THE PAKISTAN BIOSAFETY RULES, 2005

[21st April, 2005]

S.R.O. (I) 336(I)/2005 dated 21-4-2005.--In exercise of the powers conferred by section 31 of the Pakistan Environmental Protection Act, 1997 (XXXIV of 1997), the Federal Government is pleased to make the following rules, namely: -

1. Short title and commencement.-(1) These rules may be called the Pakistan Biosafety Rules, 2005.

(2) They shall come into force at once.

2. Application.- These rules shall be applicable to-

(a) manufacture, import and storage of micro-organism and gene technological products for research whether conducted in laboratories of teaching and research, research and development institutes or private companies involved in the uses and applications of genetically modified organisms and products thereof.

(b) all work involved in the field trial of genetically manipulated plants, animals (including poultry and marine life), micro-organisms and cells; and

(c) import, export, sale and purchase of living modified organism, substances or cells and products thereof for commercial purposes.

3. Definitions.-(I) In these rules, unless there is anything repugnant in the subject or context.-

(a) "Act" means the Pakistan Environmental Protection Act, 1997 (XXXIV of 1997);

(b) "applicant" means any person including an artificial judicial person, seeking licence for activities related with application of these rules;

(c) "Biosafety" means the mechanism developed through policy and procedures to ensure the environmentally safe application of biotechnology;

(d) "biosafety guidelines" means the Pakistan Biosafety Guidelines notified by the Ministry of Environment;

(e) "commercial release" means any intentional introduction of living modified organisms into the environment through sale or purchase;

(f) "contained use" means any operation or activity, undertaken within a facility, installation or other physical structure, which involves living modified organisms, substances or cells and products thereof and controlled in a manner that limit their contact with, and their impact on, the external

environment and the general population;

(g) "deliberate release" means any intentional transfer of living modified organisms to the environment or nature, irrespective of the way in which it is done;

(h) "experimental release" means any intentional introduction into the environment of living modified organisms, with containment measures and which is not used for commercialization;

(i) "export" means the intentional transboundary movement from Pakistan to another country;

(j) "Import" means the international transboundary movement into Pakistan from another country;

(k) "Institutional Biosafety Committee " means the committee constituted under rule 8;

(l) "Intentional introduction into the environment" means any deliberate release of living modified organisms subject to these rules that is not "contained use", including release for experimental purposes but does not include living modified organisms imported for direct use for food or feed or for processing;

(m) "licence" means the licence granted by the Federal Agency under section 14 of the Act;

(n) "living modified organism or genetically modified organisms" means living cells or organisms, substances, cells and products thereof whose genetic material has been altered or modified by any variety of techniques of modern biotechnology to make them capable of producing new substances or perform new functions;

(o) "living organisms" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

(p) "modern biotechnology" means the application of-

i. in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or
ii. fusion of cells beyond the taxonomic family,

to overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

(q) "National Biosafety Committee" means the committee constituted under rule 4; and

(r) "Technical Advisory Committee" means the committee constituted under rule 6.

4. Establishment of National Bio-safety Committee.--(1) The Federal Government shall, by notification in the official Gazette, establish a National Biosafety Committee consisting of the following members namely:-

(a)	Secretary, Ministry of Environment	*Chairperson*
(b)	Member (Bio-sciences), Pakistan Atomic Energy Commission	Member
(c)	Chairpersons of concerned Institutional Biosafety Committees	Members
(d)	Representatives of Provincial Governments	Members
(e)	Representatives of Government of AJK	Member
(f)	Chairman, PARC	Member
(g)	Representative Ministry of Food & Agriculture	Member
(h)	Representative Ministry of Health	Member
(i)	Representative Ministry of Science and Technology	Member
(j)	Representative Ministry of Education	Member
(k)	Director-General, Department of Plant Protection	Member
(l)	Director-General, Pakistan EPA	Member

(2) The Director-General, Pakistan EPA, shall act as Secretary of the National Bio-safety Committee

(3) The Committee may co-opt any other member as deemed necessary for its functioning.

(4) The members of the Committee, other than *ex-officio* members, shall hold office for a term of three years extendable to another term of three years with the approval of the Chairperson.

(5) The Committee shall frame its own rules and procedures.

(6) The Committee shall hold meetings as and when deemed necessary, provided that not less than four meetings shall be held in a year.

5. Functions of National Biosafety Committee.-- (1) The National Biosafety Committee shall perform the following functions namely:-

(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, the procedures established under clause (a) and any other reliable information;

(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;

(e) to cooperate with other relevant federal or provincial authorities overseeing the import and release of living organisms and formulate guidelines for the identification, inspection and regulation of transgenic species exotic organisms and others;

(f) to restrain on the advice of Technical Advisory Committee any person, authority or institute involved with genetic manipulation experiments of potential hazards;

(g) to facilitate exchange of technical expertise to various research institutions and regulatory agencies in setting up appropriate experimental conditions;

(h) to Facilitate all levels of supervision of genetic manipulation work by assisting other regulatory bodies including Institutional Biosafety Committees, in establishing pertinent codes disciplines and guidelines for the appraisal of biohazards and the management of bio- safeguards;

(i) to coordinate efforts of Institutional Biosafety Committees and inform and educate the public on biosafety issues and on proposed national policies.

(j) to ensure that laboratory, field work and commercial release of genetically modified organisms and their products conforms to the national biosafety guidelines;

(k) to prepare and provide to Institutional Biosafety Committees the various notifications and assessment forms, biosafety guidelines, related documents and assorted signs for facilities.

(l) to inform the various institutions engaged in genetic manipulation work about new developments in biosafety so as to avoid exposure of laboratory personnel, the community or the environment to undue risks;

(m) to coordinate efforts between pertinent government agencies and private organizations to maintain safety levels in biotechnological work and to prepare them for biological emergencies;

(n) to certify high-level laboratories, plant glass houses and animal houses intended for use in high-risk work. Upon request by the institution, and at the earliest convenience, the National Biosafety Committee may inspect a facility and either issue certification, or recommend additional precautions, if elements of the facility are determined to be inadequate to support the types of risk/hazard companying work requiring such physical containment;

(o) to inspect high-level laboratories and containment facilities on a regular basis. The National Biosafety Committee may inspect laboratories and facilities of containment level C2. PH 2. C2A, as specified in the biosafety guidelines, equivalent or higher at any time subsequent to certification without prior notice.

(p) to inspect systems equipment and instruments governing ambient biosafety levels in genetic manipulation laboratories;

(q) to keep information of commercial significance confidential from public domain if so requested in writing by applicant, person or institution or organization;

(r) to monitor the safety related aspects of ongoing research projects and achievements involving genetically engineered organisms/hazardous substances or cells and products thereof.

6. **Technical Advisory Committee.**-- (1) The Federal Government shall, by notification in the official Gazette, establish a Technical Advisory Committee consisting of the following members, namely:--

(i)	Director-General, Pakistan EPA	Chairperson
(ii)	Director, National Institute for Bio-Technology and Genetic Engineering, Faisalabad.	Vice Chairperson
(iii)	Executive Director, Pakistan Medical Research Council(PMRC)	Member
(iv)	Director, Pakistan Council of Industrial and Scientific Research (PCSIR)	Member
(v)	Director, Health Services Academy (HAS)	Member
(vi)	Executive Director, National Institute of Health	Member
(vii)	Representative, Pakistan Atomic Energy Commission, Islamabad	Member
(viii)	Representative, Centre for Molecular Genetics, University of Karachi	Member
(ix)	Representative, Centre for Applied and Molecular Biology, Lahore	Member
(x)	Representative, National Commission on Biotechnology	Member
(xi)	Relevant technical representative Animal, Sciences PARC	Member
(xii)	Relevant technical representative Plant Sciences, PARC	Member
(xiii)	Director, Pakistan Environmental Protection Agency, Islamabad	Member
(xiv)	Two experts from private sector/civil society	Members

(2) The Director, Pakistan Environmental Protection Agency shall act as Secretary of the Technical Advisory Committee.

(3) The Committee may co-opt any technical representative from any province.

7**. Functions of Technical Advisory Committee.-** The following are the functions of the Technical Advisory Committee, namely,--

(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 DNA work at the international level and assess the associated risks to guide relevant institutions;

(d) to monitor release of engineered organisms or products into environment and to oversee field applications and experimental field trials;

(e) to provide information or 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.

8. Institutional Biosafety Committees.- (1) The head of the institution related to biotechnology shall notify Institutional Biosafety Committee with the following minimum composition:

(a) Head of the institution	Chairperson
(b) Subject expert (s)	Members
(c) Social Scientist/economist (for social impact)	Member
(d) Representative of civil society	Member

9. Functions of Institutional Biosafety Committee.--- (1) The Committee shall perform the following functions, namely,--

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

(b) to assist researchers in undertaking risk assessment, organizing training programmes and harmonizing experimental conditions with biosafety guidelines;

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

(d) to evaluate the qualifications of researchers involved in biotechnological projects and assess whether each retains a thorough understanding of good microbiological practices necessary for the supervision of students, assistants and junior personnel;

(e) 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;

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

(g) to maintain and update a directory of all personnel engaged in activities at every biosafety level and to instruct new personnel on the correct laboratory or field practices, emergency procedures and equipment operation at the relevant level;

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

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

(j) to withhold funds and or use administrative authority to immediately refrain programmes if biosafety guidelines are violated;

(k) to prepare and implement the institutional emergency and response plan according to the details provided in the manuals and guidelines prepared by National Biosafety Committee;

(l) to assess all projects referred to it, and on the basis of the information provided and the risks forecast determine under which category of work the proposals fall and whether to endorse the work proposed;

(m) to maintain records of approved project proposals for laboratory genetic manipulation work (including notification for project exemption) and the assessments;

(n) to forward summaries of all project proposals submitted for IBC notification, and the assessments to the Technical Advisory Committee for records and information or for review and recommendation in the case of proposals for Risk Category 2 and 3 work;

(o) to undertake risk assessment, in cooperation with the research teams as necessary, to determine the appropriate containment and biosafety conditions, operating procedures and emergency safeguards for Risk Category 2 and 3 genetic manipulation work, and for the housing, storage or movement of regulated material and also the waste;

(p) to prepare, in conjunction with the research teams, specific contingency plans after undertaking risk assessments and reviewing project proposals;

(q) to enforce, with particular emphasis on Risk Category 3 work, all recommendations, and ensure that the conditions of National Biosafety Committee have been acknowledged and promptly addressed;

(r) to inspect and certify, before use in genetic manipulation work, C1 level laboratories, conventional animal houses, PH 1 plant glass houses, and quarantine and medical facilitates for infected animals; and

(s) to monitor and access the containment features of and the working conditions within all laboratories, plant glass houses and animal houses supporting the institution's work, to ensure that the various facilities are maintained at the standards and requirements delineated in Appendices 4 through 11 of biosafety guidelines.

10. The Bio-Safety Officer (BSO).-- (1) Institutions and organizations engaged in biotechnology or genetic manipulation work shall appoint or designate a Bio-Safety Officer (s) well conversant with bio-safety issues and emergency counter-measures to perform the following functions; namely,--

(a) to assist and liaison with Institutional Biosafety Committee;

(b) to review in conjunction with the Institutional Biosafety Committee and on a regular basis operating procedures and biosafety records, and to assay the integrity of containment facilities and safety equipment or utilities; and

(c) to advise on all matters pertaining to risk and biosafety, health of personnel, contingencies at work and infractions of biosafety guidelines.

11. Prohibition and Licence requirements.--(1) No person shall import, export, sell, purchase or trade living modified organisms, substances or cells and products thereof for any purposes, without the prior obtaining of licence from the Federal Agency.

(2) Applicants seeking licence for activities shall submit an application prepared in conformity with the requirements of the Biosafety Guidelines to the Federal Agency accompanied with a prescribed fee.

(3) Any person to whom a licence has been granted shall notify the Federal Agency and the National Biosafety Committee of any change in or addition to the information already submitted.

12. Confidential Information.-- Information designated as confidential by the applicant shall be protected from disclosure inconformity with Article 21 of the Cartagena Protocol as set forth in the biosafety guidelines.

13. Risk Assessments and Risk Management.--(1)The National Biosafety Committee shall ensure that risk assessment is carried out in accordance with the biosafety guidelines for all activities that require licence.

(2) Risk assessment, including the auditing of risk assessments and evaluation of proposed risk management measures, and field trials shall be carried out on a case by case basis in a scientifically sound manner, in accordance with Article 15 and Annex III of the Cartagena Protocol as set forth in the biosafety guidelines.

14. Decision making and Communication of Decision.--(1) A final decision shall be made and communicated to the applicant within--

(a) sixty days for Risk Category 2 and 3 contained use activities (as specified in the biosafety guidelines);

(b) ninety days for experimental releases; and
(c) one hundred and twenty days for commercialization.

(2) Decisions shall be based on information set forth in the application, scientific risk assessment and prior field experience with the living modified organisms in Pakistan.

(3) Final decisions shall be recorded in a decision document as described in the biosafety guidelines. No person shall vary the purpose of the licence activity as set forth in the decision document unless he obtains a licence.

(4) The licence granted by the Federal Agency under rule 11 shall not take effect until the applicant executes an undertaking in which the applicant assumes the legal duty to comply with applicable provisions of the biosafety guidelines in existence as of the date of the licence.

15. Grant of Licence.--(1) All grants of licence under rules 11 shall be subjected to terms and conditions as to the labeling, control to be exercised by the applicant, supervision, restriction on use, the layout of the enterprise and as to the submission of information or any other condition deemed appropriate by the Federal Agency.

(2) All approvals of the Federal Agency shall be for a specified period not exceeding four years at the first instance renewable for two years at a time. The Federal Agency shall have powers to revoke such approval in the following situations; namely,--

(a) if there is any new information as to the harmful effects of the genetically engineered organisms or cells;

(b) if the genetically engineered organisms or cells cause such damage to the environment, nature or health as could not be envisaged when the approval was given, or

(c) non compliance of any condition stipulated by the Federal Agency.

16. Application for re-examination.-- (1) Any applicant may file application with the National Biosafety Committee for re-examination after a minimum time of six months if the applicant considers that--

(a) a change in circumstances has occurred that may have a material effect on the outcome of the risk assessment upon which the decision was based; or

(b) additional scientific or technical information has become available that may have a material effect on the decision including any conditions, limitations or requirements imposed under an authorization.

17. Special Requirements for Import and Export of Living Modified Organisms.--(1) Living modified organisms, substances or cells and products thereof imported for contained use, for intentional introduction into the environment, or for direct use as food or feed or for processing shall be identified in accordance with the requirements of Article 18 of the Cartagena Protocol as set forth in the biosafety guidelines and such import, where required, shall be in accordance with these rules and

the National Plant Quarantine Regulations aligned with International Plant Protection Convention. All such imports will also be governed by the provision of Import Trade and Procedures Order (IT&PO) and Export Policy and Procedures Order (EPPO).

(2) Any person proposing to export living modified organisms, substances or cells and products thereof shall provide all information including risk assessment and field trials to the exporting country and such export, where required, shall be in accordance with these rules and the National Plant Quarantine Regulations aligned with International Plant Protection Convention. All such exports will also be governed by the provision of IT&PO and EPPO.

18. Transition and Reviews.-- Activities that were ongoing pursuant to the pre-existing regulatory system at the date of the entry into force of these rules shall be subject to the review procedure set forth in rule 11 but may continue until such time as a final decision is provided to the applicant. Any application pending at the date of the entry into force of these rules shall be subject to the provision of these rules.

19. **Production.--** Production in which living modified engineered organisms, substances or cells or products thereof or micro-organism are generated or used shall not be commenced except with the consent of National Biosafety Committee. This shall also apply to production taking place in connection with development, testing and experiments.

20. Deliberate or unintentional release.--(1) Deliberate or unintentional release of living modified organisms or hazardous micro-organisms, substances or cells and products thereof including deliberate release for the purpose of experiment is not allowed.

(2) National Biosafety Committee on the recommendations of the Technical Advisory Committee may in special cases give approval of deliberate release.

21. Permission and approval for certain substances:- Substances and products, which contain genetically engineered organisms or cells or micro-organisms shall not be produced, sold, imported or used except with the approval of National Biosafety Committee and in accordance with sub-rule (2) of rule 20.

22. Permission and approval for food stuffs.-- Food stuffs, ingredients in food stuffs and additives including processing aids containing or consisting of living modified organisms, substances or cells and products thereof shall not be produced, sold, imported or used except with the approval of the National Biosafety Committee and in accordance with sub-rule (2) of rule 20.

23. Responsibility to notify interruptions or accidents.--(1) Any person, institution or organization whether has obtained licence under rule 11 or not shall immediately notify the Technical Advisory Committee of any interruption of operations or accidents that may lead to discharges of genetically engineered organisms or cells which may be harmful to the environment, nature or health or involve any danger thereto.

(2) Any notice given under sub-rule (1) above shall not lessen the duty of the person who is responsible to try effectively to minimize or prevent the effects of interruptions of operations of accidents.

24. Preparation of off-site emergency plan by the Technical Advisory Committee.-- **(**1) Technical Advisory Committee may prepare an off-site emergency plan for emergencies relating to a possible major accident and prepare a plan of action in consultation with all concerned.

(2) For the purpose of enabling the Technical Advisory Committee to prepare the emergency plan required under sub-rule(1), the person, institute or organization shall provide the Technical Advisory Committee with such information relating to the handling of hazardous micro-organisms/genetically engineered organisms under his control as the Technical Advisory Committee may require including the nature, extent and likely off-site effects of a possible major accident and the Technical Advisory Committee shall provide the person, institute or organization with any information related to off-side emergency plan.

25. Information and Inspections.-- (1) Any person seeking licence or who has obtained licence under rules 11 shall at the direction of Technical Advisory Committee submit all such information deemed necessary for its functioning.

(2) The National Biosafety Committee or its Authorized Officer may at any reasonable time inspect or verify compliance of any condition laid down in the licence issued under rule 11.

26. Fees.--(1) The Technical Advisory Committee may fix a fee with the approval of National Biosafety Committee, to cover, in whole or in part, the expenses incurred by the authorities in connection with approvals, examinations, supervision and control.

27. Powers to give directions.--(1) The Federal Government may give any written direction which shall be binding on the National Biosafety Committee or the Technical Advisory Committee or the Institutional Biosafety Committees to comply with.
