

## LAW OF UKRAINE

### **ON CREATING, TESTING, TRANSPORTING AND USING GENETICALLY-MODIFIED ORGANISMS**

This Law shall regulate the development, creation, testing, study, transportation, import, export, marketing, discharge to the environment and use of genetically-modified organisms (GMOs) in Ukraine (hereinafter referred to as GMO handling) as well as products manufactured by technologies envisaging their use.

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 meanings:

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 (GMO) shall mean any organism in which the genetic material was modified by artificial techniques of gene transfer that do not occur under natural conditions, namely:

- 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; and

- 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 using GMOs shall mean products 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;

biosafety (biological safety) shall mean a field of scientific knowledge generalizing conceptions of the aggregate of criteria and conditions of their application for the assessment of the potential GMO impact on human health and the environment;

discharge of GMOs into environment shall mean an act or failure to act resulting in the introduction of GMOs to 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, the use in the agricultural practices, industry, medicine and for environment protection purposes, transfer of technologies and other fields of GMOs circulation;

risk shall mean a scientifically justified probability of a potential impact on human health and the environment in the carrying out of genetic engineering activity and GMO handling;

risk assessment shall mean a determination of the level of risk;

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

state registry of GMOs (products using GMOs) shall mean a specialized list of GMOs that underwent registration with the definition of their further business purpose.

**Article 2. Legislation of Ukraine in the field of genetic engineering activity.**

Legislation of Ukraine in the field of genetic engineering activity shall include the Constitution of Ukraine, this Law, and other legislative acts of Ukraine as well as relevant current international treaties that were recognized by the Verkhovna Rada as binding.

**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 shall be:

- ensuring guarantees of safety to human health and the environment in the creation, study and practical use of GMOs for business purposes;
- the priority of preserving human health and protecting the environment over receiving economic benefits from using GMOs;
- control over bringing GMOs and products using GMOs in the customs territory of Ukraine, their registration and circulation;
- general availability of information about biosafety and potential risks of using GMOs that are envisaged to be used in the open system;
- state support of genetic engineering research, scientific and practical developments in the field of biosafety.

The objectives of the law shall be:

- protecting human health and the natural environment in the carrying out of genetic engineering activities by ensuring the rights of citizens to the safe use of GMOs;
- creating conditions for the safe practical use of GMOs for business purposes;
- determining the fundamentals of legal regulation of the safety system and

measures that must be observed in the carrying out of genetic engineering activity;

- defining rights and obligations of participants in the genetic engineering activity and establishing their responsibility for violations of law;

- determining the mechanisms of ensuring the safety of citizens and the natural environment;

- 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 individuals carrying out activities related to GMO handling. Legal entities and individuals of Ukraine and other states as well as stateless persons shall have equal rights and obligations stipulated by this Law.

If an international treaty of Ukraine specified in an Article 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 testing of GMOs
- state registration of GMOs and products manufactured using GMOs;
- business use of GMOs;
- 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 general and special legislation.

#### **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 state measures in 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 state testing of GMOs;
- approve the procedure for licensing genetic engineering activities in closed and open systems;
- approve the safety criteria for GMO handling in closed systems.

**Article 8. Powers of the central executive authority concerning 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 the protection of international and national patents and other types of intellectual property in the field of GMO handling, genetic engineering and genetic engineering activities;
- develop the safety criteria for GMO handling and genetic engineering activities in closed systems;
- develop and improve the system of control over the observance of safety rules in genetic engineering activities;
- carry out licensing of genetic engineering activities in closed systems;
- with regard to the results of the state environmental and state sanitary and epidemiological inspections, issue permits for bringing into the territory of Ukraine unregistered GMOs, if they are used only for science research purposes as well as with the view to conducting state testing of GMOs preceding their registration.

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

The central executive authority on environment and natural resources shall:

- conduct state environmental inspections of GMOs intended for use in open and closed systems;
- develop criteria for the assessment of risk of the potential GMOs impact on the natural environment;
- carry out state registration of plant protection means manufactured using GMOs;
- exercise state supervision and control over practical use of GMOs;
- monitor the potential impact of GMOs on the natural environment;
- exercise control over observance of biosafety measures in testing GMOs within open systems;
- issue permits to discharge GMOs in open systems.

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

The central executive authority on health shall:

- develop the criteria of GMO safety for human health;
- carry out state sanitary and epidemiological inspections of GMOs and products manufactured using GMOs for the purposes of their state registration;
- carry out state registration of food products, cosmetics, and medicines containing GMOs or manufactured using GMOs;

- approve the list of food products, which are controlled for their content of genetically engineered material and the list of relevant control methods;
- monitor food products manufactured using GMOs.

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

The central executive authority on agricultural policy shall:

- ensure state testing and state registration of agricultural plant varieties, animal breeds, microbiological agricultural and veterinarian preparations created based on GMOs;
- ensure control over the observance of safety rules in the carrying out of genetic engineering activities and GMO handling at companies, institutions and organizations of the agricultural and industrial complex irrespective of their subordination and ownership.

**SECTION III  
REGULATION OF GMO HANDLING AND GENETIC ENGINEERING  
ACTIVITIES IN THE CLOSED SYSTEM**

**Article 12. Setting risk levels.**

Risk levels and the risk assessment procedure in GMO handling in closed systems shall be approved and reviewed by the Cabinet of Ministers of Ukraine in accordance with the development of scientific knowledge pursuant to a submission by the central executive authority on education and science.

**Article 13. Regulating genetic engineering activities at institutions, organizations and enterprises.**

Genetic engineering activities in a closed system shall be subject to licensing. The procedure for such licensing shall be approved by the Cabinet of Ministers of Ukraine based on a submission by the central executive authority on education and science.

Institutions, organizations and enterprises carrying out genetic engineering activities (the “institutions”) shall establish commissions on biosafety of conducting genetic engineering works within the institution. The task of the biosafety commission shall be formulating preliminary estimates of risks in planning and preparing genetic engineering works.

A model Regulation on the Biosafety Commission shall be approved by the central executive authority on education and science.

In cases where genetic engineering activities are carried out by individuals or the staff of the institution does not permit setting a biosafety commission within the institution, such individuals 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 GENETIC ENGINEERING ACTIVITIES IN THE  
OPEN SYSTEM AND STATE REGISTRATION OF GMOs**

**Article 14. Requirements to GMOs and the procedure for their discharge to the environment for testing purposes.**

GMOs used in the open system must be safe to human health and the environment provided that the stipulated use technology is observed; they must be supported by methods of their identification approved in accordance with the established procedure.

It shall be prohibited to discharge GMOs into the environment without a permit for conducting state testing in the open system.

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 environment and natural resources. The permit shall specify the conditions and terms for the conduct of state tests of GMOs.

A permit for the conduct of state tests 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 15. State registration of GMOs**

State registration shall be carried out by central executive authorities in accordance with the business purpose of GMOs and 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.

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

**SECTION V**

**USE, TRANSPORTATION, STORAGE AND RECYCLING OF GMOs.**

**Article 16. Bringing in and transit of GMOs**

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

Permits to bring in GMOs intended for science research purposes within the closed system shall be issued by the central executive authority in accordance with the procedure established by the Cabinet of Ministers of Ukraine.

Permits to bring in 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.

The procedure for bringing in GMOs for their direct use as food products or feed shall be established by the Cabinet of Ministers of Ukraine.

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

**Article 17. Practical use of GMOs**

Manufacture and sale of GMOs as well as products using GMOs shall be prohibited before their state registration.

**Article 18. 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 environment and natural resources.

**SECTION VI  
FINAL PROVISIONS**

**Article 19. 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 be subject to 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 carrying out 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 activities.

**Article 20. Access to information on GMO handling**

Information on GMO handling shall be open and public except for 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 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 biosafety and observance of biosafety requirements in conducting genetic engineering activities and GMO handling in accordance with current legislation.

**Article 22. Final provisions**

1. This Law shall take effect as of the day of its official publication.
2. The Cabinet of Ministers of Ukraine shall:
  - 1) submit for consideration by the Verkhovna Rada of Ukraine proposals to bring legislative acts of Ukraine into compliance with this Law;
  - 2) bring its normative acts into compliance with this Law;
  - 3) ensure the review and rescission by executive authorities of normative acts approved by those that are not in line with this Law.

President of Ukraine

V. Yuschenko

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