

## **Biosafety Law of the Islamic Republic of Iran\***

### Article 1- Definitions:

The terms used in the present Law shall have the meanings set out underneath:

1-1-Protocol: The Cartagena Protocol on Biosafety to the Convention on Biological Diversity, which the Islamic Parliament of Iran enacted on 20/08/2003.

1-2. Modern Biotechnology: Pursuant to definitions set forth in the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, modern biotechnology means the application of:

- a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
- b. 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.

1.3 Biosafety: A set of measures, policies, regulations and methods to ensure benefiting from the advantages of modern biotechnology and to prevent the possible bad effects of application of this technology on biodiversity, human health, livestock, plants and the environment.

1-4. Living modified organism: means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

1-5. Living organism: means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.

1-6. Release: means the first non-transboundary movement of a living modified organism in the natural and agricultural environment for the purpose of reproduction or commercial production.

1-7. Field Trial: A purely scientific study of the various traits of living modified organism under transboundary conditions with any possibility of release.

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\* This is an unofficial translation and any liability whatsoever shall lie upon user in person. Islamic Parliament of Iran

1-8 Unwanted Movement: Any undeliberate movement of living modified organism, including due to natural disasters.

Article 2. All affairs related to production, release, domestic and international movement, export, import, supply, purchase, sale, consumption and use of genetically modified live organisms are permitted in accordance with the provisions of the present Law, and the Government is obligated to make the necessary arrangements for non-state sectors to handle these affairs.

Article 3- With the intention of:

A) Policymaking, definition and approval of strategies in the field of biosafety and monitoring its implementation in accordance with the provisions of the present Law;

B) Coordination between the legal duties of competent executive bodies and the provisions of the present Law;

C) Ratification of bylaws, directives and rules of the present Law;

The National Biosafety Council is established as a regulatory body; Members of the Council are First Vice President, Minister of Agriculture, head of the Department of the Environment, Minister of Health, Treatment and Medical Education, Minister of Science, Research and Technology, one PhD-holding member of Scientific-Specialized Associations of Modern Biotechnology (Non-Governmental Organizations) proposed by NGOs to be endorsed by Minister of Science, Research and Technology and Approved by Presidential Decree, one faculty member specializing in biosafety (at least Associate Professor) proposed by Minister of Health, Treatment and Medical Education and approved by Presidential Decree, one member of Parliamentary Committee on Agriculture, Water and Natural Resources and one member of Parliamentary Committee on Health and Treatment, nominated by the Committees and voted by Parliament.

Note 1- First Vice President shall serve as Chairman of the Council.

Note 2- Representatives of NGOs and Faculty Members are named to the Council for a period of four years, subject to renewal for future terms.

Note 3 - The Secretariat of this Council is based in the Department of the Environment without organizational development and under the status quo.

Note 4. The decisions of this Council are notified for implementation after validation by President.

Article 4 - Issuance, renewal and revocation of license for activity in affairs pertaining to modern biotechnology in accordance with the laws of each organ and biosafety regulations cited in Article 3 of the present Law shall be addressed by the following competent executive organs:

A) Ministry of Agriculture Jihad in matters related to agricultural produce and natural resources.

B) Ministry of Health, Treatment and Medical Education in matters related to food, cosmetic, hygienic and medical safety and health.

C) Department of the Environment in matters related to wildlife and the assessment of environmental risks based on scientific documents provided by applicants.

Note – The issuance of license for the scientific documentation of assessment of potential risks presented by governmental or non-governmental natural and legal persons with regard to release, import, export and domestic and international transfer of all genetically modified living organisms cited in the present Law, Clause C, shall rest with the executive organs cited in clauses A and B of the present Article.

Article 5- Considering that:

A – the responsibility of protecting genetic resources and the gene bank within the boundaries of all affairs related to agriculture, gardening, forests, pastures, deserts, fishery, livestock, poultry and apiculture, and livestock and poultry food and diseases related to them rests with Ministry of Agriculture Jihad;

B - the responsibility of protecting biodiversity and its genetic resources related to wildlife, national parks, protected zones, prohibited hunting areas, rivers, lagoons and seas lies with the Department of the Environment;

C- The responsibility of protecting human health and examining the assessment of potential risks of modified living organisms that are consumed as human food, as well as the responsibility of identifying and adopting necessary measures for living organisms that are directly or indirectly pathogenic to human beings lies with Ministry of Health, Treatment and Medical Education;

All natural and legal persons who, after field trial, intend to release genetically modified living organisms in the abovementioned boundaries of responsibility, are obligated to obtain certificate from the aforesaid competent organs in addition to present identity card for the said living organisms in compliance with the provisions set out in Clause C of Article 4 of the present Law. The aforementioned executive organs are required to submit their written and substantiated opinions on agreement or disagreement with the scientific documentation of the assessment of potential risks incurred by the applicant within three months after receiving them.

Note - In order to consider the applicant's objection to the opinion of competent executive organs and to resolve disputes or to deal with probable complaints filed against competent executive organs cited in the present Law, a "Three-Member Arbitration Committee", comprising biosafety experts (at least Associate Professor) nominated by Ministry of Health, Treatment Medical Education, Ministry of Agriculture Jihad, and Department of the Environment shall be set up on the strength of the decree of "Chairman of National Biosafety Council".

Article 6 – In case any of the competent executive organs find any non-compliance with the provision of the present Law with regard to the actions of natural or legal persons active in the field of modern biotechnology they shall temporarily suspend the permission of the perpetrator and refer the case to a competent judicial body for proceedings. The judicial body is required to deal with these cases in a special or extraordinary session. If the infractions are confirmed by the judicial authority, in case the infraction has denied other people their rights or incurred losses to others or the ecosystem the offender shall be sentenced to compensating damage, and, in case of repeated offense, in addition to compensation, the defendant shall pay cash penalty twice as much as damage incurred all previous licenses will be declared null and void and will be banned from exercising his executive activities.

Article 7 – All natural and legal persons who intend to import, export or internally and internationally transport genetically modified organisms cited in the present Law are required to:

A) Submit necessary information and scientific documentation for the assessment of potential risks required under the provisions of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity to relevant executive bodies set out in Article 4 of the present Law and obtain necessary permissions.

B) Fulfill requirements for packaging, transportation and labeling. The requirements for packaging and labeling and internal and external transportation will be provided by the National Biosafety Council within six months and will be notified after validation by President.

C) If the modified living organism is enclosed for research purposes the nature of the subject needs to be clearly defined while the physical address and the identity of the recipient and the sender should be specified with precision.

Article 8 – Information and activities of natural and legal persons applying for license or those holding license from a competent executive body cited in Article 4 of the present Law except for:

A: applicant's name and address, general description of genetically modified organism(s)

B: a summary of the assessment of potential risks

C: all methods and plans for monitoring and assessing genetically modified living modified organisms and methods related to responding in emergency cases

D: the purpose and place of entry and release conditions (location and rate of release) are considered confidential and are subject to Intellectual Property Law, and no natural and legal person, whether governmental or non-governmental, is entitled to disclose or illegally use the findings of research and modified living organisms. The perpetrator shall be sentenced by a competent judicial organ to compensating for loss and damage incurred, and in the event of emergency conditions, the terms of this Article shall be subject to the provisions of Article 17 of the Protocol.

Article 9 – While submitting a request to the competent executive organ for obtaining licenses, natural and legal persons must present the competent executive organ a written continent plan including emergency measures and other services to counter unexpected conditions stemming from the involuntary movement with the intention of protecting the environment, biodiversity as well as human, livestock and plant health.

The applicant is also required to deliver the newly obtained information regarding his license as soon as possible to the relevant executive organ to be registered in the relevant database.

Note - In case of emergencies arising from natural disasters or involuntary movement of genetically modified organisms, the competent executive authority is authorized to, while

officially notifying the license holder, declassify necessary sections of confidential information and, according to the circumstances, present to other executive organs for necessary action. In this case, the license holder shall have no right to any claims.

Article 10 - Laboratory and greenhouse study of genetically modified organisms, as well as affairs related to medications and related products with human consumption, are excluded from the provisions of the present Law.

Article 11. The "Competent National Authorities and National Focal Points" cited in Article 19 of the Protocol is Ministry of Agriculture Jihad.

The above law, drawn up in 11 Articles and 7 Notes, was enacted in the open session of the Islamic Parliament of Iran on Wednesday 29/07/2009 and was validated by the Council of Guardians on 12/08/ 2009.

President of Islamic Parliament of Iran

Ali Larijani