Draft

LAW OF UKRAINE

"On the State Regulation of Genetic Engineering, Ensuring Biosafety and State Control over the Circulation of Genetically Modified Products in Agriculture"

This Law defines the legal and organizational frameworks for state regulation of genetic engineering, ensuring biosafety, state control over the use of genetically modified organisms and the circulation of genetically modified products.

Section I
GENERAL PROVISIONS

Article 1. Terms and their definitions

1. In this Law, the following terms shall be used in the following meanings:

1) GMO referee tests shall mean tests conducted at the request of a person who challenges the results of the previous test;

2) biosafety shall mean a system of measures aimed at preventing or reducing to a safe level the possible impact of GMOs on human and animal health and the environment;

3) GMO testing shall mean studying the properties and characteristics of GMOs to use them further for practical purposes;

4) open system shall mean a system that provides for the contact of GMOs with humans, other living organisms and the environment during their creation, testing and/or practical use, including cultivation, processing, storage, transportation, destruction or disposal;

5) genetically modified products (GM products) shall mean products that contain, consist of or are produced from GMOs;

6) genetically modified source (hereinafter – GM source) shall mean the starting line of genetically modified plants or animals, a strain of genetically modified microorganisms, containing a certain genetic modification with a specific localization in its genome, which was carried out by genetic engineering methods;

7) genetically modified organism (hereinafter – GMO) shall mean any living organism in which the genetic material is artificially altered by genetic engineering methods, which has led to the transfer, removal or modification of genes using methods, techniques, technologies that allow for the purposeful change of the genome of the host organism, including:

methods involving the formation of new combinations of genetic material by introducing recombinant nucleic acid molecules (produced in any way outside the organism) into any virus, bacterial plasmid or other vector system and their inclusion

in the host organism in which they do not occur, but are capable of long-term reproduction;

methods allowing to edit an existing genome by extracting genes or creating new combinations of genetic material;

methods involving the direct implanting genetic material into the organism prepared outside such an organism (microinjections, macroinjections and microencapsulations);

methods involving cell fusion (including protoplast fusion) or hybridization by fusing two or more living cells in an artificial manner, resulting in the appearance of living cells with new combinations of genetic material;

extracorporeal fertilization; conjugation, transduction, transformation that occur in natural conditions, as well as inductive polyploidy;

8) genetic engineering is a set of techniques, methods and technologies for obtaining recombinant nucleic acids, isolating genes from the organism (cells), performing manipulations with genes inside the organism and implanting them into other organisms, or editing an existing genome;

9) genetic engineering shall mean scientific and technical activities related to the GMOs creation, research and testing;

10) state registration of GMOs means entering information about the GM source into the State Register of GMOs, indicating the further purpose of its use;

11) state register of GMOs is the only state information system containing information on registered GM sources;

12) GMOs research and testing in the open system shall mean activities that lead to the release of GMOs into the open system (including greenhouses and test areas), carried out before its state registration for any purpose other than placing on the market;

13) protective measures shall mean a system of measures taken by the subject of genetic engineering to reduce possible risks;

14) closed system shall mean a system of performing genetic engineering activities in which genetic modifications are implanted into the organism or GMOs are cultivated, processed, stored, used, transported, destroyed or disposed using protective measures preventing the contact of GMOs with humans, other living organisms and the environment;

15) post-registration monitoring network is an accounting system maintained by the holder of the rights to a registered GM source and which consists of distributors and producers of genetically modified varieties of plants, seeds, planting material, animal breeds, microorganisms to which he sold the relevant GM source;

16) deliberate release of GMOs is any deliberate and permitted release of GMOs or their combinations into the environment for which no specific containment measures are used to prevent the contact of GMOs or their combinations with humans, other living organisms or the environment;

17) GMO-related emergency is any situation involving the substantial and unintentional release of GMOs that may pose a threat to human health, animals, plants and/or the environment;

18) an organism shall mean any form of biological existence capable of self-reproduction or transfer of genetic material;

19) GMO risk assessment is a theoretically substantiated analysis of the GMO properties, which is carried out to determine the possible direct, indirect or delayed risk of GMO and its possible impact on human health or environmental safety;

20) GMOs post-registration monitoring is monitoring adverse effects on human health, animals or the environment that occur when using GMOs;

21) GMO handling means any activity related to GMOs, including the creation, research, testing, production, processing, handling, packaging, storage, transportation, use, disposal, destruction, placing on the market and any other similar activities related to the transfer of possession or ownership of GMOs;

22) GMO reference samples are GMO reference material, the properties of which are homogeneous and suitable for evaluating the method of GMO determination or establishing certain properties of the investigated material;

23) risk shall mean the possibility of any adverse effects and the probable scale of possible negative impact on human health, animals, plants and/or the environment in the implementation of genetic engineering activities and the handling of GMOs;

24) levels of risk in the implementation of genetic engineering activities in a closed system shall mean the classification of risks that may arise during the implementation of genetic engineering activities, depending on the degree of potential threat to human health, animals, plants and/or the environment:

25) the first risk level in the implementation of genetic engineering activities in a closed system means risk-free activities and activities with low risk, which can be compared with the risk of using non-pathogenic microorganisms;

26) the second risk level in the implementation of genetic engineering activities in a closed system means activities with low risk, which can be compared with the risk of using opportunistic pathogens;

27) the third risk level in the implementation of genetic engineering activities in a closed system means activities with moderate risk, which can be compared with the risk of using microorganisms that are potentially capable of transmitting infections;

28) the fourth risk level in the implementation of genetic engineering activities in a closed system means activities with increased risk, which can be compared with the risk of using microorganisms capable of spreading particularly dangerous infections;

29) placing on the market means the transfer of GMOs or GM products to third parties as a result of which GMOs or GM products become available to the consumer;

30) subject of genetic engineering activity is any person engaged in scientific and technical activities in the field of genetic engineering;

31) transboundary movement of GMOs is any import (transfer) into the customs territory of Ukraine, export (transfer) from the customs territory of Ukraine or transit through the customs territory of Ukraine of GMOs and/or GM products.

2. Other terms shall be used in the meaning given in the laws of Ukraine "On

the Basic Principles and Requirements to Safety and Quality of Food Products", "On the Seeds and Planting Material", "On the Protection of Plant Variety Rights".

Article 2. Legislation of Ukraine in the field of GMO handling and ensuring biosafety

1. Legislation of Ukraine in the field of GMO handling and ensuring biosafety comprises the Constitution of Ukraine, this Law, legislation on food safety and quality; on the protection of plants; scientific and scientific and engineering efforts; in the field of activities related to high-risk facilities; as well as environmental and other special legislation governing relations in the relevant field.

Article 3. The scope of this Law

1. This Law shall apply to:

genetic engineering activities in a closed system;

GMO examination and testing in an open system;

state registration of GMOs;

placing on the market, transportation, storage, disposal of GMOs and GM-products;

GM products labeling;

measures of state supervision (control) over the creation and testing of GMOs, over labeling and placing GMOs and GM products on the market.

2. This Law shall not apply to relations arising in connection with:

1) registration and turnover of any products designated for medical purposes, including medicines;

2) registration and turnover of veterinary medicines;

3) the use of methods (techniques) of modifying the genetic material of living organisms without the use of recombinant nucleic acid molecules, including self-cloning, methods of mutagenesis, as well as:

extracorporeal fertilization;

conjugation, transduction, transformation occurring under natural conditions;

inductive polyploidy.

3. This Law does not apply to humans, tissues and separate cells in the human body.

4. If an international treaty of Ukraine, approved as binding by the Verkhovna Rada of Ukraine, establishes rules other than those provided for by this Law, the rules of the international treaty shall apply.

Article 4. Fundamentals of state policy in the field of GMO handling and ensuring biosafety

1. The state policy in the field of GMO handling and ensuring biosafety is based on the following principles:

legality – compliance with the Constitution of Ukraine and the laws of Ukraine, international commitments of Ukraine;

openness – ensuring free access to information on genetic engineering activities in Ukraine, GM products, and GMO handling;

prioritizing the protection of human health, animals, plants and the environment over the economic benefits of using GMOs;

prevention of possible risks to human health, animals, plants and the environment;

meeting the requirements of environmental safety and biosafety during the creation, investigation, testing and use of GMOs;

control over GMOs and GM products at all stages of their creation, testing and circulation;

coordination and conformity of long-term strategies, plans and programs for the development of genetic engineering activities in Ukraine with other national plans and programs.

Section II
POWERS OF CENTRAL EXECUTIVE AUTHORITIES IN THE FIELD OF GMO HANDLING AND ENSURING BIOSECURITY

Article 5. Central executive authorities in the field of GMO handling and ensuring biosafety

1. The system of executive authorities in the field of GMO handling and ensuring biosafety includes:

Cabinet of Ministers of Ukraine;

central executive authority, shaping the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture;

central executive authority implementing the state policy in the field of state supervision (control) over the circulation of genetically modified products in agriculture;

central executive authority, ensuring the formation and implementing state policy in the field of health care;

central executive authority ensuring the formation and implementing the state

policy in the field of environmental protection, environmental and, within the statutory powers, biological and genetic safety;

central executive authority implementing the state policy in the field of sanitary and epidemiological well-being of the population;

central executive authority implementing the state policy on state supervision (control) in the field of environmental protection, rational use, reproduction and protection of natural resources.

Article 6. Powers of the Cabinet of Ministers of Ukraine

In the field of GMO handling and ensuring biosafety, the Cabinet of Ministers of Ukraine:

ensures state regulation;

directs and coordinates the work of central executive authorities and other executive authorities;

directs and coordinates international cooperation to ensure safe handling of GMOs and the development of scholarly knowledge in this field;

approves procedures in accordance with this Law;

approves the rules of concurrent use of GMOs, GM products and GMO-free products;

approves the procedure for forming the cost of risk assessment services by the Scientific Committee and state registration of the GM source;

approves the regulations on the Scientific and Methodological Centre for GMO Testing;

exercises other powers prescribed by this Law.

Article 7. Powers of the central executive authority, shaping the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture

1. Central executive authority, shaping the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture:

develops the procedure for state registration of GM sources;

develops the procedure for maintaining the State Register of GMOs;

develops regulations on the Scientific Committee, coordinates its activities and provides organizational and technical support for its work;

performs state registration of GM sources, maintains the State Register of GMOs and determines the procedure for forming an extract on the registration of

GM-sources from the State Register of GMOs;

develops the Procedure for maintaining the List of persons engaged in the cultivation of genetically modified plants, animal breeds, microorganisms;

develops the procedure for traceability of GMO in varieties of plants, seeds and planting material, feed, food products during harvesting, storage, processing, movement through the territory of Ukraine, import into the customs territory of Ukraine;

develops and approves requirements for labeling GM products;

develops and approves the list of food products, feeds and feed additives that are subject to GMO content control and which must meet labeling requirements for the presence or absence of GMOs, indicating the list of products for which it is technically impossible to detect GMOs;

develops the rules of concurrent use of GMOs, GM products and GMO-free products;

upon submission of the Scientific and Methodological Centre for GMO Testing, approves methods for determining GMOs and the procedure for sampling to perform state supervision (control);

develops the procedure for forming the cost of risk assessment services by the Scientific Committee and state registration of the GM source;

exercises other powers prescribed by this Law.

Article 8. Powers of the central executive authority implementing the state policy in the field of state supervision (control) over the circulation of genetically modified products in agriculture

1. Central executive authority implementing the state policy in the field of state supervision (control) over the circulation of genetically modified products in agriculture:

maintains the List of persons engaged in the cultivation of genetically modified plants, animal breeds, microorganisms;

carries out state supervision (control) over compliance with the requirements for labeling products containing GMOs or produced with the use of GMOs in the manner prescribed by the Cabinet of Ministers of Ukraine;

carries out inspection of plant varieties, seeds and planting material, food products, feeds and feed additives for the presence of registered GM sources in the manner prescribed by the Cabinet of Ministers of Ukraine;

carries out state supervision (control) over compliance with the rules of concurrent use of GMOs, GM products and GMO-free products;

exercises other powers prescribed by this Law.

Article 9. Powers of the central executive authority, ensuring the formation and implementing state policy in the field of health care;

1. Central executive authority, ensuring the formation and implementing state policy in the field of health care:

develops and approves Model Regulation on the Commission on Biological and Genetic Safety at institutions and enterprises that carry out genetic engineering activities of the first, second, third and fourth risk levels in the closed system;

develops the procedure for assessing the risk level and rules for handling GMOs during the implementation of genetic engineering activities of the first, second, third and fourth risk levels in the closed system;

approves the requirements to the subjects of genetic engineering activities that carry out genetic engineering activities of the first, second, third and fourth risk levels in the closed system;

approves the form of notifying of the intention to carry out genetic engineering activities of the first risk level;

approves the application form for the issuance of a permit for conducting genetic engineering activities of the second, third and fourth risk levels in the closed system;

issues and revokes permits for conducting genetic engineering activities of the second, third and fourth levels of risk in the closed system, in the manner prescribed by the Cabinet of Ministers of Ukraine;

issues and revokes permits for import into the customs territory of Ukraine for the purposes of conducting genetic engineering activities of the first risk level in a closed system;

monitors the possible impact (direct or indirect) of GMOs on human health;

maintains the State Register of subjects of genetic engineering activities carrying out activities in a closed system;

approves the protective measures taken by the subject of genetic engineering activities, taking into account the scope of genetic engineering activities and the established level of risk during the implementation of genetic engineering activities in a closed system;

establishes requirements for laboratories and premises used by the subjects of genetic engineering, and documents confirming the competence level of employees performing genetic engineering activities in a closed system;

approves the rules for handling GMOs in a closed system;

exercises other powers prescribed by this Law.

Article 10. Powers of the central executive authority ensuring the formation and implementing the state policy in the field of environmental protection, environmental and, within the powers provided by law, biological and genetic safety

1. Central executive authority ensuring the formation and implementing the state policy in the field of environmental protection, environmental and, within the powers provided by law, biological and genetic safety:

develops the procedure for risk assessment during research and testing of GMOs in an open system;

develops the procedure for conducting research and testing GMOs in an open system;

issues and revokes permits for conducting research and testing GMOs in an open system;

maintains the State register of persons conducting research and testing in an open system;

carries out state supervision (control) over the observance of biosafety during investigation and testing GMOs in an open system;

monitors the possible impact (direct or indirect) of GMOs on the environment;

approves the procedure for destruction and disposal of GMOs obtained during testing, unusable or prohibited for use;

exercises other powers prescribed by this Law.

Article 11. Powers of the central executive authority implementing the state policy in the field of sanitary and epidemiological well-being of the population;

1. Central executive authority implementing the state policy in the field of sanitary and epidemiological well-being of the population;

carries out state supervision (control) over the observance of biosafety during the creation, research and use of GMOs in a closed system during the performance of works related to the second, third and fourth risk levels;

exercises other powers prescribed by this Law.

Article 12. Powers of the central executive authority implementing the state policy on state supervision (control) in the field of environmental protection, rational use, reproduction and protection of natural resources.

1. Central executive authority implementing the state policy on state supervision (control) in the field of environmental protection, rational use, reproduction and protection of natural resources:

carries out state supervision (control) over the observance of biosafety during

investigation and testing GMOs in an open system;

verifies the observance of protective measures and measures for crops destruction after harvest by the subject of genetic engineering activities.

Article 13. Scientific Committee

1. The Scientific Committee shall be established under the Cabinet of Ministers of Ukraine for a comprehensive and scientifically grounded GMO risks assessment. The Scientific Committee's activity shall be coordinated by the central executive authority, shaping the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture.

2. The Scientific Committee:

carries out a comprehensive and scientifically grounded GMO risks assessment for conducting research, testing, registration, import into the customs territory of Ukraine or transit movement;

provides recommendations on the results of risks assessment for the relevant central executive authorities;

submits proposals to the Cabinet of Ministers of Ukraine to improve the formation and implementation of state policy in the field of state regulation of genetic engineering, biosafety and state control over the circulation of genetically modified products in agriculture;

if necessary, forms permanent or temporary working groups to perform the assigned tasks and involve independent experts in its work (by agreement).

3. The work of the Scientific Committee is open. Information on the beginning and end of GMO risk assessment by the Scientific Committee shall be published on the official website of the central executive authority shaping the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture.

4. The Scientific Committee is composed of 18 members, among which there are:

five representatives of the National Academy of Sciences of Ukraine;

two representatives of the National Academy of Agrarian Sciences of Ukraine;

two representatives of the National Academy of Medical Sciences of Ukraine;

three representatives from higher education institutions;

one representative from each central executive authority belonging to the system of executive authorities in the field of state regulation of genetic engineering, ensuring biosafety and state control over the circulation of genetically modified products in agriculture.

5. Central executive authorities, belonging to the system of public administration authorities in the field of genetic engineering and GMO handling,

may, on their own behalf, recommend representatives of research institutions subordinated to these central executive authorities for work in the Scientific Committee.

In the absence of such institutions, or in the absence of specialists with the relevant qualification level, central executive authorities belonging to the system of executive authorities in the field of state regulation of genetic engineering, ensuring biosafety and state control over the circulation of genetically modified products in agriculture may, on their own behalf, recommend representatives of any other research institutions or higher educational institutions for work in the Scientific Committee.

6. Members of the Scientific Committee must have a scientific degree and experience in the relevant field of knowledge.

The personnel of the Scientific Committee on Genetically Modified Organisms and changes in its composition shall be approved by the Cabinet of Ministers of Ukraine.

Members of the Scientific Committee participate in its work on a voluntary basis. The term of office for a member of the Scientific Committee is three years, with the possibility of reappointment for another term.

Requirements for members of the Scientific Committee are defined in the regulations on the Scientific Committee.

7. GMO risks assessment by members of the Scientific Committee and/or independent experts and payment for the work performed shall be carried out under a civil law agreement between the central executive authority shaping the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture, and the person involved.

Article 14. Scientific and Methodological Centre for GMO Testing;

1. The Scientific and Methodological Centre for GMO Testing is a state-owned scientific institution authorized by the Cabinet of Ministers of Ukraine upon the submission of the National Academy of Sciences of Ukraine to perform the following functions:

development of methods for GMO testing and sampling;

providing conclusions on the compliance of the method of GMO testing provided by the applicant for state registration of GMOs, including at the request of the Scientific Committee, or any of the public administration authorities in the field of genetic engineering and GMO handling;

storage of reference GMO samples for the formation of GMO collections;

conducting inter-laboratory comparison of methods for detecting GMOs;

conducting arbitration tests on GMOs at the request of the person challenging the results of previous GMO tests.

Section III
PERFORMANCE OF GENETIC-ENGINEERING ACTIVITY AND GMOs HANDLING IN A CLOSED SYSTEM

Article 15. Determination of risk levels of genetic engineering activities

1. Subjects of genetic engineering activities are obliged to establish a commission on biological and genetic safety to assess the risk of GMOs in the planning and preparation of genetic engineering activities. The Biological and Genetic Safety Commission is the internal advisory body of the genetic engineering subject and acts on the basis of regulations. The Model Regulation on the Commission on Biological and Genetic Safety shall be approved by the central executive authority, ensuring the formation and implementing the state policy in the field of health care.

2. The level of risk shall be determined by the subject of genetic engineering activity independently based on the decision of the Commission for Biological and Genetic Safety, taking into account the risks that could potentially arise during the implementation of genetic engineering activities.

3. Subjects of genetic engineering activity in carrying out genetic engineering activity of:

the first risk level shall apply protective measures that correspond to the first level of biosafety;

the second risk level shall apply protective measures that correspond to the second level of biosafety;

the third risk level shall apply protective measures that correspond to the first level of biosafety;

works of the fourth risk level shall apply protective measures corresponding to the fourth level of biosafety.

4. The subject of genetic engineering activity is obliged to take protective measures taking into account the field of genetic engineering activity and the established level of risk. Such measures are subject to coordination with the central executive authority, ensuring the formation and implementing the state policy in the field of health care.

5. If genetic engineering activities are carried out by individuals or the personnel number of a legal entity does not allow to form a Commission on Biological and Genetic Safety, the functions of such Commission shall be performed by the Commission on Biological and Genetic Safety of another subject of genetic engineering in agreement with the central executive authority ensuring the formation and implementing the state policy in the field of health care.

6. The subject of genetic engineering activity is obliged to annually assess the level of risk during the implementation of genetic engineering activities in a closed system (hereinafter - the risk level) in accordance with the procedure established by the Cabinet of Ministers of Ukraine. In the event of an increase in the risk level, such

a subject is obliged to submit a new notification and obtain a relevant permit for genetic engineering activities of the appropriate risk level in a closed system in the manner prescribed by this Law.

7. If the subject of genetic engineering activity has doubts about the correctness of determining the risk level, he is obliged to apply protective measures corresponding to a higher risk level.

8. Control over the correctness of determining the risk level is carried out by the central executive authority, ensuring the formation and implementing the state policy in the field of health care.

9. In case of discrepancy between the risk level stated in the notification, the central executive authority ensuring the formation and implementing the state policy in the field of health care has the right to demand the termination of activities in the field of genetic engineering and GMO handling.

10. If a subject meets the requirements set for the operation of a higher level of risk, it is considered to meet the requirements of the lower risk level.

Article 16. Requirements for the performance of genetic engineering activities in a closed system

1. During the performance of works of all risk levels subjects of genetic engineering activity must follow the rules of handling GMOs in a closed system.

2. Prior to the performance of genetic engineering activity of the first risk level in a closed system, the subject of genetic engineering activity must submit a notification of the intent to carry out such activities to the central executive authority, ensuring the formation and implementing state policy in the field of health care.

3. The form of notification shall be approved by the central executive authority, ensuring the formation and implementing the state policy in the field of health care.

4. The notification must contain information on:

a person who intends to carry out genetic engineering activities;

opinion of the Commission for Biological and Genetic Safety on establishing the risk level during the implementation of genetic engineering activities in a closed system;

description of genetic engineering activities (type and characteristics of GM sources; recipient organisms, parental organisms, methods of obtaining GMOs, purpose of genetic engineering activities, expected results).

5. The notification is a sufficient ground for the commencement of genetic engineering activities of the first risk level and inclusion of a person in the State Register of subjects of genetic engineering activities carrying out activities of the first risk level in a closed system by the central executive authority ensuring the state policy in the field of health care, within 7 working days from the date of receiving such notification.

6. The only grounds for refusing to introduce a person in the State Register of subjects carrying out genetic engineering activities of the first risk level in a closed system are the inaccuracy of the information provided in the notification.

7. In order to carry out the second, third and fourth levels of risks in the closed system of genetic engineering activities, the subject of genetic engineering activities must obtain the appropriate permit for conducting genetic engineering activities in the closed system.

Article 17. Permits for conducting genetic engineering activities in a closed system

1. In order to carry out the second, third and fourth levels of risks in the closed system of genetic engineering activities, the subject of genetic engineering activities must obtain the appropriate permit for conducting genetic engineering activities in the closed system.

2. In order to obtain a permit to carry out genetic engineering activities of the appropriate risk level in a closed system, the subject of genetic engineering activities must submit an application for a permit to carry out activities of the appropriate risk level to the central executive authority ensuring the formation and implementing the state policy in the field of health care.

3. The application form shall be approved by the central executive authority, ensuring the formation and implementing the state policy in the field of health care.

The application must contain information on:

a subject that intends to carry out genetic engineering activities;

risk level of genetic engineering activities that the subject of genetic engineering activity intends to perform;

description and technical characteristics of the premises where genetic engineering activities will be carried out;

list of employees and documents confirming the competence of the personnel in the field of genetic engineering;

description of genetic engineering activities (type and characteristics of GM source, recipient organisms, parental organisms, methods of obtaining GMOs, purpose of genetic engineering activities, expected results);

a system of protective measures that meet the established risk level of genetic engineering activity;

waste disposal procedure;

action plan in case of emergency.

4. A copy of the accreditation certificate of the laboratory to be used by the subject of genetic engineering activity shall be attached to the application,

5. Requirements for laboratories and premises used by the subjects of genetic

engineering activity and documents confirming the level of competence of employees performing genetic engineering activities in a closed system shall be established by the central executive authority, ensuring the formation and implementing the state policy in the field of health care.

6. Permit for conducting genetic engineering activities in a closed system is the ground for the commencement of genetic engineering activities of the appropriate risk level and inclusion of a person in the State Register of subjects of genetic engineering activities carrying out activities in a closed system

7. Inclusion of a person in the State Register of subjects of genetic engineering activities carrying out activities of the second, third and fourth risk levels in a closed system shall be made within 7 working days from the issuance date of the relevant permit for genetic engineering activities in a closed system.

8. The procedure for maintaining the State Register of subjects of genetic engineering activities in a closed system shall be developed by the central executive authority, ensuring the formation and implementing the state policy in the field of health care and approved by the Cabinet of Ministers of Ukraine.

9. The procedure for issuing and revoking permits for carrying out genetic engineering activities in a closed system shall be approved by the Cabinet of Ministers of Ukraine.

10. The rules for GMOs handling in a closed system shall be approved by the central executive authority, ensuring the formation and implementing the state policy in the field of health care.

Section IV
GMOs HANDLING IN AN OPEN SYSTEM

Article 18. Release of GMOs into an open system for research and testing

1. The release of GMOs into the open system for research and testing is permitted with the availability of a permit for conducting research and testing of GMOs in the open system.

2. When a GMO is released into the open system, subjects of genetic engineering activity shall be obliged to take protective measures against GMO contact with humans or the environment to ensure the safety of such release.

3. Release into the open system for purposes other than research and testing shall be permitted only if the relevant GM source is registered.

Article 19. Permit for conducting research and testing GMOs in an open system

1. In order to obtain a permit for conducting research and testing GMOs in the open system, a person shall submit an application for obtaining a permit for

conducting research and testing GMOs in the open system to the central executive authority ensuring the formation and implementing the state policy in the field of environmental protection, environmental and, within the statutory powers, biological and genetic safety, which should include information on:

a subject of genetic engineering activity, which intends to conduct research and testing of GMOs in an open system;

type and characteristics of GMOs (recipient organisms, parental organisms, methods of obtaining GMOs);

purpose and expected results of the deliberate release of GMOs into the open system;

results of GMO risk assessment;

list of employees and documents confirming the level of the employees' competence;

conditions, place of release and protective measures;

plan for monitoring the deliberate release of GMOs;

action plan in case of emergency.

3. The application shall be accompanied by a summary (brief description) of the content of the research and testing of GMOs in the open system.

4. The term for consideration of the application by the central executive authority ensuring the formation and implementing the state policy in the field of environmental protection, environmental and, within the statutory powers, biological and genetic safety, shall not exceed 90 days from the application date.

5. During the examination of the application, public consultations may be held, the duration of which may not exceed 30 days and shall be included in the general term for consideration of the application.

6. The central executive authority ensuring the formation and implementing the state policy in the field of environmental protection, environmental and, within the statutory powers, biological and genetic safety, shall send a copy of the application with annexes to the Scientific Committee to obtain an opinion on possible risks of GMOs in an open system.

7. The Scientific Committee shall assess the risk of releasing GMOs into the open system in accordance with the procedure for GMO risks assessing, taking into account the possible threat of GMOs (direct, indirect or delayed) and its possible impact on human health or the environment.

8. Based on the opinion on possible risks of GMOs in the open system provided by the Scientific Committee, the central executive authority ensuring the formation and implementing the state policy in the field of environmental protection, environmental and, within the statutory powers, biological and genetic safety shall provide a permit for conducting research and testing GMOs in the open system.

9. The grounds for refusal to issue a permit for conducting research and testing

GMOs in the open system are:

submitting incorrect information by the person necessary for the implementation of GMO risk assessment;

providing a negative opinion on the possible risks of GMOs in the open system by the Scientific Committee.

10. In case of refusal to issue a permit, the grounds for refusal must be indicated. The person may re-apply after eliminating the deficiencies based on which the refusal has been issued.

11. Permit for conducting research and testing of GMOs in the open system is granted for a period of three years.

12. The procedure for issuing and revoking a permit for conducting research and testing of GMOs in the open system shall be approved by the Cabinet of Ministers of Ukraine.

13. Permit for conducting research and testing of GMOs in the open system is the ground for the commencement of research and testing of GMOs and the inclusion of a person in the State Register of persons conducting research and testing in the open system.

14. Inclusion of a person in the State register of persons conducting research and testing in the open system shall be carried out within 7 working days from the issuance date of the relevant permit.

15. In the event of a risk to humans, animals and plants, and the environment during the conduct of research and testing of GMOs in the open system, the person conducting research and testing in the open system must:

Notify of such risk the central executive authority ensuring the formation and implementing the state policy in the field of environmental protection, environmental and, within the statutory powers, biological and genetic safety;

review the preventive measures specified in the application for a permit;

take all possible measures necessary to protect human health and the environment.

16. The grounds for revoking a permit for conducting research and testing of GMOs in the open system are:

1) a person's application for revocation of the permit;

2) decision of the central executive authority ensuring the formation and implementing the state policy in the field of environmental protection, environmental and, within the statutory powers, biological and genetic safety, if

the activity of the subject of genetic engineering activity is terminated;

determining a risk to humans, animals and plants, and the environment when conducting research and testing of GMOs in the open system.

17. The procedure for risk assessment during the conduct of research and testing of GMOs in the open system shall be developed by the central executive

authority, ensuring the formation and implementing the state policy in the field of environmental protection, environmental and, within the statutory powers, biological and genetic safety, and approved by the Cabinet of Ministers of Ukraine.

18. Persons conducting research and testing of GMOs in the open system are obliged to provide the central executive authority, ensuring the formation and implementing the state policy in the field of environmental protection, environmental and, within the statutory powers, biological and genetic safety, with:

information on the time and place of GMOs release, destruction, and burial of GMOs;

a report on possible risks to human health and the environment within 6 months from the completion date of GMO research and testing in the open system.

19. The central executive authority, ensuring the formation and implementing the state policy in the field of environmental protection, environmental and, within the statutory powers, biological and genetic safety, shall publish information on the time and place of GMO research and testing in an open system on the official website.

Section V
STATE REGISTERS AND STATE REGISTRATION OF GMOs

Article 20. Requirements for state registers in the field of GMOs

1. The central executive authorities, within the limits of their powers, shall ensure the maintenance of the following state registers in electronic form:

State register of subjects of genetic engineering activity;

State register of persons conducting research and testing in an open system;

State Register of GMOs.

2. The information contained in the specified state registers is open and publicly available.

3. The central executive authorities maintaining the relevant registers shall ensure unhampered, round-the-clock and free access to the information contained in the said registers via the Internet.

4. Information from the state registers provided for in part one of this Article, obtained through accessing them via the Internet:

have the status of official information of the relevant central executive authority ensuring the formation and implementing the state agricultural policy;

do not require any additional confirmation by the relevant central executive authority;

can be used by any public authorities and local government authorities, individuals, individual entrepreneurs, legal entities.

Article 21. Application for state registration of GMOs

1. For state registration of a GM source, a person who intends to register a GM source shall submit to the central executive authority forming the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture, an application for state registration of GMOs which includes:

1) application for state registration of GMOs, containing:

a) name of the GM source and its unique identification number in the format established by the Organization for Economic Co-operation and Development (hereinafter OECD) for use in its database and in the information resources of the Biosafety Clearing-House under the Cartagena Protocol on Biosafety;

b) name and location of the applicant;

2) a document confirming that the applicant is the holder of property rights to the relevant GM source;

3) registration dossier containing detailed information on the GM source, conducted researches and testing, conditions of GMOs use and handling;

4) detailed information on the method of determining GMOs, except for GMOs obtained by genome editing methods;

5) GMO post-registration monitoring plan.

2. The applicant may be only the holder of the rights to the GM source or his/her representative.

3. Requirements for the content of the registration dossier shall be approved by the Cabinet of Ministers of Ukraine.

4. After submitting an application for state registration of GMOs, the applicant must submit detailed information on the method of determining GMOs, a sample of GMOs submitted for state registration, reference samples of GMO-sources and (if necessary) all necessary consumables and reagents within five working days. Reference samples include a positive sample (GM source or its genetic material) and a negative sample (parent organism or its genetic material that has been used for genetic modification purposes).

Article 22. Publication of information on the application for GMOs state registration

1. Information on the application for state registration of GMOs together with the materials of the registration dossier (except for confidential information) shall be posted on the official website of the central executive authority shaping the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture.

2. The decision to classify information as confidential shall be made by the

central executive authority shaping the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture, in agreement with the applicant.

3. In no case shall the information on the following be deemed confidential:

name and location of an applicant;

general description of GMO;

summary of GMO risk assessment;

methods for determining GMOs;

emergency plan.

4. The central executive authority shaping the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture shall notify the applicant of its decision on the amount of information classified as confidential no later than 7 working days before the date of publication of registration dossier materials on its official website.

5. Information on the application for state registration of GMOs is open and publicly available, except for information classified as restricted in accordance with the law.

6. Information on the potential impact of GMOs on human health and the environment cannot be classified as restricted.

Article 23. Consideration of the application for GMOs state registration

1. The central executive authority shaping the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture is obliged to consider the application and make a decision on state registration or refusal to register GM source within 180 days from the date of receiving the application.

2. Upon receiving the application, the central executive authority shaping the state policy in the field of registration of genetically modified organisms and the circulation of genetically modified products in agriculture shall send the registration dossier to the Scientific Committee.

3. The Scientific Committee shall, within 90 days from the date of receiving the registration dossier, assess the risk of GMOs in accordance with the procedure for GMO risks assessment, taking into account the possible immediate, indirect or delayed risk of GMO and its possible impact on human health or environmental safety and shall send an opinion on GMO risk assessment to the executive authority shaping the state policy in the field of registration of genetically modified organisms and the circulation of genetically modified products in agriculture.

4. Within 90 days after the publication of information on the application for state registration of GMOs, the Scientific and Methodological Centre for GMO Testing shall verify the method of determining GMOs and send an opinion on the

conformity of the method proposed by the applicant to the central executive authority shaping the state policy in the field of registration of genetically modified organisms and genetically modified products in agriculture.

5. Positive opinions on the absence of GMO risks and on the conformity of the method for determining GMOs proposed by the applicant are the ground for adoption of the decision on GMO state registration by the central executive authority shaping the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture.

6. The applicant may withdraw the application at any time before the date of the decision on the state registration of the GMO. In this case, the application together with the documents attached to it, shall be returned to the applicant.

7. The central executive authority ensuring the formation and implementing the state policy in the field of safety and certain food quality indicators may pass a decision on refusal to register GM source only on the basis of the following grounds:

submission of incomplete and/or incorrect information by a person for state registration of GMO;

providing an opinion on the possible risks of GMOs by the Scientific Committee;

providing an opinion by the Scientific and Methodological Centre for GMO testing on the inconsistency of the GMO determination method proposed by the applicant.

Article 24. State registration of GMOs

1. State registration of a GM source shall be carried out based on the decision of the central executive authority ensuring the formation and implementing the state policy in the field of food safety and certain food quality indicators by entering information on the GM source in the State Register of GMOs. The extract from the State Register of GMOs is the confirmation of the state registration of a GM source.

2. The following information shall be entered into the State Register of GMOs:

information about the owner of the GM source;

information about the GM source;

purpose of using the GM source (for growing, recycling, use in food, feed or other purposes);

validity term of the state registration.

3. A registration number shall be assigned to the GM source entered in the State Register of GMOs in accordance with the Procedure for State Registration of GMOs.

4. State registration of a GM source is carried out on a paid basis for up to 10 years. The amount of payment shall be set by the Cabinet of Ministers of Ukraine.

The GM source shall be excluded from the State Register of GMOs upon expiration of its state registration. Re-registration of a GM source shall be carried out according to a simplified procedure.

5. The procedure for state registration of GMOs shall be approved by the Cabinet of Ministers of Ukraine.

6. State registration:

of genetically modified plant varieties shall be carried out in the manner prescribed by law for plant varieties, subject to state registration of the GM source;

of the latest food products that contain GMOs or are obtained with their use shall be carried out in accordance with the procedure established by the legislation on food safety and quality, subject to the state registration of the relevant GM source.

Article 25. Temporary suspension and cancellation of state registration of GMOs

1. State registration of GMOs may be temporarily suspended or cancelled based on a decision of the central executive authority shaping the state policy in the field of registration of genetically modified organisms and the circulation of genetically modified products in agriculture.

2. The ground for the temporary suspension of state registration of GMOs is the appearance of new scientifically substantiated information on the fact that the use of the relevant GM source may have a negative impact on human health, animals, plants and the environment, the authenticity of which shall be confirmed by the Scientific Committee. State registration of GMOs shall be renewed based on the recommendation of the Scientific Committee.

3. The grounds for cancellation of state registration of GMOs are:

1) confirmation of information that the GM source has a negative impact on human health, animals, plants and the environment;

2) identifying new properties of the GM source, different from those submitted in the application;

3) application of the GM source holder

4) expiration of the state registration of GMOs.

4. To pass a decision on cancelling the state registration of GMOs on the grounds provided for in paragraphs 1 and 2 of part three hereof, the central executive authority shaping the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture shall appeal to the Scientific Committee for an opinion on the GMO risks reassessment.

5. The negative opinion of the Scientific Committee during GMO risks reassessment shall be the ground for the decision to cancel the state registration of GMOs.

6. Information on cancellation of GMOs state registration shall be included in the State Register of GMOs from the date of passing the decision to cancel state registration of GMOs, indicating the grounds and date of such cancellation.

7. The procedure for the cancellation of state registration of GMOs shall be approved by the Cabinet of Ministers of Ukraine.

Section VI
LABELING, PLACING ON THE MARKET, MONITORING, TRANSPORTATION, STORAGE, DISPOSAL OF GMO AND GM PRODUCTS

Article 26. GM products labeling

1. GMOs and GM products placed on the market must be marked in accordance with the requirements of this Law.

2. The GM products labeling shall include information on each ingredient of the product containing the GM source and on the relative amount of the ingredient containing GMOs in the total weight of the whole product.

3. The use of "GMO-free" labeling for products that can not contain GMOs is not allowed. Products for which it is technically impossible to detect GMOs (oil, sugar, soy sauce, alcoholic beverages, etc.) and products obtained using genome editing methods are exempt from mandatory labeling.

4. The use of the label "GMO-free" is allowed if the absence of GMOs in the product is confirmed in accordance with the requirements of legislation on safety and certain food quality indicators.

5. If the GMO content of any ingredient in a product exceeds 0.9 per cent, such product shall be marked with GMO label. For unpackaged products, the "GMO" label shall be indicated in the documents or individual packaging elements accompanying such a product.

6. A product in which it is impossible to exclude accidental or technically unavoidable impurities of GMOs shall not be considered to contain GMOs, provided that the minimum threshold value is 0.1% of the total weight of the whole product.

7. For certain products, other indicators of threshold values may be established by the central executive authority shaping the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture.

8. In case of exceeding the established indicator, such products are considered to be GM products and are subject to the requirements of the legislation in the field of GMO handling and ensuring biosafety.

Requirements for GM products labeling shall be determined by the central executive authority, shaping the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture.

Article 27. Placing on the market and traceability of GMOs and GM products

1. Placing GMOs and GM products on the market is allowed only after the state registration of the relevant GM source. In case of exclusion of a GM source from the State Register of GMOs, placing GMOs and GM products on the market is prohibited.

2. Persons placing GMOs and/or GM products on the market for the first time shall, for traceability purposes, draw up a written declaration on placing GMOs and GM products on the market in any form, in which the following information shall be indicated on a mandatory basis:

information about the person placing GMOs and/or GM products;

information that such products contain GMOs;

registration number of the relevant GM source in the State Register of GMOs.

3. GMOs and GM products shall be accompanied by a copy of such declaration at all stages of its circulation.

4. Producers and/or distributors of genetically modified plants, animal breeds, microorganisms shall keep records of the relevant GMO or GM products and provide the holder of the rights to the registered GMO with the information necessary for the formation of the GMO post-registration monitoring network.

5. Before the start of production (cultivation) of plants, animal breeds, microorganisms the producers must submit a notice of intent to carry out such activities to the central executive authority implementing the state policy in the field of state supervision (control) over the circulation of genetically modified products in agriculture.

6. The notice must contain information on:

a person who intends to carry out the production (cultivation) of plants, animal breeds, microorganisms;

registered GM source indicating the holder of the right to the respective GM source;

place of production and expected production volumes of GM products.

7. The notice's form shall be approved by the central executive authority, shaping the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture.

8. The notice is a sufficient ground for the start of production (cultivation) of genetically modified plants, animal breeds, microorganisms and inclusion of a person in the List of persons engaged in production (cultivation) of genetically modified plants, animal breeds, microorganisms.

9. The central executive authority implementing the state policy in the field of state supervision (control) over the circulation of genetically modified products in

agriculture shall maintain a list of persons engaged in the production (cultivation) of genetically modified plants, animal breeds, microorganisms according to the procedure established by the central executive authority shaping the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture.

10. Persons engaged in the production (cultivation) of genetically modified plants, animal breeds, microorganisms must comply with the rules of concurrent use of GMOs and GM products and GMO-free products.

Article 28. GMOs post-registration monitoring

1. The holder of the rights to a registered GM source is obliged to ensure the implementation of the GMO post-registration monitoring plan during the entire registration validity period.

2. The GMO post-registration monitoring plan shall be approved by the central executive authority shaping the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture, and the central executive authority ensuring the formation and implementing the state policy in the field of environmental protection, environmental and, within the statutory powers, biological and genetic safety.

3. The GMOs post-registration monitoring plan must contain:

measures for GMO post-registration monitoring;

data on the post-registration monitoring network.

4. The holder of the rights to a registered GM source shall form a post-registration monitoring network consisting of producers of genetically modified plants, animal breeds, microorganisms and/or distributors to whom he has sold the relevant GM source.

5. The holder of the rights to a registered GMO must:

ensure implementation of the post-registration monitoring plan;

have information about the persons carrying out the production (cultivation) of GMOs and GM products, and information about the volume of products obtained.

2. The GMO post-registration monitoring plan may be reviewed by the holder of the rights to registered GMO subject to approval by the central executive authority shaping the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture, and the central executive authority ensuring the formation and implementing the state policy in the field of environmental protection, environmental and, within the statutory powers, biological and genetic safety.

7. Following the results of GMOs post-registration monitoring, the holder of rights to a registered GMO annually submits a report on the results of GMOs post-

registration monitoring to the central executive authority, ensuring the formation and implementing the state policy in the field of environmental protection, environmental and, within the statutory powers, biological and genetic safety, and central executive authority shaping the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture.

8. The form of the report on the results of GMO post-registration monitoring shall be developed and approved by the central executive authority ensuring the formation and implementing the state policy in the field of environmental protection, environmental and, within the statutory powers, biological and genetic safety.

Article 30. Concurrent use of GMOs, GM products and GMO-free products

1. Entities shall comply with the rules on the concurrent use of GMOs, GM products and GMO-free products in order to avoid the accidental presence of GMOs in other crops and organic products.

2. Rules for concurrent use of GMOs, GM products and GMO-free products shall be established for each registered genetically modified variety of plants, animal breeds, strain of microorganisms, taking into account their biological characteristics and the introduced genetically modified trait.

3. Rules for concurrent use of GMOs, GM products and GMO-free products shall be approved by the Cabinet of Ministers of Ukraine at the request of the central executive authority shaping the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture.

Article 31. Transportation, destruction, disposal of GMOs and withdrawal from circulation, recycling, utilization, destruction of GM products

1. GMOs that are not intended for release into the open system shall be transported only in sealed packaging, container or vehicles closed in such a way as to prevent its opening without damaging the seal and unintentional release of the GMO. Sealing of package, container or vehicle shall be carried out by the subject of genetic engineering activity, a note whereof is made in the consignment note. GMOs and GM products that are not intended to be released into the open system should be stored in a way to prevent the unintentional release of GMOs.

2. GMOs obtained during testing, unusable or prohibited for use, containers from them, are subject to destruction and disposal by a special commission consisting of representatives of the subject of genetic engineering activity and the central executive authority ensuring the formation of state policy in the field of protection environment and environmental safety.

3. The transportation and storage of GMOs and GM products placed on the market shall be permitted only if appropriate measures are taken to prevent mixing GMOs and GM products with GMO-free products.

4. GM products are subject to withdrawal from circulation and seizure in the case of:

exclusion of a GM source from the State Register of GMOs or cancellation of its state registration;

GM products are of poor quality and dangerous in the sense of the legislation on withdrawal from circulation, GMO recycling, disposal, destruction or further use of low-quality and dangerous products.

5. The procedure for withdrawal from circulation and seizure of GM products that do not meet the requirements established by legislation in the field of state regulation of genetic engineering, biosafety and state control over the circulation of genetically modified products in agriculture shall be determined by legislation on withdrawal from circulation, recycling, disposal, destruction or further use of low-quality and dangerous products.

Section VII
CROSS-BORDER MOVEMENT OF GMOs

Article 32. Requirements for the export of GMOs and GM products

1. Export of GMOs and GM products from the customs territory of Ukraine shall be carried out in accordance with the requirements of international treaties of Ukraine, as well as taking into account the requirements of the destination country.

2. Export of GMOs and GM products from the customs territory of Ukraine is allowed only subject to state registration of the GM source, except for their transit movement through the customs territory of Ukraine or export of GMOs for research purposes.

Article 33. Requirements for the import of GMOs to Ukraine

1. Import of GMOs or GM products into the customs territory of Ukraine is allowed only subject to state registration of the GM source, except for import of GMOs for research purposes, or transit movement of GMOs or GM products through the customs territory of Ukraine.

2. Import of GMOs intended for research purposes, without registration of the GM source, is allowed only if there is a permit for import of GMOs for conducting research works of the first risk level in a closed system issued by the central executive authority ensuring the formation and implementing the state policy in the field of health care.

3. The procedure for issuing (revoking) permits for the import of unregistered GMOs to conduct research work of the first risk level in a closed system shall be established by the Cabinet of Ministers of Ukraine.

Article 34. Requirements for the transit of GMOs or GM products through the customs territory of Ukraine

1. Transit movement of GMOs or GM products through the customs territory of Ukraine is allowed only if there is a permit for transit movement of genetically modified organisms issued by the central executive authority ensuring the formation of state policy in the field of environmental protection and environmental safety.

2. The procedure for issuing (revoking) permits for transit movement of GMOs through the territory of Ukraine shall be established by the Cabinet of Ministers of Ukraine.

Article 35. Unintentional release of GMOs into the environment during the transit movement of GMOs

1. In the event of unintentional release of GMOs into the environment during the transit movement of GMOs, which has led or may lead to significant adverse effects on the conservation and sustainable use of biological diversity, including risks to human health, persons carrying out such movements must immediately inform the central executive authority ensuring the formation and implementation of state policy in the field of environmental protection, environmental and, within the statutory powers, biological and genetic safety.

2. In case of receiving information about the unintentional release of GMOs into the environment during transit movement of GMO, the central executive authority ensuring the formation and implementation of state policy in the field of environmental protection, environmental and, within the statutory powers, biological and genetic safety, must take appropriate measures to immediately inform the population and, if necessary, partner countries, international organizations to which Ukraine is a party, if prescribed by international treaties.

3. The procedure for informing about the fact of unintentional release of GMOs into the environment during transit movement of GMOs, which has led or may lead to significant adverse consequences for the conservation and sustainable use of biological diversity, taking into account risks to human health shall be approved by the Cabinet of Ministers.

Section VII
STATE SUPERVISION (CONTROL) IN THE FIELD OF GENETIC ENGINEERING ACTIVITY AND GMO HANDLING

Article 36. State supervision (control) over GMOs handling in a closed system and during GMOs research and testing in an open system

1. State supervision (control) over the observance of biosafety in the creation,

research and use of GMOs in a closed system during the implementation of works of the second, third and fourth risk levels shall be carried out by the central executive authority implementing the state policy in the field of sanitation and epidemic well-being of the population.

2. State supervision (control) over the observance of biosafety of biological objects of the natural environment during research and testing of GMOs in the open system shall be carried out by the central executive authority ensuring the implementation of state policy on state supervision (control) in the field of environmental protection, rational use, reproduction and protection of natural resources.

3. During the implementation of measures of state control over the conduct of research and testing of GMOs in the open system, the central executive authority ensuring the implementation of state policy on state supervision (control) in the field of environmental protection, rational use, reproduction and protection of natural resources shall verify the compliance of the following measures by the subject of genetic engineering activity, taking into account the conditions specified in the relevant permit:

preventive measures;

measures to destroy crops after harvest.

4. Additional measures of state control over the research and testing of GMOs include monitoring research sites where research and testing of GMOs were conducted during the next growing season.

5. State supervision (control) over GMOs handling in a closed system and during research and testing of GMOs in an open system shall be carried out in accordance with the Law of Ukraine "On Basic Principles of State Supervision (Control) in the Sphere of Economic Activity".

Article 37. State supervision (control) over the labeling and placing GMOs and GM products on the market

1. State supervision (control) over compliance with the requirements for labeling and circulation of GM products, as well as compliance with the rules of concurrent use of GMOs, GM products and GMO-free products shall be carried out by the central executive authority implementing state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture.

2. The central executive authority ensuring the formation and implementing the state policy in the field of health care shall approve the list of relevant methods for detection and identification of GMOs in accordance with the recommendations of the Scientific and Methodological Centre for GMO Testing.

3. GMO content is not monitored for products for which it is technically impossible to detect GMOs.

4. In order to exercise state control over the circulation of GMOs and GM products, the central executive authority implementing the state policy in the field of registration of genetically modified organisms and circulation of genetically modified products in agriculture shall create a network of testing laboratories for GMO detection.

5. Regulations on the network of testing laboratories for determining GMOs shall be approved by the Cabinet of Ministers of Ukraine.

6. Scientific and methodological coordination of the activities of testing laboratories for determining GMOs in products shall be carried out by the Scientific and Methodological Centre for GMO Testing.

7. State supervision (control) over the labeling and placing GMOs and GM products on the market shall be carried out in accordance with the Law of Ukraine "On Basic Principles of State Supervision (Control) in Economic Activity" and legislation in the field of control over genetically modified products in agriculture.

Article 38. Liability for violation of legislation in the field of control over genetically modified products in agriculture

1. Violation of the requirements of this Law and legal regulations adopted on its basis entails civil, administrative, disciplinary or criminal liability in accordance with the law.

2. Responsibility shall be borne by persons guilty of:

violation of the procedure for genetic engineering activity and GMOs handling in a closed system;

GMOs handling in the open system, labeling, placing on the market, transportation, storage, disposal of GMOs and GM products;

concealing or misrepresenting GMO information that may or has caused a threat to human life and health or the environment;

violation of the rules on placing GMOs and GM products on the market.

Section IX
INTERNATIONAL COOPERATION

Article 39. International cooperation of Ukraine in the field of genetic engineering activity and GMO handling

1. International cooperation of Ukraine in the field of genetic engineering activity and GMO handling shall be carried out by:

concluding international treaties, including bilateral agreements on mutual recognition in the field of genetic engineering activity;

bringing the legislation of Ukraine on genetic engineering activities and GMOs

handling in compliance with the relevant legislation of the European Union;

harmonization of national legislation in the field of control over genetically modified products in agriculture with the norms and standards of relevant international organizations;

exchange of information in the field of genetic engineering activity and GMO handling.

Section X
FINAL AND TRANSITIONAL PROVISIONS

1. This Law shall come into effect on the day following the day of its publication and shall be enacted two years after its coming into effect, except for Articles 26, 27, 34, subparagraph 3 of paragraph 4 and paragraph 5 of this section, which shall become effective from its entry into force.

2. To recognize the Law of Ukraine "On the State System of Biosafety in Creating, Testing, Transporting and Using Genetically Modified Organisms" as invalid (The Official Bulletin of the Verkhovna Rada of Ukraine, 2007, No. 35, p. 484).

3. To establish that the documents submitted for state registration of GMOs and products produced with their use, in accordance with the Law of Ukraine "On the State System of Biosafety in Creating, Testing, Transporting and Using Genetically Modified Organisms", for which no decision on state registration has been made as of the date of this Law's entry into force shall be returned to the applicant.

4. To amend the following laws of Ukraine:

1) in the List of permitting documents in the sphere of economic activity, approved by the Law of Ukraine "On the List of Permitting Documents in the Sphere of Economic Activity" (The Official Bulletin of the Verkhovna Rada of Ukraine, 2011, No.47, p. 532 with the following amendments):

paragraphs 28, 74, 146, 148 to be omitted;

new paragraphs 156-161 to be added as follows:

156.	Permit for the import of unregistered GMOs to conduct genetic engineering activities of the first risk level in a closed system	The Law of Ukraine "On the State Regulation of Genetic Engineering, Ensuring Biosafety and State Control Over the Circulation of Genetically Modified Products in Agriculture"
157.	Permit for genetic engineering activities of the 2nd risk level in the closed system	The Law of Ukraine "On the State Regulation of Genetic Engineering, Ensuring Biosafety and State Control Over the Circulation of Genetically Modified Products in Agriculture"

158.	Permit for genetic engineering activities of the 3rd risk level in the closed system	The Law of Ukraine "On the State Regulation of Genetic Engineering, Ensuring Biosafety and State Control Over the Circulation of Genetically Modified Products in Agriculture"
159.	Permit for genetic engineering activities of the 4th risk level in the closed system	The Law of Ukraine "On the State Regulation of Genetic Engineering, Ensuring Biosafety and State Control Over the Circulation of Genetically Modified Products in Agriculture"
160.	Permit for conducting research and testing GMOs in an open system	The Law of Ukraine "On the State Regulation of Genetic Engineering, Ensuring Biosafety and State Control Over the Circulation of Genetically Modified Products in Agriculture"
161.	Permit for transit movement through the territory of Ukraine	The Law of Ukraine "On the State Regulation of Genetic Engineering, Ensuring Biosafety and State Control Over the Circulation of Genetically Modified Products in Agriculture"

2) Part three of Article 6 of the Law of Ukraine "On Consumer Information on Food Products" (The Official Bulletin of the Verkhovna Rada of Ukraine, 2019, No. 7, Art. 41) shall be worded as follows:

«3. Labeling of genetically modified products shall be carried out in accordance with the Law of Ukraine "On State Regulation of Genetic Engineering Activity, Biosafety and State Control over the Circulation of Genetically Modified Products in Agriculture."

5. Prior to the relevant provisions of this Law entering into force, the Cabinet of Ministers of Ukraine shall ensure that:

its legal regulations are brought in compliance with this Law;

legal regulations of the ministries, other central executive authorities are brought in compliance with this Law by them.

Chairperson

of the Verkhovna Rada of Ukraine