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**LAW OF THE REPUBLIC OF BELARUS
of January 9, 2006 No. 96-3**

ON SAFETY IN GENETIC ENGINEERING ACTIVITY

Adopted by the House of Representatives on December 8, 2005
Approved by the Council of the Republic on December 21, 2005

(as worded in the Law of the Republic of Belarus of December 24, 2007 No. 299-3; of November 10, 2008 No. 444-3; of July 2, 2009 No. 31-3; of January 4, 2010 No. 109-3; of January 4, 2014 No. 130-3; of December 18, 2018 No. 154-3; of January 4, 2022 No. 145-3)

This Law establishes legal and institutional frameworks for ensuring safety in genetic engineering activity and aims to protect human health and the environment and implement the international commitments of the Republic of Belarus in the field of safety in genetic engineering activity.

**CHAPTER 1
GENERAL PROVISIONS**

Article 1. General Terms and their Definitions

The following general terms and their definitions shall be used for the purposes of this Law:

“Safety in genetic engineering activity” means the state of protectability achieved by implementing measures aimed at the prevention or reduction of possible adverse effects of genetically engineered organisms on human health and the environment to the safe level in carrying out of genetic engineering activity;

“Release of genetically engineered organisms into the environment for testing” means introduction of genetically engineered organisms into the environment;

“Genetic engineering” means technology for obtaining of new combinations of genetic material by means of extracellular manipulations with nucleic acid molecules and transfer of designed gene constructs into a living organism as a result of which their incorporation into and activity in this organism and its progeny are achieved;

“Genetic engineering activity” means the activity associated with the development of genetically engineered organisms, carrying out of operations with genetically engineered organisms in self-contained systems, their release into the environment for testing, use for economic purposes, import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of genetically engineered organisms, their storage and deactivation;

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

“Genetically engineered organism” (genetically changed (modified, transgenic) organism) means a living organism containing a new combination of genetic material obtained using genetic engineering;

“Genotype” means an aggregate of all inheritable characters of an organism information on which is encoded in genes;

“State legal entities” means legal entities (unitary enterprises, institutions, and state associations) whose property is state-owned and owned by them on the basis of the right of economic management or operative administration;

(the Paragraph introduced by the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

“Living organism” means any biological entity capable of transferring or replicating (reproducing) genetic material, including sterile organisms, viruses and viroids;

“Conclusion (an authorization document) on import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of potentially pathogenic and pathogenic genetically engineered organisms” means a document confirming the right for import into the Republic of Belarus, export from the Republic of Belarus, and transit through its territory of a certain genotype of potentially pathogenic and pathogenic genetically engineered organisms and of non-recurring nature;

(the Paragraph introduced by the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

“Self-contained system” means a system, where operations with genetically engineered organisms are undertaken, equipped with special facilities and devices that eliminate contact of genetically engineered organisms with the environment and impact on it;

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

“Use of genetically engineered organisms for economic purposes” means breeding and/or rearing/cultivation of genetically engineered animals, genetically engineered plant varieties, and strains of non-pathogenic genetically engineered microorganisms for the production of agricultural and microbiology products;

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

“Non-pathogenic genetically engineered organisms” means genetically engineered organisms incapable of causing human diseases;

“Deactivation of genetically engineered organisms” means activities aimed at the isolation of genetically engineered organisms, as well as their destruction, including by burning in specialized facilities, to prevent harmful effects of genetically engineered organisms on human health and the environment;

(the Paragraph introduced by the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

“Pathogenic genetically engineered organisms” means genetically engineered organisms capable of causing human diseases;

“Permit for release of non-pathogenic genetically engineered organisms into the environment for testing” means a document issued by the specially authorized Republican Body

of the State Administration in the field of safety in genetic engineering activity to legal entities and/or individual entrepreneurs, confirming a right to the release of non-pathogenic genetically engineered organisms of a certain genotype into the environment for testing;

“Risk of possible harmful effects of genetically engineered organisms on human health and the environment” means a combination of the likelihood of adverse effects of genetically engineered organisms on human health and the environment and the magnitude of the consequences of such effects, leading to an emerging threat to human health and the environment;
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

“Potentially pathogenic genetically engineered organisms” means genetically engineered organisms, which may cause human diseases under certain conditions;

“Strains of non-pathogenic genetically engineered microorganisms” means hereditarily supported homogeneous cultures of bacteria, viruses, and fungi containing a new combination of genetic material obtained using genetic engineering, incapable of causing human diseases.

The terms “pathogenic biological agents” and “potentially pathogenic microorganisms” used in this Law shall be applied in the meanings defined by Article 1 of the Law “On the Sanitary and Epidemiological Well-being of a Population” of the Republic of Belarus of January 7, 2012 No. 340-3.

(Part II of Article 1 introduced by the Law of the Republic of Belarus of December 18, 2018 No. 154-3; as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Article 1-1. Legal Regulation of Relations in the Field of Safety in Genetic Engineering Activity

(introduced by the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Relations in the field of safety in genetic engineering activity shall be regulated by this Law and other legislative acts in the field of safety in genetic engineering activity, international treaties of the Republic of Belarus and international legal acts that constitute the Law of the Eurasian Economic Union.

If an international treaty of the Republic of Belarus establishes other rules than those of this Law, then the rules of an international treaty shall apply.

Article 2. Scope of the Present Law

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

The present Law shall regulate relations in the field of safety in genetic engineering activity.

This Law shall not apply to relations associated with the application of genetic engineering to a human being, his/her organs and tissues, handling of pharmaceutical preparations, food raw materials and food products, and animal feeds derived from genetically engineered organisms or their components.

In carrying out of operations with potentially pathogenic microorganisms and pathogenic biological agents that are genetically engineered organisms, the requirements of the legislation in the field of sanitary and epidemiological welfare of population shall apply, taking into account the specifics established by legislation in the field of safety in genetic engineering activity.

With regard to relations arising in connection with import into the Republic of Belarus, export from the Republic of Belarus, transit through its territory and use of genetically engineered organisms that are subject to export control, this Law shall apply in part not regulated by legislation in the field of export control.

Article 3. Basic Principles to Ensure Safety in Genetic Engineering Activity

Basic principles to ensure safety in genetic engineering activity shall be as follows:

Taking of precautionary measures in carrying out of genetic engineering activity;

Scientifically substantiated, integrated and individual approaches to risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment; (as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

The Paragraph excluded. – The Law of the Republic of Belarus of December 18, 2018 No. 154-3);

Access to information on safety in genetic engineering activity.

Article 4. Objects and Subjects of Relations in the Field of Safety in Genetic Engineering Activity

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Objects of relations in the field of safety in genetic engineering activity shall be genetically engineered organisms and rights to carry out genetic engineering activity.

Subjects of relations in the field of safety in genetic engineering activity are as follows:

State bodies that exercise state administration and control/supervision in the field of safety in genetic engineering activity, as well as the Expert Board on Safety of Genetically Engineered Organisms of the Ministry of Natural Resources and Environmental Protection (hereinafter referred to as “the Expert Board”);

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Legal entities and individual entrepreneurs involved in genetic engineering activity;

Organizations authorized to carry out risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment (unless otherwise provided, hereinafter referred to as “authorized organizations”).

Article 5. Measures to Ensure Safety in Genetic Engineering Activity

Safety in genetic engineering activity shall be ensured by:

Adoption (issuance) of normative legal acts, approval and enforcement of technical normative legal acts in the field of safety in genetic engineering activity and their implementation;

Issuance of conclusions (authorization documents) on import, export or transit of potentially pathogenic and pathogenic genetically engineered organisms and permits for release of non-

pathogenic genetically engineered organisms into the environment for testing by specially authorized Republican Bodies of the State Administration in the field of safety in genetic engineering activity;

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

The Paragraph excluded. – The Law of the Republic of Belarus of December 18, 2018 No. 154-3);

Carrying out of State Registration of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms;

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Keeping record of genetically engineered organisms in accordance with legislation;

The Paragraph excluded. – The Law of the Republic of Belarus of December 18, 2018 No. 154-3);

Planning and fulfilling of activities to ensure safety in genetic engineering activity;

Carrying out of risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment;

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Performing of control/supervision over safety in genetic engineering activity;

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Establishing responsibility for a violation of requirements for legislation on safety in genetic engineering activity;

Implementing other measures for safety in genetic engineering activity in accordance with legislation.

CHAPTER 2 STATE ADMINISTRATION IN THE FIELD OF SAFETY IN GENETIC ENGINEERING ACTIVITY

Article 6. State Administration in the Field of Safety in Genetic Engineering Activity

The State Administration in the field of safety in genetic engineering activity shall be exercised by the President of the Republic of Belarus, the Council of Ministers of the Republic of Belarus and specially authorized Republican Bodies of the State Administration in the field of safety in genetic engineering activity.

Specially authorized Republican Bodies of the State Administration in the field of safety in genetic engineering activity shall be the Ministry of Natural Resources and Environmental Protection, the Ministry of Health, and the Ministry of Agriculture and Food.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Article 7. Powers of the President of the Republic of Belarus in the Field of Safety in Genetic Engineering Activity

The President of the Republic of Belarus shall determine the state policy and execute other forms of state regulation in the field of safety in genetic engineering activity in accordance with the Constitution of the Republic of Belarus, this Law and other legislative acts.

Article 8. Powers of the Council of Ministers of the Republic of Belarus in the Field of Safety in Genetic Engineering Activity

The Council of Ministers of the Republic of Belarus shall:

Adopt normative legal acts in the field of safety in genetic engineering activity;

Establish a procedure and terms of issuance of a permit for release of non-pathogenic genetically engineered organisms into the environment for testing;
(as worded in the Law of the Republic of Belarus of November 10, 2008 No. 444-3)

Establish a procedure for issuance of conclusions (authorization documents) on import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of potentially pathogenic and pathogenic genetically engineered organisms;
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Paragraphs 5-7 excluded. – The Law of the Republic of Belarus of December 18, 2018 No. 154-3;

Establish a list of organizations authorized to carry out risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment, as well as a procedure for carrying it out;
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Establish a procedure for the State Registration of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms;
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

The Paragraph excluded. – The Law of the Republic of Belarus of January 4, 2014 No. 130-3;

Establish a procedure and terms of providing information from the databank on genetically engineered organisms;

Exercise other powers in the field of safety in genetic engineering activity in accordance with the Constitution of the Republic of Belarus, Acts of the President of the Republic of Belarus, this Law and other laws.

(as worded in the Law of the Republic of Belarus of November 10, 2008 No. 444-3; of December 18, 2018 No. 154-3; of January 4, 2022 No. 145-3)

Article 9. Powers of the Ministry of Natural Resources and Environmental Protection in the Field of Safety in Genetic Engineering Activity

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

The Ministry of Natural Resources and Environmental Protection within the scope of its competence shall:

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Adopt/issue normative legal acts and approve, enforce technical normative legal acts in the field of safety in genetic engineering activity;

Issue permits for release of non-pathogenic genetically engineered organisms into the environment for testing;

Establish safety requirements for self-contained systems to perform operations of Risk Level I in genetic engineering activity;

Establish in coordination with the National Academy of Sciences of Belarus safety requirements for experimental fields and other objects destined for testing of non-pathogenic genetically engineered organisms upon their first release into the environment;

Establish in coordination with the National Academy of Sciences of Belarus a procedure for testing of non-pathogenic genetically engineered organisms upon their release into the environment;

Establish a procedure for deactivating of non-pathogenic genetically engineered organisms;

Establish a procedure for notifying the Ministry of Natural Resources and Environmental Protection by the owner of non-pathogenic genetically engineered organisms or the person, realizing their import into the Republic of Belarus, of the transit through the territory of the Republic of Belarus of non-pathogenic genetically engineered organisms or their import into the Republic of Belarus for scientific research without their release into the environment for testing;

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Establish a procedure for keeping record by legal entities and individual entrepreneurs of non-pathogenic genetically engineered organisms developed by them and exported from the Republic of Belarus;

Exercise control over compliance with requirements for legislation on environmental protection in the areas of conservation, protection, reproduction and use of wild plants and animals listed in the Red Book of the Republic of Belarus, tree and shrub vegetation and other wild plants within the boundaries of inhabited localities, as well as wild animals that are not the objects of hunting and fishing; protection and use of waters; waste management in carrying out of genetic engineering activity;

Deliver/direct a proposal for the suspension of/ban on the activities of legal entities and/or individual entrepreneurs until the elimination of infringements serving as a basis for the delivery/direction of such a proposal in case of detected legislative violations that pose a threat to the environment;

Raise grievances with legal entities and/or individual entrepreneurs that have caused harm to the environment and make court claims to indemnify for the harm caused to the environment;

Apply to court with a statement on the suspension of activities of legal entities and/or individual entrepreneurs in case of detection of legislative violations that pose a threat to the environment in the case, where they make a decision that the suspension of activities is inexpedient;

Exercise other powers in accordance with this Law, other acts of legislation in the field of safety in genetic engineering activity and other legislative acts.

Article 10. Powers of the Ministry of Health in the Field of Safety in Genetic Engineering Activity

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

The Ministry of Health within the scope of its competence shall:

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Adopt/issue normative legal acts and approve, enforce technical normative legal acts in the field of safety in genetic engineering activity;

Establish safety requirements for self-contained systems in performing of operations of Risk Levels II, III, and IV in genetic engineering activity;

Issue conclusions (authorization documents) for import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of potentially pathogenic and pathogenic genetically engineered organisms;

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3);

The Paragraph excluded. – The Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Establish safety requirements for the transport of potentially pathogenic and pathogenic genetically engineered organisms;

The Paragraph excluded. – The Law of the Republic of Belarus of December 18, 2018 No. 154-3

The Paragraph excluded. – The Law of the Republic of Belarus of January 4, 2010 No. 109-3

Establish a procedure for keeping record by state legal entities of potentially pathogenic and pathogenic genetically engineered organisms developed by them, imported into the Republic of Belarus, exported from the Republic of Belarus and conveyed in transit through its territory;

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3);

Keep record of potentially pathogenic and pathogenic genetically engineered organisms developed in the Republic of Belarus, imported into the Republic of Belarus, exported from the Republic of Belarus and conveyed in transit through its territory;

Organize supervision over compliance with legislative requirements for the sanitary and epidemiological welfare of a population in carrying out of genetic engineering activity;

(as worded in the Law of the Republic of Belarus of January 4, 2014 No. 130-3)

Exercise other powers in accordance with this Law, other acts of legislation in the field of safety in genetic engineering activity and other legislative acts.
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3);

Article 11. Powers of the Ministry of Agriculture and Food in the Field of Safety in Genetic Engineering Activity

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

The Ministry of Agriculture and Food within the scope of its competence shall:
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Adopt/issue normative legal acts and approve, enforce technical normative legal acts in the field of safety in genetic engineering activity;

Exercise, in accordance with the procedure established by the Council of Ministers of the Republic of Belarus, State Registration of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms and issue their State Registration Certificate;

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Organize supervision over compliance with legislative requirements in the field of pedigree work, veterinary medicine, seed production, quarantine and protection of agricultural plants in carrying out of genetic engineering activity;

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Exercise other powers in accordance with legislative acts in the field of safety in genetic engineering activity and other acts of legislation.

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

CHAPTER 3

OBLIGATIONS OF PERSONS CARRYING OUT OF GENETIC ENGINEERING ACTIVITY. SAFETY REQUIREMENTS FOR CARRYING OUT OF GENETIC ENGINEERING ACTIVITY

Article 12. Obligations of Persons Carrying out of Genetic Engineering Activity

Legal entities and individual entrepreneurs carrying out of genetic engineering activity shall:

Observe safety requirements for genetic engineering activity established by normative legal acts, including technical normative legal acts mandatory for compliance;

(as worded in the Law of the Republic of Belarus of December 18, 2018 No.154-3)

Plan and implement measures for ensuring safety in genetic engineering activity carried out by them;

Have a permit for release of non-pathogenic genetically engineered organisms into the environment for testing in cases, where they are tested in the environment;

Use for economic purposes only genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms that have their State Registration Certificate or its copy;
(as worded in the Law of the Republic of Belarus December 18, 2018 No. 154-3; of January 4, 2022 No. 145-3)

Ensure separate containment of genetically engineered organisms during their transport and storage;

Provide for carrying out of risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment and during the State Registration of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms materials, containing complete and reliable information about genetically engineered organisms, as well as measures for preventing of possible harmful effects of genetically engineered organisms on human health and the environment;

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3; of January 4, 2022 No. 145-3)

The Paragraph excluded. – The Law of the Republic of Belarus of December 18, 2018 No. 154-3);

Organize and exercise production control in the field of safety in genetic engineering activity;

Fulfill requirements/directions of authorized state bodies and their officials exercising control/supervision in the field of safety in genetic engineering activity to remedy established violations of legislation on safety in genetic engineering activity;

(as worded in the Law of the Republic of Belarus of January 4, 2014 No. 130-3; of December 18, 2018 No. 154-3)

Perform other obligations in accordance with this Law and other acts of legislation in the field of safety in genetic engineering activity.

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Part II of Article 12 excluded. – The Law of the Republic of Belarus of December 18, 2018 No. 154-3.

Article 13. Risk Levels of Genetic Engineering Activity

When carrying out operations with genetically engineered organisms the following Risk Levels of genetic engineering activity shall be established:

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Risk Level I – operations with non-pathogenic genetically engineered organisms;

Risk Level II – operations with potentially pathogenic genetically engineered organisms;

Risk Level III – operations with pathogenic genetically engineered organisms capable of causing dangerous infectious diseases and spreading of infection and for which effective prevention and treatment measures are known;

Risk Level IV – operations with pathogenic genetically engineered organisms, which are

pathogens of particularly dangerous infectious diseases demonstrating the ability to spread quickly, and for which effective prevention and treatment measures are not known.

Individual entrepreneurs shall have the right to carry out genetic engineering activity of Risk Level I only.

The genetic engineering activity of Risk Levels II, III and IV shall be carried out solely by state legal entities.

Article 14. Safety Requirements for Genetic Engineering Activity in the Self-Contained System

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

When carrying out of operations of Risk Level I of genetic engineering activity in the self-contained system, safety requirements for self-contained systems established by the Ministry of Natural Resources and Environmental Protection must be observed.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

When carrying out operations of Risk Levels II, III and IV of genetic engineering activity in the self-contained system, safety requirements for self-contained systems established by the Ministry of Health must be observed.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Article 15. Safety Requirements upon Release of Genetically Engineered Organisms into the Environment for Testing

Release of potentially pathogenic and pathogenic genetically engineered organisms into the environment for testing shall not be allowed.

Release of non-pathogenic genetically engineered organisms into the environment for testing shall be carried out, provided there is a permit for release of non-pathogenic genetically engineered organisms into the environment issued by the Ministry of Natural Resources and Environmental Protection. A permit shall be issued, taking into account recommendations of the Expert Board for admissibility of release of non-pathogenic genetically engineered organisms into the environment. A permit obtained upon first release of non-pathogenic genetically engineered organisms shall be valid upon subsequent release of genetically engineered organisms of a certain genotype into the environment.

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-4; of January 4, 2022 No. 145-3)

Testing of non-pathogenic genetically engineered organisms upon their first release into the environment must be carried out in experimental fields and other facilities specially equipped to prevent possible harmful effects of these organisms on the environment and that comply with safety requirements established by the Ministry of Natural Resources and Environmental Protection subject to agreement with the National Academy of Sciences of Belarus.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Article 16. Safety Requirements for the Use of Genetically Engineered Organisms for Economic Purposes

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Use of potentially pathogenic and pathogenic genetically engineered organisms for economic purposes shall not be allowed.

Use for economic purposes of non-pathogenic genetically engineered organisms in the form of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms shall be allowed upon their State Registration with the Ministry of Agriculture and Food.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Realization of genetically engineered organisms to legal entities and individual entrepreneurs for subsequent use for economic purposes shall be carried out with the delivery of a copy of the State Registration Certificate for genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms to them.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Article 16-1. State Registration of Genetically Engineered Animals, Genetically Engineered Plant Varieties and Strains of Non-pathogenic Genetically Engineered Microorganisms

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

(introduced by the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

State Registration of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms destined for release into the environment shall be carried out taking into account of recommendations of the Expert Board for admissibility of use of non-pathogenic genetically engineered organisms for economic purposes after testing conducted in line with safety requirements stipulated by Article 15 of this Law by entering information related to the State Registration of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms in the State Register of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

State Registration of strains of non-pathogenic genetically engineered microorganisms not destined for release into the environment shall be carried out taking into account recommendations of the Expert Board for admissibility of use of non-pathogenic genetically engineered organisms for economic purposes by entering information related to the State Registration of strains of non-pathogenic genetically engineered organisms in the State Register of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

State Registration of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms shall be confirmed by their State Registration Certificate.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Article 17. Safety Requirements during the Transportation of Genetically Engineered Organisms

Means of transport used for the transportation of non-pathogenic genetically engineered organisms must be equipped with devices that exclude the possibility of unauthorized release of genetically engineered organisms into the environment.

Transportation of potentially pathogenic and pathogenic genetically engineered organisms must be carried out in accordance with legislation in the field of transport of hazardous cargo and safety requirements during the transportation of these organisms established by the Ministry of Health.

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3; of January 4, 2022 No. 145-3)

Article 18. Safety Requirements for Import into the Republic of Belarus, Export from the Republic of Belarus and Transit through its Territory of Genetically Engineered Organisms

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Import into the Republic of Belarus and transit through its territory of genetically engineered organisms shall be allowed, provided that the exporting country (the country exercising transit) is a Party to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity adopted in Montreal on 29 January 2000.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Import into the Republic of Belarus of non-pathogenic genetically engineered organisms shall be allowed for:

Scientific research without release of non-pathogenic genetically engineered organisms into the environment for testing upon notification of the Ministry of Natural Resources and Environmental Protection by the owner of non-pathogenic genetically engineered organisms or the person realizing their import into the Republic of Belarus, in accordance with the procedure established by this Ministry;

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Testing with release of non-pathogenic genetically engineered organisms into the environment after obtaining a permit for release of non-pathogenic genetically engineered organisms into the environment the issuance of which is stipulated by Part 2 of Article 15 of this Law.

Use for economic purposes, provided that there is information related to the State Registration of genetically engineered organisms in the State Register of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered organisms in line with Article 16-1 of this Law.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Transit through the territory of the Republic of Belarus of non-pathogenic genetically engineered organisms shall be allowed upon notification of the Ministry of Natural Resources and Environmental Protection by the owner of non-pathogenic genetically engineered organisms or the person realizing their transit through the territory of the Republic of Belarus, in accordance with the procedure established by this Ministry.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

The export of non-pathogenic genetically engineered organisms shall be allowed upon notification of the specially authorized body (organization) of the destination country and obtaining of consent to import.

The import into the Republic of Belarus of potentially pathogenic and pathogenic genetically engineered organisms shall be exercised for scientific purposes only.

A right to import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of potentially pathogenic and pathogenic genetically engineered organisms shall be possessed by state legal entities only.

Import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of potentially pathogenic and pathogenic genetically engineered organisms shall be realized upon availability of a conclusion (an authorization document) on import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of potentially pathogenic and pathogenic genetically engineered organisms issued by the Ministry of Health, in accordance with international legal acts constituting the Law of the Eurasian Economic Union and a procedure established by the Council of Ministers of the Republic of Belarus.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

The rules stipulated by Parts 5-7 of this Article shall apply to potentially pathogenic and pathogenic genetically engineered organisms in line with the list determined by the international legal act constituting the Law of the Eurasian Economic Union.

In case of import into the Republic of Belarus and transit through its territory of genetically engineered organisms in breach of the requirements of this Article, these genetically engineered organisms shall be subject to immediate removal from the Republic of Belarus by the owner of genetically engineered organisms or the person who has realized their import into the Republic of Belarus.

Article 19. Safety Requirements for Deactivation of Genetically Engineered Organisms

(as worded in the Law of the Republic of Belarus of December 18, 2018 No.154-3)

Genetically engineered organisms classified in accordance with legislation as waste shall be subject to deactivation, including the remains of non-pathogenic genetically engineered plants, animals and microorganisms upon completion of testing in experimental fields and in self-contained systems, including genetically engineered organisms:

Release of which into the environment for testing was carried out without a permit for release of non-pathogenic genetically engineered organisms into the environment;

Used for economic purposes by legal entities and individual entrepreneurs without the State Registration Certificate for genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered organisms or its copy.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Deactivation of non-pathogenic genetically engineered organisms, including those classified in accordance with legislation as waste, shall be carried out in accordance with the procedure

established by the Ministry of Natural Resources and Environmental Protection.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Deactivation of potentially pathogenic and pathogenic genetically engineered organisms, including those classified in accordance with legislation as waste, shall be carried out in accordance with the procedure established by the Ministry of Health.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

CHAPTER 4

RISK ASSESSMENT OF POSSIBLE HARMFUL EFFECTS OF GENETICALLY ENGINEERED ORGANISMS ON HUMAN HEALTH AND THE ENVIRONMENT

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Article 20. Risk Assessment of Possible Adverse Effects of Genetically Engineered Organisms on Human Health and the Environment

Risk assessment of possible adverse effects on human health and the environment shall be carried out to establish admissibility of their release into the environment for testing or use for economic purposes based on the identification of genetically engineered organisms and the study of materials containing information on genetically engineered organisms, as well as measures to prevent possible harmful effects of genetically engineered organisms on human health and the environment.

Non-pathogenic genetically engineered organisms upon their first release into the environment for testing and during the State Registration of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered organisms destined for use for economic purposes shall be subject to risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Objects of risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment shall be as follows:

Samples of genetically engineered organisms;

Materials containing information on genetically engineered organisms, as well as measures for preventing of possible harmful effects of genetically engineered organisms on human health and the environment.

21. Carrying out of Risk Assessment of Possible Harmful Effects of Genetically Engineered Organisms on Human Health and the Environment. Expert Board

Risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment shall be regulated by this Law and carried out in accordance with a procedure established by the Council of Ministers of the Republic of Belarus.

Risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment shall be carried out on the basis of a request of a legal entity or an individual entrepreneur, its initiators (hereinafter “a person concerned”) to one of authorized

organizations.

Risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment shall be carried out at the expense of a person concerned in accordance with the civil law contract concluded between a person concerned and an authorized organization.

A person concerned may not act in the capacity of an authorized organization.

An authorized organization shall, within five days from the date of the conclusion of a contract on risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment, submit materials containing information on a genetically engineered organism, as well as measures for preventing of possible harmful effects of a genetically engineered organism on human health and the environment, to the State Scientific Institution “Institute of Genetics and Cytology of the National Academy of Sciences of Belarus” fulfilling the functions of the National Coordination Biosafety Centre (hereinafter referred to as “the National Coordination Biosafety Centre”) for the publication of the specified information on its official website over the global computer network Internet to discuss with legal persons and individuals.

Legal persons and individuals may, within 60 (sixty) days from the publication date of the specified information on the official website of the National Coordination Biosafety Centre over the global computer network Internet, familiarize themselves with it and direct their comments and proposals to the National Coordination Biosafety Centre, which shall consolidate the received comments and proposals and within 10 days direct them to the Ministry of Natural Resources and Environmental Protection for consideration at the Expert Board’s Meeting upon adopting recommendations on admissibility (inadmissibility) of release of genetically engineered organisms into the environment for testing or use for economic purposes.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Based on risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment, an authorized organization shall prepare a Protocol containing conclusions on admissibility/inadmissibility of release of genetically engineered organisms into the environment for testing or use for economic purposes issued to a person concerned. The specified Protocol shall not be limited in time.

A protocol on admissibility (inadmissibility) of release of genetically engineered organisms into the environment for testing or use for economic purposes, as well as comments and proposals received by the National Coordination Biosafety Centre from legal persons and individuals shall be considered at the Expert Board’s Meeting. Recommendations accepted based on the conclusions of the Expert Board’s Meeting on admissibility (inadmissibility) of release of genetically engineered organisms into the environment for testing or use for economic purposes shall be taken into account in making of a decision: by the Ministry of Natural Resources and Environmental Protection — on the issuance (non-issuance) of a permit for release of non-pathogenic genetically engineered organisms into the environment for testing; by the Ministry of Agriculture and Food — on the issuance (non-issuance) of the State Registration Certificate for genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

The Expert Board is a collegial consultative body and shall be formed from a number of officials of specially authorized Republican Bodies of the State Administration in the field of safety

in genetic engineering activity, scientists and other specialists. A provision on the Expert Board and its members shall be approved by the Ministry of Natural Resources and Environmental Protection. (as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

CHAPTER 5
INFORMATION AND RECORD KEEPING IN THE FIELD OF SAFETY IN
GENETIC ENGINEERING ACTIVITY

(as worded in the Law of the Republic of Belarus of July 2, 2009 No. 31-3)

Article 22. Informational Support in the Field of Safety in Genetic Engineering Activity
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

The following shall be implemented within the framework of informational support in the field of safety in genetic engineering activity:

Collection, analysis and systematization of information on safety in genetic engineering activity;

Formation of the Databank on genetically engineered organisms;

Furnishing of information on safety in genetic engineering activity to legal entities and individual entrepreneurs;

Information exchange with Coordination Biosafety Centres of other states and international organizations.

In order to form a Databank on genetically engineered organisms and achieve other objectives specified in Part 1 of this Article, specially authorized Republican Bodies of the State Administration in the field of safety in genetic engineering activity shall submit related information to the National Coordination Biosafety Centre within five days from/after:

Issuance of a permit for release of non-pathogenic genetically engineered organisms into the environment for testing;

Issuance of the State Registration Certificate for genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms;
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Issuance of a conclusion (an authorization document) for import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of potentially pathogenic and pathogenic genetically engineered organisms;

Receiving of notification of transit through the territory of the Republic of Belarus of non-pathogenic genetically engineered organisms or their import into the Republic of Belarus for scientific research without release into the environment for testing.

The State Customs Committee of the Republic of Belarus shall, within five days after the cargo with genetically engineered organisms has crossed the Customs Border of the Eurasian Economic Union in the Republic of Belarus, submit related information to the National Coordination Biosafety Centre.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Information shall be submitted to the National Coordination Biosafety Centre according to forms established by State Bodies specified in this Article subject to coordination with the National Academy of Sciences of Belarus.

A right to obtain full, timely and accurate information in the field of safety in genetic engineering activity contained in the Databank on genetically engineered organisms shall be guaranteed to legal entities and individuals.

A procedure and terms of information delivery to legal entities and individual entrepreneurs from the Databank on genetically engineered organisms shall be established by the Council of Ministers of the Republic of Belarus.

Article 23. Excluded

(Article 23 excluded. – The Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Article 24. Requirements for Information on Safety of Genetically Engineered Organisms during their Transportation and Storage

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Information on safety of genetically engineered organisms during their transportation must be shown on packaging (container, another object destined for containing (keeping) of genetically engineered organisms) and include:

Name of a genetically engineered organism;

Number and issuance date of the State Registration Certificate for genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms (for genetically engineered organisms destined for use for economic purposes);
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Data on transportation, storage, application and deactivation methods for genetically engineered organisms;

Name and location of a legal entity or a surname, a proper name, a patronymic (if any) and a place of residence/stay of an individual entrepreneur forwarding genetically engineered organisms;

Name and location of a legal entity or a surname, a proper name, a patronymic (if any) and a place of residence/stay of an individual entrepreneur genetically engineered organisms are forwarded to;

Transportation of genetically engineered organisms shall be carried out upon availability of accompanying documentation stipulated by legislation in the field of cargo transport and international legal acts constituting the Law of the Eurasian Economic Union.

Information on safety of genetically engineered organisms during their storage must be shown on packaging (container, another object destined for containing (keeping) of genetically engineered organisms) and include data specified in Paragraphs 2-4 of Part 1 of this Article.

Article 25. Record of Genetically Engineered Organisms Developed, Imported into the Republic of Belarus, Exported from the Republic of Belarus and Conveyed in Transit through its Territory

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Legal entities and individual entrepreneurs exercising genetic engineering activity shall keep records of non-pathogenic genetically engineered organisms developed by them and exported from the Republic of Belarus in accordance with the procedure established by the Ministry of Natural Resources and Environmental Protection.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

State legal entities shall keep record of potentially pathogenic and pathogenic genetically engineered organisms developed by them, imported into the Republic of Belarus, exported from the Republic of Belarus and conveyed in transit through its territory, in accordance with the procedure established by the Ministry of Health, as well as submit to the Ministry of Health data on such genetically engineered organisms, in accordance with the procedure established by this Ministry.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

**CHAPTER 6
CONTROL (SUPERVISION) IN THE FIELD OF SAFETY
IN GENETIC ENGINEERING ACTIVITY**

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Article 26. Control (Supervision) in the field of Safety in Genetic Engineering Activity

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Control over compliance with the requirements of legislation on environmental protection during the exercise of genetic engineering activity shall be part of control in the areas of conservation, protection, reproduction and use of wild plants and animals included in the Red Book of the Republic of Belarus, tree and shrub vegetation and other wild plants within the boundaries of inhabited localities, as well as wild animals that are not objects of hunting and fishing; conservation and use of waters; waste management and shall be exercised by the Ministry of Natural Resources and Environmental Protection, its territorial bodies determined by the Council of Ministers of the Republic of Belarus.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Supervision over compliance with requirements for legislation in the field of sanitary and epidemiological welfare of a population in carrying out of genetic engineering activity shall be part of the state sanitary supervision over compliance, subject to checks, with legislation in the field of sanitary and epidemiological welfare of a population and shall be exercised by authorities and institutions that carry out the state sanitary supervision determined by the Council of Ministers of the Republic of Belarus.

Supervision over compliance with legislative requirements in the field of pedigree work, veterinary medicine, seed production, quarantine and protection of agricultural plants in carrying out of genetic engineering activity shall be part of state supervision over pedigree work, supervision in the field of veterinary medicine, seed production, quarantine and protection of agricultural plants and shall be exercised by the Ministry of Agriculture and Food, the Veterinary and Food Supervision Department of the Ministry of Agriculture and Food, state organizations reporting to the Ministry of Agriculture and Food determined by the Council of Ministers of the Republic of

Belarus.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Control/supervision in the field of safety in genetic engineering activity shall be exercised in accordance with the procedure established by legislation on control/supervision activity and other acts of legislation.

Article 27. Production Control in the Field of Safety in Genetic Engineering Activity

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

(as worded in the Law of the Republic of Belarus of January 4, 2014 No.130-3)

Part 1 of Article 27 excluded. – The Law of the Republic of Belarus of December 18, 2018 No. 154-3.

Legal entities and individual entrepreneurs carrying out genetic engineering activity shall organize and exercise production control in accordance with the procedure established by them in order to check compliance with requirements for safety in genetic engineering activity established by normative legal acts, including technical normative legal acts mandatory for compliance.
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Production control over safety in genetic engineering activity shall be exercised at own cost and expense and from other sources of funding in accordance with local acts developed and approved by a legal entity or an individual entrepreneur, in accordance with the procedure established by specially authorized Republican Bodies of the State Administration in the field of safety in genetic engineering activity.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

**CHAPTER 7
FINAL PROVISIONS**

Article 28. Bringing this Law into Effect

The present Law shall enter into effect in six months after its official promulgation, except for this Article and Article 29, which shall become effective from the official promulgation date of this Law.

Article 29. Bringing of Legislative Acts of the Republic of Belarus into Line with this Law

The Council of Ministers of the Republic of Belarus within six months from the date of the official promulgation of this Law shall:

Prepare and introduce, in accordance with the procedure established by the House of Representatives of the National Assembly of the Republic of Belarus, proposals for bringing of legislative acts in line with the present Law;

Bring Decisions of the Government of the Republic of Belarus in line with this Law;

Ensure that Republican Bodies of the State Administration reporting to the Council of Ministers of the Republic of Belarus bring their normative legal acts in line with this Law;

Ensure the adoption of normative legal acts required for the implementation of the present Law;

Adopt other measures required for the implementation of the present Law.

President of the Republic of Belarus

A. Lukashenko
