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LAW OF THE REPUBLIC OF BELARUS
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 Laws of the Republic of Belarus of 24.12.2007 [No. 299-3](#),
10.11.2008 [No. 444-3](#), 02.07.2009 [No. 31-3](#), 04.01.2010 [No. 109-3](#), 04.01.2014
[No. 130-3](#))

The present Law establishes legal and organizational principles to ensure safety in genetic engineering activity; it aims to protect the environment and human health and to implement international commitments of the Republic of Belarus in this field.

Chapter 1
GENERAL PROVISIONS

Article 1.
Basic Terms and their Definitions

The following basic definitions are used for the purposes of the present Law:

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

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

“Genetic engineering” means the technology for producing new combinations of a genetic material by means of extracellular manipulations with nucleic acid molecules and transfer of designed gene constructions 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, 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;

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

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

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

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

“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 agricultural and microbiological produce development;

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

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

“Permit for import, export or transit of potentially pathogenic and pathogenic genetically engineered organisms” means a document issued by specially authorized Republican body of State Administration in the field of safety in genetic engineering activity to State legal entities, confirming the right to import into the Republic of Belarus, export from the Republic of Belarus or transit through its territory of potentially pathogenic and pathogenic genetically engineered organisms of a certain genotype, and valid for one occasion;

“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.

Article 2. Scope of the Present Law

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

The Law does not cover relations associated with use of genetic engineering to a human, his organs and tissues, handling of pharmaceutical preparations, food raw materials and foodstuffs, and animal feeds derived from genetically engineered organisms or their components.

(as worded in the [Law](#) of the Republic of Belarus of December 24, 2007 No. 299-3)

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

Basic principles to ensure safety in genetic engineering activity are as follows:
take precautionary measures in carrying out of genetic engineering activity;
scientifically substantiated integrated and individual approaches to risk assessment of possible adverse effects of genetically engineered organisms on human health and the environment;

independence of the State Safety Expertise of genetically engineered organisms;

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

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

Subjects of relations in the field of safety in genetic engineering activity:

State bodies that exercise State Administration and control in the field of safety in genetic engineering activity;

Legal entities and individual entrepreneurs engaged in genetic engineering activity;

Experts, carrying out the State Safety Expertise of genetically engineered organisms;

the paragraph was excluded. – The [Law](#) of the Republic of Belarus of January 4, 2014 No. 130-3.

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 permits for 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 State Administration in the field of safety in genetic engineering activity;
- accreditation of a self-contained system to perform works of Risk Levels I, II, III and IV in genetic engineering activity;
- state registration of genetically engineered plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms;
- registration of genetically engineered organisms in compliance with the legislation;
- prescription and observance of requirements for safety in genetic engineering activity;
- planning and fulfillment of arrangements to ensure safety in genetic engineering activity;
- State Safety Expertise of genetically engineered organisms;
- Safety control over genetic engineering activity;
- prescription of responsibility for infringement of legislation requirements to safety in genetic engineering activity;
- implementation of other safety measures in genetic engineering activity in compliance 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

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 State Administration in the field of safety in genetic engineering activity.

Specially authorized Republican bodies of State Administration in 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.

Authorities 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 executes other forms of Government regulation in the field of safety in genetic engineering activity in accordance with the [Constitution](#) of the Republic of Belarus, the present Law and other legislative acts.

Article 8.

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

establish the [procedure](#) and terms of permit issue 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)

approve the [Regulation](#), in consultation with the President of the Republic of Belarus, for the procedure and terms of permit issue by the Ministry of Health for import and (or) export of potentially pathogenic and pathogenic genetically engineered organisms restricted to movement through the customs border of the Republic of Belarus on the grounds of uneconomic character;
(the paragraph was introduced by the [Law](#) of the Republic of Belarus of November 10, 2008 No. 444-3)

approve, in consultation with the President of the Republic of Belarus, a [list](#) of potentially pathogenic and pathogenic genetically engineered organisms restricted to movement through the customs border of the Republic of Belarus during import and (or) export on the grounds of uneconomic character;
(the paragraph was introduced by the [Law](#) of the Republic of Belarus of November

10, 2008 No. 444-3)

prescribe a procedure for permit issue for transit through the customs territory of the Republic of Belarus of potentially pathogenic and pathogenic genetically engineered organisms;

(the paragraph was introduced by the [Law](#) of the Republic of Belarus of November 10, 2008 No. 444-3)

prescribe a [procedure](#) for the State Safety Expertise of genetically engineered organisms and approximate terms of agreements to carry it out;

prescribe a procedure for risk assessment of possible adverse effects of genetically engineered organisms on human health;

(the paragraph was introduced by the [Law](#) of the Republic of Belarus of January 4, 2010 No. 109-3)

prescribe 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 was excluded. – The [Law](#) of the Republic of Belarus of January 4, 2014 No. 130-3;

prescribe a [procedure](#) and conditions to submit information on genetically engineered organisms from the Databank;

perform other authorities 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, the present Law and Laws of the Republic of Belarus.

(as worded in the [Law](#) of the Republic of Belarus of November 10, 2008 No. 444-3)

Article 9.

Authorities of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus in the Field of Safety in Genetic Engineering Activity

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 release of non-pathogenic genetically engineered organisms into the environment for testing in accordance with the [procedure](#) established by the Council of Ministers of the Republic of Belarus;

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

prescribe, in consultation with the National Academy of Sciences of Belarus, safety requirements for trial fields and other objects intended for testing of non-pathogenic genetically engineered organisms under their first release into the

environment;

prescribe, in consultation with the National Academy of Sciences of Belarus, a [procedure](#) for testing of non-pathogenic genetically engineered organisms under their release into the environment;

prescribe a [procedure](#) to estimate risks of possible adverse effects of genetically engineered organisms on the environment;

prescribe a [procedure](#) to inform the Ministry of Natural Resources and Environmental Protection by a carrier on transit through the territory of the Republic of Belarus of non-pathogenic genetically engineered organisms;

prescribe a registration [procedure](#), subject to execution by legal entities and individual entrepreneurs, for non-pathogenic genetically engineered organisms developed, imported into the Republic of Belarus, exported from the Republic of Belarus and conveyed in transit through its territory;

exercise State control over compliance with requirements to the legislation on environmental protection in carrying out genetic engineering activity;

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

make decisions on complete or partial suspension of genetic engineering activity of legal entities and (or) individual entrepreneurs, exerting harmful effects on the environment, till elimination of the revealed breach, in cases and in accordance with the procedure established by the legislation on safety in genetic engineering activity;

(the paragraph was introduced by the [Law](#) of the Republic of Belarus of November 10, 2008 No. 444-3)

submit claims to legal entities and (or) individual entrepreneurs that have caused harm to the environment and claims for damages to the environment;

(the paragraph was introduced by the [Law](#) of the Republic of Belarus of November 10, 2008 No. 444-3)

submit claims for termination of genetic engineering activity, exerting harmful effects on the environment, by legal entities and (or) individual entrepreneurs in cases of legislation violation on safety in genetic engineering activity as well as in cases specified in the legislation on the environmental protection;

(the paragraph was introduced by the [Law](#) of the Republic of Belarus of November 10, 2008 No. 444-3)

exercise other authorities in accordance with the legislation on safety in genetic engineering activity.

Article 10.

Authorities 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 legal acts in the field of safety in genetic engineering activity;

prescribe safety requirements to self-contained systems when performing works of Risk Levels II, III, and IV in the genetic engineering activity;

issue permits for import and (or) export of potentially pathogenic and pathogenic genetically engineered organisms restricted to movement through the customs border of the Republic of Belarus on the grounds of uneconomic character;

(as worded in the [Law](#) of the Republic of Belarus of November 10, 2008 No. 444-3)

issue [permits](#) for transit through the customs territory of the Republic of Belarus of potentially pathogenic and pathogenic genetically engineered organisms;

(the paragraph was introduced by the [Law](#) of the Republic of Belarus of November 10, 2008 No. 444-3)

prescribe safety [requirements](#) for transport of potentially pathogenic and pathogenic genetically engineered organisms;

perform accreditation of self-contained systems to perform works of Risk Levels II, III and IV in genetic engineering activity in accordance with the established [procedure](#);

(as worded in the [Law](#) of the Republic of Belarus of January 4, 2010 No. 109-3)

the paragraph was excluded. – The [Law](#) of the Republic of Belarus of January 4, 2010 No. 109-3

prescribe a registration [procedure](#), subject to execution by State legal entities, for potentially pathogenic and pathogenic genetically engineered organisms developed, imported into the Republic of Belarus, exported from the Republic of Belarus and conveyed in transit through its territory;

[register](#) 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 of compliance with legislative requirements to the sanitary and epidemiological welfare of the population in engineering activity;

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

exercise other authorities in accordance with the legislation on safety in genetic engineering activity and other legislative acts of the Republic of Belarus.

(as worded in the [Law](#) of the Republic of Belarus of November 10, 2008 No. 444-3)

Article 11.
Authorities 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) standard normative legal acts and approve, implement technical normative legal acts in the field of safety in genetic engineering activity;

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

organize supervision of compliance with legislative requirements to pedigree work, veterinary activity, seed breeding and plant protection in 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 the legislation on safety in genetic engineering activity.

Chapter 3
OBLIGATIONS OF PERSONS ENGAGED IN GENETIC ENGINEERING ACTIVITY, SAFETY REQUIREMENTS TO GENETIC ENGINEERING ACTIVITY

Article 12.
Obligations of Persons Engaged in Genetic Engineering Activity

Legal entities and individual entrepreneurs engaged in the genetic engineering activity **shall be obliged to:**

observe safety requirements for genetic engineering activity established by both normative legal acts and technical normative legal acts;

plan and implement arrangements to ensure safety in genetic engineering activity performed by them;

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

use only the genetically engineered plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms for economic purposes that have a Certificate of State Registration;

ensure separate keeping of genetically engineered organisms during their transportation and storage;

submit documents that contain complete and reliable information on safety of

genetically engineered organisms to the State Safety Expertise of genetically engineered organisms and for the State Registration of genetically engineered plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms;

submit, at request of persons concerned and public associations, information on safety in genetic engineering activity carried out by them;

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 over safety in genetic engineering activity to eliminate 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)

perform other obligations in accordance with legislation on safety in genetic engineering activity.

State legal entities are obliged to have a permit for import, export or transit of potentially pathogenic and pathogenic genetically engineered organisms during their import into the Republic of Belarus, their export from the Republic of Belarus or their transit through its territory.

Article 13.

Risk Levels of Genetic Engineering Activity

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

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

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

Risk Level III – work 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 – work 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 activity only of Risk Level I.

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

When carrying out genetic engineering activity in the self-contained system, the premises, equipment, personnel training, work performance procedures, registration, storage and use of genetically engineered organisms should conform to both normative legal acts and technical normative legal acts in the field of safety in genetic engineering activity.

When performing work of Risk Level I of genetic engineering activity 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 should be observed.

When performing work 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 should be observed. The self-contained system should be accredited by the Ministry.

(as worded in the Law of the Republic of Belarus of January 4, 2010 No.109-3)

In case of positive accreditation results of the self-contained system, a Certificate of Accreditation shall be issued to ascertain that work of Risk Levels II, III and IV of genetic engineering activity is allowed in the given self-contained system.

Article 15.

Safety Requirements for 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 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 upon a positive decision of the State Safety Expertise of genetically engineered organisms. The permit issued for the first release of non-pathogenic genetically engineered organisms is valid for subsequent releases of genetically engineered organisms of a certain genotype into the environment.

Trials of non-pathogenic genetically engineered organisms under their first release into the environment should be conducted in trial fields and other objects specially equipped to prevent possible adverse effects of these organisms on the environment and should comply with the safety [requirements](#) established by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus by agreement with the National Academy of Sciences of Belarus.

Article 16.

Safety Requirements for Use of Genetically Engineered Organisms for Economic Purposes

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 as genetically engineered plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms is allowed after their State Registration by the Ministry of Agriculture and Food of the Republic of Belarus. State Registration shall be exercised upon a positive decision of the State Safety Expertise of genetically engineered organisms and positive test results of genetically engineered organisms under their release into the environment by including information related to 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. Confirmation of the State Registration of genetically engineered plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms is a [Certificate](#) of their State Registration.

Article 17.

Safety Requirements for Transport of Genetically Engineered Organisms

Travel facilities used to transport non-pathogenic genetically engineered organisms should be equipped with devices that exclude the possibility of unauthorized release of genetically engineered organisms into the environment.

Potentially pathogenic and pathogenic genetically engineered organisms should be transported in accordance with the legislation on transport of dangerous goods and safety [requirements](#) to transport of these organisms established by the Ministry of Health of the Republic of Belarus.

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

Import into the Republic of Belarus and transit through its territory of genetically engineered organisms shall be allowed, provided that the exporting country (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.

Import into the Republic of Belarus of non-pathogenic genetically engineered organisms intended for release into the environment for testing shall be allowed, provided there is a [permit](#) for release of non-pathogenic genetically engineered organisms into the environment for testing, issue of which is stipulated by [Part 2](#) of Article 15 of the present Law.

Import into the Republic of Belarus of non-pathogenic genetically engineered organisms intended for use for economic purposes shall be allowed, provided there is a [Certificate](#) of State Registration for genetically engineered plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms, issue of which is stipulated by [Part 2](#) of Article 16 of the present Law.

Import into the Republic of Belarus of potentially pathogenic and pathogenic genetically engineered organisms restricted to movement through the customs border of the Republic of Belarus on the grounds of uneconomic character shall be allowed, provided there is a permit for import issued by the Ministry of Health of the Republic of Belarus in accordance with the [procedure](#) established by the Council of Ministers of the Republic of Belarus in consultation with the President of the Republic of Belarus, and carried out solely for scientific studies.

(as worded in the [Law](#) of the Republic of Belarus of November 10, 2008 No. 444-3)

In case of unauthorized import of genetically engineered organisms, an importer removes them from the territory of the Republic of Belarus at his own expense in accordance with the procedure established by the legislation.

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 the carrier in accordance with the procedure established by the Ministry.

Transit through the territory of the Republic of Belarus of potentially pathogenic and pathogenic genetically engineered organisms shall be allowed provided there is a permit for transit issued by the Ministry of Health of the Republic of Belarus in accordance with the procedure established by the Council of Ministers of the Republic of Belarus.

Export from the Republic of Belarus of non-pathogenic genetically engineered organisms is allowed, provided there is a permit for import issued by the specially authorized body (organization) of the destination country.

Export from the Republic of Belarus of potentially pathogenic and pathogenic genetically engineered organisms restricted to movement through the customs border of the Republic of Belarus on the grounds of uneconomic character is allowed provided there are a permit for import issued by the specially authorized body (organization) of the destination country and a permit for export issued by the

Ministry of Health of the Republic of Belarus in accordance with the [procedure](#) established by the Council of Ministers of the Republic of Belarus in consultation with the President of the Republic of Belarus.

(as worded in the [Law](#) of the Republic of Belarus of November 10, 2008 No. 444-3)

Article 19. Safety Requirements for Deactivation of Genetically Engineered Organisms

Deactivation of genetically engineered organisms shall be carried out in accordance with the legislation on waste and this Article.

Genetically engineered organisms attributed to waste in accordance with the legislation, as well as genetically engineered organisms are subject to deactivation provided:

their release into the environment for testing was carried out without a proper [permit](#) issued in accordance with the established [procedure](#);

they are used by legal entities and individual entrepreneurs for economic purposes without a [Certificate](#) of State Registration for genetically engineered plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms.

Deactivation of potentially pathogenic and pathogenic genetically engineered organisms shall be carried out in accordance with the requirements of normative legal acts adopted (issued) by the Ministry of Health of the Republic of Belarus and technical normative legal acts approved and implemented by this Ministry.

Chapter 4 STATE SAFETY EXPRTISE OF GENETICALLY ENGINEERED ORGANISMS

Article 20. State Safety Expertise of Genetically Engineered Organisms

State Safety [Expertise](#) of genetically engineered organisms shall be carried out

to determine the permissibility of their release into the environment for testing or use for economic purposes based on the detection of genetically engineered organisms and examination of materials on risk assessment of possible adverse effects of genetically engineered organisms on human health and the environment.

Non-pathogenic genetically engineered organisms are subject to the State Safety Expertise under their first release into the environment for testing and under the State registration of genetically engineered plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms intended for use for economic purposes.

Objects of the State Safety Expertise of genetically engineered organisms are as follows:

samples of genetically engineered organisms;

information materials on risk assessment of possible adverse effects of genetically engineered organisms on human health and the environment, including the risk prevention measures.

Article 21.

Carrying out of the State Safety Expertise of Genetically Engineered Organisms

The State Safety Expertise of genetically engineered organisms shall be carried out on the grounds of an [application](#) of the person concerned submitted to the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus. The State Safety Expertise of genetically engineered organisms shall be carried out at the person's expense, being its initiator, in accordance with the agreement concluded by the person concerned with the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus.

The State Safety Expertise of genetically engineered organisms shall be organized by 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"). The Expert Board is a collective consultative body, formed out of officials of specially authorized Republican bodies of State Administration in the field of safety in genetic engineering activity, scientists and specialists. The [Provision](#) on the Expert Board and its structure shall be approved by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus.

The State Safety Expertise of genetically engineered organisms shall be carried out by experts in accordance with the agreement concluded by the Ministry of Natural Resources and Environmental Protection with them. The Expert Board nominates candidatures of experts for the State Safety Expertise of genetically engineered organisms to the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus. Experts can be scientific institutions of the Republic of Belarus, leading in the appropriate field of knowledge, scientists and

specialists -- citizens of the Republic of Belarus. The persons concerned, including workers of the initiator for the State Safety Expertise of genetically engineered organisms, cannot be involved as experts.

Based on the findings of the State Safety Expertise of genetically engineered organisms, experts prepare a statement of the State Safety Expertise of genetically engineered organisms that contains definite conclusions on the permissibility (impermissibility) of release of genetically engineered organisms into the environment for testing or use for economic purposes. The conclusions of the State Safety Expertise of genetically engineered organisms are considered at the meeting of the Expert Board to verify the validity of conclusions, accept recommendations on the permissibility of release of genetically engineered organisms into the environment for testing or use for economic purposes and to send recommendations and the conclusions of the State Safety Expertise of genetically engineered organisms to the relevant specially authorized Republican body of the State Administration in the field of safety of genetically engineered organisms and to a person concerned -- an initiator of the expertise.

The conclusions of the State Safety Expertise of genetically engineered organisms and recommendations of the Expert Board shall be taken into consideration in the course of decision-making: by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus – on issue (refusal to issue) of a [permit](#) for release of non-pathogenic genetically engineered organisms into the environment for testing; by the Ministry of Agriculture and Food of the Republic of Belarus – on issue (refusal to issue) of a [Certificate](#) of State Registration for genetically engineered plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms.

Chapter 5
INFORMATION AND REGISTRATION 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 Support on Safety in Genetic Engineering Activity

The following measures shall be taken within the framework of information support on safety in genetic engineering activity:

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

formation of the Databank of genetically engineered organisms;

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

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

Specially authorized Republican bodies of State Administration in the field of safety in genetic engineering activity **shall**, within 5 days upon issuance of a [permit](#) for release of non-pathogenic genetically engineered organisms into the environment for testing, and a Certificate of State Registration for genetically engineered plant cultivars, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms, as well as the State Customs Committee of the Republic of Belarus, within 5 days after crossing the customs border of the Republic of Belarus by goods with genetically engineered organisms, **submit** appropriate information to the State Scientific Institution “Institute of Genetics and Cytology of the National Academy of Sciences of Belarus” to form the Databank of genetically engineered organisms and exchange information with Coordination Biosafety Centers of other states and international organizations. Information shall be submitted to the State Scientific Institution “Institute of Genetics and Cytology of the National Academy of Sciences of Belarus” in line with the forms established by these State bodies in consultation with the National Academy of Sciences of Belarus.

The [Procedure](#) and conditions for information submission to legal entities and individual entrepreneurs concerned from the Databank of genetically engineered organisms shall be established by the Council of Ministers of the Republic of Belarus.

Article 23.

Right of Citizens and Public Associations to Obtain Information on Safety in Genetic Engineering Activity

The right to obtain complete, timely and reliable information on safety in genetic engineering activity shall be secured to citizens and public associations.

Specially authorized Republican bodies of State Administration in the field of safety in genetic engineering activity, as well as legal entities and individual

entrepreneurs engaged in genetic engineering activity are obliged to submit information on safety in genetic engineering activity in accordance with the legislation at the request of citizens and public associations concerned.

Article 24.
Requirements to Information on Safety of Genetically Engineered Organisms during their Transport and Storage

Information on safety of genetically engineered organisms during their transport should be shown in shipping documentation and on packaging and should include:

name of genetically engineered organism;

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

information on methods of transport, storage, application and deactivation of genetically engineered organisms;

name and location of a legal entity or an individual entrepreneur that provides genetically engineered organisms;

name and location of a legal entity or an individual entrepreneur genetically engineered organisms to be provided to.

Information on safety of genetically engineered organisms during their storage should be shown in an inventory, on packaging and should include information stated in [paragraphs 2-4](#) of Part 1 of this Article.

Article 25.
Registration 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 July 2, 2009 No. 31-3)

Legal entities and individual entrepreneurs engaged in genetic engineering activity shall keep records of genetically engineered organisms developed, imported into the Republic of Belarus, exported from the Republic of Belarus and conveyed in transit through its territory in accordance with the legislation.

State legal entities engaged in genetic engineering activity of Risk Levels II, III and IV shall submit information on potentially pathogenic and pathogenic genetically engineered organisms developed, imported into the Republic of Belarus, exported from the Republic of Belarus and conveyed in transit through its territory to the Ministry of Health of the Republic of Belarus in accordance with the procedure established by the Ministry.

Part 3 of Article 25 was excluded. – The [Law](#) of the Republic of Belarus of

Chapter 6
CONTROL OVER SAFETY
IN GENETIC ENGINEERING ACTIVITY

Article 26.

Control (Supervision) over Safety in Genetic Engineering Activity
(as worded in the [Law](#) of the Republic of Belarus of January 4, 2014 No. 130-3)

Control over safety in genetic engineering activity shall be exercised to check the observance of normative legal acts and technical normative legal acts and perform arrangements to ensure safety in this activity.

Control over the compliance with requirements to the legislation on environmental protection in the implementation of genetic engineering activity is a part of control in the area of the environmental protection, efficient use of natural resources, hydrometeorological activity 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 of compliance with the legislation requirements in the field of sanitary and epidemiological welfare of the population in the implementation of genetic engineering activity is a part of State sanitary supervision of compliance by the checked entities of legislation in the field of sanitary and epidemiological welfare of the population and shall be exercised by the authorities and establishments that carry out State sanitary supervision and determined by the Council of Ministers of the Republic of Belarus.

Supervision of compliance with requirements to the legislation in the field of pedigree work, veterinary activity, seed breeding, plant protection in genetic engineering activity is a part of the State supervision of pedigree work, supervision in the field of veterinary, quality assurance of raw materials and food products, grain, combined (compound) feed, quarantine and plant protection, supervision during export, import and transit of cargo, which is under the jurisdiction of State veterinary supervision, and shall be exercised by the Ministry of Agriculture and Food of the Republic of Belarus, the Department of Veterinary and Food Control of the Ministry of Agriculture and Food, State organizations subordinated to the Ministry of Agriculture and Food of the Republic of Belarus determined by the Council.

Control and supervision procedures specified in [parts 2-4](#) of this Article shall be established by legislative acts.

Article 27.
**Departmental and Production Control over Safety in Genetic
Engineering Activity**

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

Departmental control over safety in genetic engineering activity shall be exercised according to the procedure established by legislation on the control (supervisory) activity.

Legal entities and individual entrepreneurs engaged in genetic engineering activity are obliged, under the established procedure, to organize and exercise production control to check the observance of safety requirements to genetic engineering activity provided for by normative legal acts and technical normative legal acts.

Production control over safety in genetic engineering activity shall be exercised from its own funds and other funding sources in accordance with the local normative legal acts elaborated and approved by a legal entity or an individual entrepreneur under the [procedure](#) established by the specially authorized Republican bodies of State Administration in the field of safety in genetic engineering activity.

Chapter 7
FINAL PROVISIONS

Article 28 entered into force from the date of its official promulgation

Article 28.
Entry into Force of the Present Law

The present Law shall enter into force in six months after its official promulgation with the exception of the present Article and [Article 29](#), which shall enter into force from the date of official promulgation of the present Law.

Article 29 entered into force from the date of its official promulgation ([Article 28](#) of this document)

Article 29.
**Bringing Legislative Acts of the Republic of Belarus into Compliance
with the Present Law**

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

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

bring Decisions of the Government of the Republic of Belarus into compliance with the present Law;

ensure that normative legal acts of Republican bodies of State Administration, subordinated to the Council of Ministers of the Republic of Belarus, be brought into compliance with the present Law;

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

take other measures required for implementation of the present Law.

President of the Republic of Belarus

A. Lukashenko
