Balochistan Bio Safety Rules 2020

1. Short title and commencement:-

(1) These rules may be cited as the Balochistan Bio-safety Rules 2020.

(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 use and application of genetically modified organisms and the products thereof;

(b) all works 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 organisms, substances or cells and products thereof for commercial purposes.

3. Definitions.– (1) In these rules:

(a) "Act" means the Balochistan Environmental Protection Act 2012;

(b) "applicant" means any person including an artificial juridical person, seeking authorization for activities relating to the application of these rules;

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

(d) "Bio-safety Committee" means the committee constituted under rule 4;

(e) "bio-safety guidelines" means the bio-safety guidelines notified by the Government;

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

(g) "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;

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

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

(j) "export" means the intentional trans-boundary movement from the area of the jurisdiction of the Balochistan to any other area;

(k) "import" means the trans-boundary movement into the area of the jurisdiction of the Balochistan from any other area;

(l) "Institutional Bio-safety Committee" means the committee constituted under rule 8;

(m) "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;

(n) "license" means the license granted by the Provincial Agency under section 13 of the Act;

(o) "living organism" 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 which are not a technique used in traditional breeding and selection; and

(q) "Technical Advisory Committee" means the Committee under rule 6.

(2) The words and expressions used but not defined in these rules shall have the same meanings as assigned to them in the Act.

4. Establishment of Bio-safety Committee.–

(1) The Government shall, by notification in the official Gazette, establish a Bio-safety Committee consisting of the Secretary to Government, Environment Protection and Climate Change Department as Chairperson and the following members:

(a) representative of Agriculture Department;

(b) representative of Food Department;

(c) representative of Health Department;

(d) representative of Education Department;

(e) representative of Livestock & Dairy Development Department;

(f) representative of Industries Department;

(g) representative of Forest, Fisheries and Wildlife Department; and

(h) Director General.

(2) The Director General shall act as Secretary of the Bio-safety Committee.

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

(4) 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 Bio-safety Committee.

(1) The Bio-safety Committee shall perform the following functions:

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

(b) to consider any application for export, import 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 bio-safety 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 Bio-safety agencies to ensure that genetic manipulation practices in the Balochistan address international bio-safety concerns and observe universal codes of conduct;

(e) to cooperate with other relevant national 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 in 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 Bio-safety 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 Bio-safety Committees and inform and educate the public on bio-safety issues and on proposed Provincial policies;

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

(k) to prepare and provide to Institutional Bio-safety Committees the various notifications and assessment forms, bio-safety guidelines, related documents and assorted signs for facilities;

(l) to inform the various institutions engaged in genetic manipulation work about new developments in bio-safety 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; and, on request by the institution, and at the earliest convenience, the Bio-safety 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 or hazard companying work requiring such physical containment;

(o) to inspect high-level laboratories and containment facilities on a regular basis;

(p) to inspect systems equipment and instruments governing ambient bio-safety 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; and

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

(2) The Bio-safety Committee may inspect laboratories and facilities of containment level C2, PH2 or C2A, as specified in the bio-safety guidelines, equivalent or higher at any time subsequent to certification without prior notice.

6. Technical Advisory Committee.

(1) The Government shall, by notification in the official Gazette, establish a Technical Advisory Committee consisting of the Director General as its Chairman and the following members:

(a) Vice Chancellor; University of Agricultural, Faisalabad;

(b) Vice Chancellor, University of Veterinary and Animal Sciences, Lahore;

(c) Vice Chancellor, University of Health Sciences, Lahore;

(d) Vice Chancellor, University of the Balochistan, Lahore;

(e) Director General Agriculture (Research), AARI, Faisalabad;

(f) Director General Health;

(g) Director General; Livestock & Dairy Development Department;

(h) Director, National Institute for Bio-Technology & Genetic Engineering;

(i) Director, Center for Molecular Biology, Lahore;

(j) Director Food;

(k) Director Industries;

(l) Chief Conservator Forest;

(m) two experts from private sector; and

(n) Director, Provincial Agency.

(2) The Director Provincial Agency shall act as Secretary of the Technical Advisory Committee.

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

7. Functions of Technical Advisory Committee.

The following are the functions of the Technical Advisory Committee:

(a) to examine applications and recommend to the Bio-safety Committee for permitting or otherwise laboratory work, field work or release of living modified organism, substances, cells, and products thereof;

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

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

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

(e) to provide information or data input to the Bio-safety Committee upon surveillance of approved projects under industrial production and 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 decisions of the Bio-safety Committee.

8. Institutional Bio-safety Committee.

The head of the institution related to biotechnology shall notify Institutional Bio-safety Committee with the following minimum composition:

(a) Head of the institution; Chairperson

(b) Subject expert or experts; Members

(c) Social Scientists or Economists (for social impact); and Members

(d) Representatives of civil society.

9. Functions of Institutional Bio-safety Committee.

The Committee shall perform the following functions:

(a) to assist in the activities of Bio-safety 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 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 has 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 advise the proponents on issues of bio-safety and on compliance with bio-safety 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 Bio-safety Committee and the research teams;

(g) to maintain and update a directory of all personnel engaged in activities at every bio-safety level, and 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 Bio-safety Committee and Technical Advisory Committee on import, export, manufacture, process, use or sale of any genetically modified organisms or substances or cells and products thereof for the purpose of research;

(j) to withhold funds or use administrative authority for immediate stoppage of programs if bio-safety guidelines are being violated;

(k) to prepare and implement the institutional emergency and response plan according to the details provided in the manuals or guidelines prepared by Bio-safety 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 bio-safety 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) particular emphasis on Risk Category 3 work, to enforce all recommendations, and ensure that the conditions of Bio-safety 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 assay the containment features of and the working conditions in all laboratories, plant glass houses and animal houses supporting the institution's work, to ensure that various facilities are maintained at the standards and requirements mentioned in Appendices 4 to 11 of bio-safety guidelines.

10. Bio-safety officer

Institutions and organizations involved in biotechnology or genetic manipulation work shall appoint or designate a bio safety officer well conversant with bio-safety issues and emergency countermeasures to perform the following functions:

(a) to assist and liaison with Institutional Bio-safety Committee;

(b) to review, in conjunction with the Institutional Bio-safety Committee and on a regular basis, operating procedures and bio-safety 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 bio-safety, health of personnel, contingencies at work and infractions of bio-safety guidelines.

11. Prohibition and authorization requirements.

(1) No person shall import, export, sell, purchase or trade living modified organisms, substances or cells and products thereof for any purposes, without obtaining license from the Provincial Agency

(2) An applicant seeking license for activities shall submit an application prepared in conformity with the requirements of the Bio-safety guidelines to the Provincial Agency accompanied by a copy of the receipt of the deposit of the prescribed fee.

(3) Any person to whom a license has been granted shall notify the Provincial Agency and the Bio-safety Committee of any change in or addition to the information already submitted.

12. Confidential information.

Commercially significant information designated as confidential by the applicant shall be protected from disclosure in conformity with Article 21 of the Cartagena Protocol as set forth in the bio-safety guidelines.

13. Risk assessments and risk management.

(1) The Bio-safety Committee shall ensure that risk assessment is carried out in accordance with the bio-safety guidelines for all activities that require license.

(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 bio-safety 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 Bio-safety 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 the Balochistan.

(3) Final decisions shall be recorded in a decision document as mentioned in the bio-safety guidelines.

(4) No person shall vary the purpose of the licensed activity as set forth in the decision document unless he obtains a new license.

(5) The license granted by the Bio-safety Committee pursuant to rule 12 shall not take effect until the applicant executes an undertaking by which the applicant assumes the legal duty to comply with the applicable provisions of the bio-safety guidelines issued.

15. Grant of license.

(1) A license issued under rule 11 shall be subject 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 Agency.

(2) All approvals of the Agency shall be for a specified period not exceeding four years in the first instance and renewable for two years at a time.

(3) The Agency shall have powers to revoke such approval in the following situations:

(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 Bio-safety Committee.

16. Import 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 bio-safety guidelines and such import, where required, shall be in accordance with the National Plant Quarantine Regulations aligned with International Plant Protection Convention.

(2) All such imports shall also be governed by the provision of import trade and procedures order and export policy and procedures order.

(3) 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.

(4) All such export, where required, shall be in accordance with the National Plant Quarantine Regulations aligned with International Plant Protection Convention and all such exports shall also be governed by the provision of import trade and procedures order and export policy and procedures order.

17. Transition and reviews.

(1) Activities that were ongoing pursuant to the pre-existing regulatory system at the commencement 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.

(2) Any application pending commencement of these rules shall be subject to the provision of these rules.

18. Production.

Production in which living modified engineered organisms, substances or cells or products thereof or microorganism are generated or used shall not be commenced except with the consent of Bio-safety Committee and this shall also apply to production taking place in connection with development, testing and experiments.

19. Deliberate or unintentional release.

(1) Subject to sub-rule (2), the deliberate or unintentional release of living modified organisms or hazardous microorganisms, substances or cells and products thereof, including deliberate release for the purpose of experiment is prohibited.

(2) The Bio-safety Committee may, in a special case and on the recommendations of the Technical Advisory Committee, give approval of deliberate release.

20. Permission and approval for certain substances.

Substances and products, which contain genetically engineered organisms or cells or microorganisms shall not be produced, sold, imported or used except with the approval of the Bio-safety Committee and in accordance with sub-rule (2) of rule 19.

21. 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 Bio-safety Committee and in accordance with sub-rule (2) of rule 19.

22. Responsibility to notify interruptions or accidents.

(1) Any person, institution or organization whether having license 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) 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.

23. Off-site emergency plan.

(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 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 or 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.

(3) The Technical Advisory Committee shall provide the person, institute or organization with any information pertaining to off-side emergency plan.

24. Information and inspections.

(1) Any person seeking license or who has obtained license under rule4 11 shall, at the direction of Technical Advisory Committee, submit all such information as is deemed necessary for its functioning.

(2) The Bio-safety Committee or its authorized officer may at any reasonable time, inspect or verify compliance of any condition laid down in the license issued under rule 11.

25. Fees.

The Technical Advisory Committee may, with the approval of the Bio-safety Committee, fix a fee to cover, in whole or in part, the expenses incurred by the authorities in connection with approvals, examinations, supervision and control.

26. Powers to give directions.

(1) The Government may give any written direction to the Bio-safety Committee, Technical Advisory Committee or an Institutional Bio-safety Committee.

(2) The Bio-safety Committee, Technical Advisory Committee or the Institutional Bio-safety Committee shall comply with the directions given under schedule (1).