Biosafety Law of Islamic Republic of Iran

Article 1- Definitions

The purpose of this Act:

1-1- “Protocol” means Cartagena Protocol on Biosafety which has been enacted by Islamic Consultative Assembly on August 20, 2003.

1-2- "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” means a set of measures, policies, regulations and procedures to ensure the use of benefits of the modern biotechnology and to prevent the potential adverse effects of application of this technology on biodiversity, human health, animal, plant 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-confined introduction of a living modified organism in the natural environment and agriculture for the purpose of reproduction or commercial production.

1-7- “Field trial” means a purely scientific study of the various traits of the living modified organism in confined conditions and without the possibility of release.

1-8- “Unintended release” means non-deliberate release of living modified organism, including those due to unexpected accidents.

Article 2- All affairs related to production, release, domestic and transboundary movement, export, import, placing in the market, buying, selling, consumption and use of living modified organisms are permitted following the provisions of this act and the government is obliged to provide the necessary facilitations for these affairs through nongovernmental sectors.

Article 3- In order to:

A- Policy making, setting and approval of strategies in the field of biosafety and supervising on their implementation in accordance with the provisions of this act;

B- Coordination between the legal functions of competent executive authorities with the provisions of this act;

C- Approval of executive orders, guidelines and requirements to this act;

“National Biosafety Council” is established consisting of First Vice President, Minister of Agriculture Jihad, Head of the Department of Environment, Minister of Health and Medical Education, Minister of Science, Research and Technology, one member scientific specialized societies (NGOs) in the field of modern biotechnology holding a PhD degree recommended by these NGOs and by the approval of Minister of Science, Research and Technology, appointed by the President of the country, one faculty member (at least associate professor) specialized in biosafety recommended by the Minister of Health and Medical Education, appointed by the President, and one member of agriculture, water and natural resources commission and one member of health and treatment commission of the Islamic Consultative Assembly elected by the said commissions and by the vote of Islamic Consultative Assembly as observers.

Note 1- This council is headed by First Vice President.

Note 2- Duration of responsibility for representatives of NGOs and the faculty member is four years, which can be extended for subsequent periods.

Note 3- Secretariat of this council without any organizational expansion and with the current situation is placed in the Department of Environment.

Note 4- Enactments of this council are circulated for execution notified for execution after being approved by the President.

Article 4- Issuance, extension and cancellation of activity licenses for the affairs related to modern biotechnology, while observing the laws related to any authority and biosafety requirements subject to article 3 of this act are entrusted to the competent executive authorities as follows:

A- Ministry of Agriculture Jihad in the affairs related to products of agriculture and natural resources sector;

B- Ministry of Health and Medical Education in the affairs related to the safety and health of foodstuffs, cosmetics, health and medical materials;

C- Department of Environment in the affairs related to wild life and the review of environmental risk assessment based on the scientific documents provided by applicants.

Note- Issuance of approval in return to scientific documents of risk assessment presented by real and legal governmental and non-governmental entities, for release, import, export, and domestic and transboundary movement of all living modified organisms subject to this act are entrusted to executive authorities of paragraphs A and B while observing the paragraph C of this article.

Article 5- Whereas:

A- Ministry of Agriculture Jihad is responsible for protecting genetic resources and the gene banks in the field of agriculture, horticulture, forest, pasture, desert, fisheries, livestock, poultry and beekeeping, and livestock and poultry feed and diseases related to theses issues;

B- Department of Environment is responsible for protecting biodiversity and its genetic resources in the wildlife, national parks, protected areas, prohibited hunting areas, rivers, wetlands and seas;

C- Ministry of Health and Medical Education is responsible for the protection of human health and the assessment of the probable risk of living modified organisms which are consumed as human food, as well as it is responsible for identifying and taking necessary measures for those living organisms which are directly or indirectly harmful to humans;

All real and legal persons who after field trails intend to release living modified organisms into the above mentioned responsibility areas, while preparing identification documents of the said living organism and observing the provisions of paragraph C, article 4 of this act, shall obtain the license from the said competent authorities. The said executive authorities are obliged after receiving scientific documents of risk assessment which prepared by the applicant, to respond in written including their reasons the approval or rejection of the application within maximum of 3 months.

Note- In order to attend the applicant's objection to the views of the competent executive authorities and to resolve disputes, and /or to deal with possible complaints between individuals and competent executive authorities of this act, the "Arbitration Tripartite Commission" composed of biosafety experts (at least associate professor) from Ministries of “Health and Medical Education", "Agriculture Jihad" and "Department of Environment" with the introduction of these authorities and appointment of " National Biosafety Council Chairman” is established.

Article 6- In case any competent executive authority, observes violation of this act from any real or legal person active in the field of modern biotechnology, they should temporarily suspend the license of violator and at the time should forward the issue to the competent judicial authorities for handling the case. In case of the confirmation of violation by the judicial authority, if the violation has caused damage to the rights of other people or has caused damage to other people or the environment, the violator is sentenced to compensate the occurred damages, and in case of repeating for the second time, apart from compensating the damages, he/she is sentenced to pay double the amount of the occurred damages as cash penalty and all of the previous issued licenses will be cancelled and his/her executive activities will be prevented.

Article 7- All real and legal persons who intend to import, export and/ or domestic and transboundary movement of living modified organisms, are obliged to:

A- To submit the required information and scientific documents concerning risk assessment conducted according to Cartagena Biosafety Protocol to the related executive authorities mentioned in article 4 of this act and obtain the required license.

B- To observe the required conditions concerning the packaging and transport and labeling. Conditions of packaging and labeling and domestic and transboundary movement will be approved by the National Biosecurity Council within 6 months and will be notified following the approval of the President.

C- If the living modified organism is intended for contained use and for research, the nature of the subject material has to be clearly defined and the address and identity of the recipient and sender have to be specified.

Article 8- Information and activities of real and legal applicants to obtain the license or have obtained the license from the competent executive authority subject to article 4 of this act, except the followings:

A- The name and address of the applicant, a general description of living modified organism or organisms;

B- A summary of risk assessment;

C- All methods and plans for monitoring and assessment of the living modified organism and methods related to responding in emergency cases.

D- Purpose and location of introduction and mode of release (location and scope of the release) are considered "confidential" and are subject to intellectual property right and no real or legal governmental and non-governmental entities has the right to disclose, or illegal use of results of researches and living modified organisms. The violator according to the verdict of competent judicial authority is condemned to compensate all occurred damages. In case of occurring the emergencies conditions, the conditions of this article is dependent to the provisions of article 17 of the Protocol.

Article 9- In order to protect the environment, biodiversity, the human, animal and plant health, real or legal applicants at the time of submission their application to competent executive authority for approval, have to prepare a written emergency plan including emergency activities and other services to campaign the established conditions due to unintended release and submit it to the related competent executive authority.

Applicant is also obliged to submit promptly the obtained new information concerning the subject of his/her license to the competent executive authority in order to register in the relevant data base.

Note- In case of emergency conditions arising from unexpected accidents and or unintended release of living modified organisms, the competent executive authority is authorized while officially notify to license holder, withdraw a part of required confidential information from classification status and submit them according to the case, to other executive authorities to carry out the required actions. In this case, the license holder has no right to claim.

Article 10- Laboratory and green house research on living modified organisms and also the affairs related to pharmaceuticals and relevant products for human use are exempted from the provisions of this act.

Article 11- Ministry of Agriculture Jihad is appointed as the National Focal Point subject to article 19 of the Protocol.

This act including eleven articles and seven notes was enacted in plenary meeting of Islamic Consultative Assembly dated Wednesday, July 29, 2009 and approved by Guardian Council on August 12, 2009.

Ali Larijani, signed.

True translation is certified by the Cartagena Protocol on Biosafety National Focal Point
Consultative Committee of Islamic republic of Iran.