Registered in the Legal Register of Legal Acts
of the Republic of Belarus of June 13, 2019 No. 5/46619

**RESOLUTION OF THE COUNCIL OF MINISTERS OF THE REPUBLIC OF BELARUS**
**of June 12, 2019 No. 382**

**ON A RISK ASSESSMENT IN GENETIC ENGINEERING ACTIVITY AND THE ISSUANCE OF AN AUTHORIZATION DOCUMENT**

Pursuant to the Paragraph 3 and Paragraph 5 of the Law “On Safety in Genetic Engineering Activity” of the Republic of Belarus of January 9, 2006 No. 96-3, the Council of Ministers of the Republic of Belarus DECIDES to:

1. Approve:

Provision on the procedure for a risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment (enclosed);

Provision on the procedure and terms of the issuance of permits for the release of non-pathogenic genetically engineered organisms into the environment for testing (enclosed).

2. Establish a list of organizations authorized to assess risks of possible harmful effects of genetically engineered organisms on human health and the environment in line with the Annex.

3. On a unified list of administrative procedures carried out by state bodies and other organizations in relation to legal persons and individual entrepreneurs approved by the Resolution of the Council of Ministers of the Republic of Belarus of February 17, 2012 No. 156:

Exclude clause 6.35;

The Paragraph "A List of Documents and/or Information Submitted by Stakeholders to the Authorized Body to Exercise an Administrative Procedure" of clause 6.36 shall be supplemented with a paragraph as follows:

"Protocol on the admissibility/inadmissibility of the release of genetically engineered organisms into the environment for testing or for economic purposes."

4. Declare to be no longer in force:

Resolution “On Approval of Provisions on the State Expertise Procedure for Safety of Genetically Engineered Organisms and the Model Clauses of Contracts Concluded for its Implementation and the Issuance of Permits for the Release of Non-pathogenic Genetically Engineered Organisms into the Environment for Testing” of the Council of Ministers of the Republic of Belarus of September 8, 2006 No. 1160;

Sub-clause 1.4 of clause 1 of the Resolution “On Introducing Amendments and Additions to Some Resolutions of the Council of Ministers of the Republic of Belarus on the Issues of Administrative Procedures in Relation to Legal Persons and Individual Entrepreneurs” of the Council of Ministers of the Republic of Belarus of February 7, 2008 No. 166;

Sub-clause 1.46 of clause 1 of the Resolution “On Introducing Changes and Additions to Some Resolutions of the Council of Ministers of the Republic of Belarus on the Issue Related to the Documentation of the Population of the Republic of Belarus” of the Council of Ministers of the Republic of Belarus of December 23, 2008 No. 2010;

Sub-clause 1.25 of clause 1 of the Resolution “On Introducing Changes and Additions to Some Resolutions of the Council of Ministers of the Republic of Belarus on the Issues Related to Carrying Out of Administrative Procedures” of the Council of Ministers of the Republic of Belarus of May 6, 2009 No. 599;

Sub-clause 1.18 of clause 1 of the Resolution “On Introducing Changes and Additions to Some Resolutions of the Council of Ministers of the Republic of Belarus” of the Council of Ministers of the Republic of Belarus of October 12, 2012 No. 926;

Sub-clause 1.7 of clause 1 of the Resolution “On Introducing Changes and Additions to Some Resolutions of the Council of Ministers of the Republic of Belarus on the Issues Related to Carrying Out of Administrative Procedures and Declaring of Sub-clause 1.7 of Clause 1 of the Resolution of the Council of Ministers of the Republic of Belarus of February 6, 2012 No. 123 to Be No Longer in Force” of the Council of Ministers of the Republic of Belarus of March 29, 2013 No. 234.

5. The Resolution shall come into force from 29 June 2019

Prime Minister of the Republic of Belarus S. Rumas

Annex
to the Resolution
of the Council of Ministers
of the Republic of Belarus
of June 12, 2019 No. 382

**LIST**
**OF ORGANIZATIONS AUTHORIZED TO ASSESS THE RISKS OF POSSIBLE HARMFUL AFFECTS OF GENETICALLY ENGINEERED ORGANISMS ON HUMAN HEALTH AND THE ENVIRONMENT**

1. The State Scientific Institution “Institute of Genetics and Cytology of the National Academy of Sciences of Belarus.”

2. The State Scientific Institution "Institute of Microbiology of the National Academy of Sciences of Belarus.”

3. The State Scientific Institution "Institute of Forest of the National Academy of Sciences of Belarus.”

4. The State Scientific Institution "Institute of Biophysics and Cell Engineering of the National Academy of Sciences of Belarus.”

5. The State Scientific Institution "Institute of Physiology of the National Academy of Sciences of Belarus.”

6. The State Scientific and Production Amalgamation "Scientific and Practical Centre for Bioresources of the National Academy of Sciences of Belarus.”

7. The Educational Institution "Grodno State Agrarian University.”

8. The State Institution "Republican Scientific and Practical Centre for Epidemiology and Microbiology.”

9. The Republican Unitary Enterprise “Scientific and Practical Centre for Hygiene.”

APPROVED
Resolution
of the Council of Ministers
of the Republic of Belarus
of June 12, 2019 No.382

**PROVISION**
**ON THE PROCEDURE FOR A RISK ASSESSMENT OF POSSIBLE HARMFUL AFFECTS OF GENETICALLY ENGINEERED ORGANISMS ON HUMAN HEALTH AND THE ENVIRONMENT**

1. This Provision establishes the procedure for a risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment (hereinafter referred to as "the risk assessment").

2. A risk assessment shall be carried out on the basis of the request of a legal person or an individual entrepreneur, initiators of its conduct (hereinafter referred to as "the interested individual"), to one of the organizations authorized to assess risks of possible harmful effects of genetically engineered organisms on human health and the environment a list which is determined by the Resolution approving this Provision (hereinafter referred to as "the authorized organization").

An interested individual cannot act as an authorized organization.

3. In order to conduct a risk assessment, an interested individual shall submit the samples of genetically engineered organisms (hereinafter referred to as "samples") to an authorized organization, as well as materials containing information on a genetically engineered organism and measures to prevent possible harmful effects of a genetically engineered organism on human health and the environment (hereinafter referred to as "materials"), including:

genetically engineered organisms belonging to higher plants in line with a list of Annex 1 in hard copy and on electronic media;

genetically engineered organisms belonging to other organisms different from higher plants in line with a list of Annex 2 in hard copy and on electronic media.

If necessary, an interested individual may provide justification for the need to consider risk assessment information as confidential, which is used in accordance with legislation. In that case, an interested individual shall provide information on a risk assessment in two versions. In doing so, a version containing confidential information shall be presented on paper in one copy with the indication "Contains confidential information" and the second version – on electronic media the confidential information on which shall be replaced by the inscription "Confidential information."

For the purposes of this Provision, the following information cannot be declared as confidential:

name and postal address of an applicant;

taxonomic description of a recipient organism used in developing of genetically engineered organisms;

taxonomic description of a donor organism used in developing of genetically engineered organisms;

general description of a vector used and an insertion method for the transgenic construct;

general description of all genes inserted in genetically engineered organisms and their functions;

testing results on genetically engineered organisms needed to assess risks of possible harmful effects of genetically engineered organisms on human health and the environment;

results of earlier risk assessments of possible harmful effects of genetically engineered organisms on human health and the environment and decisions made on their basis on the release of genetically engineered organisms into the environment;

emergency plan.

4. An authorized organization shall within 30 days from the date of an application and submission of required samples and materials from an interested individual enter into an agreement with him/her on a risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment (hereinafter referred to as "the agreement") in respect of which the rules provided for by the Civil Code of the Republic of Belarus on fee-based service agreements shall be applied, taking into account the specifics established by this Provision.

5. A risk assessment shall be carried out within 120 days from the date an agreement specified in clause 4 of this Provision has been concluded.

6. An authorized organization shall be under an obligation of submitting materials to the National Coordination Biosafety Centre founded at the Institute of Genetics and Cytology of the National Academy of Sciences of Belarus (hereinafter referred to as "the National Coordination Biosafety Centre") within five days from the date an agreement has been concluded.

Consultant Plus: comment.
Information on a risk assessment of possible harmful effects of genetically engineered organisms is available on the information website of the National Coordination Biosafety Centre of the Republic of Belarus (http://www.biosafety.by/)

7. The National Coordination Biosafety Centre shall within three working days after obtaining information on a risk assessment post it on its information website over the global computer network Internet to inform the public about planned genetic engineering activities.

8. Interested legal persons and individuals may send comments and suggestions regarding information on planned genetic engineering activities to the National Coordination Biosafety Centre.

The deadline for submitting comments and suggestions may not be more than 60 days from the date of posting of this information on the information website of the National Coordination Biosafety Centre.

The National Coordination Biosafety Centre shall summarize the comments and suggestions received and within 10 days direct them to the Ministry of Natural Resources and Environmental Protection for consideration at the meeting of an Expert Board on safety of genetically engineered organisms of the Ministry of Natural Resources and Environmental Protection (hereinafter referred to as "the Expert Board) with a view of adopting recommendations on the admissibility (inadmissibility) of the release of genetically engineered organisms into the environment for testing or use for economic purposes.

9. When conducting risk assessment, an authorized organization may request additional information on genetically engineered organisms from an interested individual in cases where the risk acceptability of possible harmful effects of genetically engineered organisms on the environment or human health is impossible to assess.

An interested individual shall be under an obligation of providing to the specialists of an authorized organization access to the samples of genetically engineered organisms for a risk assessment.

10. Based on risk assessment results, an authorized organization shall draw up a Protocol containing conclusions on the admissibility/inadmissibility of the release of genetically engineered organisms into the environment for testing or use for economic purposes, and give it to an interested individual. The specified Protocol is not limited in time.

The Protocol on the admissibility/inadmissibility of the release of genetically engineered organisms into the environment for testing or use for economic purposes shall be considered at the Expert Board meeting.

Recommendations adopted on the basis of the Expert Board meeting for the admissibility/ inadmissibility of the release of genetically engineered organisms into the environment for testing or use for economic purposes shall be taken into account when a decision is made by:

the Ministry of Natural Resources and Environmental Protection on the issue/non-issue of a permit for the release of non-pathogenic genetically engineered organisms into the environment for testing;

the Ministry of Agriculture and Food – on the issue/non-issue of the State Registration Certificate for genetically engineered plant varieties, breeds of genetically engineered animals and strains of non-pathogenic genetically engineered microorganisms.

Annex 1
to the Provision on the Procedure
for a Risk Assessment of Possible Harmful
Effects of Genetically Engineered
Organisms on Human Health
and the Environment

**LIST**
**OF INFORMATION ON GENETICALLY ENGINEERED ORGANISMS RELATING TO HIGHER PLANTS (GYMNOSPERMS AND ANGYOSPERMS), AS WELL AS MEASURES TO PREVENT POSSIBLE HARMFUL EFFECTS OF A GENETICALLY ENGINEERED ORGANISM ON HUMAN HEALTH AND THE ENVIRONMENT**

1. Information on the biological make-up of a recipient organism:

1.1. full name:

family;

genus;

species;

sub-species;

variety/breeding line;

common name;

1.2. Information related to reproduction characteristics:

reproduction method(s);

specific factors affecting reproduction;

offspring production time;

sexual compatibility with other cultivated or wild species;

1.3. environmental survival ability:

ability to form structures for survival or move into a state of dormancy;

specific factors affecting survival;

1.4. dissemination:

dissemination ways and degree;

specific factors affecting dissemination;

1.5. geographic range;

1.6. description of natural habitats, including information about natural predators, parasites, competitors and symbionts;

1.7. potentially important interactions with organisms other than plants in ecosystems characteristic of common growth, including information on toxicity for humans, animals, or other organisms.

2. Information on the biological make-up of donor organisms:

2.1. full name:

family;

genus;

species;

sub-species;

variety/breed/strain;

common name;

2.2. donor organism origin;

2.3. biological characteristics of a donor organism.

3. Biological make-up of a vector:

3.1. nature and origin of a vector, natural habitat and related safety characteristics;

3.2. structure of transposons, promoters, and other non-coding genetic segments used to develop the genetic construct necessary for its transfer and functioning in the recipient organism;

3.3. mobilization frequency (ability to acquire mobility) of the inserted vector or its transfer into other organisms;

3.4. factors that may affect the vector’s ability to adapt in other host organisms.

4. Information related to the character of genetic engineering modification:

4.1. methods used for the development, transfer of a transgenic construct and the selection of transgenic organisms;

4.2. description of a DNA fragment inserted in the recipient organism's genome (plasmon) (size and source, i.e. the name of a donor organism (s) and the putative function of each component or region of the inserted DNA, including regulatory and other elements that affect transgene functioning), structure (sequence) and functional correspondence of the inserted DNA fragment, the presence of known potentially dangerous sequences in it;

4.3. presence of any unknown sequences in the inserted DNA and information about the degree to which the insert is restricted by DNA necessary to carry out the putative function;

4.4. characteristics of a modification region of the recipient genome (plasmon); localization of the insert (incorporated into the chromosome, chloroplasts, mitochondria, or is in the non-integrated state);

4.5. incorporation stability of the DNA inserted into the genome (plasmon) of the recipient organism;

4.6. number of transgene copies;

4.7. description of the method for detecting and identifying of an inserted DNA fragment; sensitivity, reliability and specificity of this technique.

5. Information related to the biological make-up of genetically engineered organisms:

5.1. description of genetic characters or phenotypic characteristics, in particular new characters and characteristics that start to appear or cease to appear in genetically engineered organisms as compared to the recipient organism;

5.2. genetic stability of genetically engineered organisms;

5.3. transgene(s) expression degree and level; an evaluation method for the transgene expression, its sensitivity;

5.4. activity and properties of the protein(s) encoded by the transgene(s);

5.5. plant parts in which transgenes are expressed (roots, leaves, pollen, and others);

5.6. history of previous genetic engineering modifications of genetically engineered organisms;

5.7. characteristics of genetically engineered organisms in connection with safety for human health: toxic or allergenic effects of genetically engineered organisms and/or products derived from genetically engineered organisms;

5.8. proposed methods for the detection and identification of genetically engineered organisms; their accuracy, sensitivity and reliability.

6. Information on the potential receiving environment:

6.1. release site’s location (region, district, settlement, land plot ownership by the landowner or land user with its full name)

6.2. proximity to nature reserves, wildlife sanctuaries and other nature conservation sites and territories;

6.3. site description: size and cultivation degree, climatic, geological and soil characteristics, flora and fauna;

6.4. comparing of the natural habitats of recipient organisms with the intended release site of genetically engineered organisms;

6.5. methods of intervention in the land plot nature (cultivation methods, irrigation, etc.).

7. Information on the interaction of genetically engineered organisms with the environment:

7.1. biological make-up of genetically engineered organisms (as compared to intact recipient organisms), which may affect survival, reproduction and distribution/dissemination in the potential receiving environment;

7.2. known and anticipated conditions of the potential receiving environment that may affect the survival, reproduction, and dispersal of genetically engineered organisms;

7.3. competitive advantage of genetically engineered organisms (as compared to intact recipient organisms);

7.4. probability of manifestation in genetically engineered organisms of undesirable properties and characters in the potential receiving environment;

7.5. probability of a sharp increase in the population of genetically engineered organisms in the potential receiving environment;

7.6. ability to transfer genetic information: the presence in the potential receiving environment of wild or cultivated related species capable of hybridization with genetically engineered organisms; the likelihood of transgene transfer from genetically engineered organisms to such organisms;

7.7. identification and description of target organisms of transgene products;

7.8. proposed mechanism and result of the interaction of genetically engineered organisms with target organisms;

7.9. identification and description of non-target organisms of transgene products that may be affected by genetically engineered organisms;

7.10. other potential interactions of genetically engineered organisms with the environment;

7.11. information on the intended use of genetically engineered organisms, including a new or modified use as compared to the recipient organism.

8. Information on the exercised release of genetically engineered organisms into the environment, monitoring, control, cleaning up the area and actions in unforeseen circumstances during the release and testing:

8.1. information on the release of genetically engineered organisms:

description of the intended release process for genetically engineered organisms; purpose of the release;

estimated timing of the start and end of the release and a schedule plan for experiments related to the release, including the number and duration of experiments;

estimated number of genetically engineered organisms subject to the release, the number of genetically engineered organisms per unit area of the site;

distance from the site to the planting of wild and cultivated related species capable of hybridization with genetically engineered organisms;

information on the presence and results of previous releases of genetically engineered organisms into the environment;

8.2. monitoring methods:

observation methods for genetically engineered organisms, as well as monitoring of their possible interactions with potentially vulnerable elements of the environment;

specificity, that is the ability to identify genetically engineered organisms, distinguish them from recipient organisms, as well as the sensitivity and reliability of monitoring methods for genetically engineered organisms;

methods to detect transgene transfer into other organisms;

monitoring duration and frequency

8.3. control over the release of genetically engineered organisms:

measures to prevent the dispersal of pollen, seeds of genetically engineered organisms;

methods and procedures aimed at protecting the release area from the intrusion of unauthorized persons;

methods and procedures that protect the area from undesirable visits of other organisms;

8.4. territory cleaning:

treatment procedure for the site after the release;

methods to remove genetically engineered organisms after experiments;

8.5. emergency plan for the unforeseen spread of genetically engineered organisms:

methods and procedures to control genetically engineered organisms in the event of unforeseen spread;

utilization or recovery methods for plants, animals and other that have been exposed to genetically engineered organisms during or after their unforeseen spread;

plans to protect human health and the environment in case of detection of undesirable effects of genetically engineered organisms.

Annex 2
to the Provision on the Procedure
for a Risk Assessment of Possible Harmful
Effects of Genetically Engineered
Organisms on Human Health
and the Environment

**LIST**
**OF INFORMATION ON GENETICALLY ENGINEERED ORGANISMS RELATING TO OTHER ORGANISMS DIFFERENT FROM HIGHER PLANTS, AS WELL AS MEASURES TO PREVENT POSSIBLE HARMFUL EFFECTS OF GENETICALLY ENGINEERED ORGANISMS ON HUMAN HEALTH AND THE ENVIRONMENT**

1. Biological make-up of donor and recipient organisms:

1.1. full name:

family;

genus;

species;

sub-species;

common name;

other names;

1.2. degree of relationship between donor and recipient organisms, information on the possibility of the genetic material exchange between them in a natural way;

1.3. methods to identify donor and recipient organisms (phenotypic and genetic markers);

1.4. methods used in the laboratory or environment for the detection, monitoring, estimation of donor and recipient organism numbers; sensitivity, reliability and specificity of methods for detecting and identifying donor and recipient organisms;

1.5. description of the geographical range and natural habitats of donor and recipient organisms, including information on natural predators, prey, parasites, competitors, symbionts and hosts;

1.6. potential for the transfer and exchange of genetic information with other organisms;

1.7. genetic stability of donor and recipient organisms and factors influencing it;

1.8. pathogenic, environmental and physiological make-up of donor and recipient organisms:

generation period in natural ecosystems; sexual and asexual reproductive cycles;

information on environmental survival, including seasonal patterns and the ability to form structures necessary for survival (spores, sclerotia, etc.);

pathogenicity (infectious ability, toxinogenicity, virulence, allergenicity, the presence of vectors for the transfer of pathogens, possible vectors, host circle, possible activation of latent viruses (proviruses), the ability to colonize other organisms);

resistance to antibiotics, possible uses of such antibiotics for the preventive care and therapy of

humans and pets;

nature of congenital vectors (structure, mobilization frequency, specificity, presence of resistance genes).

2. Biological make-up of a vector:

2.1. vector's nature and origin, natural habitat and related safety characteristics;

2.2. structure of transposons, promoters, and other non-coding genetic segments used to develop the genetic construct necessary for its transfer and functioning in the recipient organism;

2.3. mobilization frequency (ability to acquire mobility) of the inserted vector or transfer into other organisms;

2.4. factors that may affect the vector's adaptation ability in other host organisms.

3. Genetically engineered organism characteristics:

3.1. information on the genetic engineering modification:

methods used to develop, transfer the transgenic construct and select transgenic organisms;

description of a DNA fragment inserted in the recipient organism genome, including regulatory and other elements that affect transgene functioning;

structure (sequence) and functional correspondence of the inserted DNA fragment; the presence of known potentially dangerous sequences in it;

presence of any unknown sequences in the inserted DNA and information on the extent to which the insert is restricted by DNA necessary to carry out the intended function;

modification region characteristics of the recipient; insert localization;

incorporation stability of the DNA inserted in the recipient organism genome;

description of the method for detecting and identifying of an inserted DNA fragment; sensitivity, reliability and specificity of this technique;

3.2. information on the genetically engineered organism:

description of genetic characters or phenotypic characteristics, in particular new characters and characteristics that start to appear or cease to appear in genetically engineered organisms as compared to recipient organisms;

genetic stability of genetically engineered organisms;

transgene expression degree and level; a method to assess the transgene expression and its sensitivity;

activity and properties of the protein (s) encoded by the transgene (s);

history of previous genetic engineering modifications of genetically engineered organisms;

3.3. genetically engineered organism characteristics in connection with safety to human health:

toxic or allergenic effects of genetically engineered organisms and/or their metabolism products;

risks of possible harmful effects on human health associated with the use of products derived from genetically engineered organisms;

colonialization ability of genetically engineered organisms;

pathogenicity of genetically engineered organisms for an immunocompetent human organism.

4. Information on the potential receiving environment:

4.1. intended release site location (region, district, settlement, land plot ownership by the landowner or land user with its full name)

4.2. physical and biological proximity to humans and/or any other significant biota;

4.3. proximity to nature reserves, sanctuaries and other nature conservation sites and territories; site distance from water intake (drinking water) areas;

4.4. population size of the release area and population activities economically related to the use of natural resources of the area;

4.5. site description, including its size and refinement, climatic, geological and agrochemical characteristics;

4.6. flora and fauna, including domestic animals, migratory species and cultivated agricultural crops;

4.7. description of ecosystems, target organisms, and organisms that are not transgenic products, which may be affected as a result the release of genetically engineered organisms;

4.8. comparing the natural habitats of recipient organisms with the intended release site of genetically engineered organisms;

4.9. methods of intervention in the site's nature (cultivation methods, irrigation, and others).

5. Information on the interaction of genetically engineered organisms with the environment:

5.1. biological make-up of genetically engineered organisms (as compared to intact recipient organisms), which may affect survival, reproduction and distribution in the potential receiving environment;

5.2. known and anticipated conditions of the potential receiving environment that may affect the survival, reproduction, and dispersal of genetically engineered organisms;

5.3. sensitivity or resistance to specific agents;

5.4. characteristics and behaviour of genetically engineered organisms and their environmental impacts in conditions that simulate the natural environment (greenhouse, growth room);

5.5. ability to transfer genetic information: probability of transgene transfer from genetically engineered organisms to organisms inhabiting the potential receiving environment, or from these organisms to genetically engineered organisms;

5.6. probability of manifestation in genetically engineered organisms of unforeseen and/or undesirable properties and characters in the potential receiving environment;

5.7. dispersal ways of genetically engineered organisms in the potential receiving environment; known or potential methods of interaction with dispersing agents, including inhalation, ingestion, surface contact, penetration into pores and other;

5.8. probability of a sharp increase in the population of genetically engineered organisms in the potential receiving environment;

5.9. competitive advantage of genetically engineered organisms as compared to intact recipient organisms;

5.10. identification and description of target organisms of transgenic products;

5.11. probable mechanism for and interaction result of genetically engineered organisms with target organisms;

5.12. identification and description of non-target organisms of transgene products that may be affected by genetically engineered organisms;

5.13. probable shift in the relationship nature of genetically engineered organisms with other organisms, changes in the circle of hosts;

5.14. known or alleged involvement of genetically engineered organisms in biogeochemical processes;

5.15. other potential interactions of genetically engineered organisms with the environment.

6. Information on the release, monitoring, control, cleaning of the territory and actions in unforeseen circumstances:

6.1. information on the release of genetically engineered organisms:

description of the alleged release of genetically engineered organisms, its purpose;

estimated timing of the start and end of the release and a schedule plan for experiments related to the release, including the number and duration of experiments;

estimated amount of genetically engineered organisms subject to the release;

method for the release of genetically engineered organisms;

preparing a site for the release;

measures to protect employees during the release;

post-release site treatment;

information on the presence and results of previous releases of genetically engineered organisms into the environment;

6.2. monitoring methods:

observation methods for genetically engineered organisms, monitoring their interactions with the environment;

specificity (that is the ability to identify genetically engineered organisms, distinguish them from recipient and donor organisms); sensitivity and reliability of monitoring methods for genetically engineered organisms;

methods for detecting transgene transfer to other organisms;

monitoring duration and frequency;

6.3. control over the release of genetically engineered organisms:

methods and procedures allowing to avoid or minimize the dispersal of genetically engineered organisms beyond the site defined for the release of genetically engineered organisms;

methods and procedures to protect the release territory from the intrusion of unauthorized persons;

methods and procedures to protect the territory from unwanted visits of other organisms;

6.4. territory cleaning:

contamination type and estimated territory contamination volumes as a result of the release of genetically engineered organisms;

possible risks associated with the territory contamination;

description of proposed decontamination actions;

6.5. emergency plan:

methods and procedures to control genetically engineered organisms in the event of unforeseen spread;

disinfection methods for affected territories, such as the destruction of genetically engineered organisms;

methods of utilization or recovery of plants, animals and other organisms that have been exposed to genetically engineered organisms during or after their unforeseen spread;

isolation methods for affected territories;

protection plans for human health and the environment in case of detection of undesirable effects of genetically engineered organisms.

APPROVED
Resolution
of the Council of Ministers
of the Republic of Belarus
of June 12, 2019 No.382

**PROVISION**
**ON THE PROCEDURE AND TERMS OF THE ISSUANCE OF PERMITS FOR THE RELEASE OF NON-PATHOGENIC GENETICALLY ENGINEERED ORGANISMS INTO THE ENVIRONMENT FOR TESTING**

1. This Provision establishes the procedure and terms of the issuance of permits for the release of non-pathogenic genetically engineered organisms into the environment for testing (hereinafter referred to as “the permit”).

The Provision shall not apply to the release into the environment for testing of non-pathogenic genetically engineered organisms developed by traditional breeding methods using genetically engineered plant varieties, animal breeds, microorganism strains included in the State Register of

genetically engineered plant varieties, breeds of genetically engineered animals and strains of non-pathogenic genetically engineered microorganisms.

2. The release of non-pathogenic genetically engineered organisms into the environment for testing shall be carried out on the basis of a permit issued by the Ministry of Natural Resources and Environmental Protection (hereinafter referred to as "the Ministry of Natural Resources"). The permit shall be issued taking into account the recommendations of the Expert Board on safety of genetically engineered organisms of the Ministry of Natural Resources and Environmental Protection (hereinafter referred to as "the Expert Board") for the admissibility of the release of non-pathogenic genetically engineered organisms into the environment for testing.

3. In order to obtain a permit for the release of non-pathogenic genetically engineered organisms into the environment for testing, a legal person or an individual entrepreneur shall submit to the Ministry of Natural Resources an application according to the form of Annex 1 and other documents stipulated by the clause 6.36 of a unified list of administrative procedures exercised by state bodies and other organizations in relation to legal persons and individual entrepreneurs.

4. As part of the consideration of a submitted permit application, the Ministry of Natural Resources shall organize an Expert Board meeting at which the Protocol submitted by an applicant on the admissibility/inadmissibility of the release of genetically engineered organisms into the environment for testing prepared by one of the organizations authorized to assess risks of possible harmful effects of genetically engineered organisms on human health and the environment a list of which is established by the Resolution approving this Provision shall be considered.

Based on the meeting outcomes, the Expert Board shall adopt recommendations on the admissibility/inadmissibility of the release of non-pathogenic genetically engineered organisms into the environment for testing, which are reflected in Expert Board minutes.

5. The Ministry of Natural Resources shall within 20 working days from the date an application specified in clause 3 of this Provision has been submitted draw up a permit for the release of genetically engineered organisms into the environment for testing according to the form of Annex 2 or reject its issuance.

6. A permit shall be issued on the basis of Expert Board recommendations on the admissibility of the release of non-pathogenic genetically engineered organisms into the environment for testing.

7. A permit shall be signed by the Minister of Natural Resources and Environmental Protection or his/her Deputy and issued upon presentation of:

a document confirming the official position of the Head of a legal person, as well as a document attesting to their identity, to the Head of a legal person;

the State Registration Certificate to an individual entrepreneur;

an identity document and a power of attorney to an authorized representative of a legal person or an individual entrepreneur.

The issued permit shall be registered by the Ministry of Natural Resources in the Log of permits for the release of genetically engineered organisms into the environment for testing according to the form of Annex 3.

8. A decision to reject the issuance of a permit shall be made on the grounds stipulated by Article 25 of the Law "On the Basics of Administrative Procedures" of the Republic of Belarus of October 28, 2008 No. 433-3.

A notification of the decision made shall be directed to the applicant in line with Article 27 of the

Law “On the Basics of Administrative Procedures” of the Republic of Belarus.

9. Permit blank forms are the forms of documents with a certain degree of protection and shall be produced by order of the Ministry of Natural Resources according to the procedure stipulated by legislation.

10. Within five days from the date of a decision to issue a permit, the Ministry of Natural Resources shall inform the State Scientific Institution “Institute of Genetics and Cytology of the National Academy of Sciences of Belarus” on the permit issue.

11. Transfer of a permit to other legal persons and individual entrepreneurs for the release of non-pathogenic genetically engineered organisms into the environment for testing is not allowed.

12. If a legal person or an individual entrepreneur decide to terminate the activities for which a permit has been issued, the legal person or individual entrepreneur shall be under an obligation of notifying the Ministry of Natural Resources in writing.

13. In the event of a permit loss or its spoiling, a legal person or an individual entrepreneur shall be under an obligation of applying for a new permit according to the procedure established by this Provision.

14. A permit shall be cancelled on the basis of a decision of the Ministry of Natural Resources in the cases as follows:

liquidation, reorganization of a legal person or termination of an individual entrepreneur;

adoption by a legal person or an individual entrepreneur of a decision to terminate the activities for which a permit has been issued;

if a legal person or an individual entrepreneur fail to apply for a permit within six months from the date of a decision on its issuance;

failure to submit a report on the first release of genetically engineered organisms into the environment for testing or obtaining negative test results during the first release of genetically engineered organisms into the environment, following the results of which the negative effect of these organisms on the environment or human health has been established;

violation by a legal person or an individual entrepreneur of the terms contained in the permit and/or legislative requirements for genetic engineering activities.

15. The Ministry of Natural Resources shall within five days from the date of a decision to cancel the permit notify a legal person or an individual entrepreneur the permits have been issued to in writing and indicate the grounds for their cancellation and also inform the State Scientific Institution “Institute of Genetics and Cytology of the National Academy of Sciences of Belarus” about it.

16. Within 15 days from the date of the receipt of a permit cancellation notice, a legal person or an individual entrepreneur whose permits have been cancelled shall be under an obligation of submitting the permits to the Ministry of Natural Resources for their cancellation mark with the date and grounds for such cancellation.

17. After the first release of genetically engineered organisms into the environment for testing, a legal person or an individual entrepreneur shall submit a report to the Ministry of Natural Resources within 60 days from the date of tests’ completion, indicating test results, conclusions on the effectiveness of the measures used to prevent risks of possible harmful effects of genetically engineered organisms on the environment and human health, on the appropriateness of applying such measures in subsequent releases of tested genetically engineered organisms into the environment for testing or other purposes.

Annex 1
to the Provision on the Procedure and terms
of the Issuance of Permits for the Release
of Non-pathogenic Genetically Engineered
Organisms into the Environment
for Testing

Form

**APPLICATION**
**to obtain a permit for the release of non-pathogenic genetically engineered organisms into the environment for testing**

1. General information:
1.1. Applicant _____
(family name, initials, position, name
_____
of an organization, address, telephone, fax)
1.2. designation, registration number and code of genetically engineered organisms destined for the release into the environment _____
_____
1.3. expected period of the release of genetically engineered organisms
_____
2. Information on genetically engineered organisms:
2.1. full name of a recipient organism:
family _____
genus _____
species _____
sub-species _____
variety/breeding line _____
common name _____
2.2. introduced or modified characters _____
(description of characters and
_____
characteristics introduced or modified by
_____
the genetic engineering modification, including a marker
_____
gene and previous genetic engineering modifications)
2.3. genetically engineered construct _____
(description of the genetically engineered
_____
construct (insertion), source
_____
of each insertion fragment, its putative function)
2.4. transfer method of the genetically engineered construct into the recipient organism _____
3. Information on the release:
3.1. release site location _____
(region, district,
_____
settlement, land plot ownership by the landowner
_____
or land user with its full name)

_____

3.2. land plot size (square meters) _____

3.3. the number of genetically engineered organisms subject to release _____

_____

4. Effects of genetically engineered organisms on the environment

_____

(intended environmental implications of the release

_____

of genetically engineered organisms

_____

into the environment, their hazard evaluation)

_____

5. Risk prevention measures _____

(brief description of

_____

risk prevention measures for possible adverse

_____

effects of the release of genetically engineered

_____

organisms into the environment)

6. Number and date of the state expertise decision on safety of genetically engineered organisms _____

_____ _____

(applicant's signature) (initials, family name)

Application date _____

Annex 2
to the Provision on the Procedure and Terms
of the Issuance of Permits for the Release
of Non-pathogenic Genetically Engineered
Organisms into the Environment
for Testing

Form

Ministry of Natural Resources and Environmental Protection
of the Republic of Belarus

**PERMIT No. ____**
**for the release of non-pathogenic genetically engineered organisms into the environment for testing**

Hereby permitted _____

(name and location

_____

of a legal person, family name, initials and place of residence

_____

of an individual entrepreneur)

the release into the environment of non-pathogenic genetically engineered organisms

_____

(Russian and Latin names of a species or

_____

species of genetically engineered organisms)

on the site _____
(region, district, settlement, land plot
_____
ownership by a landowner or
_____
a land user with his/her full name)
provided that the following risk prevention measures for possible harmful effects of such release are complied with: _____
(a list of
_____
risk prevention measures)

_____ _____ _____
(position) (signature) (initials, family name)

L.S.
Date of issue _____

Annex 3
to the Provision on the Procedure and Terms
of the Issuance of Permits for the Release
of Non-pathogenic Genetically Engineered
Organisms into the Environment
for Testing

Form

**REGISTRATION LOG**
**of permits for the release of genetically engineered organisms**
**into the environment for testing**

| Permit No. | Permit issuance date | Name of a legal person; family name, initials and place of residence of an individual entrepreneur | Genetically engineered organism species | Geographic and administrative location of a site where the release of genetically engineered organisms takes place | Permit validity | Results of the first release of a genetically engineered organism into the environment | Comment |
|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| | | | | | | | |