procedures, training, programs and facilities pursuant to the safe use of biological agents, other biological materials, and toxins.

The IBC is responsible for reviewing and approving those research and teaching activities conducted by faculty, staff, students, and/or visiting scientists on Cornell property, and/or under the control of Cornell faculty, staff or students, that involve the use of biohazardous materials including regulated animal and plant pathogens, biological toxins, and recombinant or synthetic nucleic acid molecules (The NIH Guidelines-Appendix E1-3).

Regulatory Authority: RCGM is the Regulatory Authority functioning in DBT to whom IBSCs shall report and Genetic Engineering Appraisal Committee (GEAC) is the apex Regulatory Authority functioning in MoEF responsible for authorizing environmental release.

Constitution of IBSC

i. 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.

ii. The IBSC shall be registered with DBT.

Composition

1. IBSC membership

The IBSC shall have the following members:

- Head of the organisation or his designate (a suitable senior officer) as the Chairperson
- Three or more scientists engaged in rDNA work or molecular biology with at least one outside expert in the relevant discipline.
- A member with medical qualifications - Biosafety Officer (in case of work with pathogenic agents/large scale use).
- A nominee of DBT.

One of the in house scientists may be designated as Member Secretary. The IBSC may comprise as many member as the organisation consider necessary to enable proper examining the type of activities with GMOs/LMOs and rDNA materials being undertaken with the organisation. There is no upper limit to the membership of IBSC (Guidelines and Handbook for Institutional Biosafety Committees (IBSCs) prepared by Department of Biotechnology, Ministry of Science & Technology).

Tenure of IBSC

i. Each IBSC shall be registered for a period of three years.

ii. The registration needs to be renewed after every three years.

iii. The request for renewal must be submitted 60 days in advance before the expiry of the tenure of IBSC.

2. IBSC Chairperson

3. Appointment of IBSC Members

4. Biosafety Officer

5. DBT Nominee

6. Changes in IBSC Membership

7. Use of Experts/Consultants.

Role of IBSC in approval

The role of IBSC in research, large-scale experiments/ production/field release and import and shipment shall be as under:

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

Responsible of IBC

1. Review and approval of the research or teaching activity performed by individual researchers, on a regular and continuing basis.
2. Independently assess the containment levels of the work, as required by the *NIH Guidelines*, for all experiments, including those involving whole plants and/or animals, cell cultures, tissues, human-derived materials, biological toxins, infectious agents, and regulated pathogens and pests.
3. Assess the facilities, procedures, practices, and training and expertise of personnel involved with biohazardous research.
4. Lower the containment levels for certain experiments in which DNA from Risk Group 2, 3, or 4 or Restricted Agents is cloned into nonpathogenic prokaryotic or lower eukaryotic

host-vector systems.

5. Perform periodic reviews and/or require modifications of recombinant or synthetic nucleic acid molecules and/or biohazardous research and research facilities at Cornell to ensure compliance with the *NIH Guidelines* and other government regulations.
6. Notify the Principal Investigator of the results of the IBC's review and approval.
7. Adopt emergency plans covering accidental spills and personnel contamination resulting from research using recombinant or synthetic nucleic acid molecules.
8. Report significant problems with or violations of the *NIH Guidelines* and any significant research related accidents or illnesses to ORIA and the appropriate institutional official and when necessary to NIH/OBA.
9. In cooperation with ORIA, suspend or terminate approval of research that is not being conducted in accordance with the IBC's requirements

Functions

On behalf of the institution, the Institutional Biosafety Committee is responsible for (Guidelines and Handbook for Institutional Biosafety Committees (IBSCs) prepared by Department of Biotechnology, Ministry of Science & Technology):

- **Section IV-B-2-b-(1).** Reviewing recombinant DNA research conducted at or sponsored by the institution for compliance with the *NIH Guidelines* as specified in Section III, *Experiments Covered by the NIH Guidelines*, and approving those research projects that are found to conform to the *NIH Guidelines*. This review shall include: (i) independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research; (ii) assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant DNA research; and (iii) ensuring compliance with all surveillance, data reporting, and adverse event reporting requirements required by the *NIH Guidelines*.
- **Section IV-B-2-b-(2).** Notifying the Principal Investigator of the results of the Institutional Biosafety Committee's review and approval.
- **Section IV-B-2-b-(3).** Lowering containment levels for certain experiments as specified in Section III-D-2-a, *Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems*.
- **Section IV-B-2-b-(4).** Setting containment levels as specified in Sections III-D-4-b, *Experiments Involving Whole Animals*, and III-D-5, *Experiments Involving Whole Plants*.
- **Section IV-B-2-b-(5).** Periodically reviewing recombinant DNA research conducted at the institution to ensure compliance with the *NIH Guidelines*.
- **Section IV-B-2-b-(6).** Adopting emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA research.
- **Note:** The *Laboratory Safety Monograph* describes basic elements for developing specific procedures dealing with major spills of potential hazardous materials in the laboratory, including information and references about decontamination and emergency plans. The NIH and Centers for Disease Control and Prevention are available to provide consultation and direct assistance, if necessary, as posted in the *Laboratory Safety Monograph*. The institution shall cooperate with the state and local public health departments by reporting any significant research-related illness or accident that may be hazardous to the public health.
- **Section IV-B-2-b-(7).** Reporting any significant problems with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the appropriate institutional official and NIH/ORDA within 30 days, unless the Institutional Biosafety Committee determines that a report has already been filed by the Principal Investigator. Reports to NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health/MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892-7010, (301) 496-9838.
- **Section IV-B-2-b-(8).** The Institutional Biosafety Committee may not authorize initiation of experiments which are not explicitly covered by the *NIH Guidelines* until NIH (with the advice of the RAC when required) establishes the containment requirement.
- **Section IV-B-2-b-(9).** Performing such other functions as may be delegated to the Institutional Biosafety Committee under Section IV-B-2, *Institutional Biosafety Committee*.

Conclusion

IBSC mainly a vital role in the authorizing environmental release recombinant or synthetic nucleic acid molecules and other biohazardous materials to safeguard protection of personnel, the general public, and the environment. IBC imposes safe laboratory and biological safety practices; reviews and approves policies, procedures, training, programs and facilities pursuant to the safe use of biological agents, other biological materials, and toxins.

Conflict of Interest: Nil

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