

**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; November 10, 2008 No. 444-3; July 2, 2009 No. 31-3; January 4, 2010 No. 109-3; January 4, 2014 No. 130-3; December 18, 2018 No. 154-3)

The present Law establishes legal and institutional frameworks to ensure 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 definitions are used for the purposes of this Law:

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

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

“Genetic engineering” means the technology for producing 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 and activity are achieved in this organism and in its progeny;

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

“Genotype” means a set of all hereditary characters of an organism, information on which is encoded in genes;

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

(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;

“Decision (authorization document) on the import into the Republic of Belarus, the export from the Republic of Belarus and the transit through its territory of potentially pathogenic and pathogenic genetically engineered organisms” means a document confirming the right for the import into the Republic of Belarus, the export from the Republic of Belarus, and the transit through its territory of a certain genotype of potentially pathogenic and pathogenic genetically engineered organisms valid for one-time use;

(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 growing (cultivation) and (or) breeding of genetically engineered plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms for the agricultural and microbiological production;

“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 the 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 the 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 maintained homogeneous cultures of bacteria, viruses, fungi containing a new combination of genetic material produced by genetic engineering, incapable of causing human diseases.

The terms “pathogenic biological agents” and “potentially pathogenic microorganisms” used in this Law are used in the meanings defined by Article 1 of the Law of the Republic of Belarus of January 7, 2012 “On the Sanitary and Epidemiological Well-being of Population” (the National Register of Legal Acts of the Republic of Belarus 2012, No. 8, 2/1892).

(Part II of Article 1 was introduced by the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

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, the 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 regulates relations in the field of safety in genetic engineering activity.

The operation of this Law does not cover relations associated with the application of genetic engineering to a human being, his/her organs and tissues, handling of medicines, food raw materials and foodstuffs, and animal feeds derived from genetically engineered organisms or their components.

In carrying out 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 be applied, taking into account the specifics established by legislation in the field of safety in genetic engineering activity.

With regard to the relations arising in connection with the import into the Republic of Belarus, the export from the Republic of Belarus, the transit through its territory and use of genetically engineered organisms that are subject to export control, this Law shall be applied 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 are as follows:

Taking of precautionary measures in carrying out genetic engineering activities;

Scientifically substantiated, integrated and individual approaches to risk assessment of possible adverse 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 are genetically engineered organisms and rights to carry out genetic engineering activities.

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

State bodies that exercise the 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 of the Republic of Belarus (hereinafter referred to as “the Expert Board”);

Legal entities and individual entrepreneurs engaged in genetic engineering activities;

Organizations authorized to assess the risks 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 decisions (authorization documents) on the import, export or transit of potentially pathogenic and pathogenic genetically engineered organisms and permits for the release of non-pathogenic genetically engineered organisms into the environment for trials by the 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;

State registration of genetically engineered plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms;

Record of genetically engineered organisms in accordance with the 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;

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)

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)

Establishment of responsibility for the violation of legislation requirements for safety in genetic engineering activity;

Implementation of other safety measures in genetic engineering activities in accordance with the 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 are headed by the President of the Republic of Belarus, the Council of Ministers of the Republic of Belarus and the specially authorized Republican bodies of the State Administration in the field of safety in genetic engineering activity.

The specially authorized Republican bodies of the State Administration in the field of safety in genetic engineering activity are the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus, the Ministry of Health of the Republic of Belarus, and the Ministry of Agriculture and Food of the Republic of Belarus.

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 determines 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:

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

activity;

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

Establish a procedure for issuance of decisions (authorization documents) on the import into the Republic of Belarus, the export from the Republic of Belarus and the 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 adverse effects of genetically engineered organisms on human health and the environment, as well as a procedure for its performance;
(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 plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms;

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

Establish a procedure and terms to submit information on genetically engineered organisms from the Databank;

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

Article 9. Powers of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus 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 Ministry of Natural Resources and Environmental Protection of the Republic of Belarus within its competence shall:

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

Issue permits for the 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 activities;

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 under 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 under their release into the environment;

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

Establish a procedure to inform the Ministry of Natural Resources and Environmental Protection by an owner of non-pathogenic genetically engineered organisms or a person, realizing their import into the Republic of Belarus, about 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;

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

Exercise control over compliance with legislative requirements for 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 shrubbery vegetation and other wild plants within the boundaries of inhabited localities, as well as wild animals that are not hunting and fishing objects; water protection and use; waste management in the implementation of genetic engineering activities;

Deliver (direct) a proposal for the suspension (ban on) of 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 bring cases to court 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 the detection of legislative violations that pose a threat to the environment, if they decide that the suspension of activities is inexpedient;

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

Article 10. Powers of the Ministry of Health of the Republic of Belarus in the field of Safety in Genetic Engineering Activity

The Ministry of Health of the Republic of Belarus within its competence shall:

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 operations of Risk Levels II, III, and IV in genetic engineering activities;

Issue decisions (authorization documents) for the import into the Republic of Belarus, the export from the Republic of Belarus and the 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 registry procedure subject to execution by State legal entities for 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 population in carrying out of genetic engineering activities;

(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 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);

Article 11. Powers of the Ministry of Agriculture and Food of the Republic of Belarus in the field of Safety in Genetic Engineering Activity

The Ministry of Agriculture and Food of the Republic of Belarus within its competence shall:

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

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

Organize supervision over compliance with legislative requirements in the field of pedigree work, veterinary, seed breeding, quarantine and protection of agricultural plants in carrying out of genetic engineering activities;
(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 ENGAGED IN GENETIC ENGINEERING ACTIVITY. SAFETY REQUIREMENTS IN CARRYING OUT OF GENETIC ENGINEERING ACTIVITY

Article 12. Obligations of Persons Engaged in Genetic Engineering Activity

Legal entities and individual entrepreneurs engaged in genetic engineering activities shall:

Observe safety requirements for genetic engineering activities 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 arrangements to ensure safety in genetic engineering activity carried out by them;

Have a permit for the release of non-pathogenic genetically engineered organisms into the environment for trials when tested in the environment;

Use only those genetically engineered plant cultivars, genetically engineered

animal breeds and strains of non-pathogenic genetically engineered microorganisms for economic purposes that have a State Registration Certificate or its copy;

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

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

Provide in 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 plant cultivars, breeds of genetically engineered animals and strains of non-pathogenic genetically engineered microorganisms materials, containing complete and reliable information about genetically engineered organisms, as well as measures to prevent 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);

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 State control (supervision) over safety in genetic engineering activity to address the 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, for which effective prophylaxis and treatment measures exist;

Risk Level IV – operations with pathogenic genetically engineered organisms, which are pathogens of particularly dangerous infectious diseases that show the ability to spread quickly and for which effective prophylaxis and treatment measures are not known.

Individual entrepreneurs have a right to carry out genetic engineering activities of Risk Level I only.

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

Article 14. Safety Requirements for Genetic Engineering Activities 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 operations of Risk Level I of genetic engineering activities in the self-contained system, safety requirements for the self-contained systems established by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus must be observed.

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

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

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

Release of non-pathogenic genetically engineered organisms into the environment for testing shall be carried out, provided there is a permit for the release of non-pathogenic genetically engineered organisms into the environment issued by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus. The permit shall be issued taking into account recommendations of an Expert Board for admissibility of the release of non-pathogenic genetically engineered organisms into the environment. A permit issued for the first release of non-pathogenic genetically engineered organisms is valid for the subsequent releases 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. 154-3)

Testing of non-pathogenic genetically engineered organisms under their first release into the environment must be carried out in experimental fields and other

facilities specially equipped to prevent possible adverse effects of these organisms on the environment and that comply with the safety requirements established by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus in consultation with the National Academy of Sciences of Belarus.

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 is not allowed.

Use of non-pathogenic genetically engineered organisms for economic purposes in the form of genetically engineered plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms is allowed upon their State Registration with the Ministry of Agriculture and Food of the Republic of Belarus.

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

Article 16-1. State Registration of Genetically Engineered Plant Cultivars, Genetically Engineered Animal Breeds and Strains of Non-pathogenic Genetically Engineered Microorganisms

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

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

State registration of strains of non-pathogenic genetically engineered microorganisms not destined for the release into the environment shall be carried out taking into account recommendations of an Expert Board for admissibility of the 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 plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms.

The State Registration Certificate serves as confirmation of the State registration of genetically engineered plant varieties, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms.

Article 17. Safety Requirements for the Transport of Genetically Engineered Organisms

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

Potentially pathogenic and pathogenic genetically engineered organisms must be transported in accordance with the legislation related to the transport of dangerous goods and safety requirements for the transport of these organisms established by the Ministry of Health of the Republic of Belarus.

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

Article 18. Safety Requirements for the Import into the Republic of Belarus, the Export from the Republic of Belarus and the 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)

The 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.

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

scientific research with no release of non-pathogenic genetically engineered organisms into the environment for trials upon notification of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus by an owner of non-pathogenic genetically engineered organisms or a person realizing their import into the Republic of Belarus according to the procedure established by this Ministry;

trials with the release of non-pathogenic genetically engineered organisms into the environment after obtaining a permit for the 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 plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered organisms in line with Article 16-1 of this Law.

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 of the Republic of Belarus by an owner of non-pathogenic genetically engineered organisms or a person realizing their transit through the territory of the Republic of Belarus according to a procedure established by this Ministry.

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 the 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 the import into the Republic of Belarus, the export from the Republic of Belarus and the transit through its territory of potentially pathogenic and pathogenic genetically engineered organisms is possessed by State legal entities only.

The import into the Republic of Belarus, the 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 decision (an authorization document) on the import into the Republic of Belarus, the export from the Republic of Belarus and the transit through its territory of potentially pathogenic and pathogenic genetically engineered organisms issued by the Ministry of Health of the Republic of Belarus according to international law acts constituting the law of the Eurasian Economic Union and a procedure established by the Council of Ministers of the Republic of Belarus.

The rules stipulated by Parts 5-7 of this Article shall be applied 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 the 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 the immediate removal from the Republic of Belarus by an owner of genetically engineered organisms or a 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 the legislation as waste subject to deactivation, including the remains of non-pathogenic genetically engineered plants, animals and microorganisms upon completion of trials in experimental fields and in self-contained systems, including genetically engineered organisms:

the release of which into the environment for testing was realized with no permit for the 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 plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered organisms or its copy.

deactivation of non-pathogenic genetically engineered organisms, including those classified in accordance with the legislation as waste, shall be realized according to a procedure established by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus.

Deactivation of non-pathogenic genetically engineered organisms, including those classified in accordance with the legislation as waste, shall be realized according to a procedure established by the Ministry of Health of the Republic of Belarus.

CHAPTER 4

RISK ASSESSMENT OF POSSIBLE ADVERSE 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 adverse effects of genetically engineered organisms on human health and the environment.

Non-pathogenic genetically engineered organisms shall be subject to the risk

assessment of possible adverse effects of genetically engineered organisms on human health and the environment under their first release into the environment for trials and during the State registration of genetically engineered plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered organisms destined for use for economic purposes.

The objects of risk assessment of possible adverse effects of genetically engineered organisms on human health and the environment are as follows: genetically engineered organism samples; materials containing information on genetically engineered organisms, as well as measures to prevent possible adverse effects of genetically engineered organisms on human health and the environment.

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

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

Risk assessment of possible adverse 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 the authorized organizations.

Risk assessment of possible adverse 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 by 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 adverse effects of genetically engineered organisms on human health and the environment submit materials containing information on a genetically engineered organism, as well as measures to prevent possible adverse 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 days from the date of the specified information publication 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 summarize the received comments and suggestions and within 10 days direct them to the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus for consideration at an Expert Board Meeting when adopting recommendations on admissibility (inadmissibility) of the release of genetically engineered organisms into the environment for trials or use for economic purposes.

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

The Protocol on admissibility (inadmissibility) of the release of genetically engineered organisms into the environment for trials 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 an Expert Board Meeting. The recommendations accepted based on the conclusions of an Expert Board Meeting for admissibility (inadmissibility) of the release of genetically engineered organisms into the environment for trials or use for economic purposes shall be taken into account in making of a decision on the issue (non-issue) of a permit for the release of non-pathogenic genetically engineered organisms for trials by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus; the issue (non-issue) of a State Registration Certificate for genetically engineered plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms.

An Expert Board is a collegial consultative body and is formed from a number of officials of the specially authorized Republican bodies of the State Administration in the field of safety in genetic engineering activity, scientists and other specialists. A Provision on an Expert Board and its members shall be approved by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus.

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. Information Management 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 information

management 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;

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

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

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

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

Issuance of the State Registration Certificate for genetically engineered plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms;

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

Receiving of notification 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 with no release into the environment for trials.

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.

Information to the National Coordination Biosafety Centre shall be submitted according to the forms established by State bodies specified in this Article in 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 the 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 Transport 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 transport must be shown on packaging (container, other object destined for remaining (keeping) of genetically engineered organisms) and include:

Name of a genetically engineered organism;

Number and issuance date of a State Registration Certificate for genetically engineered plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms (for genetically engineered organisms destined for use for economic purposes);

Data on transport, 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 place of residence (stay) of an individual entrepreneur delivering genetically engineered organisms;

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

The transport 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, other object destined for remaining (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 engaged in genetic engineering activities shall keep records of non-pathogenic genetically engineered organisms developed by them and exported from the Republic of Belarus according to a procedure established by the Ministry of Natural Resources and Environmental

Protection of the Republic of Belarus.

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 according to a procedure established by the Ministry of Health of the Republic of Belarus, as well as submit data on such genetically engineered organisms to the Ministry of Health of the Republic of Belarus according to a procedure established by this Ministry.

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 legislation on environmental protection during genetic engineering activities is part of the control in the areas of protection, safeguarding, reproduction and use of wild plants and animals included in the Red Book of the Republic of Belarus, tree and shrubbery vegetation and other wild plants within the boundaries of inhabited localities, as well as wild animals that are not objects of hunting and fishing; water protection and use; and waste management and shall be exercised by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus and its territorial bodies determined by the Council of Ministers of the Republic of Belarus.

Supervision over compliance with legislation requirements in the field of sanitary and epidemiological welfare of population in carrying out of genetic engineering activities is part of the State sanitary supervision over compliance by legislation agents subject to checks with legislation in the field of sanitary and epidemiological welfare of population and shall be exercised by the 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, seed breeding, agricultural plant quarantine and protection in carrying out of genetic engineering activities is part of the State supervision over pedigree work, supervision in the field of veterinary, seed breeding, the quarantine and protection of agricultural plants and shall be exercised by the Ministry of Agriculture and Food of the Republic of Belarus, the Veterinary and Food Supervision Department of the Ministry of Agriculture and Food of the

Republic of Belarus, State authorities reporting to the Ministry of Agriculture and Food of the Republic of Belarus determined by the Council of Ministers of the Republic of Belarus.

Control (supervision) in the field of safety in genetic engineering activity shall be exercised according to a procedure established by the legislation on the monitoring (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 activities shall organize and exercise production control according to a procedure established by them to check the compliance with safety requirements for genetic engineering activities 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 activities shall be exercised at the own expense and from other sources of funding according to local normative legal acts developed and approved by a legal entity or an individual entrepreneur in line with a procedure established by the specially authorized Republican bodies of the State Administration in the field of safety in genetic engineering activity.

**CHAPTER 7
FINAL PROVISIONS**

Article 28. Bringing this Law into Effect

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

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 this Law promulgation shall:

prepare and introduce according to a procedure established by the House of Representatives of the National Assembly of the Republic of Belarus proposals for bringing of legislative acts into line with the present Law;

bring Decisions of the Government of the Republic of Belarus into line with this Law;

ensure that the Republican bodies of the State Administration reporting to the Council of Ministers of the Republic of Belarus bring their normative legal acts into line with this Law;

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

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

President of the Republic of Belarus

A. Lukashenko
