

LAW OF UKRAINE

On the State System of Biosafety in Creating, Testing, Transporting and Using Genetically-Modified Organisms

No 1102-V

of May 31, 2007

This Law shall regulate relations between executive authorities, manufacturers, vendors (suppliers), developers, researchers, scholars and consumers of genetically-modified organisms and products manufactured by technologies envisaging their development, creation, testing, study, transportation, import, export, marketing, discharge to the environment and use in Ukraine (hereinafter referred to as GMO handling) and ensuring biological and genetic safety.

This Law shall not apply to humans, tissues and individual cells being part of a human body.

SECTION 1 GENERAL PROVISIONS

Article 1. Terms and definitions.

The below terms used in this Law shall have the following meaning:

biological safety shall mean the state of the human environment where there is no negative impact of its factors (biological, chemical, physical) on the biological structure and function of the human person in the present or future generations as well as no irreversible negative impact on biological objects of the natural environment (biosphere) and agricultural plants and animals.

genetic safety shall mean the state of the human environment where there is no unnatural impact on human genes, no unnatural impact on biosphere genes as well as no uncontrolled impact on genes of agricultural plants and animals, industrial microorganisms that causes negative and/or unwanted characteristics in those.

organism, live organism shall mean any form of biological existence (including sterile organisms, viruses and viroids) capable of reproduction or transmission of hereditary factors.

genetically-modified organism, live modified organism (GMO) shall mean any organism in which the genetic material was modified by artificial techniques of gene transfer, which do not occur in the natural conditions, in particular:

- by recombinant methods envisaging formation of new combinations of genetic material by introducing nucleic acid molecules (produced in any manner outside the organism) to any virus, bacterial plasmid or other vector system and their inclusion in the host organism in which they usually do not occur but are able of continuous reproduction;

- by methods envisaging a direct introduction to the organism of hereditary material prepared outside the organism including micro-injections, macro-injections and micro-capsulations;

- by merging cells (including merging protoplasm) or by hybridization methods whereby live cells with new combinations of genetic material are formed by merging two or more cells in a way that is not realized under natural conditions.

products manufactured using GMOs shall mean products, including food products and feed, whose manufacturing technology envisages the use of GMOs at any stage;

genetic engineering activity shall mean a practical field of activity related to the creation, testing and introduction of GMOs into circulation;

discharge of GMOs into the environment shall mean an act (act or failure to act) resulting in the introduction of GMOs into the environment;

closed systems shall mean the system of carrying out genetic engineering activity whereby genetic modifications are introduced

for assessing safety for ~~ma~~ human health and the environment, an opinion has been formulated regarding the possibility of their ~~use~~ use as food products and/ or feed and/ or their sources;

circulation shall mean movement (transportation) or storage and any actions related to the transfer of ownership or ~~possession~~ possession, including sale, exchange or giving.

Article 2. Legislation of Ukraine in th

Article 5. Fields of activity subject to regulation in the course of GMO handling.

This Law shall regulate the following:

- genetic engineering activity carried out within the closed system;
- genetic engineering activity carried out within the open system;
- state registration of GMOs and products manufactured using GMOs;
- introduction of GMOs and products manufactured using GMOs into circulation;
- export, import and transit of GMOs.

SECTION 1 1

ENFORCEMENT OF THE LAW

Article 6. Subjects ensuring enforcement of the Law.

Enforcement of this Law shall be ensured by central executive bodies within the scope of their authority and in accordance with the procedure stipulated by law.

Article 7. Powers of the Cabinet of Ministers of Ukraine.

The Cabinet of Ministers of Ukraine shall:

- ensure state regulation and control in the field of GMO handling and the genetic engineering activity;
- ensure measures regarding state support of the genetic engineering activities;
- direct and coordinate work of centra

- develop and improve the system of control over the observance of safety rules in the genetic engineering activity;
- carry out licensing of the genetic engineering activity in closed systems;
- with regard to the results of the state ecological and state sanitary and epidemiological inspections regarding the biological and genetic safety of GMOs that are carried out based on recognized international approaches, issue permits for importation of unregistered GMOs, if they are used exclusively for science research purposes in closed systems and open systems also with the view to their state testing.

Article 9. Powers of the central executive authority on ecology and natural resources.

The central executive authority on ecology and natural resources shall:

- conduct state ecological inspections of GMOs intended for use in open systems;
- based on scientific principles and international experience, develop criteria for the assessment of risk of the potential GMO impact on the natural environment;
- carry out state registration of plant protection means manufactured using GMOs;
- exercise state supervision and control over the observance of biological and genetic safety measures in respect of biological objects of the natural environment in creating, studying and practical use of GMOs in open systems;
- issue permits to discharge GMOs in open systems.

Article 10. Powers of the central executive authority on health protection.

The central executive authority on health protection shall:

- based on scientific principles and international experience, develop the criteria for assessing the risk of a potential impact on human health of GMOs and products manufactured using GMOs including food products;
- carry out state sanitary and epidemiological inspections of GMOs that are used in open systems to justify the opinion on their biological and genetic safety for humans with the view to their state registration;
- carry out state supervision and control over observing biological and genetic safety measures in respect of humans in creating, studying and practical use of GMOs in open systems;
- carry out state sanitary and epidemiological inspections of products manufactured using GMOs to justify the opinion their safety for human health and life;
- carry out state registration of GMO sources of food products as well as state registration of food products, cosmetic and medicines containing GMOs or manufactured using GMOs;
- approve the list of food products, which are controlled for the content of GMOs in them and the list of relevant methodologies for detecting and identifying GMOs;

Article 11. Powers of the central executive authority on agricultural policy.

The central executive authority on agricultural policy shall:

- ensure state approbation (testing) and state registration of agricultural plant varieties, animal breeds, microbiological, agricultural and veterinarian preparations created based on GMOs;
- carry out state supervision and control over the observance of biological and genetic safety measures in respect of agricultural plants and animals in creating,

The amount of tariffs for the conduct of expert evaluations that shall be the basis for state registration of GMOs and products manufactured using GMOs shall be approved by the Cabinet of Ministers of Ukraine following a submission by a relevant central executive authority.

State registration of GMOs and products manufactured using GMOs may be refused in cases where scientifically justified information has been obtained regarding their danger to human health and the natural environment, if they are used in accordance with their intended purpose.

Genetically-modified plant varieties may be covered by restrictions on their growing in the territories, whose list shall be stipulated by the central executive authority on the ecology and natural resources.

SECTION V

USE, TRANSPORTATION, STORAGE AND RECYCLING OF GMOS.

Article 15. Use of GMOs.

Industrial production and introduction to circulation of GMOs as well as products manufactured using GMOs shall be prohibited prior to their state registration.

Article 16. Importation and transit of GMOs.

It shall be prohibited to import into the customs territory of Ukraine, GMOs and products manufactured using GMOs before their state registration, except those intended for science research purposes or state testing.

Permits to import GMOs intended for science research purposes or state testing shall be issued by the central executive authority on education and science in accordance with the procedure established by the Cabinet of Ministers.

Permits import products manufactured using GMOs intended for science research purposes shall be issued by the central executive bodies within the scope of their authority stipulated in Articles 8-11 of this Law in accordance with the procedure established by the Cabinet of Ministers of Ukraine.

Importation of food products, cosmetic medicines, feed additives and veterinarian preparations containing GMOs or manufactured using GMOs for their direct consumption in accordance with their intended purpose shall be possible only under the condition of state registration of relevant GMOs and products specified in the present passage.

The procedure for such importation shall be established by the Cabinet of Ministers of Ukraine.

Permits for transit carriage of GMOs registered in Ukraine shall be issued by the central executive authority on the ecology and natural resources in accordance with the procedure established by the Cabinet of Ministers of Ukraine.

Article 17. Transportation, storage and recycling of GMOs

Transportation and storage of GMOs must be conditioned upon the taking of a set of measures preventing uncontrolled discharge of GMOs into the natural environment.

GMO materials obtained in the course of testing and unusable or prohibited GMOs as well as containers that used to hold those shall be recycled, destroyed and rendered harmless in accordance with the procedure to be established by the central

executive authority on education and science and the central executive authority on the ecology and natural resources.

