

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 I 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 the 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 system shall mean the system of carrying out genetic engineering activity whereby genetic modifications are introduced to an organism or GMOs are cultivated, processed, stored, used, transported, destroyed or buried in the conditions of existing protection systems preventing their contact with the population and the environment;

open system shall mean the system of carrying out genetic engineering activity envisaging the contact of GMOs with the population and the environment in planned discharges of those into the environment, their use in the agricultural practices, industry, medicine and for environment protection purposes, transfer of technologies and other fields of GMOs circulation;

risk shall mean the possibility of occurrence and a probable scale of consequences of the negative impact on human health and the environment in the carrying out of genetic engineering activity and GMO handling during a certain period of time;

risk analysis shall mean a process including three mutually-related components: GMO risk assessment, risk management and risk notification;

risk assessment shall mean a scientifically-justified process including the identification of GMO danger, characteristics of the danger, assessment of the impact and characteristics of the risk;

risk management shall mean a process of selecting alternative solutions based on GMO risk assessment results and, if necessary, the need to select and introduce the appropriate means of management (control) including regulatory measures;

risk notification shall mean mutual sharing of information about the GMO risk among risk assessment specialists, persons dealing with risk management, interested trade partners and other interested parties;

state registration of GMOs shall mean inputting GMOs onto the registry with due regard to the assessment of the risk of their impact on human health and the environmental situation with the view to further receiving permits for the practical use of GMOs in Ukraine in accordance with their economic purpose;

State Registry of GMOs shall mean a specialized list of GMOs that underwent registration defining their further economic purpose;

State Registry of GMO Sources of Food Products and Feed shall mean a specialized list of GMOs in respect of which, based on international rules and criteria

for assessing safety for human health and the environment, an opinion has been formulated regarding the possibility of their 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, including sale, exchange or giving.

Article 2. Legislation of Ukraine in the field of genetic engineering activity and GMO handling.

Legislation of Ukraine in the field of genetic engineering activity and GMO handling shall include this Law, other legislative acts of Ukraine published in accordance with it as well as relevant current international treaties whose binding nature has been confirmed by the Verkhovna Rada of Ukraine.

Article 3. Main principles of the state policy in the field of GMO handling and the objectives of the law.

The main principles of the state policy in the field of genetic engineering activity and GMO handling shall be:

- the priority of preserving human health and protecting the natural environment over receiving economic benefits from using GMOs;
- ensuring measures to observe biological and genetic safety in the creation, study and practical use of GMOs for economic purposes;
- control over bringing GMOs and products manufactured using GMOs into the customs territory of Ukraine, their registration and circulation;
- the public availability of information about potential risks of using GMOs that are envisaged to be used in the open system and measures regarding the observation of biological and genetic safety;
- state support of genetic engineering research, scientific and practical engineering in the field of biological and genetic safety in creating, studying and practical use of GMOs for economic purposes.

The objectives of the law shall be:

- protecting human health and the natural environment in the carrying out of the genetic engineering activity and GMO handling;
- ensuring the rights of citizens to the safe use of GMOs;
- creating conditions for the safe practical use of GMOs for economic purposes;
- determining rights and responsibilities of subjects of regulation in GMO handling and establishing their responsibility for violations of law;
- protecting citizens against harm to their health as a result of consuming GMOs;
- establishing legal foundations of the international cooperation in the field of genetic engineering activity and GMO handling.

Article 4. Subjects of regulation.

Provisions of this law shall apply in the territory of Ukraine to legal entities and natural persons carrying out activities related to GMO handling. Legal entities and natural persons of Ukraine and other states as well as persons without citizenship shall have equal rights and responsibilities stipulated by this Law.

If an international treaty of Ukraine specified in Article 2 of this Law stipulates other rules than those provided by this Law, the rules of the relevant international treaty shall apply.

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 II

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 central executive authorities and other executive bodies in the field of GMO handling and genetic engineering activity;
- organize international cooperation to ensure safe GMO handling and the development of scientific knowledge in this field;
- approve the procedure for state registration of GMOs and products manufactured using GMOs;
- approve the procedure for importation of GMO sources of food products and feed and food products and feed manufactured from GMOs;
- approve the procedure for granting a permit for transit transportation of GMOs across the territory of Ukraine;
- approve the procedure for licensing genetic engineering activities in closed and open systems;
- approve the procedure for conducting state approbation (tests) of GMOs in the open system and obtaining a permit for conducting those;
- approve the safety criteria for GMO handling in closed systems.

Article 8. Powers of the central executive authority on education and science.

The central executive authority on education and science shall:

- ensure the development of scientific and scientific-and-technical potential in the field of genetic engineering activity;
- ensure protection of international and national patents and other types of intellectual property in the field of GMO handling, genetic engineering and the genetic engineering activity;
- develop the safety criteria for GMO handling and the genetic engineering activity in closed systems;

- 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 and 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 on 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, cosmetics, 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;
- monitor food products manufactured using GMOs by the criterion of the presence in those of only registered GMO sources.

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, studying and practical use of GMOs in open systems at companies, institutions and organizations of the agricultural and industrial complex irrespective of their subordination and ownership;
- carry out state registration of GMO sources of feed as well as registration of feed additives and veterinarian preparations containing GMOs or manufactured with the use thereof;
- approve the list of feed in which control over the content of GMOs is carried out as well as the list of relevant methodologies for detecting and identifying GMOs;
- monitor feed manufactured using GMOs by the criterion of the presence in those of only registered GMO sources.

SECTION III

REGULATION OF GMO HANDLING AND THE GENETIC ENGINEERING ACTIVITY IN THE CLOSED SYSTEM

Article 12. Regulating genetic engineering activities at institutions, organizations and enterprises.

Genetic engineering activity in a closed system shall be subject to licensing.

Licensing of such activity shall be carried out based on risk assessment in GMO handling in closed systems.

The procedure for such licensing shall be approved by the Cabinet of Ministers based on a submission by the central executive authority on education and science.

Institutions, organizations and enterprises carrying out genetic engineering activities (further on - the “institutions”) shall establish, within the institution, the Commission on Biological and Genetic Safety of Conducting Genetic Engineering Works. The task of the Commission shall be formulating a preliminary assessment of risks in planning and preparing genetic engineering works.

A model Regulation on the Commission on Biological and Genetic Safety of Conducting Genetic Engineering Works shall be approved by the central executive authority on education and science.

In cases where genetic engineering activities are carried out by natural persons or the number of staff of the institution does not permit setting up the Commission within the institution, such persons or institutions shall be within the competence of one of the existing commissions subject to approval by the central executive authority on education and science.

SECTION IV

REGULATION OF THE GENETIC ENGINEERING ACTIVITY IN THE OPEN SYSTEM AND STATE REGISTRATION OF GMOs

Article 13. Requirements to GMOs and the procedure for their discharge to the environment for the purposes of approbation (testing).

GMOs used in the open system must comply with the requirements of biological and genetic safety provided that their envisaged technology of use thereof is observed.

The mandatory requirement for using GMOs in the open system shall be the availability of methods and methodologies for their identification developed in accordance with international standards and approved in accordance with the established procedure in Ukraine.

It shall be prohibited to discharge GMOs into the environment prior to their state registration.

Before state registration, GMO discharge into the environment shall be possible only for the purpose of state approbation (testing). State approbation (testing) of GMOs in the open system shall be conducted only based on a permit to be issued by the central executive authority on environment and natural resources. The permit shall be a one-time permit to conduct state approbation (testing) of a specified GMO.

The procedure for obtaining such a permit and its form shall be approved by the Cabinet of Ministers of Ukraine following a submission by the central executive authority on the ecology and natural resources. The permit shall specify the conditions and terms for the conduct of state approbation (testing) of GMOs.

A permit for the conduct of state testing of GMOs in the open system may be revoked in cases where scientifically justified information has been obtained that may lead to overestimating the level of risk of GMO impact on human health and the natural environment as well as violating the terms of the permit.

Article 14. State registration of GMOs and establishing restrictions on their use.

State registration of GMOs and products manufactured using GMOs shall be carried out by central executive authorities in accordance with the authority stipulated in Articles 8-11 of this law.

Central executive authorities shall maintain registries of GMOs and products manufactured using GMOs, post them on their official websites and regularly publish them in the mass media.

Products that shall be registered in State Registries:

- plant varieties and animal breeds created based on GMOs;
- plant protection means created based on GMOs;
- GMO sources of food products as well as food products, cosmetics, medicines containing GMOs or manufactured using GMOs;
- GMO sources of feed as well as feed additives and veterinarian preparations containing GMOs or manufactured using GMOs.

State registration shall be valid during a five-year term and shall be free of charge. Re-registration shall be carried out in accordance with the same procedure as registration.

The term for reviewing registration document may not exceed 120 days from the day of their submission including the time needed to conduct relevant expert evaluations.

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 into 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, cosmetics, 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 GMO sources 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 unregistered 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.

The provisions of the present Article shall not concern GMOs of food products and feed registered in accordance with the requirements of Article 14 of this Law.

SECTION VI FINAL PROVISIONS

Article 18. Responsibility for violations of law in the field of GMO handling.

Violations of the requirements of this Law and normative acts passed on its basis shall entail civil, administrative, disciplinary or criminal responsibility in accordance with current legislation.

Responsibility shall be imposed on persons guilty of:

- concealing or distorting information, which could cause or caused danger to human life and health or to the environment;
- not observing or violating requirements of standards, regulations, sanitary rules and regulations governing the use, transportation, storage and sale of GMOs;
- using unregistered GMOs or products manufactured using unregistered GMOs (except for science research purposes);
- violating the rules for recycling and destroying GMOs;
- not fulfilling legitimate requirements of officials exercising state supervision and control.

Legislation of Ukraine may establish responsibility also for other types of violations of Ukrainian legislation in the field of genetic engineering activity.

Article 19. Main requirements to the permit system in the field of carrying out business activity in the course of GMO handling.

Permits for importation of unregistered GMOs for science research purposes in closed and open systems as well as with the view to their state testing; for importation of products manufactured using GMOs intended for science research purposes; for transit carriage of GMOs unregistered in Ukraine; for discharge of GMOs in open systems shall be issued by central executive authorities in accordance with their scope of authority stipulated in Articles 8-11 of this Law pursuant to the procedure established by the Cabinet of Ministers of Ukraine free of charge.

The issuance of a permit 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.

The term for reviewing documents required to issue a permit may not exceed 45 days from the day of their submission including the time needed to conduct relevant expert evaluations.

The amounts of tariffs for the conduct of expert evaluations that are the basis for the issuance of the said documents shall be approved by the Cabinet of Ministers of Ukraine based on a submission by the relevant central executive authority.

Article 20. Access to information on GMO handling

Information on GMO handling shall be open and publicly available except that classified by legislation of Ukraine as confidential and secret.

Information about the potential impact of GMOs on human health and the natural environment may not be considered as confidential and secret.

Article 21. International cooperation

Ukraine shall enter into international treaties, participate in international information sharing with the view to ensuring further development and strengthening of international cooperation in the field of biological and genetic safety in conducting the genetic engineering activity and GMO handling in accordance with current legislation.

Article 22. Final provisions

This Law shall take effect as of the day of its official publication.

The Cabinet of Ministers of Ukraine shall:

submit for consideration by the Verkhovna Rada of Ukraine proposals to bring legislative acts of Ukraine into compliance with this Law;

bring its normative acts into compliance with this Law;

ensure the review and rescission by executive authorities of normative acts approved by those that are not in line with this Law.

31.05.2007

President of Ukraine

No 1102-V

V. YUSCHENKO