Biosafety Regulations in Pakistan

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PAKISTAN ENVIRONMENT PROTECTION AGENCY

www.environment.gov.pk
Pakistan is a party to the Cartagena Protocol on Biosafety (CPB)

National Biosafety Centre (NBC) was established as a project to cater the Obligation of Cartagena Protocol on Biosafety

The main objectives of the NBC are;

- To provide safeguard against the undesirable effects of the Genetically Modified Organisms (GMOs)
- Implementation of Pakistan Biosafety Rules and National Biosafety Guidelines as they provide the necessary management and regulatory framework for the GMOs.
- Regulate the import, export, production, store, handle, sell or release the GMOs
- To predict the effect of GMOs on the environment, plants, animals and human health.
Implementation Mechanism

- **NBC**
  - National Biosafety Committee

- **TAC**
  - Technical Advisory Committee

- **IBC**
  - Institutional Biosafety Committee
Chairman: Secretary, Ministry of Climate Change
Secretary: Director General, Pak-EPA

National Biosafety Committee

Chairman Pakistan Atomic Energy Commission

Representatives of Provincial Governments

Representative, Ministry of Commerce

Representative, Federal Board of Revenue

Representative, Ministry of National Health Services, Regulation and Coordination

Representative, Ministry of Science and Technology

Representative, Ministry of Industries & Production

Representative, Higher Education Commission

Representative, Ministry of National Food Security & Research
Functions of National Biosafety Committee:

a) to establish standards and procedures for risk assessment and labeling of living modified organisms, substances or cells and products thereof.

b) to consider application(s) for import, export or commercial release of living modified organisms, and on the recommendations of Technical Advisory Committee allow release or reject applications after reviewing the risk assessment carried out in accordance with the Biosafety guidelines.

c) to ban or restrict import, export, sale, purchase or trading of any living modified organism causing or likely to cause risk to public health, safety or environment.

d) to develop linkages with foreign Biosafety committees and relevant agencies to ensure that genetic manipulation practices in Pakistan address international Biosafety concerns and observe universal codes of conduct.
Technical Advisory Committee

Chairperson: Director General, Pakistan Environmental Protection Agency
Vice Chairperson: Director, National Institute for Biotechnology & Genetic Engineering

- Executive Director, Pakistan Medical Research Council (PMRC)
- Representative Pakistan Atomic Energy Commission
- Executive Director, National Institute of Health (NIH)
- Representatives of Provincial Governments
- Representatives of NGOs
- Member (Science), Pakistan Council of Industrial and Scientific Research (PCSIR)
- Representative Centre for Molecular Genetics, University of Karachi
- Representative Centre for Applied and Molecular Biology
- Member (Plant Sciences), Pakistan Agriculture Research Council
- Cotton Commissioner, Ministry of Textile Industries
- Member (Animal Sciences), Pakistan Agriculture Research Council
- Director Pakistan Environmental Protection Agency
- Director General, Federal Seed Certification & Registration Department
Functions of Technical Advisory Committee.

a) to examine applications and recommend to National Biosafety Committee on permitting or otherwise laboratory work, field work or release of living modified organism, substances, cells, and products thereof;

b) to review and control of safety measures adopted while handling large scale use of genetically engineered organisms/classified organisms in research, developmental and industrial production activities;

c) to review research methodologies in genetic engineering and recombinant work at the international level and assess the associated risks to guide institutions;

d) to monitoring release of engineered organisms/products into environment, oversee field applications and experimental field trials;

e) to provide information/data inputs to National Biosafety Committee upon surveillance of approved projects under industrial production, and in case of environmental releases with respect to safety risks and accidents; and

f) to supervise directly or through any person authorized in this behalf the implementation of the terms and conditions laid down in connection with the approvals accorded by the National Biosafety Committee.
### Institutional Biosafety Committees

**Head of the Institution (Chairperson)**

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<tr>
<th>Subject Experts and Biosafety Officer (Members)</th>
<th>Social Scientist/Economist (Member)</th>
<th>Representative of Civil Society (Member)</th>
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Functions of Institutional Biosafety Committee:

a) to assist in the activities of National Biosafety Committee and Technical Advisory Committee;

b) to assist researchers in undertaking risk assessment, organizing training programs and harmonizing experimental conditions with Biosafety guidelines;

c) to determine additional safeguards and draft supplementary operating instructions the institution, in line with and addressing the specific risks and concerns uncovered;

d) to monitor all regulated work under progress within the institution and counsel the proponents on issues of Biosafety and on compliance with Biosafety guidelines on a regular basis, or as requested;

e) to serve, where appropriate as a gateway for the flow of information, ideas and opinion between the National Biosafety Committee and the research teams;

f) to ensure health of laboratory and field personnel as may deem necessary from medical records;

g) to liaise with National Biosafety Committee and Technical Advisory Committee on import export, manufacture, process, use or sale of any genetically modified organism/substance or cells and products thereof for the purpose of research; and

h) to prepare, in conjunction with the research teams, specific contingency plans after undertaking risk assessments and reviewing project proposals
NBC Situation After 18th Amendment to the Constitution of Pakistan

- After devolution of the subject environment under 18th amendment NBC is facing legal problems, however with the enactment of the Pakistan Biosafety Act 2015, such legal issues would hopefully be resolved
Establishment of NBC on the regular budget/non-development side

Pakistan Biosafety Act 2015

Challenges

Capacity building/Mass awareness

Establishment of National Biosafety Laboratory
Thanks!

Have a nice day!