

ON LIVING MODIFIED ORGANISMS

CHAPTER ONE General provisions

Article 1 The objective of the Law

1.1. The purpose of this Law is to regulate the relations in respect of producing, handling and use of living modified organisms, its trans-boundary movement through the state border and protection of bio-safety within the state territory.

Article 2 Applicable legislations with respect to the living modified organisms

2.1. The applicable legislations with respect to the living modified organisms shall include the Constitution of Mongolia, the Law of National Security, the Law on Quarantine and Verification of trans-boundary movement of animals and plants or commodities and raw materials originated thereof, the Law on Transfer of Technology, this Law and/or any other rules and regulation adopted in compliance with them.

2.2. If any other international agreement, to which Mongolia is a Party, stipulates other than the present Law, the provisions of the international agreement shall prevail.

Article 3 Use of terms

3.1. For the purposes of the this Law;

3.1.1. "Protection of bio-safety" means a set of precautionary measures taken to prevent from the adverse effects resulted from the living modified organisms that may have on human health, animals and



plants or any other biological diversity and measures taken to eliminate the caused harms, damages and dangers.

3.1.2. "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

3.1.3. "Biotechnology" means the application of nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

3.1.4. "Use of living modified organisms" means the course of actions to own, possess and use of living modified organisms produced through of scientific, experimental conduct and manufacturing methods.

3.1.5. "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

3.1.6. "Risks" means any likely risks of adverse effects that may have on human health and environment resulted from living modified organisms

3.1.7. "Risk assessment" means the conclusive assessments made by the expertise establishment confirming that living modified organisms have no adverse effects on human health and environment

Article 4 National Committee on Bio-safety

4.1. National Committee on Bio-safety (hereinafter referred to as the "National Committee") is hereby established within the framework of state administrative authority responsible for nature and environment to supervise and handle the bio-safety related matters throughout Mongolia.

4.2. The fundamental guidelines of the National Committee shall be the principles of national security, protection of consumers' rights and transparency.

4.3. The National Committee shall consist of the representatives of such state administrative authorities responsible for nature and environment, trade and industry, health, food and agriculture as well as the representatives of state expertise auditing and verification establishments, biological research institutions and the relevant non-governmental organizations.



4.4. The Government Cabinet Member responsible for nature and environment shall approve the Charter of the National Committee and appoints or dismisses its members.

4.5. The Meetings shall serve as the main conduct of work of the National Committee and it may have a full time Office.

4.6. The National Committee may set up, under its competence, a part time scientific expertise Council who shall evaluate the risk assessment reports on living modified organisms.

4.7. The National Committee shall adopt its Meeting procedures and the Rules of the Council, referred to in paragraph 4.6 of this Law.

4.8. The Coordinator and/or the Secretary of the National Committee, who functions on a full time bases, shall liaise with Secretariat of the Cartagena Protocol.

Article 5 The Power of the National Committee

5.1. The National Committee has the following full powers;

5.1.1. To develop and implement the state policy on bio-safety provided the policy has been approved by the Government and to assist in creating a favorable environment for overall biotechnology development;

5.1.2. To work out various bio-safety related regulations and planning and approval by the competent authorities and officials;

5.1.3. To evaluate and verify the trans-boundary movement of living modified organisms;

5.1.4. To review and consider any projects to produce living modified organisms or to carry out assessment on the use of produced living modified organisms;

5.1.5. Coordination of operations and activities of relevant bio-safety establishments and cooperation with them;

5.1.6. To take appropriate measures on destroying the living modified organisms within related law framework.

5.1.7. To demand the related individuals, business entities and organizations to produce new additional information and data to perform the duties specified in paragraph 5.1.3 and 5.1.4.

5.2. Any decision adopted by the National Committee shall be accessible and available to the public knowledge through mass media.

CHAPTER TWO

Trans-boundary movement, producing and risk assessment of living modified organisms

Article 6 Trans-boundary movement of living modified organisms

6.1. The state administrative authority responsible for nature and environment shall issue the licenses to export, import and transit the living modified organisms to individuals, business entities and organizations based on National Committee recommendation provided the licenses are not permissible to be transferred to any other party.

6.2. The Government Cabinet Member responsible for nature and environment shall approve the sample of the License.

6.3. The individuals, business entities and organizations shall submit their requests, in written, to the state administrative authority responsible for nature and environment for state trans-boundary movement of living modified organisms.

6.4. The requests of the individuals, business entities and organizations shall be accompanied by the following documents;

6.4.1. The notification of importing party or the recommendation on completion of risk assessment on the living modified organisms by the accredited and competent scientific establishment of the importing or exporting country Government;

6.4.2. Introduction of specifications of the living modified organisms, descriptions of conditions enabling the living modified organisms breeding;

6.4.3. Assessment report of the living modified organisms effects on the environment;

6.4.4. Safety handling rules and recommendations and instructions on any risk preventive measures;

6.4.5. Notarized copy of ID cards of the individuals or certifications of business entities or organizations.

6.5. The state administrative authority responsible for nature and environment shall decide upon whether or not to issue the license based on the National Committee assessment recommendation on the request and its accompanied documents.

6.6. The state administrative authority responsible for nature and environment shall annul the licenses on the following grounds;

6.6.1. It is proved that the documents produced under paragraph 6.4 are failed to be true or false.

6.6.2. It is proved that the licensed living modified organisms to cross the border are unsafe and dangerous.

6.7. Government cabinet member responsible for emergency shall approve the living modified organisms' safety handling rules and recommendations and instructions on any risk preventive measures

Article 7

General requirements on trans-boundary movement of living modified organism, its prohibition, suspension and destroying.

7.1. The relevant provisions of the Law on Quarantine and Verification of trans-boundary movement of animals and plants or commodities and raw materials originated thereof shall apply on general requirements for trans-boundary movement of living modified organism, its prohibition, suspension and destroying.

7.2. Operations of destroying or detoxification of living modified organisms proved to have adverse effects following risk assessment shall be carried out under the control of the state inspector.

Article 8

Border check point for living modified organisms trans-boundary movement

8.1. The Government shall determine the border check point for the living modified organisms' trans-boundary movement based on the National Committee recommendation.

Article 9 Producing and manufacturing of living modified organisms

9.1. Any individuals, business entities and organizations shall submit, in advance, their projects on producing or manufacturing of living modified organisms to the National Committee for consideration and review.

9.2. The National Committee, having considered the project, shall make one of the following decisions;

9.2.1. To make a decision that the project shall undergo a test on environment impact assessment and risk assessment;

9.2.2. To make a decision to reject the implementation of the submitted project.

9.3. If a decision is made in accordance with paragraph 9.2.1 of this Law, the individual, business entity or the organization shall submit the project for a test on environmental impact assessment and risk assessment in accordance with Article 4.1 of the Law on Environmental impact assessment and Article 10 of this Law and resubmit the reports back to the National Committee.

9.4. National Committee shall make recommendations on whether or not to produce or manufacture the living modified organisms having reviewed the reports referred to in paragraph 9.3.

9.5. The individuals, business entities and organizations shall carry out any project on conduct of experiments of living modified organisms in a manner of contained use only.

Article 10 Risk assessment of living modified organisms

10.1. Risk assessment of living modified organisms shall be carried out by a scientific institution with due mandate.

10.2. The right to carry out risk assessment of living modified organisms shall be guaranteed by the Government to a scientific institution with due mandate on recommendations submitted by the National Committee.

10.3. Risk assessment of living modified organisms shall be carried out in strict compliance with the provisions of Annex III of the Cartagena Protocol.

Article 11 Technology confidentiality

11.1. The Members of the National Committee, relevant personnel of the state administrative authority accountable for nature and environment and Members of the Council referred to in paragraph 4.6. of this Law, are obliged to protect the technology confidentiality of living modified organisms, obtained in the course of their duties and assignments.

11.2. Any individual or business entity and organization shall provide the National Committee Task force with sufficient proof for the protection of technology confidentiality of living modified organisms, if it deems necessary.

11.3. The Task force, having considered the proofs and notifications, shall submit the relevant data and documents requesting the confidentiality to the state administrative authority accountable for state secrecy for a decision.

11.4. The National Committee Task force shall have a personnel specifically designated for the purposes of technology confidentiality.

11.5. Confidentiality of technology shall be applied in accordance Law on State Secrecy.

CHAPTER THREE Bio-safety

Article 12 Bio-safety

12.1. The Government shall adopt a basic directive on implementation of the Law on living modified organisms.

12.2. The basic directive referred to in paragraph 12.1. shall take account of such provisions on bio-safety as the liabilities and appropriate measures to be taken by state administrative authority accountable for emergency as well as each and every individual, business entity, organization and non governmental organization.

Article 13 Use of living modified organisms

13.1. Any individual, business entity or organization shall be entitled to produce, conduct experiments, use and manufacture the living modified organism provided that they have been guaranteed permission subsequent to due assessments.

13.2. Any individual, business entity or organization shall abide by the bio-safety basic directives when using the living modified organism.

13.3. Any individual, business entity or organization shall use special container, packaging or wrapping with description mark and logo for identifying the origin of living modified organisms or any products originated thereof, produced, manufactured or in use.

13.4. All products in use or recently produced products originated from the living modified organisms shall be accompanied with appropriate instruction for safe use and handling.

Article 14

Rights and obligations of individuals, business entities or organizations in regard of bio-safety

14.1. Individuals, business entities or organizations shall have the following rights in regard of bio-safety;

14.1.1. To use the living modified organisms at their own choice and provided that the organisms have no adverse effects on human health and environment.

14.1.2. To import or export living modified organisms through the state border or produce them provided that the organisms have no adverse effects on human health and environment on the basis of special licenses

14.1.3. To request the relevant authorities to provide any information on living modified organisms;

14.1.4. To request the National Committee to take various measures on bio-safety;

14.1.5. To make complaints at various relevant organizations and officials in regard of producing, use, import and export of living modified organisms;

14.2. Individuals, business entities or organizations shall have the following obligations in regard of bio-safety;

14.2.1. To abide by the relevant laws and regulations and follow the legitimate decisions made by the competent authorities in regard of bio-safety;

14.2.2. To carry out risk assessments of the living modified organisms by the scientific research institutions with due mandate;

14.2.3. To abide by the instructions and directives on use and producing

14.2.4 To compensate any damage caused to the third party when using and producing living modified organisms.

Article 15

Involvement of individuals and non governmental organizations in preventing from and abolition of damages caused by living modified organisms

15.1. Individuals and non governmental organizations, within their legitimate framework, may be involved in verification of the implementation processes of any bio-safety related laws and regulations and if it is believed to have any breach may apply to the competent authorities for an appropriate decision.

15.2. Individuals and non governmental organizations may collaborate and work in partnership with any governmental or non governmental organizations or any other interested organizations in preventing from and abolition of damages caused by living modified organisms

15.3. State budget may render support and assistance in implementing the actions referred to in paragraph 15.2, within the framework of relevant laws and regulations.

CHAPTER FOUR Miscellaneous

Article 16 Financing of bio-safety

16.1. Bio-safety related actions and operations shall be financed from the state budget.

16.2. In an emergency situation where abolition of damages caused by living modified organisms require an immediate financing from the state budget the financed expenses shall be compensated by the faulty party.

16.3. In case of any project financed by the state budget as a result of its importance and efficiency, the financed expenses shall be compensated by the project implementing party on contract bases.

Article 17

Professional inspection of living modified organism its use and trans-boundary movement

17.1. The related professional inspection authorities and state inspectors shall carry out inspections on the use and trans-boundary movement of living modified organisms on the ground of permissions granted by the state administrative authorities responsible for nature and environment.

17.2. The related professional inspection authorities and state inspectors enjoy the rights and obligations empowered by the Law on State inspection and verification.

Article 18

Trans-boundary movement related dispute settlement of living modified organisms

18.1. Any dispute arisen between individuals, business entities and organizations with state inspector in connection with trans-boundary movement of living modified organisms shall settled by the State Professional Inspection Authority and if the concerned individuals, business entities and organizations do not agree with decision they may claim the case to the Court.

Article 19 Registration of living modified organisms

19.1. Any organizations with the rights to conduct experiment or producing and manufacturing the living modified organisms shall be registered at the state registry and are obliged to submit the living modified organisms in use or processed for registration.

19.2. The registration processes shall be carried out by the National Committee Office.

Article 20 Liability

20.1. The aftermath relief expenses caused by the living modified organisms shall be compensated by the guilty party.

20.2. Any breach occurred during the trans-boundary movement of living modified organisms shall be imposed by relevant administrative penalty provisions of the Law on Quarantine and Verification of trans-boundary movement of animals and plants or commodities and raw materials originated thereof.

20.3. Any breach of relevant laws and regulations on living modified organisms qualified as non criminal liability, the Court or the competent State Inspector may impose an administrative penalty.

20.3.1. Depending on the character of the breach and caused amount of damages an individual shall be fined by 25000T to 50000T and an official by 25000? to 100000T.

20.3.2. Any business entity and organization shall be fined by 50000T to 150000T and the operations on certain activities to be suspended until the breach adjusted accordingly and living modified organisms to be destroyed.

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