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# DESK STUDY ON THE PROJECT "CAPACITY-BUILDING TO PROMOTE INTEGRATED IMPLEMENTATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY AND THE CONVENTION ON BIOLOGICAL DIVERSITY AT THE NATIONAL LEVEL"

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# 1. EXISTING NATIONAL POLICIES RELEVANT TO BIOSAFETY. NATIONAL INSTITUTIONS AND BODIES INVOLVED IN BIOSAFETY ISSUES, INCLUDING INTER-SECTORAL BODIES AND COORDINATION MECHANISMS AND THEIR RESPECTIVE ROLES AND RESPONSIBILITIES WITH RESPECT TO BIOSAFETY

## 1.1. GENERAL PROVISIONS

The Republic of Belarus being a Party to the Convention on Biological Diversity and in accordance with the Law of the Republic of Belarus of 6 May, 2002 "On Accession of the Republic of Belarus to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity", the Republic of Belarus became a Party to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the Cartagena Protocol).

In accordance with Article 20 of the Law of 10 January, 2000 "On Normative Legal Acts of the Republic of Belarus", the Republic of Belarus recognizes the priority of generally accepted principles of International Law and ensures compliance of the Republic of Belarus legislation with them.

The provisions of law contained in international treaties of the Republic of Belarus constitute a part of existing in the territory of the Republic of Belarus legislation subject to direct application, except when it follows from the International treaty that the application of these rules requires adoption (issuance) of a domestic normative legal act and have the force of a normative legal act, which expresses consent of the Republic of Belarus to be bound by a relevant international treaty.

Thus, the Cartagena Protocol has the force of law in the Republic of Belarus.

Also, in order to fulfill obligations under the Cartagena Protocol, the Republic of Belarus adopted legal, administrative and other measures to carry out its obligations under this Protocol. The Law of the Republic of Belarus “On Safety in Genetic Engineering Activity” of 9 January, 2006 establishes fundamental legal principles and the institutional basis to ensure safety in genetic engineering activity and intends to protect human health and the environment, fulfill international obligations by the Republic of Belarus in the field of safety in genetic engineering activity.

In the Republic of Belarus there are three State bodies responsible for implementation of the Cartagena Protocol and, respectively, the provision of safety in genetic engineering activity with regard to biosafety and human health: the Ministry of Natural Resources and Environmental Protection, the Ministry of Health and the Ministry of Agriculture and Food. They were the main developers of the Law “On Safety in Genetic Engineering Activity” and other normative legal acts that provide the fulfillment of this Law. Subordinated authorities (institutions, centers) of the

Ministry of Natural Resources and Environmental Protection, the Ministry of Health, the Ministry of Agriculture and Food, the National Academy of Sciences, as well as of the National Centre of Legislation and Legal Research were involved in the process of Law and by-laws' development. The national legislation is drawn up in such a way that as many specialists as possible of all areas related to this field are attracted to the process of such documents' development. In the course of the national legislation development in the field of biosafety, draft documents were sent to all competent organizations in this area (head organizations have a list of institutions competent in a particular area and messaging is done according to the list). In the course of the legal and regulatory framework development, a number of consensus meetings among the concerned bodies were held. In accordance with the legislation of the Republic of Belarus, the draft Law and by-Laws were subject to public discussion. Information on the project approval was posted on the institution website responsible (the Ministry of Natural Resources and Environmental Protection, the Ministry of Health, the Ministry of Agriculture and Food or other organizations responsible for the particular project development) for the project development and within 30 days any public association or any individual could participate in the discussion.

Article 1 of the Law of the Republic of Belarus "On Safety in Genetic Engineering Activity" specifies general terms and their definitions:

"safety in genetic engineering activity" means a degree of protection achieved by taking measures, aimed at prevention or reduction to a safe level of possible adverse effects of genetically engineered organisms on human health and the environment when carrying out genetic engineering activity;

"release of genetically engineered organisms into the environment for testing" means introduction of genetically engineered organisms into the environment;

"genetic engineering" means a technology for the development of 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 an activity associated with 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 organism hereditary characters, the information on which is encoded in genes;

“living organism” means any biological entity 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, fitted with special equipment and devices for eliminating a 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 varieties of plants, genetically engineered breeds of animals and strains of non-pathogenic genetically engineered microorganisms for production of agricultural and microbiological products;

“non-pathogenic genetically engineered organisms” mean genetically engineered organisms incapable of provoking human diseases;

“pathogenic genetically engineered organisms” mean genetically engineered organisms capable of provoking human diseases;

“permit for release of non-pathogenic genetically engineered organisms into the environment for testing” means a document, issued by the specially authorized Republican body of State Administration in the field of safety in genetic engineering activity to legal entities and (or) individual entrepreneurs that confirms a 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 the specially authorized Republican body of State Administration in the field of safety in genetic engineering activity to State legal entities that confirms a 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” mean genetically engineered organisms which may give rise to human diseases under certain conditions;

“strains of non-pathogenic genetically engineered microorganisms” mean hereditarily maintained homogeneous cultures of bacteria, viruses, fungi that contain a new combination of the genetic material produced by genetic engineering incapable of provoking human diseases.

Article 2 of the Law of the Republic of Belarus "On Safety in Genetic Engineering Activity" defines the purview of this Law. The present Law also regulates relations in field of safety in genetic engineering activity. This Law does not cover relations associated with application of genetic engineering to a human, their

organs and tissues, handling of drugs, food raw materials and foodstuffs and animal feeds derived from genetically engineered organisms or their components.

Under Article 4 of the Law of the Republic of Belarus "On Safety in Genetic Engineering Activity", objects of relation in the field of safety in genetic engineering activity are genetically engineered organisms and rights to carry out genetic engineering activity.

Parties to a relationship in the field of safety in genetic engineering activity are as follows:

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

legal entities and individual entrepreneurs that carry out genetic engineering activity;

experts that carry out the State Safety Expertise of genetically engineered organisms.

Article 3 of this Law defines basic principles to ensure safety in genetic engineering activity. They are as follows:

taking precautionary measures carrying out 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 in the field of safety in genetic engineering activity;

Article 13 of the Law of the Republic of Belarus "On Safety in Genetic Engineering Activity" defines risk levels of genetic engineering activity:

"risk level I" means work with non-pathogenic genetically engineered organisms;

"risk level II" means work with potentially pathogenic genetically engineered organisms;

"risk level III" means work with pathogenic genetically engineered organisms capable of causing dangerous infectious diseases and spreading infection and against which effective measures of prophylaxis and treatment exist;

"risk level IV" means work with pathogenic genetically engineered organisms which are pathogens of particularly dangerous infectious diseases having the ability to spread quickly and against which effective measures of prophylaxis and treatment are unknown.

This Law establishes a right of individual entrepreneurs 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 5 of this Law defines measures to ensure safety in genetic engineering activity. The safety in genetic engineering activity is ensured by:

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

issue of permits for import, export or transit of potentially pathogenic and pathogenic genetically engineered organisms, as well as 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 II, III and IV in genetic engineering activity;

state registration of genetically engineered varieties of plants, genetically engineered breeds of animals and strains of non-pathogenic genetically engineered microorganisms;

record (accounting) of genetically engineered organisms in accordance with the legislation;

establishment and compliance with safety requirements in genetic engineering activity;

planning and implementation of measures to ensure safety in genetic engineering activities;

State Safety Expertise of genetically engineered organisms;

exercising control in the field of safety in genetic engineering activity;

establishment of liability for violation of legislative requirements to safety in genetic engineering activity;

implementation of other safety measures in genetic engineering activity in accordance with the legislation.

State Administration in the field of safety in genetic engineering activity is exercised by the President of the Republic of Belarus, the Council of Ministers of the Republic of Belarus, specially authorized Republican bodies of State Administration in the field of safety in genetic engineering activity.

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

By Order of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of 5 December 2012, №412-OD (with amendments introduced by orders of 12 January 2015, №14-OD and 28 October 2015, №370-OD), the Expert Safety Board of Genetically Engineered Organisms of the Ministry of

Natural Resources and Environmental Protection of the Republic of Belarus was established in the Republic of Belarus.

The Regulation on the Expert Safety Board for Genetically Engineered Organisms of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus was approved by the Resolution of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of 17 August 2006 No. 52. The Expert Safety Board is a collegial advisory body that incorporates a Chairperson, a Deputy Chairperson, a Secretary and Board members from the officials of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus, other specially authorized bodies of State Administration in the field of safety in genetic engineering activity and specialists in this field, as well as citizens of the Republic of Belarus.

Duties of a Chairperson, the Deputies and Expert Board members are exercised on a pro-bono basis.

Objectives of the Expert Board are as follows:

organization and carrying out of the State Safety Expertise of genetically engineered organisms;

recommendation of candidates to carry out the State Safety Expertise of genetically engineered organisms;

consideration of the State Safety Expertise findings on genetically engineered organisms;

adoption of recommendations on admissibility of release of genetically engineered organisms into the environment for testing or use for economic purposes.

Expert Board meetings shall be held by perforce and decision of a Chairman. Expert Board Decisions shall be taken by open voting by a simple majority of member votes, participating in the meeting and recorded in a protocol. In the event of a tie, the Chairman shall be entitled to a casting vote. Minutes of Expert Board meetings formalized in decisions shall be signed by the Chairman and Secretary. Organizational and technical support shall be provided by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus.

In Belarus cross-sectoral, i.e. inter-departmental (inter-industry), functions are exercised by so-called Inter-agency Councils (Boards); in addition, there are Inter-agency Expert Councils (Boards). The Expert Board for Biosafety of Genetically Engineered Organisms of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus belongs to this type of Inter-agency Council (Board). A list of Expert Board members on biosafety of genetically engineered organisms of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus, provided in Appendix 5, clearly shows that the Board includes representatives of the establishments subordinated to different agencies (institutions) and it ensures the representation of all involved and competent in the area of biosafety

establishments and agencies (institutions). The work of the Expert Board for Biosafety allows, using the knowledge and experience of all country organizations competent in the issues of safety in genetic engineering activity, listed the Appendix 5, to decide on the admissibility of release of genetically engineered organisms into the environment for testing or their use for economic purposes; it also allows to identify risk management techniques of their release and monitoring methods.

The Resolution of the Council of Ministers of the Republic of Belarus of 30 October 2002, № 1504 "On Cooperation of the Republic of Belarus and International Organizations" establishes that the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus shall provide a liaison with the Secretariat of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety to the Convention and that it has been entrusted with powers of the National Competent Body and Coordination Centre.

The National Co-ordination Biosafety Centre (NCBC) was established in accordance with the Resolution of the Council of Ministers of the Republic of Belarus of 19 June 1998, № 963. The State Scientific Institution "Institute of Genetics & Cytology of the National Academy of Sciences of Belarus" was entrusted with functions of this Centre.

The main objectives of the National Co-ordination Biosafety Centre are as follows:

collection, analysis and systematization of information on legislation and scientific research in the field of biosafety, field trials of genetically engineered objects, import / export, commercial use of genetically modified organisms (GMOs) and the products derived from them in the Republic of Belarus, as well as of the specified information on biosafety obtained from the International Information Network Databases, generation of the National Biosafety Database;

delivery of information on biosafety issues to the involved Ministries and other Republican bodies of State Administration and the mass media;

information exchange with Coordination Biosafety Centers of other countries and international organizations;

organization of the Scientific Safety Expertise of genetically engineered organisms and products derived from them, destined for use in the territory of the Republic of Belarus;

provision of advisory services to the Ministries and other Republican bodies of State Administration in drafting legislative acts on import (export) and safe use of genetically engineered organisms and the products derived from them, Guidelines on environmental risks' assessment and prevention, including risks to human health; Safety Guidelines for Genetic Engineering Laboratories;

provision of advisory services to the Ministries and other Republican bodies of State Administration in formulation of proposals on entry into bilateral and regional

agreements, as well as drawing up international agreements (treaties) on biosafety issues.

NCBC maintains the biosafety website http://biosafety.org.by/, which contains information on the legislation and scientific research on biosafety issues, methodological guidelines and study materials, risk assessment of GMOs and the results of GMO field trials, on import/export, commercial use of GMOs and the products derived from them in Belarus, as well as information on biosafety issues from the databases of International Information Networks;

NCBC provides a number of biosafety educational resources, including online modules, biosafety courses and educational articles that are available on the website at the link: http://biosafety.org.by/.

NCBC staff members initiate meetings related to the issues of GMO release for trials, as well as their placement at the market, a number of training workshops and seminars for any of the specialist groups engaged in biosafety activity (GMO developers, biosafety experts, staff members of the GMO Detection Laboratories, public associations) and the representatives of all country institutions engaged in biosafety of genetic engineering activity are invited to take part in them. Such activities (events) are organized at the Institute of Genetics and Cytology, as well as at other institutions in the form of issue-related (thematic) workshops. The officials of State bodies responsible for the implementation of biosafety at the country level in accordance with the Law "On Safety in Genetic Engineering Activity" (the Ministry of Nature, the Ministry of Agriculture and Food, the Ministry of Health), their subordinated establishments (institutions, scientific and practical centres), the Aarhus Centre specialists and public associations are invited on a regular basis.

First NCBC Head was directly involved in the development of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. On 31 May 2005 at the Meeting of the Parties to the Cartagena Protocol on Biosafety (Montreal, Canada) the work of the National Coordination Biosafety Centre was noted with the Certificate of Merit by UNEP and GEF "Award for Completing its Draft National Biosafety Framework with Financial Support from the Global Environmental Facility (GEF)". NCBC staff members were directly involved in the development of the Law of the Republic of Belarus "On Safety in Genetic Engineering Activity". As a result of consultations carried out by the National Focal Point on the Cartagena Protocol implementation in Belarus with GEF coordinators and the Intergovernmental Committee for the Cartagena Protocol, NCBC was designated to hold responsibility for joint projects between Belarus and the United Nations Environment Programme (UNEP) "Development of the National Biosafety Framework for the Republic of Belarus" (2003-2004) and "Capacity-building for Effective Participation in the Biosafety Clearing-House" (2006-2007). NCBC was also the National executing agency in the preparation of the Second and Third National Reports on

Implementation of the Cartagena Protocol on Biosafety in Belarus. NCBC employees, members of the Informal Advisory Committee on the effective operation of the Cartagena Protocol Internet portal, as well as members of ad hoc working groups of experts on the GMO risk assessment, synthetic biology and socio-economic biosafety issues at the Secretariat to the Convention on Biological Diversity, use recommendations made by the named committees and expert groups in their daily work.

NCBC employees are the members of the Expert Board for Biosafety of Genetically Engineered Organisms of the Ministry of Natural Resources and the Environmental Protection of the Republic of Belarus; they take an active role in the development of National methodological guidelines and study materials in these biosafety areas, submit within the scope of their competence information on biosafety in genetic engineering activity in the country, including the proposals on amendments and (or) additions to the existing legislation that regulates the activity to be directed to the appropriate State bodies.

NCBC employees work out online modules on GMO biosafety issues, including modules relevant to new methods of GMO detection and identification for the GMO Detection Laboratories, the experts performing GMO risk assessment, the persons responsible for GMO authorization and the public concerned. Education and training courses developed and seminars hosted in collaboration with the Aarhus Centre (http://www.aarhusbel.com/), including the presentation on "Sharing Experience in the Field of Education and Raising Public Awareness of Biosafety Issues" (http://biosafety.org.by/cei-2013) and "Public Participation in Biosafety Issues" (http://biosafety.org.by/seminar_17-07-2015) are available at the NCBC website. Books and guidelines are also available through the link for the primary, secondary and tertiary level, including the Belarusian State University course of the Microbiology Cathedra (Department) "Transgenic Eukaryotic Microorganisms" (http://www.bio.bsu.by/microbio/kursy_transgen_eukariot_org.html). Finally, some educational materials, including articles for outreach purposes (http://biosafety.org.by/publications and http://biosafety.org.by/faq) and radio and TV records of interviews delivered can also be found at https://www.youtube.com/watch?v=tVEI4lFNVnI&list=PLmGv3zIr0LKCB3Vzk6nqzo7ic30SKhj7P).

The National Coordination Biosafety Centre exercises the Biosafety Clearing-House functions and provides information on a number of biosafety issues for the Biosafety Clearing-House website.

NCBC functions include providing information to the Secretariat of the Convention on the activity undertaken in the country on the implementation of the Cartagena Protocol through the Biosafety Clearing-House. The activity meets one of the mandatory requirements for the country, which is a Party to the Protocol.

As of 30 September 2016, all major normative legal acts on the Biosafety regulation in the Republic of Belarus, reports on Risk Assessment, Country's Decision or any other Communication, Reports on Implementation of the Protocol and other relevant documents were published on the Internet portal of the Biosafety Clearing-House, 50 documents in total. This work is carried out on an on-going basis by a specially authorized person – Head of the National Co-ordination Biosafety Centre.

It should be noted that Specially designated Republican bodies of State Administration in the field of Safety in Genetic Engineering Activity, National Co-ordination Biosafety Centre, as well as legal entities and individual entrepreneurs engaged in genetic engineering activity, lie under an obligation of providing information on safety in genetic engineering activity on request of concerned citizens and NGOs in accordance with the legislation.

## 1.2. IMPORT INTO THE REPUBLIC OF BELARUS, EXPORT FROM THE REPUBLIC OF BELARUS AND TRANSIT THROUGH ITS TERRITORY OF GENETICALLY ENGINEERED ORGANISMS

Article 18 of the Law of the Republic of Belarus "On Safety in Genetic Engineering Activity" establishes safety requirements to 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 exporter (the country that carries out transit) is a Party to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

Import into the Republic of Belarus of non-pathogenic genetically engineered organisms destined for release into the environment for testing shall be allowed, provided that there is a permit for release of non-pathogenic genetically engineered organisms into the environment for testing, the issuance of which is stipulated by Article 15, Part 2 of this Law.

Import into the Republic of Belarus of non-pathogenic genetically engineered organisms intended for use for economic purposes shall be allowed, provided that there is a State Registration Certificate for genetically engineered varieties of plants, genetically engineered breeds of animals and strains of non-pathogenic genetically engineered microorganisms, the issuance of which is stipulated by Article 16, Part 2 of this Law.

Transit through the territory of the Republic of Belarus of non-pathogenic genetically engineered organisms shall be allowed upon notification of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus by the carrier in accordance with the procedure, established by the Resolution of the

Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of 17 August 2006, № 49. The Resolution establishes that:

legal entities and individual entrepreneurs involved in transport of non-pathogenic genetically engineered organisms shall submit to the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus a notification of transit through the territory of the Republic of Belarus of non-pathogenic genetically engineered organisms in line with the Annex to this Resolution.

**NOTIFICATION OF TRANSIT THROUGH THE TERRITORY OF THE REPUBLIC OF BELARUS OF NON-PATHOGENIC GENETICALLY ENGINEERED ORGANISMS**

| Name of a legal entity, full name of an individual entrepreneur engaged in transit of non-pathogenic genetically engineered organisms, contact telephone number | Name of the transported genetically engineered organism and its biological form (entire living organism, dead organism, its parts) | Vehicle type and number, used to transport genetically engineered organisms | Country of export of non-pathogenic genetically engineered organisms | Country of import of non-pathogenic genetically engineered organisms | Route description for transport of genetically engineered organisms through the territory of the Republic of Belarus, including the description of inhabited localities planned for long stay (more than 3 hours) | Packaging description, used for genetically engineered organisms, their quantity and weight |
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| | | | | | | |

Head of the legal entity or individual entrepreneur _____
(signature)

The notification shall be submitted 7 days prior to the intended crossing of the State border of the Republic of Belarus by a means of transport used for the transit transportation of non-pathogenic genetically engineered organisms .

The procedure of record-keeping (accounting) by legal entities and individual entrepreneurs of developed, imported into the Republic of Belarus, exported from it or conveyed in transit non-pathogenic genetically engineered organisms is established

by the Resolution of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of 17 August, № 51. The Resolution establishes that:

legal entities and individual entrepreneurs engaged in genetic engineering activity of risk level I shall keep a record of developed, imported into the Republic of Belarus, exported from the Republic of Belarus and conveyed in transit through its territory genetically engineered organisms by completing a record list of non-pathogenic genetically engineered organisms in accordance with Annex to this Resolution.

## RECORD LIST OF NON-PATHOGENIC GENETICALLY ENGINEERED ORGANISMS

| Name of a legal entity, full name of an individual entrepreneur, engaged in the development, import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of non-pathogenic genetically engineered organisms (hereafter referred to as " the organism") | Information on organisms | | | | Type of intended activity for organisms (development, import into the Republic of Belarus, export from the Republic of Belarus, transit through its territory) | Name of the exporter of organisms (for cases of import of organisms into the Republic of Belarus) | Name of the importer of organisms (for cases of export of organisms from the Republic of Belarus) | Name of the exporter and importer of organisms (for cases of transit of organisms through the territory of the Republic of Belarus) |
|---|---|---|---|---|---|---|---|---|
| | name of the organism | biological form of the organism (entire living organism, dead organism, its parts) | brief characteristic of genetically engineering modifications of the organism and a genetic modification code | quantity and (or) weight of the developed or transported organisms | | | | |
| | | | | | | | | |

Head of the legal entity or
individual entrepreneur _____
(signature)

A record list of non-pathogenic genetically engineered organisms shall be completed within a month from the date of development, import into the Republic of Belarus, export from the Republic of Belarus or conveyance in transit through its territory of non-pathogenic genetically engineered organisms in two copies, one copy remains with a legal entity or individual entrepreneur and the other one shall be

submitted to the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus within a week from the date of its filling in.

Export from the Republic of Belarus of non-pathogenic genetically engineered organisms shall be allowed upon availability of a permit for import, issued by the designated authority (organization) of the destination country.

The Resolution of the Council of Ministers of the Republic of Belarus of 23 September №1397 establishes a list of potentially pathogenic and pathogenic genetically engineered organisms, limited for conveyance through the State border of the Republic of Belarus during their import and (or) export on non-economic grounds, the import and (or) export of which shall be allowed upon availability of a permit (an authorization document), issued by the Ministry of Health of the Republic of Belarus.

| Name | **Unified Product Code Listing** related to the EAEU international economic activity |
|---|---|
| Potentially pathogenic and pathogenic genetically engineered organisms: | |
| any genetically modified microorganism or genetic element (fragment), which contains sequences (areas) of nucleic acid encoding pathogenicity factors and derived from microorganisms | out of 3002 90 900 0 |
| any genetically modified microorganism or genetic element (fragment),which contains sequences (areas) of nucleic acid encoding any of toxins | out of 3002 90 900 0 |

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<*> To use this list it is necessary to be guided by the Unified Product Code Listing related to the EAEU international economic activity, as well as by specific identification attributes, indicated in forwarding (transportation) documents or on the packaging (e.g. “Perishable biological substances” ("Substances biologiques perissables"),“Danger: do not open during transportation” ("Dangereux: Ne pas ouvrir pendant le transporte").

Import into the Republic of Belarus of potentially pathogenic and pathogenic genetically engineered organisms, limited to transport through the Customs border of the Republic of Belarus on the basis of non-economic character shall be allowed upon availability of a permit for import, issued by the Ministry of Health of the Republic of Belarus in accordance with the procedures, established by the Council of Ministers of the Republic of Belarus by agreement with the President of the Republic of Belarus and for scientific purposes only.

Export from the Republic of Belarus of potentially pathogenic and pathogenic genetically engineered organisms, limited to transport through the Customs border of the Republic of Belarus on the basis of non-economic character and the transit shall be allowed upon availability of a permit for import, issued by the designated authority (organization) of the destination country, as well as a permit for import or transit, issued by the Ministry of Health of the Republic of Belarus in accordance with the procedures, established by the Council of Ministers of the Republic of Belarus by agreement with the President of the Republic of Belarus.

Import into the Republic of Belarus and export from the Republic of Belarus, as well as transit of potentially pathogenic and pathogenic genetically engineered organisms shall be regulated by the Provision on procedures and conditions for issuance by the Ministry of Health of the Republic of Belarus of decisions (authorization documents) for import and (or) export of potentially pathogenic and pathogenic genetically engineered organisms, limited to transportation through the State border of the Republic of Belarus on the basis of non-economic character, established by the Resolution of the Council of Ministers of the Republic of Belarus of 23 September 2008, № 1397.

This Provision shall not apply to state-owned legal entities engaged in genetic engineering activity of risk levels II, III and IV and import into the Republic of Belarus, export outside its territory and transit of potentially pathogenic and pathogenic genetically engineered organisms (a declarant), included in a list of potentially pathogenic and pathogenic genetically engineered organisms, limited to transportation through the State border of the Republic of Belarus when imported and (or) exported on grounds of non-economic character, the import and (or) export of which shall be allowed upon availability of a decision (an authorization document), issued by the Ministry of Health of the Republic of Belarus and established in accordance with the given Provision.

The organization and performance of a range of works on acceptance and consideration of documents, submitted by the declarant with a view of receiving a decision (authorization documents) shall be exercised by the Ministry of Health of the Republic of Belarus through the State Institution “Republican Research & Practical Center for Epidemiology and Microbiology” (RRPCEM).

In order to receive a decision (an authorization document), a declarant shall submit to the Republican Research & Practical Center for Epidemiology and Microbiology (RRPCEM) the documents provided for in clause 10.4 of a consolidated list of administrative procedures that are exercised by State bodies and other organizations in relation to legal entities and individual entrepreneurs and established by the Resolution of the Council of Ministers of the Republic of Belarus of 17 February 2012, № 156:

| **Administrative Procedure** | **Designated Authority to Exercise the Administrative Procedure** | **List of Documents and (or) Data, Submitted by the Involved Parties to the Designated Authority to Exercise the Administrative Procedure** | **Duration of the Administrative Procedure** | **Validity of Certificates or other Documents, Issued in the Administrative Procedure** | **Administrative Procedure Fee** |
|---|---|---|---|---|---|
| | | | | | |
| 10.4.1.<br>for import | Ministry of Health (the State Institution "Republican Research & Practical Center for Epidemiology and Microbiology ") | A declaration in the prescribed form and in line with the Annex to the Provision on terms and procedures for the issue by the Ministry of Health of decisions (authorization documents) for import (or) export of potentially pathogenic and pathogenic genetically engineered organisms, limited to transport through the State border of the Republic of Belarus on grounds of non-economic character, by the Resolution of the Council of Ministers of the Republic of Belarus of 23 September 2008, №1397<br><br>The original or a notarially certified copy of the Accreditation Certificate for self-contained systems of the organization<br><br>A permit for export, issued by the designated authority (organization) of the country of origin | 10 days | 1 month from the date in a decision (an authorization document / permit) | No fee |

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| 10.4.2.<br>for export | Ministry of Health (the State Institution "Republican Research & Practical Center for Epidemiology and Microbiology ") | A declaration in the prescribed form and in line with the Annex to the Provision on terms and procedures for the issue by the Ministry of Health of decisions (authorization documents / permits) for import and (or) export of potentially pathogenic and pathogenic genetically engineered organisms, limited to transport through the State border of the Republic of Belarus on grounds of non-economic character, established by the Resolution of the Council of Ministers of the Republic of Belarus of 23 September 2008, №1397<br><br>The original or a notarially certified copy of the Accreditation Certificate for the self-contained system of the organization<br><br>A permit for import, issued by the designated authority (organization) of the country of origin<br><br>A packaging certificate for potentially pathogenic and pathogenic genetically engineered organisms | 10 days | 1 month from the date in a decision (an authorization document/permit) | No fee |

| | | | | | |
|---|---|---|---|---|---|
| 10.4.3.<br>for transit | Ministry of Health (the State Institution "Republican Research & Practical Center for Epidemiology and Microbiology ") | A declaration in the prescribed form and in line with the Annex to the Provision on terms and procedures for the issue by the Ministry of Health of decisions (authorization documents) for import and (or) export of potentially pathogenic and pathogenic genetically engineered organisms, limited to transport through the State border of the Republic of Belarus on grounds of non-economic character, established by the Resolution of the Council of Ministers of the Republic of Belarus of 23 September 2008, №1397<br><br>A permit for export, issued by the designated authority (organization) of the country of origin<br><br>A permit for import, issued by the designated authority (organization) of the country of origin<br><br>A packaging certificate for potentially pathogenic and pathogenic genetically engineered organisms | 10 days | 1 month from the date in a decision (an authorization document/permit) | No fee |

The Republican Research and Practical Center for Epidemiology and Microbiology shall consider the submitted declaration and documents and forward to the Ministry of Health a decision, issued by the Head of the Centre on the feasibility to issue a decision (an authorization document). Following a decision of the Centre, the Ministry of Health shall conclude on the issuance or rejection to issue a decision (an authorization document). The decision-making and issuance of a decision (an authorization document) shall be implemented in line with the Resolution of the Eurasian Economic Commission Board of 16 May 2012, №45 "On Unified Form of a Decision (an Authorization Document) on Import, Export and Transit of Commodity Items Included in a Consolidated List of Commodity Items Subject to Bans and Restrictions on Import or Export by the Member-states of the Customs Union within the EurAsEC in Trade with Third Countries and Methodology Guidelines on its

Completion" shall be exercised by the Ministry of Health within the time limits provided for in clause 10.4 of the list.

The specimens' seal impression and sample signatures of the Ministry of Health officials authorized to issue decisions (authorization documents) shall be submitted to the State Customs Committee.

The Ministry of Health shall reject the issuance of a decision (an authorization document) on the occurrence of any of the following:

failure to comply with the prescribed form;

failure to submit the documents required for its receipt;

in the event of inaccurate information in the submitted documents.

In case of rejection to issue a decision (an authorization document), the Ministry of Health shall give a written notice to a declarant, specifying grounds for a decision.

A decision (an authorization document) shall be terminated:

upon the expiration of its term;

from the date of the Ministry of Health Decision on its annulment;

in the event of inaccurate information identification subsequent to the issue of a decision (an authorization document) and submitted for its receipt;

in the event of liquidation (termination of activity) or reorganization of a declarant;

by the court decision.

The Ministry of Health shall within 3 days prior to the decision-making on the annulment of a decision (an authorization document) give a written notice to a declarant, specifying grounds for annulment, as well as to Customs bodies and other involved State authorities.

After receiving a decision (an authorization document), a declarant lies under an obligation to return a decision (an authorization document) within 15 days following its annulment to the Ministry of Health.

Rejection to issue a decision (an authorization document) may be appealed in accordance with the procedures, established by the legislation.

Authorization forms (permits) and declarations for import, export or transit of potentially pathogenic and pathogenic genetically engineered organisms are established by the Resolution of the Ministry of Health of the Republic of Belarus of 21 September 2006, № 73.

**PERMIT**

for import of potentially pathogenic and pathogenic
genetically engineered organisms into the Republic of Belarus
N _____ "__" _____ 20__

This is to certify that the Ministry of Health of the Republic of Belarus authorizes the import into the Republic of Belarus of genetically engineered organisms

_____
(name, specific name (identification),

_____
number (code) of strains of genetically engineered organisms)

in quantity_____
(designated name and number of containers)

Receiver_____
(full details of the receiver, address)

Provider _____
(full details of the provider, address)

Permit valid until "__" _____ 20__

Deputy Minister of Health -
Chief State
Sanitary Inspector
of the Republic of Belarus_____ _____
(signature) (initials, surname)

**PERMIT**

for export of potentially pathogenic and pathogenic
genetically engineered organisms from the Republic of Belarus
N ____ "__" _____ 20__

This is to certify that the Ministry of Health of the Republic of Belarus authorizes the export from the Republic of Belarus of genetically engineered organisms _____

_____
(name, specific name (identification),

_____
( number (code) of strains of genetically engineered organisms)

in quantity_____
(designated name and number of containers)

Provider_____
(full details of the provider, address)

Receiver _____
(full details of the receiver, address)

Permit valid until "__" _____ 20__

Deputy Minister of Health -
Chief State
Sanitary Inspector
of the Republic of Belarus_____ _____
(signature) (initials, surname)

**PERMIT**

for transit of potentially pathogenic and pathogenic
genetically engineered organisms through the territory
of the Republic of Belarus
N ____ "__" _____ 20__

This is to certify that the Ministry of Health of the Republic of Belarus authorizes the transit through the territory of the Republic of Belarus of genetically engineered organisms

_____
(name, specific name (identification),

_____
(number (code) of strains of genetically engineered organisms)

in quantity _____
(designated name and number of containers)

Provider_____
(full details of the provider, address)

Receiver_____
(full details of the receiver, address)

Permit valid until "__" _____ 20__

Deputy Minister of Health -
Chief State
Sanitary Inspector
Of the Republic of Belarus_____ _____
(signature) (initials, surname)

**DECLARATION**
for import (export, transit) of potentially pathogenic and
pathogenic genetically engineered organisms

_____
(full details of state legal entity,

_____
registered address)

applies for import (export, transit) permit into (from, through the territory of the Republic of Belarus of genetically engineered organisms

_____
(name, specific name (identification),

_____
(number (code) of strains of genetically engineered organisms)

in quantity _____
(designated name and number of containers)

Provider _____
(full details of the provider, address)

Receiver_____
(full details of the receiver, address)

Annex: 1. _____
2. _____
... _____

Head of the State
legal entity_____ _____
(signature) (initials, surname)
"___" _____ 20__

In the event of an unauthorized import of genetically engineered organisms, a person providing the import shall remove genetically engineered organisms from the territory of the Republic of Belarus at its own cost and expense in accordance with the procedures, established by the legislation.

Article 17 of the Law of the Republic of Belarus "On Safety in Genetic Engineering Activity" establishes safety requirements for transport of genetically engineered organisms. Means of transport used to transport non-pathogenic genetically engineered organisms should be equipped with facilities that eliminate the possibility of unauthorized release of genetically engineered organisms into the environment.

Transport of potentially pathogenic and pathogenic genetically engineered organisms shall be exercised in accordance with the legislation on Dangerous Goods and safety requirements for transport of these organisms.

The Resolution of the Ministry of Health of the Republic of Belarus of 25 August 2006, №65 establishes safety requirements for transport of potentially pathogenic and pathogenic genetically engineered organisms. The Resolution establishes that transport of potentially pathogenic and pathogenic genetically engineered organisms from one structural subdivision of the organization to another shall be allowed upon availability of a written authorization document, issued by authority of the Head of a structural subdivision of the organization with regard to potentially pathogenic genetically engineered organisms and in the event of pathogenic genetically engineered organisms by the Head of the organization.

A written authorization form for transport of potentially pathogenic and pathogenic genetically engineered organisms is established by the Head of the organization.

In the event of transport, a Certificate of Transfer of potentially pathogenic and pathogenic genetically engineered organisms from one structural subdivision to another shall be issued in line with Annex I and registration in the Log of release of genetically engineered organisms shall be completed in line with Annex V to the Instruction "On Accountability Procedures by State Legal Entities of Developed, Imported into the Republic of Belarus, Exported from the Republic of Belarus and Conveyed in Transit through its Territory Potentially Pathogenic and Pathogenic Genetically Engineered Organisms", established by the Resolution of the Ministry of Health of the Republic of Belarus of 25 August 2006, №65.

The transport of potentially pathogenic and pathogenic genetically engineered organisms from one organization to another shall be allowed on the ground of:

a written inquiry from the organization that wants to receive potentially pathogenic and pathogenic genetically engineered organisms (a recipient organization), signed by the Head of the recipient organization and certified by seal with the indication of the Accreditation Certificate number and date of its issue to

certify that works of risk levels II, III and IV in genetic engineering activity are allowed in this self-contained system of the organization, issued in accordance with the Instruction "On Accreditation Procedures for Self-contained Systems to Carry out Works of Risk Levels II, III and IV in Genetic Engineering Activity" and approved by the Resolution of the Ministry of Health of the Republic of Belarus of 25 August 2006, №65;

a written inquiry from the Head of the organization that transports potentially pathogenic and pathogenic genetically engineered organisms (a provider organization) to a recipient organization.

In the event of transport, a Certificate of Transfer of potentially pathogenic and pathogenic genetically engineered organisms outside the organization shall be issued in line with Annex II and registration in the Log of release of genetically engineered organisms shall be completed in line with Annex V to the Instruction "On Accountability Procedures by State Legal Entities of Developed, Imported into the Republic of Belarus, Exported from the Republic of Belarus and Conveyed in Transit through its Territory Potentially Pathogenic and Pathogenic Genetically Engineered Organisms", established by this Resolution.

The transport of potentially pathogenic and pathogenic genetically engineered organisms outside the Republic of Belarus, into the Republic of Belarus and conveyance in transit through its territory shall be allowed only upon availability of a permit for import, export and transit of potentially pathogenic and pathogenic genetically engineered organisms, issued to the organization and shall be handled in accordance with the legislation on the carriage of dangerous goods and escorted by one or two Laboratory workers of the recipient organization authorized to carry out genetic engineering activity in accordance with the procedures, established by the Instruction "On Safety Requirements for Self-contained Systems to Carry out Works of Risk Levels II, III and IV in Genetic Engineering Activity", approved by the Resolution of the Ministry of Health of 25 August 2006, №65. The provider organization shall inform the recipient organization on the date of dispatch and the transport mode used to transport potentially pathogenic and pathogenic genetically engineered organisms. Upon receipt of potentially pathogenic and pathogenic genetically engineered organisms, the recipient organization employees should produce to the provider organization:

a Power of Attorney for receiving of potentially pathogenic and pathogenic genetically engineered organisms, issued in accordance with the established procedures by the Head of the organization;

a passport of the Republic of Belarus citizen, a Leave to Remain in the Republic of Belarus, a refugee certificate, a passport or any other document that replaces it and valid for travelling abroad with regard to foreign citizens or stateless persons, issued by the designated authority of the country of nationality or at the

place of residence of a foreign citizen or stateless person or by an international organization;

a permit for import, export or transit of potentially pathogenic and pathogenic genetically engineered organisms.

Potentially pathogenic and pathogenic genetically engineered organisms shall be transported in the lyophilized state or on the solid medium. The transport is allowed in the preserving liquid or in a frozen state.

The transport of potentially pathogenic and pathogenic genetically engineered organisms shall be carried out in hermetically sealed containers (sealed ampullas, test tubes, crimped tubes made of thick glass or soft-solid material, as well as stoppered test tubes, hermetically sealed with different plasticizers).

Hermetically sealed containers with potentially pathogenic and pathogenic genetically engineered organisms are wrapped in the absorbing material (lignin or gyroscopic cotton) and placed into the metal tightly-closed (hermetic) or screw-top canister.

The packaging of hermetically sealed containers with potentially pathogenic and pathogenic genetically engineered organisms in the canister should exclude any possibility of their free movement inside the canister to avoid disruption of continuity during the transport and there should be sufficient amount of the absorbing material for all liquid sorption in the event of damage to packaging.

Canisters with hermetically sealed containers that contain potentially pathogenic and pathogenic genetically engineered organisms are wrapped in paper (sheathed with material), bandaged (laced) and sealed with a wafer of the sender organization or sealed with lead.

In order to transport potentially pathogenic and pathogenic genetically engineered organisms, canisters with hermetically sealed containers are additionally wrapped in cotton to exclude any possibility of their free movement and placed into the wooden or plastic box. The box is sheathed with material and sealed with a wafer of the sender organization or sealed with lead.

A side of the box with designated name and location of the provider and recipient organizations should have:

a violet mark “Danger! Do not open during transportation”.

In the event of transport outside the Republic of Belarus territory, the following violet marks both in the Russian and French languages are additionally made: “Perishable biological substances” ("Substances biologiques perissables"),“Danger: do not open during transportation” ("Dangereux: Ne pas ouvrir pendant le transporte");

name of a genetically engineered organism;

number and issue date of the Registration Certificate for a genetically engineered organism issued by the Ministry of Health in line with Annex 10 to the

Instruction “On Accountability Procedures by State Legal Entities of Developed, Imported into the Republic of Belarus, Exported from the Republic of Belarus and Conveyed in Transit through its Territory Potentially Pathogenic and Pathogenic Genetically Engineered Organisms”, approved by the Resolution of the Ministry of Health of the Republic of Belarus of 25 August 2006, №65.

data on transport, storage, use and deactivation of genetically engineered organisms.

An inventory sheet with a check-list and quantity of potentially pathogenic and pathogenic genetically engineered organisms contained in it is put into the box with potentially pathogenic and pathogenic genetically engineered organisms. A copy of the inventory sheet remains with the provider organization.

A provider organization shall draw up a Packaging Act for potentially pathogenic and pathogenic genetically engineered organisms in line with Annex III in two copies, one copy is handed over to the recipient organization employees and the other one remains with the sender organization.

Within three days following the delivery of potentially pathogenic and pathogenic genetically engineered organisms, a recipient organization shall draw up an open box report in any format and in two copies, one of which along with an acknowledgement letter of receipt of potentially pathogenic and pathogenic genetically engineered organisms shall be submitted to the provider organization.

A recipient organization should send copies of an open box report and acknowledgement letter of receipt of potentially pathogenic and pathogenic genetically engineered organisms to the State Institution “Republican Research & Practical Center for Epidemiology and Microbiology” of the Ministry of Health of the Republic of Belarus for a record of 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 potentially pathogenic and pathogenic genetically engineered organisms.

Employees of a recipient organization involved in transport of potentially pathogenic and pathogenic genetically engineered organisms, as well as transport workers in the event of accidents, disasters, loss and theft of boxes during the transportation should inform on this fact the authorities and establishments (institutions) exercising State Sanitary Supervision, the State Security Committee of the Republic of Belarus, the Ministry of Internal Affairs of the Republic of Belarus, the Emergency Situations Ministry of the Republic of Belarus to take measures on the accident/incident site protection, consequence management, search for lost and stolen items.

Such cases should be reported both to the provider and recipient organizations and the State Institution “Republican Research & Practical Center for Epidemiology and Microbiology” of the Ministry of Health of the Republic of Belarus. The control

**Annex I**
to the Instruction on
Safety Requirements for Transport of
Potentially Pathogenic and Pathogenic
Genetically Engineered Organisms

AFFIRM
Head of organization
_____
(signature, initials, surname)
_____
(date, month, year)

ACT
of transfer of potentially pathogenic
and pathogenic genetically engineered organisms
from one structural subdivision of organization to another

"__" _____ 20__ N _____

We, the undersigned, _____
(position, name of a structural subdivision,
_____
surname, provider of genetically engineered organisms)

_____
(position, name of structural subdivision,
_____
surname, initials of receiver of genetically engineered organisms)
_____
made this Act upon written authorization of the Head of a structural subdivision
of the organization
_____
(name of a structural subdivision,
_____
written authorization issue date)
_____
the transfer of genetically engineered organisms was made_____
(name,
_____
specific name (identification), No. (code) of
_____
strains of genetically engineered organisms, number of containers)
_____
from_____
(name of a structural subdivision of the organization)
to_____
(name of a structural subdivision of the organization)

Provided (delivered) _____ _____
(signature) (initials, surname)
Received_____ _____
(signature) (initials, surname)

**Annex II**
to the Instruction on
Safety Requirements for Transport of
Potentially Pathogenic and Pathogenic
Genetically Engineered Organisms

AFFIRM
Head of organization
_____
(signature, initials, surname)
_____
(date, month, year)

ACT
of transfer of potentially pathogenic
and pathogenic genetically engineered organisms
outside organization

"__" _____ 20__ N _____

We, the undersigned, _____
(position, surname, initials
_____
of organization representative, provider of genetically engineered organisms)
_____
(position, surname, initials of organization representative,
_____
receiver of genetically engineered organisms)
made this Act upon written authorization of the Head of a structural subdivision of the organization and a letter of inquiry of a recipient organization
_____
(corporate name of a recipient, date and letter of inquiry №)
the transfer of genetically engineered organisms was made_____
(name,
_____
specific name (identification), No. (code) of
_____
strains of genetically engineered organisms, number of containers)

Provided (delivered) _____ _____
(signature) (initials, surname)
Received _____ _____
(signature) (initials, surname)

**Annex III**

to the Instruction on
Safety Requirements for Transport of
Potentially Pathogenic and Pathogenic
Genetically Engineered Organisms

AFFIRM
Head of organization
_____
(signature, initials, surname)
_____
(date, month, year)

PACKAGING ACT
of potentially pathogenic
and pathogenic genetically engineered organisms

"__" _____ 20__ N _____

We, the undersigned,_____
(surname, initials, position of
_____
employees, responsible for packaging )
_____
made this Act to state the fact of packaging
_____
(kind of packaging)
of genetically engineered organisms
_____
(name, specific name
_____
(identification), No. (code) of strains of genetically engineered organisms)
for transport to _____
(name of a recipient organization,
_____
city, country)
_____
(name and quantity of containers)
placed into the canister, sealed with a wafer impression _____
_____ N _____
(name of a structural subdivision of the organization)
put into the box, sheathed with white cloth and sealed with the same impression stamp.
Package content _____ of no explosive danger,
(kind of packaging)
not flammable, no alien enclosure .

_____ _____ _____
(position) (signature) (initials, surname)
_____ _____ _____
(position) (signature) (initials, surname)

over compliance with safety requirements during transportation of potentially pathogenic and pathogenic genetically engineered organisms shall be carried out by the Compliance Committee on Biosafety Requirements and Anti-epidemic Regime of Regional Centers for Hygiene, Epidemiology and Public Health of the State Institution “Minsk City Centre for Hygiene and Epidemiology” of the Ministry of Health of the Republic of Belarus, as well as institutions and bodies exercising State Sanitary Supervision.

Collections of type, designer and deposit strains that are classified collections of studied by main characteristics and certified potentially pathogenic and pathogenic genetically engineered organisms may be created in organizations for research, production and diagnostic purposes.

Record-keeping of potentially pathogenic and pathogenic genetically engineered organisms within an organization shall be carried out by making entries in Registration Logs of genetically engineered organisms in line with Annexes I - VII.

Record-keeping in organizations of type, designer and deposit strain collection holders of potentially pathogenic and pathogenic genetically engineered organisms shall be carried out in line with Annexes I-VII and an individual registration card of the collection genetically engineered organism of Annex VIII.

When including a potentially pathogenic and pathogenic genetically engineered organism in type, designer and deposit strain collections, it shall be given a specific name (identification), which is shown in the appropriate box of the Inventory Log of collection genetically engineered organisms in line with Annex IV and an individual registration card of the collection genetically engineered organism of Annex VIII and a number (code) of the strain entry in this collection.

The attributed to the collection strain name, specific name (identification), number (code) shall not be changed in its transfer to another organization.

In case of collection strain death (deactivation), its name, specific name (identification), number (code) may not be used for newly-developed strains.

Deactivation of potentially pathogenic and pathogenic genetically engineered organisms in all structural subdivisions of the organization shall be recorded in line with the Deactivation Act of Annex IX.

Log forms of Annexes I-VII must be numbered, bound and signed by the Head of the organization, certified by seal and kept by a person responsible for their logging.

All completed Logs should be kept for 3 years in structural subdivisions of the organization. Logs of Annexes I, III and VI are then destroyed and an act on their destruction is made in a free form; Logs of Annexes II, IV, V and VII are deposited in the organization archives.

Record-keeping of imported into the Republic of Belarus, exported from the Republic of Belarus and conveyed in transit potentially pathogenic and pathogenic genetically engineered organisms shall be carried out by the Ministry of Health of the Republic of Belarus through the State Institution "Republican Research & Practical Center for Epidemiology and Microbiology" of the Ministry of Health of the Republic of Belarus.

Record-keeping of imported into the Republic of Belarus, exported from the Republic of Belarus and conveyed in transit through its territory potentially pathogenic and pathogenic genetically engineered organisms shall be carried out by the Institution by their registration in a structural subdivision of the Institution -- a classified collection of viruses and bacteria, pathogenic for a human when obtaining a permit for import, export and transit of potentially pathogenic and pathogenic genetically engineered organisms, issued by the Ministry of Health of the Republic of Belarus.

Record-keeping of developed in the Republic of Belarus potentially pathogenic and pathogenic genetically engineered organisms shall be carried out by the Institution by registering the developed in the Republic of Belarus potentially pathogenic and pathogenic genetically engineered organisms according to the form of Annex X.

For record-keeping of developed in the Republic of Belarus potentially pathogenic and pathogenic genetically engineered organisms, organizations within one month from the date of their registration in the organization submit to the named Institution the documents as follows:

an application for registration of potentially pathogenic and pathogenic genetically engineered organisms and issuance of a Registration Certificate;

a copy of the Accreditation Certificate to ascertain that carrying out of works of risk levels II, III and IV in genetic engineering activity is allowed in this self-contained system of the organization;

a copy of the strain certificate of a genetically engineered organism according to the form of Annex XI.

Documents submitted in foreign languages should have both Russian and Belarusian translations according to the established procedures.

Subsequent to the results of documentation expertise, the Institution takes a decision on registration (denial of registration) of a potentially pathogenic and pathogenic genetically engineered organism and issuance (refusal to issue) a Registration Certificate to the organization.

Execution and issuance (refusal to issue) of a Registration Certificate shall be carried out by the Institution within 10 days from the date of submission of all relevant documentation by the organization.

A Registration Certificate shall be drawn up in two copies, one copy is returned to the organization and the other one remains with the collection.

Refusal to issue a Registration Certificate:

failure to submit all required documentation by the organization;

in the event of inaccurate information in the submitted documentation.

In the event of one of the aforementioned grounds, the Institute may refuse to issue a Registration Certificate and shall notify the organization in writing, stating reasons for the refusal.

Annually, by 15 January of the year to follow the reporting year, organizations shall submit to the Institution data on developed, imported into the Republic of Belarus, exported from the Republic of Belarus and conveyed in transit through its territory potentially pathogenic and pathogenic genetically engineered organisms according to form of Annex XII.

**Annex I**
to the Instruction on registration procedures
by State legal entities of developed, imported into
the Republic of Belarus, exported from
the Republic of Belarus and conveyed in transit
potentially pathogenic and
pathogenic genetically engineered organisms

_____
(name of the organization)

REGISTRATION LOG
of potentially pathogenic and pathogenic
genetically engineered organisms, received
for research (identification) and storage

Date started "__" _____ 20__
Date closed "__" _____ 20__

| N | Date of receipt | Name of a genetically engineered organism | Capacity number (test-tubes, ampullas and other) | Provider (received from) | Research (identification) objective | Research (identification) findings and issue date | Signature of an individual, responsible for record keeping | Comment |
|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| | | | | | | | | |

**Annex II**
to the Instruction on registration procedures
by State legal entities of developed, imported into
the Republic of Belarus, exported from
the Republic of Belarus and conveyed in transit
through its territory of potentially pathogenic
and pathogenic genetically engineered organisms

_____
(name of the organization)

REGISTRATION LOG
of isolated potentially pathogenic and pathogenic
genetically engineered organisms

Date started "__" _____ 20__
Date closed "__" _____ 20__

| N | Assay number | Date and place of sampling | Name of a genetically engineered organism | Strain number (code) | Isolation Source | Isolation date | Brief description of genetically engineered organism | deactivated, transferred, released (date and act number) | Comment |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| | | | | | | | | | |

**Annex III**
to the Instruction on registration procedures
by State legal entities of developed, imported into
the Republic of Belarus, exported from
the Republic of Belarus and conveyed in transit
through its territory potentially pathogenic and
pathogenic genetically engineered organisms

_____
(name of the organization)

REGISTRATION LOG
of movement of collection potentially pathogenic
and pathogenic genetically engineered organisms

Date started "__" _____ 20__
Date closed "__" _____ 20__

| Date | Name of genetically engineered organism and research technique | Number of inoculations "A" | | | | Number of infected animals (by species) "B" | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | by start of day | inoculated/ plated (received) | deactivated (released) | by end of day | by start of day | inoculated / plated (received) | deactivated, transferred, released (date and act number) | by end of day |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| | | | | | | | | | |

| Number of infected ectoparasites (assays / samples) "B" | | | | Number of infected organs (assays / samples) "G" | | | | Number of dry agents "D" | | | | Signature of a person, responsible for record keeping | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| by start of day | inoculated / plated (received) | deactivated, transferred, handed out | by end of day (date and act number) | by start of day | Inoculated / plated (received) | deactivated, transferred, handed out (date and act number) | by end of day | by start of day | inoculated / plated (received) | deactivated transferred released (date and act number) | by end of day | | |
| 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 |
| | | | | | | | | | | | | | |

**Annex IV**
to the Instruction on registration procedures
by State legal entities of developed, imported into
the Republic of Belarus, exported from
the Republic of Belarus and conveyed in transit
through its territory potentially pathogenic
and pathogenic genetically engineered organisms

_____
(name of the organization)

INVENTORY LOG
of collection potentially pathogenic
and pathogenic genetically engineered organisms

Date started "__" _____ 20__
Date closed "__" _____ 20__

| N | Generic (specific) name in Roman transliter a-tion | Specific name (identificatio n) of a strain | Numb er (code) of a strain | Isolatio n source | Isolatio n techniq ue | Isolatio n date | isolatio n techniq ue | Isolated (surnam e, initials) | Receiv ed from | Acquisiti on date | Deactivate d, transferred , released (date and act number) | Comme nt |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 |
| | | | | | | | | | | | | |

**Annex V**
to the Instruction on registration procedures
by State legal entities of developed, imported into
the Republic of Belarus, exported from
the Republic of Belarus and conveyed in transit
through its territory potentially pathogenic and
pathogenic genetically engineered organisms

_____
(name of the organization)

REGISTRATION LOG
of release of potentially pathogenic
and pathogenic genetically engineered organisms

Date started "__" _____ 20__
Date closed "__" _____ 20__

| N | Acquisition date | Received from (organization), permit date and number | Name and number (code) of a strain, a developed genetically engineered organism | Number of released containers with genetically engineered organisms (specify type of containers, packaging) | Date of release | Surname, initials of a recipient, registered number of the power of attorney, number of an identity document, issuing authority, issue date | Signed acknowledgement of receipt | Issuing authority (surname, initials, name of the structural subdivision, signature) | Comment |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| | | | | | | | | | |

**Annex VI**
to the Instruction on registration procedures
by State legal entities of developed, imported into
the Republic of Belarus, exported from
the Republic of Belarus and conveyed in transit
through its territory potentially pathogenic and
pathogenic genetically engineered organisms

_____
(name of the organization)

REGISTRATION LOG
of disinfected potentially pathogenic
and pathogenic genetically engineered organisms

Date started "__" _____ 20__
Date closed "__" _____ 20__

| Date | Brand, number (No) of sterilizer, air-steam autoclave | Sterilized items | | Signature | | Sterilization mode | | | | | Test, control | | | Signature of a person responsible for disinfection |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Material name | Number of containers | Material released by | Material received by | start | end | Exposure (time) | pressure | temperature | biologic | thermic | chemical | |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
| | | | | | | | | | | | | | | |

**Annex VII**
to the Instruction on registration procedures
by State legal entities of developed, imported into
the Republic of Belarus, exported from
the Republic of Belarus and conveyed in transit
through its territory potentially pathogenic and
pathogenic genetically engineered organisms

_____
(name of the organization)

REGISTRATION LOG
of lyophilisation of potentially pathogenic
and pathogenic genetically engineered organisms

Date started "__" _____ 20__
Date closed "__" _____ 20__

| N | Date of application receipt for lyophilisation and the structural subdivision (organization) | Lyophilisation of genetically engineered organisms allowed by (full name) and when | Liophilisation | | | | | | | Number of ampulae released | Date of release | Surname, initials, signature | | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Date and number (No) of lyophilisation protocol | Name of genetically engineered organism | Number of ampullae | | | | | | | Ampulae received by | Ampullae released by | |
| | | | | | Spilt | Connected | Unsoldered | Got under control | Faulty | | | | | |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
| | | | | | | | | | | | | | | |

**Annex VIII**
to the Instruction on registration procedures
by State legal entities of developed, imported into
the Republic of Belarus, exported from
the Republic of Belarus and conveyed in transit
through its territory potentially pathogenic and
pathogenic genetically engineered organisms

_____
(name of the organization)

INDIVIDUAL REGISTRATION CARD
of a collection genetically engineered organism

1. Section of a collection _____ 6. Cell _____
2. Specific name of a strain _____ 7. Cabinet _____
3. Strain No (code) _____ 8. Fridge _____
4. Unique name 9. Shelf _____
(identification) of a strain_____
5. Strain inventory No _____ 10. Case (box) _____

| Date | | Name of organization (structural subdivision) | | Number of genetically engineered organism containers received | Number of genetically engineered organism containers released | Availability (remainder) | Signature of a person, responsible for individual registration | Comment |
|---|---|---|---|---|---|---|---|---|
| received | released | strain received by | strain released by | | | | | |
| 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
| | | | | | | | | |

**Annex IX**
to the Instruction on registration procedures
by State legal entities of developed, imported into
the Republic of Belarus, exported from
the Republic of Belarus and conveyed in transit
through its territory of potentially pathogenic and
pathogenic genetically engineered organisms

AFFIRM

Head of the structural
subdivision

_____
(name of the organization)

_____
(signature, initials, surname)

_____
(date, month, year)

ACT
of genetically engineered organism deactivation

"__" _____ 20__ N _____

We, the undersigned, _____
(position, surname, initials)
_____

deactivated genetically engineered organisms _____
(name, specific
_____
name (identification), number (code) of strains,
_____
number of containers)
by autoclaving _____
(autoclaving mode)
by immersion _____
(name of disinfection solution, its concentration (strength), deactivation time)
reason for deactivation _____

| _____ | _____ | _____ |
|---|---|---|
| (position) | (signature) | (initials, surname) |
| _____ | _____ | _____ |
| (position) | (signature) | (initials, surname) |

**Annex X**
to the Instruction on registration procedures
by State legal entities of developed, imported into
the Republic of Belarus, exported from
the Republic of Belarus and conveyed in transit
through its territory potentially pathogenic and
pathogenic genetically engineered organisms

REGISTRATION CERTIFICATE
of a genetically engineered organism
developed in the Republic of Belarus

"__" _____ 20__ N _____

This certificate issued by _____
(full name
_____
of the organization, its location)
_____
and certifies that in the territory of the Republic of Belarus developed and registered _____
_____
(name of a genetically engineered organism)
Ground _____
_____

This certificate id valid until "__" _____ 20__

Deputy Minister of Health -
Chief State
Sanitary Inspector
of the Republic of Belarus _____ _____
(signature) (initials, surname)

**Annex XI**
to the Instruction on registration procedures
by State legal entities of developed, imported into
the Republic of Belarus, exported from
the Republic of Belarus and conveyed in transit
through its territory potentially pathogenic and
pathogenic genetically engineered organisms

STRAIN CERTIFICATE
of a genetically engineered organism

"__" _____ 20__

Strain number (code) _____
Name, specific name (identification) of a strain _____
_____
Place in the universal system _____
(family, taxonomic group (phylum)
_____
and antigenic group)
Developed: year_____ where_____
_____
(from, material type)
Extracted _____
(country, organization, originator)
Genetic traits _____
_____
_____
Passage number _____
Optimal titer _____
Drying mode_____ Drying date _____
Date of placement into the museum _____
Storage conditions _____
Date of strain check _____
Research specialist _____
Pathogenicity for a human _____
Sensitivity to experimental infection _____
(animals, embryos and cell cultures)
_____

| Experimental (test) model | Age | Infection | | Incubation period | Infection manifestation | Titer |
|---|---|---|---|---|---|---|
| | | technique | ml | | | |
| | | | | | | |
| | | | | | | |

Developed _____
(specify a technique)
_____
Storage of a genetically engineered organism _____
(specify the storage place)
_____
Official responsible
for issuing this certificate _____ _____
(signature) (initials, surname)

**Annex XII**
to the Instruction on registration procedures
by State legal entities of developed, imported into
the Republic of Belarus, exported from
the Republic of Belarus and conveyed in transit
through its territory potentially pathogenic and
pathogenic genetically engineered organisms

DATA
on developed, imported into the Republic of Belarus, exported from the Republic of Belarus and conveyed in transit through its territory genetically engineered organisms

| Indicator name | Quantity |
|---|---|
| Genetically engineered organisms developed | |
| Genetically engineered organisms imported into the Republic of Belarus | |
| Genetically engineered organisms exported from the Republic of Belarus | |
| Genetically engineered organisms conveyed in transit through the territory of the Republic of Belarus | |

Head of the organization_____ _____
(signature) (initials, surname)
Official, responsible for
furnishing of information _____ _____
(signature) (initials, surname)

_____ _____ _____
(contact telephone number) (date information submitted, to be completed by the organization) (date of information receipt, to be completed by the Institution)

## 1.3. WORK IN SELF-CONTAINED SYSTEMS

The Resolution of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of 17 August 2006, № 50 establishes "Safety Requirements for Self-Contained Systems to Carry out Works of Risk Level I in Genetic Engineering Activity".

The Resolution determines:

works of risk level I of genetic engineering activity in self-contained systems shall be carried out in isolated units (premises) excluding release of genetically engineered organisms into the environment. Premises used for works with genetically engineered plants shall be located at a distance of no less than 300 meters from nurseries, greenhouses and fields for growing of related plant species that belong to the same taxonomic plant genus with those used in works;

waste products of genetically engineered organisms generated as a result of works shall be deactivated by the method excluding preservation of viable spores, pollen, fruits or seeds. Waste products of genetically engineered microorganisms shall be deactivated in accordance with the procedure, established by the Instruction "On Rules and Methods for Deactivation of Waste Products of Medicinal Agents, Healthcare Products and Medical Equipment", approved by the Resolution of the Ministry of Health of 22 November 2002, № 81;

legal entities and individual entrepreneurs engaged in genetic engineering activity of risk level I of genetic engineering activity shall:

ensure execution of works in accordance with the instruction on work safety, established by legal entities and individual entrepreneurs engaged in genetic engineering activity of risk level I on agreement with the competent territorial body of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus;

instruct employees engaged in the activity on work safety procedures.

Safety Requirements for Self-Contained Systems to Carry out Works of Risk Levels II, III and IV in Genetic Engineering Activity are established by the Resolution of the Ministry of Health of the Republic of Belarus of 25 August 2006, № 65.

Main safety requirements for self-contained systems to carry out works of risk levels II, III and IV in genetic engineering activity are as follows:

an accreditation certificate to ascertain that execution of works of risk levels II, III and IV in genetic engineering activity is allowed in this self-contained system of the organization, issued in accordance with the Instruction "On Accreditation Procedures for Self-Contained Systems to Carry out Works of Risk Levels II, III and IV in Genetic Engineering Activity", established by this Resolution;

availability with organization employees of a permit for carrying out works of risk levels II, III and IV in genetic engineering activity;

arrangement of work in organization laboratories in accordance with sanitary norms and regulations and hygienic standards.

Organization employees are allowed to perform works of risk levels II, III and IV in genetic engineering activity, provided that:

they have higher and (or) secondary medical, biological, veterinary education;

they have been instructed on the compliance with biological safety requirements by the Lab Supervisor. The fact that they have passed safety induction shall be confirmed by a signature of the Lab Supervisor in the Registration Log of staff workplace briefing (Tool Box Talk) in line with Annex I. The follow-up briefing shall be carried out at least twice a year.

Admission of employees to perform works of risk levels II, III and IV of genetic engineering activity, as well as engineering and technical personnel to maintain laboratory equipment shall be made by order of the Head of the organization following a decision of the Compliance Committee on Biosafety Requirements and Anti-epidemic Regime established within an organization and endowed with powers to:

exercise control over compliance with safety requirements for self-contained systems by an organization when carrying out works of risk levels II, III and IV of genetic engineering activity;

take measures to carry out activities aimed at prevention of emergency situations and liquidation of their consequences in the implementation of genetic engineering activity;

take decisions on admission of organization employees to works of risk levels II, III and IV of genetic engineering activity and maintenance of laboratory equipment;

exercise control over staff training on works with genetically engineered organisms, their fulfillment of sanitary-epidemic and personal hygiene requirements.

Personal composition and operation procedures for Compliance Committee on Biosafety Requirements and Anti-epidemic Regime of an organization shall be established by statutes and approved by the Head of the organization.

Organization staff members shall undergo periodic medical examination in accordance with the Procedures of Compulsory Medical Examination for Employees, established by the Resolution of the Ministry of Health of the Republic of Belarus of 8 August 2000, № 33.

In order to prevent unauthorized intrusion into the territory of an organization, its territory should be fenced, laboratory facilities are subject to 24-hour security.

Laboratories should be located in a separate building or isolated part of the building with a separate entrance. The Lab entrance door should be equipped with a

locking device, a sign indicating laboratory name and (or) number and sign "Biological Hazard" should be placed at its front in line with Annex II.

Requirements to the laboratory space planning, its facilities, interior furnishing, water supply facilities, canalization, laboratory equipment and furniture, the operation of supply and exhaust ventilation systems and other technical requirements shall be established in accordance with sanitary norms, rules and hygienic standards.

Laboratory premises should be separated into the “infectious” area to carry out genetic engineering activity and “clean” area, which is not used for genetic engineering activity.

Biological safety cabinets of classes II and III are used in the laboratory premises of the “infectious” area. The following main types of genetic engineering activity are carried out there:

studies in animal (infection, autopsy);

infected animal management;

centrifugation of genetically engineered organisms, drying, disintegration and other operations with probable aerosol formation;

infection of cell cultures and chicken embryos;

making suspensions;

work on keeping collection strains and other.

All types of genetic engineering activity shall be carried out in accordance with sanitary norms, rules and hygienic standards.

When works are being carried out, the doors of cabinet and pre-cabinet laboratory premises should be closed, exit from side premises is prohibited. Cabinet premises should be equipped with alarm systems for emergencies.

When carrying out genetic engineering activity, at least 2 people shall be present in the laboratory premises of the “infectious” area, one of them is either a medical specialist or a research scientist. The continuous work time with genetically engineered organisms of risk levels II, III and IV shall not exceed 4 hours with 30-60 minute breaks to follow.

Calling out of employees from the “infectious” area of laboratory premises during works is not allowed.

Permission to visit laboratories by engineering and technical personnel, non-permanent laboratory staff, shall be issued by the Lab Supervisor. A visit to the laboratory is carried out when the laboratory work has been finished and current disinfection is being performed. Engineering and technical personnel are accompanied by either a medical specialist or research scientist of the laboratory and their visit is registered in the Laboratory Visit Log.

Laboratory visit authorization forms and the Laboratory Visit Log are subject to approval by the Head of the organization.

As soon as all woks have been finished, the laboratory should be locked and sealed. If there are collection microorganism cultures, their storage facilities should be additionally sealed.

Genetically engineered organisms should be kept in the “infectious” area of laboratory facilities in the sealed refrigerator destined for assay storing. Inoculated medium (plating) should be placed into thermostats, refrigerators and cabinet units pursuant to corresponding methods. Isolated cultures of genetically engineered organisms and collection strains should be stored in the separate dedicated refrigerator, also sealed.

An inventory sheet shall be compiled for the stored genetically engineered organisms. It includes:

name of a genetically engineered organism;

number and date of issue of the Registration Certificate for a genetically engineered organism, issued according to the form of Annex X to the Instruction “On Accounting Procedures by State Legal Entities of Developed, Imported into the Republic of Belarus, Exported from the Republic of Belarus and Conveyed in Transit through its Territory Potentially Pathogenic and Pathogenic Genetically Engineered Organisms”;

data on transport, storage, use and deactivation of a genetically engineered organism.

Capacities containing genetically engineered organisms should have clear indelible endorsements or firmly glued labels with name of a genetically engineered organism, a strain number and lyophilisation date.

Organizations should use genetically engineered organisms for scientific research, vaccine development and immunobiological medicinal products.

Organizations should keep a record of genetically engineered organisms in accordance with the Instruction “On Accounting Procedures by State Legal Entities of Developed, Imported into the Republic of Belarus, Exported from the Republic of Belarus and Conveyed in Transit through its Territory Potentially Pathogenic and Pathogenic Genetically Engineered Organisms”. The Head of the organization shall hold responsibility for compliance with safety requirements for self-contained systems to carry out works of risk levels II, III and IV of genetic engineering activity in the organization.

**Annex I**
to the Instruction on safety requirements
for self-contained systems to carry out
works of risk levels II, III and IV
in genetic engineering activity

_____
(name of the organization)

_____
(name of the laboratory)

REGISTRATION LOG
of staff briefing at workplaces

Date started "__" _____ 20__
Date closed "__" _____ 20__

| N | Briefing date | Employee's surname and initials | Surname and initials of the Head of the laboratory providing briefing | Briefing subject matter | Employee's signature | Signature of the Head of the laboratory providing briefing |
|---|---|---|---|---|---|---|
| | | | | | | |

## SIGN "BIOLOGICAL HAZARD"

Accreditation procedure for self-contained systems to perform works of risk levels II, III and IV of genetic engineering activity shall be carried out in accordance with the Instruction, established by the Resolution of the Ministry of Health of the Republic of Belarus of 25 August 2006, № 65.

Accreditation of self-contained systems to perform works of risk level II of genetic engineering activity shall be carried out by the Compliance Committee on Biosafety Requirements and Anti-epidemic Regime of Regional Centers for Hygiene, Epidemiology and Public Health and the State Institution "Minsk City Center for Hygiene and Epidemiology" (Regional (Minsk City) Regime Committees).

Accreditation of self-contained systems to perform works of risk levels III and IV of genetic engineering activity shall be carried out by the Compliance Committee on Biosafety Requirements and Anti-epidemic Regime of the Ministry of Health of the Republic of Belarus (the Republican Regime Committee).

Regional (Minsk City) Regime Committees issue to organizations, located within relevant administrative-territorial entity an Accreditation Certificate to ascertain that carrying out works of risk level II of genetic engineering activity according to the form of Annex I shall be allowed in this self-contained system of the organization.

The Republican Regime Committee issues to organizations, located in the territory of the Republic of Belarus, an Accreditation Certificate to ascertain that carrying out works of risk levels III and IV of genetic engineering activity according to the form of Annex II shall be allowed in this self-contained system of the organization.

Documents to obtaining an Accreditation Certificate by organizations shall be submitted to:

Regional Centers for Hygiene, Epidemiology and Public Health, the State Institution "Minsk City Center for Hygiene and Epidemiology" to perform works of risk level II of genetic engineering activity;

the Ministry of Health of the Republic of Belarus to perform works of risk levels III and IV of genetic engineering activity.

An Accreditation Certificate to ascertain that carrying out works of risk levels II, III and IV of genetic engineering activity is allowed in these self-contained systems shall be issued on the basis of:

an application submitted by the Head of the organization;

an explanatory note that specifies technological procedures, carried out operations, biomass volumes, equipment location in the premises, motion scheme of genetic engineering activity products, personnel, by-products, availability and assessment of engineering and technical systems, provided safety measures and environmental protection (wastewater management system, ventilation management system, management of transfer units, autoclaves, sterilization and bath units), data on personnel training, vaccination dates, arrangements for use of personal protection equipment;

graphic material (planning scheme of structural subdivisions of the organization, functional purpose of premises, equipment layout, distribution of ventilation systems, heating, sewerage and water supply);

inspection acts of sanitary and epidemiological state of the organization laboratory (of the date of its last certification):

the Compliance Committee on Biosafety Requirements and Anti-epidemic Regime;

Regional (Minsk City) Regime Committees to obtain an Accreditation Certificate for genetic engineering activity in the self-contained systems of risk level II;

The Republican Regime Committee to obtain an Accreditation Certificate for genetic engineering activity in the self-contained systems of risk levels III and IV.

The following shall be evaluated in the course of accreditation procedures for self-contained systems of risk levels II, III and IV of genetic engineering activity:

meeting requirements of the Law of the Republic of Belarus "On Safety in Genetic Engineering Activity";

meeting requirements of the Sanitary-epidemic Regime and personal hygiene by organization employees;

meeting requirements to the layout and interior decoration of premises of organization laboratories, their heating and ventilation, natural and artificial illumination, sanitary and technical equipment, arrangements for use of personal protection equipment;

organization laboratory staffing;

efficient planning for localization and accident management.

In order to obtain an Accreditation Certificate, the investigation for compliance with the specified requirements by organizations engaged in genetic engineering activity in self-contained systems of:

risk levels III and IV by representatives of the Republican Regime Committee is mandatory;

risk level II by representatives of Regional (Minsk City) Regime Committees shall be carried on when required.

Subsequent to the investigation results, the Republican (Regional, Minsk City) Regime Committee shall within a month of the date of submission of all necessary documentation by the organization draw up its conclusion on issue (refusal to issue) of an Accreditation Certificate.

A conclusion on issue (refusal to issue) of an Accreditation Certificate shall be drawn up in two copies, one copy remains with the Republican (Regional, Minsk City) Regime Committee and the other one shall be directed to the Head of the organization.

In the event of a refusal to issue an Accreditation Certificate to the organization, the organization may not earlier than in six months of the date of the conclusion on a refusal to issue an Accreditation Certificate submit the documents for re-accreditation.

A conclusion of the Republican (Regional, Minsk City) Regime Committee on issue of an Accreditation Certificate provides authority for issue of an Accreditation Certificate. An Accreditation Certificate shall be issued within 5 days from finalizing a conclusion on its issue. An Accreditation Certificate is valid for up to 5 years.

An Accreditation Certificate may be invalidated, provided that the specified requirements have been violated or the premises layout and their functional purpose have been changed without authorization.

Methodological Guidelines and counseling on compliance procedures for safety requirements to genetic engineering activity in self-contained systems of risk levels II, III and IV are provided by the State Institution “Republican Center for Hygiene, Epidemiology and Public Health”.

**Annex I**
to the Instruction on accreditation
procedures for self-contained systems
to carry out works of risk levels II, III
and IV in genetic engineering activity

AFFIRM
Chief State
Sanitary Inspector
_____
(name of
_____
administrative-territorial entity)
_____
(signature, initials, surname)
_____
(date, month, year)

ACCREDETATION CERTIFICATE
for the self-contained system of risk level II
of genetic engineering activity

"__" _____ 20__ N _____

This Accreditation Certificate issued by _____
(full name
_____
of the organization, its registered address)
and certifies that _____
(name of the laboratory)
complies with the Sanitary-Epidemiological
Legislation of the Republic of Belarus_____
(specify details of sanitary
_____
regulations, rules and hygienic standards)
Scope of accreditation – Genetic Engineering Activity in
Self-contained Systems of Risk Level II.
Accreditation Certificate valid until "__" _____ 20__

Chairman of the Regional
(Minsk city)
Regime Committee_____ _____
(signature) (initials, surname)

**Annex II**
to the Instruction on accreditation
procedures for self-contained systems
to carry out works of risk levels II, III
and IV of genetic engineering activity

AFFIRM
Deputy Minister of Health -
Chief State Sanitary Inspector
of the Republic of Belarus

_____
(signature, initials, surname)

_____
(date, month, year)

ACCREDETATION CERTIFICATE
for the self-contained system of risk levels III and IV
of genetic engineering activity

"__" _____ 20__ N _____

This Accreditation Certificate issued by _____
(full name

_____
of the organization, its registered address )

and certifies that _____
(name of the laboratory)

complies with the Sanitary-Epidemiological
Legislation of the Republic of Belarus _____
(specify details of sanitary

_____
regulations, rules and hygienic standards)

Scope of accreditation - Genetic Engineering Activity in Self-contained Systems of Risk Levels III and IV.

Accreditation Certificate valid until "__" _____ 20__

Chairman of the Republican
Regime Committee _____ _____
(signature) (initials, surname)

## 1.4. RISK ASSESSMENT OF POSSIBLE ADVERSE EFFECTS OF GENETICALLY ENGINEERED ORGANISMS ON THE ENVIRONMENT AND HUMAN HEALTH

Risk assessment of possible adverse effects of genetically engineered organisms on the environment shall be conducted according to the procedures, established by the Instruction and approved by the Resolution of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of 29

August 2006, №55 to identify risk factors of possible adverse effects of genetically engineered organisms on the environment, estimate of probability and danger level of adverse effects of genetically engineered organisms on the environment, determine methods for their prevention and control.

Risk assessment shall be performed by:

legal entities and individual entrepreneurs that carry out genetic engineering activity in their preparation of materials to be submitted for cases, stipulated by the Republic of Belarus legislation;

experts for cases, stipulated by the Republic of Belarus legislation.

Risk assessment shall be performed by the investigation of:

recipient organisms and parental organisms (biological characteristics of recipient organisms and parental organisms, including information on Centers for their development and Genetic Diversity Centers, their habitats and conditions, under which organisms may have high survival potential and fast reproduction ability);

donor organisms (sources and corresponding characteristics of donor organisms);

vectors – self-replicating DNA molecules, used in genetic engineering for gene transfer of a donor organism into a recipient organism (vector characteristics, including its identification data, sources of origin and its host range);

insertions and (or) characteristics of genetic engineering modifications (genetic characteristics of the inserted deoxyribonucleic acid sequence, biochemical and physiological protein functions, which are the products of the inserted deoxyribonucleic acid sequence and characteristics of genetic engineering modifications);

genetically engineered organisms (identification data of a genetically engineered organism, distinctions between biological characteristics of a genetically engineered organism and recipient or parental organism characteristics, including identification and detection methods of a genetically engineered organism, their accuracy, sensibility and reliability);

destined use of genetically engineered organisms, including new or changed (modified) use as compared to recipient or parental organisms;

environment in places of intended release of a genetically engineered organism (receiving environment) and interaction of a genetically engineered organism with parts of the receiving environment (information on geographic, climatic and environmental characteristics of the receiving environment, including relevant information on possible effects of genetically engineered organisms on biodiversity in the prospective potential receiving environment).

Risk assessment shall include:

identification of risk factors (identification of any genotypic and phenotypic characteristics of genetically engineered organisms, associated with genetic

engineering modifications, which may have adverse effects on the environment and human health);

probability estimate of a risk factor, taking into account the receiving environment character;

scale estimate of possible effects on the environment and human health of the identified risk factor;

estimate of possible prevention and control over the identified risk factor effects on the receiving environment;

acceptability estimate of the identified risk factor effects on the environment and human health and, if required, the strategy determination to monitor these effects;

risk assessment of cumulative harmful impacts of genetically engineered organisms on the environment and human health on the basis of estimate of probability and effects of all identified risk factors;

conclusion on whether the overall risk is acceptable and (or) controllable;

in the event of unassessability of a risk factor and (or) overall risk acceptability, a conclusion on necessity to obtain further information by experts involved in the State Expertise or elaboration of an activity plan for risk prevention, control and management, as well as monitoring plan for release of genetically engineered organisms into the environment.

Risk assessment data shall be included by:

legal entities and individual entrepreneurs engaged in genetic engineering activity in the materials for cases, stipulated by the Republic of Belarus legislation;

experts for cases, stipulated by the Republic of Belarus legislation.

Procedures and uniform requirements to risk assessment of possible adverse effects of genetically engineered organisms on human health shall be established by the Provision, approved by the Resolution of the Council of Ministers of the Republic of Belarus of 4 May 2010, № 677.

Risk assessment is carried out to identify possible adverse effects of genetically engineered organisms on human health, probability estimate and danger levels of such effects, methods for their prevention and control.

Risk assessment procedure of possible adverse effects of genetically engineered organisms on human health shall include the following steps:

identification of risk factors;

assessment of possible adverse effects of each identified risk factor on human health, taking into account use of genetically engineered organisms;

scale assessment of possible impacts of each identified adverse effect of genetically engineered organisms on human health in their potential use (realization);

determination of risk magnitude associated with each identified risk factor, taking into account probability and scales of possible adverse effects;

assessment of overall risk on the basis of estimate of probability and scales of all identified risk factor effects;

data compilation on risk assessment in regard to its acceptability;

strategy determination for the risk management.

Risk assessment criteria:

scientifically grounded, integrated and individual approaches;

collation of identified characteristics of genetically engineered organisms that jeopardize human health with analogous characteristics of non-genetically modified parent organisms;

sequential analysis of each stage of the genetically engineered organism development, its intended use and potential environment for its release;

Risk assessment procedures of possible adverse effects of genetically engineered organisms on human health shall determine:

safety of any effects resulting from genetic modifications;

safety of new proteins resulting from genetic modifications (toxicity, allergenicity);

nutrition value reduction of genetically modified food products;

possible transfer into the gastrointestinal microflora of antibiotic-resistant genes.

Risk assessment of possible adverse effects of genetically engineered organisms on human health shall be undertaken by legal entities and individual entrepreneurs engaged in genetic engineering activity. Risk assessment data shall be included according to the procedures, established by the legislation, in materials submitted by specified legal entities and individual entrepreneurs to the Ministry of Natural Resources and Environmental Protection to carry out the State Safety Expertise of Genetically Engineered Organisms.

Risk assessment results may be reviewed, provided that new information on a genetically engineered organism and its effects on human health has been submitted.

Materials that contain risk assessment data on possible adverse effects of genetically engineered organisms on human health and the environment, as well as such risk prevention measures and genetically engineered specimens are objects of the State Safety Expertise of Genetically Engineered Organisms.

The State Safety Expertise of Genetically Engineered Organisms shall be carried out to identify permissibility of their release into the environment for testing and use for economic purposes based on genetically engineered organism detection and analysis of risk assessment data on possible adverse effects of genetically engineered organisms on human health and the environment.

Non-pathogenic genetically engineered organisms under their first release into the environment for testing and in the course of the State Registration of genetically engineered varieties of plants, breeds of animals and strains of non-pathogenic

genetically engineered microorganisms destined for use for economic purposes are subject to the State Safety Expertise of Genetically Engineered Organisms.

The State Safety Expertise of Genetically Engineered Organisms shall be carried out on the basis of an application of the interested individual, 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 expense of the Expertise initiator in accordance with the Agreement, concluded by the interested individual and 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 Safety Expert Board 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 Collegial Consultative Body formed from a number of officials of authorized Republican Bodies of State Administration in the area of genetic engineering activity, scientists and professionals. The Regulation on the Expert Board and its members 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 with them by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus. Expert candidates for the State Safety Expertise of Genetically Engineered Organisms are recommended to the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus by the Expert Board. Leading in a particular area of expertise research organizations of the Republic of Belarus, scientists and professionals who are the citizens of the Republic of Belarus may act as experts. Interested individuals, including the employees of the State Safety Expertise of Genetically Engineered Organisms initiator may not be recruited as experts.

Based on the findings of the State Safety Expertise of Genetically Engineered Organisms, experts prepare a conclusion of the State Safety Expertise of Genetically Engineered Organisms, which offers firm conclusions on feasibility (infeasibility) of release of genetically engineered organisms into the environment for testing or their use for economic purposes. A conclusion of the State Safety Expertise of Genetically Engineered Organisms shall be analyzed at the Expert Board Meeting to check the validity of its conclusions, accept recommendations on feasibility of release of genetically engineered organisms into the environment for testing or their use for economic purposes and direct recommendations and conclusions of the State Safety Expertise of Genetically Engineered Organisms to the appropriate specially authorized Republican Body of State Administration in the area of safety in genetic engineering activity and interested individual, acting as the initiator of this Expertise.

Procedures for the State Safety Expertise of Genetically Engineered Organisms and indicative terms of agreements, concluded for its execution shall be established by the Provision, approved by the Resolution of the Council of Ministers of the Republic of Belarus of 8 September 2006, №1160.

In order to carry out an expertise and obtain expertise conclusions, an interested legal entity or individual entrepreneur, the expertise initiator (applicant), shall submit to the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus the documents specified in a consolidated list of administrative procedures, which are exercised by State bodies and other organizations with regard to legal entities and individual entrepreneurs, approved by the Council of Ministers of the Republic of Belarus of 17 February 2012, № 156. In such a case an application (a form) for the State Safety Expertise of Genetically Engineered Organisms shall be completed according to form of Annex I.

Risk assessment data on possible adverse effects of genetically engineered organisms on human health and the environment, as well as risk prevention measures (hereafter referred to as "risk assessment data") for genetically engineered organisms belonging to higher plants shall be submitted according to an information list in line with Annex II; for genetically engineered organisms belonging to other organisms different from higher plants according to an information list in line with Annex III both in hard copy and electronic format.

When found appropriate, an applicant may submit arguments to support the proposal to consider risk assessment data as sensitive data that shall be used in accordance with legislation. In such a case an applicant shall submit risk assessment data in two copies, one of them shall be submitted as hard copy with specification "it contains sensitive data", the other one in electronic format, in which sensitive data shall be substituted for an endorsement "sensitive data".

The following data may not be considered as sensitive:

name and postal address;

taxonomic description of a recipient organism used for the development of genetically engineered organisms;

taxonomic description of a donor organism used for the development of genetically engineered organisms;

generic description of the used vector and insertion technique of the transgenic construction;

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

testing results of genetically engineered organisms, needed for risk assessment of possible adverse effects of genetically engineered organisms on human health and the environment;

earlier risk assessment testing results of possible adverse effects of genetically engineered organisms on human health and the environment and decisions on release of genetically engineered organisms taken on the basis of these results;

Emergency Action Plan.

The Ministry of Natural Resources and Environmental Protection of the Republic of Belarus registers an application and within 30 days of the day of it receipt shall conclude an Expertise Agreement with the applicant.

A conclusion of the State Safety Expertise of Genetic Engineering Activity shall be submitted within the time limits, specified in a list of administrative procedures that are carried out by the Ministry of Natural Resources and Environmental Protection and its territorial bodies with regard to legal entities and individual entrepreneurs.

After signing an Agreement, the Ministry of Natural Resources and Environmental Protection shall within five days submit:

a copy of the application together with all required documentation to the Safety Expert Board of Genetically Engineered Organisms of the Ministry of Natural Resources and Environmental Protection to arrange an expertise;

risk assessment data to the State Scientific Institution "Institute of Genetics and Cytology of the National Academy of Sciences of Belarus", exercising functions of the National Co-ordination Biosafety Centre to furnish information to all concerned.

The National Co-ordination Biosafety Centre shall within five days after obtaining risk assessment data publish them on its website.

Legal entities and individual entrepreneurs concerned may within 60 days of the day of risk assessment data publication on the information site of the National Co-ordination Biosafety Centre familiarize themselves with the data and forward their comments and proposals to the National Co-ordination Biosafety Centre, which after the specified deadline, shall summarize comments and proposals and submit them within 10 days for the Expert Board approval.

The Expert Board shall within 10 days of the day of obtaining of all the required documentation recommend expert candidates to carry out an expertise.

In line with the Expert Board recommendations the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus shall choose expert candidates to carry out an expertise and within 30 days of the decision day on expert candidates enter with them into the Expertise Agreement.

The following refers to model agreement clauses:

scope of an Agreement;

rights and liabilities of the Agreement Parties;

amount and payment terms for the services rendered under the Agreement;

responsibility for failure to perform obligations or default in performance of obligations under the Agreement;

effective period of an Agreement;

procedures for change of Agreement conditions, cancellation and termination of Agreements;

other, not contradicting the legislation in force conditions the Parties find necessary to stipulate in Agreements;

The Expertise shall be carried out within 120 days of the day of entry into the Agreement.

During the Expertise if faced with impossibility to assess the risk acceptability of possible adverse effects of genetically engineered organisms on the environment, may recommend to the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus to request additional information on genetically engineered organisms from the applicant.

The Ministry of Natural Resources and Environmental Protection of the Republic of Belarus shall within 5 days of the day of receiving recommendations direct a written notification to the applicant on the need for additional information to be submitted within 30 days. In such a case the Expertise period shall be extended for the time elapsed after the direction of a notification to the applicant and receiving further materials from them.

An applicant should give experts access to the specimens of genetically engineered organisms to carry out an expertise.

Subsequent to the expertise findings, the experts shall prepare and submit to the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus a conclusion of the State Safety Expertise of Genetically Engineered Organisms, which shall be signed by the experts or if a legal entity fulfils function of an expert, by the Head of a legal entity and certified by official seal of the legal entity.

Within 5 days of the day of obtaining a conclusion, the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus shall submit it to the Expert Board.

The Expert Board shall within 30 days of the day of receiving a conclusion consider it, accept recommendations on possible release of genetically engineered organisms into the environment for testing and their use for economic purposes and direct the recommendations and conclusion to the appropriate designated Republican body of State Administration in the area of safety in genetic engineering activity and the applicant.

**Annex I**
to the Provision on
State Safety Expertise procedures
for genetically engineered organisms
and tentative terms of Agreement
established for its execution

Form

APPLICATION
for execution of the State Safety Expertise
in Genetic Engineering Activity

Applicant _____
(name of the legal entity and surname

_____
and initials of the entrepreneur, mail address,

_____
telephone, fax, e-mail)

in the name of _____
(position, surname, initials of the Head of the legal entity)

addresses request to the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus to carry out the State Safety Expertise of genetically engineered organisms.

1. Information on genetically engineered organisms:

1.1. recipient organism:

family_____

genus_____

species _____

subspecies _____

1.2. variety / breeding line _____

1.3. code of genetically engineered organisms _____

2. Description of characters and characteristics, introduced or changed by genetic engineering modification

_____

3. Expertise objective of genetically engineered organisms <*>.

Hereby certify that the data submitted by me for the State Safety Expertise of genetically engineered organisms are full and accurate. I was warned of the responsibility for non-disclosure of information on adverse effects of declared by me genetically engineered organisms on human health and the environment condition in accordance with the Republic of Belarus legislation.

Enclosure: in ___ pages, in ____ copies

_____ _____
(signature of the applicant) (initials, surname)

Date "__" _____ ____

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<*> Obtaining a permit for release of non-pathogenic genetically engineered organisms into the environment for testing or a State Registration Certificate of genetically engineered varieties of plants, breeds of genetically engineered animals, strains of non-pathogenic genetically engineered microorganisms.

**Annex II**
to the Provision on
State Safety Expertise procedures
for genetically engineered organisms
and tentative terms of Agreement
established for its execution

## DATA LIST
## ON RISK ASSESSMENT OF POSSIBLE ADVERSE EFFECTS OF GENETICALLY ENGINEERED ORGANISMS BELONING TO HIGHER PLANTS (GYMNOSPERMOUS AND ANGIOSPERMOUS) ON HUMAN HEALTH AND THE ENVIRONMENT AND RISK MANAGEMENT MEASURES

1. Information on biological features of a recipient organism:
1.1. full name:
family;
genus;
species;
subspecies;
variety / breeding line;
common name;
1.2. information on reproduction features:
reproduction method;
specific reproduction factors;
procreation period (time);
sexual compatibility with other cultivated species and wildlife species;
1.3. survival in the environment:
ability to form structures for survival or pass into the dormant state;
specific survival factors;
1.4. dissemination:
pathways and degree of dissemination;
specific dissemination factors;
1.5. geographic range;
1.6. description of natural habitats, including data on natural predators, parasites, competitors and symbionts;
1.7. potentially significant interaction with other organisms, different from plants, in ecosystems specific to natural habitats, including information on toxicity to humans, animals and other organisms;
2. Information on biological features of a donor organism:

2.1. full name:
family;
genus;
species;
subspecies;
variety / breed / strain;
common name;
2.2. donor organism origin;
2.3. biological features of a donor organism.
3. biological features of a vector:
3.1. vector nature and origin, natural habitat and corresponding safety characteristics;
3.2. structure of transposons, promoters and other noncoding genetic segments used for the genetic construction development, needed for its transfer into and functioning in a recipient organism;
3.3. frequency of mobilization (mobile capacity) of the inserted vector or transfer into other organisms;
3.4. factors that may affect vector adaptive ability in other host organisms.
4. information on genetic engineering modification character;
4.1. techniques used for the genetic construction development and transfer and transgenic organisms' selection;
4.2. DNA fragment description of the inserted into genome (plasmon) recipient organism (size and source, i.e. the donor organism (organisms) name and the estimated function of each component or DNA insertion region, including regulatory and other elements of transgenic functioning), structure (sequencing) and functional correspondence of the inserted DNA fragment, the presence of known potentially harmful sequences in it.
4.3. presence in the inserted DNA of any unknown sequences and information on the extent, to which the insertion is limited by the DNA required for the intended function;
4.4. characterization of the recipient genome (plasmon) modification site, the insertion location (incorporated into the chromosome, chloroplasts, mitochondria or in non-integrated state);
4.5. incorporation stability of the DNA introduced into genome (plasmon) of a recipient organism;
4.6. quantity of transgenic copies;
4.7. description of the detection and identification technique for the inserted DNA fragment; sensitivity, reliability and specificity of the technique.
5. Information on biological features of genetically engineered organisms:

5.1. description of genetic features and phenotypic characteristics, in particular new unknown traits and characteristics that have started to show up or stopped showing up in genetically engineered organisms as compared to the recipient organism;

5.2. genetic stability of genetically engineered organisms;

5.3. level and extent of transgenic expression; the evaluation method for transgenic expression, its sensitivity;

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

5.5. parts of a plant, in which transgenes are expressed (roots, leaves, pollen etc.);

5.6. information on earlier genetic engineering modifications of genetically engineered organisms;

5.7. genetically engineered organism characteristic in relation to human health safety: toxic or allergenic effects of genetically engineered organisms and / or products derived from genetically engineered organisms;

5.8. offered techniques for detection and identification of genetically engineered organisms, their accuracy, sensitivity and reliability.

6. information on potentially receiving environment:

6.1. the intended release field location (region, district, settlement, land plot belonging to the land-owner or land-user, including its full name);

6.2. proximity to nature reserves, sanctuaries and other environmental facilities and areas;

6.3. plot description: its size and treated area; climatic, geological and agrological characteristics; flora and fauna;

6.4. comparison of recipient organism natural habitats with the field destined for release of genetically engineered organisms;

6.5. intervention in natural area methods (cultivation and irrigation methods etc.)

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

7.1. biological features of genetically engineered organisms (as compared to intact recipient organisms), which may have an effect on survival, propagation and dissemination in the potential receiving environment;

7.2. known and predicted conditions of the potential receiving environment, which may have an effect on survival, propagation and dissemination of genetically engineered organisms;

7.3. genetically engineered organisms' competitiveness (as compared to intake recipient organisms);

7.4. manifestation probability in genetically engineered organisms of undesirable properties, characters;

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

7.6. ability to transfer genetic information: occurrence in the potential receiving environment of wildlife or culture allied species capable for hybridization with genetically engineered organisms, the likelihood of transfer of genetically engineered organism transgenes to such organisms;

7.7. detection and description of target organisms of transgenic products;

7.8. probable mechanism and interaction result of genetically engineered and target organisms;

7.9. detection and description of organisms, which are not targets of transgenic products and may be exposed to the genetically engineered organism effect;

7.10. other potentially possible interactions of genetically modified organisms with the environment;

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

8. information on release of genetically engineered organisms into the environment; monitoring, control and clearing of a field; response to emergencies during release and testing:

8.1. information on release of genetically engineered organisms:

description of procedures for intended release of genetically engineered organisms, release objectives;

estimated start and end dates of release and a calendar plan for experiments associated with release, including the number and duration of experiments;

estimated number of released genetically engineered organisms, the quantity of genetically engineered organisms as per unit of field area;

distance from the field to plantings of wildlife and cultivated related species capable for hybridization with genetically engineered organisms;

information on the fact and earlier release results of genetically engineered organisms into the environment;

8.2. monitoring techniques:

monitoring techniques for genetically engineered organisms, as well as monitoring of possible interactions with potentially vulnerable environmental elements;

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

methods to identify the transfer of transgenes to other organisms;

monitoring frequency and duration;

8.3. control over release of genetically engineered organisms:

measures to be used to prevent the dispersal of pollen and seeds of genetically engineered organisms;

methods and procedures aimed at protecting the release field from the invasion of unauthorized persons;

methods and procedures to protect the field from undesirable attendance of other organisms;

8.4. field clearing:

procedures for field clearing after the release;

methods for deactivation of genetically engineered organisms at the end of experiments;

8.5. action plan for emergency situations related to unintended spread of genetically engineered organisms:

methods and procedures to monitor genetically engineered organisms in case of their unexpected spread;

disposal and recovery methods for plants, animals, etc. exposed to genetically engineered organisms during or after their unexpected spread;

protection plans for human health and the environment in the event of adverse effects of genetically engineered organisms.

_____ _____

(signature of the applicant) (initials, surname)

Annex III
to the Provision on
State Safety Expertise Procedures
for genetically engineered organisms
and tentative terms of Agreement
established for its execution

**DATA LIST**
**ON RISK ASSESSMENT OF POSSIBLE ADVERSE EFFECTS OF GENETICALLY ENGINEERED ORGANISMS, BELONGING TO OTHER ORGANISMS DIFFERENT FROM HIGHER PLANTS, ON HUMAN HEALTH AND THE ENVIRONMENT AND RISK MANAGEMENT MEASURES**

1. Biological features of donor and recipient organisms:

1.1. full name;

family;

genus;

species;

subspecies;

common name;

other names (of a strain, etc.);

1.2. degree of relationship between donor and recipient organisms, whether it is possible to exchange genetic material between them in a natural way;

1.3. identification methods for donor and recipient organisms: phenotypic and genetic markers;

1.4. laboratory or natural habitat techniques for detection, monitoring, quantity assessment of donor and recipient organisms; sensitivity, reliability and specificity of methods used for detection and identification of donor and recipient organisms;

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

1.6. ability to transfer or exchange genetic information with other organisms;

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

1.8. pathogenic, ecological and physiological characteristics of donor and recipient organisms:

generation period in natural ecosystems, gamic and agamic reproductive cycles;

information on survival ability in the environment, including seasonality and ability to form necessary for survival structures: spores, sclerotia etc.;

pathogenity: infectivity, toxigenicity, virulence, allergenicity, the presence of pathogen transfer vectors, feasible vectors, host range, the possible activation of latent viruses (proviruses), the ability to colonize other organisms;

antibiotic resistance, possible use of these antibiotics for the prophylaxis and therapy in humans and domestic animals;

congenital vector nature: structure, mobilization frequency, specificity, the presence of resistance genes.

2. Biological features of a vector:

2.1. vector nature and origin, natural habitat and corresponding safety characteristics;

2.2. structure of transposons, promoters and other genetic noncoding segments, used to develop the genetic construction and needed for its transfer and functioning in the recipient organism;

2.3. mobilization frequency (mobile ability) of the inserted vector or its transfer to other organisms;

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

3. Genetically engineered organisms' characteristic:

3.1. information on genetic engineering modification:

techniques used for development and transfer of the transgenic construction and selection of transgenic organisms;

description of the DNA fragment inserted into the recipient organism genome, including regulatory and other elements that affect the performance of transgenes;

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

presence in the inserted DNA of unknown sequences and information on the extent to which the insertion is limited by the DNA required for the intended function;

characteristic of modification site of the recipient genome, the insertion localization;

incorporation stability of the DNA, introduced into the genome of the recipient organism;

technique description for the detection and identification of the inserted DNA fragment; sensitivity, reliability and specificity of this technique (s);

3.2. information on a genetically engineered organism:

description of genetic traits or phenotypic characteristics, especially new traits and characteristics, which have started to show up or stopped showing up in genetically engineered organisms as compared to recipient organisms;

genetic stability of genetically engineered organisms;

transgene (s) expression degree and level. Method for transgene expression estimate, its sensitivity;

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

history of earlier genetic engineering modifications of genetically engineered organisms;

3.3. characteristics of genetically engineered organisms in relation to human health;

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

risks of possible adverse effects on human health, associated with use of products developed from genetically engineered organisms;

colonization ability of genetically engineered organisms;

pathogenicity of genetically engineered organisms in relation to immunocompetent human organism.

4. Information on potential receiving environment:

4.1. intended release field location (region, district, settlement, land plot belonging to the land-owner or land-user, including its full name);

4.2. physical and biological affinity for a human and / or any other significant biota;

4.3. proximity to nature reserves, sanctuaries and other protected nature facilities and areas; distance from the land plot (field) to places of water intake (drinking water);

4.4. population size in the area of release and population activity, economically associated with use of natural resources of the area;

4.5. site (field) description, including its size, cultivation, climatic, geological and agrochemical characteristics;

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

4.7. description of ecosystems, target organisms and organisms belonging to non-transgenic products, which may be affected by release of genetically engineered organisms;

4.8. comparison of recipient organism natural habitats with the intended release field (site) of genetically engineered organisms;

4.9. methods for natural area intervention (cultivation, irrigation methods, etc.).

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

5.1. biological features of genetically engineered organisms (as compared to intact recipient organisms), which may affect survival ability, propagation (reproduction) and dissemination in the potential receiving environment;

5.2. known and prognosticated conditions of the potential receiving environment, which may affect survival ability, propagation (reproduction) and dissemination of genetically engineered organisms;

5.3. specific agent sensitivity and resistance;

5.4. genetically engineered organism characteristic and behavior, their environmental impact under the conditions, stimulating the natural habitat (environment) (greenhouse, growth chamber);

5.5. ability to transfer genetic information: transgenic transfer probability from genetically engineered organisms to the organisms, inhabiting the potential receiving habitat (environment) or from these organisms to genetically engineered organisms;

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

5.7. dissemination pathways of genetically engineered organisms in the potential receiving environment (habitat), known or potential means of interaction with dissemination agents, including inhalation, ingestion, surface contact, penetration into pores, etc. .;

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

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

5.10. identification and description of target organism transgenic products;

5.11. proposed mechanism and interaction result of genetically engineered and target organisms;

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

5.13. shift probability in the nature of relationship of genetically engineered organisms with other organisms, changes in host range;

5.14. known or possible involvement of genetically engineered organisms in biochemical processes;

5.15. other potentially-enable interactions of genetically engineered organisms with the environment.

6. Information on release, monitoring, control, field (site) clearing and response to emergencies;

6.1. information on release of genetically engineered organisms:

description of intended genetically engineered organism release, its objectives;

anticipated dates for the beginning and end of release, a calendar plan for experiments associated with release, including the number and duration of experiments;

proposed quantity of genetically engineered organisms to be released;

release technique of genetically engineered organisms;

field preparation for release;

staff protection measures during the release;

field treatment after the release;

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

6.2. monitoring methods (techniques):

observation techniques for genetically engineered organisms, their environmental interaction monitoring;

specificity (possibility to identify genetically engineered organisms, distinguish them from donor and recipient organisms), sensitivity and reliability of genetically engineered organism monitoring techniques;

identification methods for the transgene transfer to other organisms;

monitoring duration and frequency;

6.3. control over genetically engineered organisms release;

methods and procedures that allow to avoid or minimize the genetically engineered organism dissemination outside the territory (field), determined for release of genetically engineered organisms;

methods and procedures aimed at protecting the intended for release territory (field) from the invasion of unauthorized persons; methods and procedures that protect the territory from unwanted visits of other organisms;

6.4. territory (field) clearing:

type and size of the alleged territory contamination as a result of genetically engineered organisms' release;

possible risks, associated with the territory contamination;

prospective depollution actions;

6.5. disaster contingency plan:

control methods and procedures of genetically engineered organisms in the event of unexpected dissemination;

decontamination methods for contaminated territories, e.g. genetically engineered organisms' deactivation;

disposal or recovery methods for plants, animals and other organisms, exposed to genetically engineered organisms during or after their unexpected dissemination;

isolation methods for infected territories;

protection plans for human health and the environment in the event of identified adverse effects of genetically engineered organisms.

A conclusion of the State Safety Expertise of Genetically Engineered Organisms and Expert Board recommendations shall be considered in taking a decision: 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; the Ministry of Agriculture and Food of the Republic of Belarus – on issue (refusal to issue) of the State Registration Certificate for genetically engineered varieties of plants, breeds of

genetically engineered animals and strains of non-pathogenic genetically engineered microorganisms.

## 1.5. RELEASE OF GENETICALLY ENGINEERED ORGANISMS INTO THE ENVIRONMENT

Article 15 of the Law of the Republic of Belarus "On Safety in Genetic Engineering Activity" provides that release of potentially pathogenic and pathogenic genetically engineered organisms is not allowed.

Release of non-pathogenic genetically engineered organisms into the environment for testing is carried out, provided that 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 is issued on the basis of 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.

Tests of non-pathogenic genetically engineered organisms on their first release into the environment should be conducted in trial fields and other objects, specially equipped for preventing possible adverse effects of these organisms on the environment and meeting the safety requirements, established by the Resolution of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of 29 August 2006, № 56. The Resolution establishes that the test field or other facility, destined for testing of non-pathogenic genetically engineered organisms on their first release into the environment shall have:

an announcement board, which is placed at entrance to the test field and provides information as follows:

a name of the legal entity or surname and initials of the individual entrepreneur engaged in testing of genetically engineered organisms (hereinafter referred to as "legal entity or individual entrepreneur");

test field area;

a warning sign to state that this trial field is used for testing of genetically engineered organisms;

a Trial Field Certificate, which is in the possession of a legal entity or an individual entrepreneur. A Trial Field Certificate shall be approved by the Head of a legal entity or individual entrepreneur by agreement with appropriate territorial body of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus. The following shall be specified in the Trial Field Certificate:

a name of the legal entity or surname and initials of the individual entrepreneur engaged in testing of genetically engineered organisms;

a species (species) of a genetically engineered organism, subject to testing;

region, district, land-owner, land-user or owner of a land plot, used for testing of genetically engineered organisms;

a trial field structure with reference to nearby settlements and indication of the trial field area;

information on located at a distance of 500 meters from the trial field crops and plantings of genetically engineered plants and traditional breeding cultures;

a list of wild animal species, inhabiting the trial field and at a distance of 300 meters from it, species of wild plants, growing in the adjoining to trial field territories at a distance of 300 meters from the trial field;

a description of the soil type, the crop rotation system, used organic and mineral fertilizers, plant protection products against pests, diseases and weeds;

a fence, preventing unauthorized entry into their territory of people and animals and providing protection for genetically engineered organisms from unauthorized move beyond the trial field, the transfer of properties they have gained as a result of genetic engineering activity to other organisms;

facilities for deactivation of genetically engineered organisms and their residues;

a storage for genetically engineered products with protection against unauthorized access, provided that the storage of such products should be carried out in the trial field;

a ground or room for cleaning equipment after its contact with genetically engineered organisms, which exclude unauthorized movement beyond the trial field of genetically engineered organisms or their parts.

a legal entity or individual entrepreneur engaged in testing of genetically engineered organisms in the trial field should exercise control over effectiveness of protection measures and observe safety procedures when performing works with genetically engineered organisms.

A legal entity or individual entrepreneur engaged in testing of genetically engineered organisms in the trial field shall bear responsibility for safety in genetic engineering activity in accordance with the procedures, established by the Republic of Belarus legislation.

The procedure for issuance of release certificates for non-pathogenic genetically engineered organisms into the environment for testing is established by the Regulation, approved by the Council of Ministers of the Republic of Belarus of 8 September 2006, №1160.

The effect of this Regulation shall not apply to release into the environment for testing of non-pathogenic genetically engineered organisms, developed by traditional breeding techniques with use as an initial material of genetically engineered varieties of plants, breeds of animals, strains of microorganisms included in the State Register

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

Release of non-pathogenic genetically engineered organisms into the environment for testing shall be carried out by virtue of a permit, issued by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus on the basis of a positive conclusion of the State Safety Expertise of Genetically Engineered Organisms.

In order to obtain a permit, a legal entity or individual entrepreneur shall submit to the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus the documents, specified in a consolidated list of administrative procedures performed by State bodies and other organizations with regard to legal entities and individual entrepreneurs, established by the Resolution of the Council of Ministers of the Republic of Belarus of 17 February 2012, № 156. In such a case, an application for a permit shall be prepared according to the form of Annex I.

The Ministry of Natural Resources and Environmental Protection of the Republic of Belarus shall consider the submitted documents within the time limit specified in a list of administrative procedures, performed by the Ministry of Natural Resources and Environmental Protection and its territorial bodies with regard to legal entities and individual entrepreneurs and take a decision on issuance or refusal to issue a permit.

A positive conclusion of the State Safety Expertise of Genetically Engineered Organisms shall be considered as a basis for issuance of a permit.

A refusal to issue a permit applies to cases, stipulated by Article 25 of the Law of the Republic of Belarus of 28 October 2008 “On Fundamentals of Administrative Procedures”

A permit shall be issued by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus according to the form of Annex II and signed by the Deputy Minister of Natural Resources and Environmental Protection in charge of a corresponding direction of activity of the Ministry of Natural Resources. A permit approval document (form) is a document with a certain degree of protection (security).

The Ministry of Natural Resources and Environmental Protection of the Republic of Belarus shall register an executed permit in the Permit Registration Log for release of genetically engineered organisms into the environment for testing, issued by the Ministry of Natural Resources according to the form of Annex III. Permits are issued upon presentation of:

a document to confirm an official status of the Head of the legal entity and an identification document to the Head of a legal entity;

a State Registration Certificate to the individual entrepreneur;

an identification document and power of attorney to the duly authorized representative of a legal entity or individual entrepreneur.

The Ministry of Natural Resources and Environmental Protection of the Republic of Belarus shall within 5 days of the day of arrival at a decision inform the State Scientific Institution "Institute of Genetics and Cytology of the National Academy of Sciences of Belarus" on issuance of a permit.

A permit shall not be given to other legal entities and individual entrepreneurs for release of non-pathogenic genetically engineered organisms into the environment for testing.

If a legal entity or individual entrepreneur takes a decision on termination of activities the permit was issued for, a legal entity or individual entrepreneur shall submit a written notification on this to the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus. In case of loss or damage of a permit, a legal entity or individual entrepreneur shall apply for a new permit in accordance with the procedures, established by this Provision.

A permit shall be cancelled by a Decision of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus on the occurrence of any of the following:

liquidation or reorganization of a legal entity or cessation of the activity of an individual entrepreneur;

a decision of the legal entity or individual entrepreneur on termination of the activity a permit was issued for;

a legal entity or individual entrepreneur has not applied to collect a permit within six months of the day of the decision on its issuance was made;

failure to submit a report on the first release of genetically engineered organisms into the environment for testing or negative findings as a result of the first release of genetically engineered organisms into the environment that have determined adverse effects of these organisms on the environment or human health;

infringement of conditions by a legal entity or individual entrepreneur, specified in a permit and (or) legislative requirements to genetic engineering activity.

The Ministry of Natural Resources and Environmental Protection of the Republic of Belarus shall, within 5 days of the day of a decision on cancellation of a permit, notify in writing a legal entity or individual entrepreneur the permit has been issued to, denote a reason for the permit cancellation and inform the State Scientific Institution "Institute of Genetics and Cytology of the National Academy of Sciences of Belarus" on this.

A legal entity or individual entrepreneur, the permit of which has been cancelled, shall within 15 days of the day of the notification on the permit cancellation submit the permit to the Ministry of Natural Resources and

Environmental Protection of the Republic of Belarus for a permit cancellation mark, stating the date and cancellation grounds.

Following the first release of genetically engineered organisms into the environment for testing, a legal entity or individual entrepreneur shall within 60 days after the testing submit to the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus a report that shows test results, conclusions on effectiveness of the used protection measures for risk management of possible adverse effects of genetically engineered organisms on the environment and human health, appropriateness of the used measures for further releases of the tested genetically engineered organisms for testing or other purposes.

**Annex I**
to the Provision on issue
procedure of permits for release
of non-pathogenic genetically
engineered organisms into
the environment for testing

Form

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

1. General information:

1.1. applicant _____
(surname, initials, position, organization name,

_____
address, telephone, fax)

1.2. name, registration number and code of genetically engineered organisms, destined for release into the environment

_____

1.3. estimated period for release of genetically engineered organisms_____

2. Information on genetically engineered organisms:

2.1. full name of a recipient organism:

family _____

genus _____

species _____

subspecies _____

variety / breeding line_____

common name _____

2.2. contributable or variable characters _____

(description of characters and

_____

characteristics, introduced or changed by

_____

genetic engineering modification, including a marker

_____

gene and earlier genetic engineering modifications)

2.3. genetic engineering construction _____

(description of a genetic engineering

_____

construction (insertion) and a source of each

_____

insertion fragment, its estimated function)

2.4. technique for genetic engineering construction transfer to the recipient organism_____

3. Information on release:

3.1. release field location _____

(region, district,

_____

settlement, land plot belonging to the land-owner

_____

or land-user, its full name)

_____

3.2. land plot size (square meters) _____

3.3. quantity of genetically engineered organisms for release

_____

4. Impacts of genetically engineered organisms on the environment

_____

(intended environmental implications, resulting from release of

_____

genetically engineered organisms

_____

into the environment. Their danger level evaluation)

_____

_____

5. risk management measures _____

(brief description of

_____

risk management measures for possible adverse effects of

_____

genetically engineered organisms' release

_____

into the environment)

6. Number and date of the Expert review of the State Safety Expertise of Genetically Engineered Organisms_____

_____ _____

(applicant's signature) (initials, surname)

Application date "__" _____ ____

**Annex II**
to the Provision on issue
procedure of permits for release
of non-pathogenic genetically
engineered organisms into
the environment for testing

REPUBLIC OF BELARUS
Ministry of Natural Resources and Environmental Protection
of the Republic of Belarus

PERMIT N ____
for release of non-pathogenic genetically engineered organisms
into the environment

Hereby allow _____

(name and location of

_____

a legal entity, surname, initials and place of residence

_____

an individual entrepreneur)

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

(a species name in Russian and Latin or

_____

species (plural) of genetically engineered organisms)

in the field_____

(region, district, settlement, land plot belonging to

_____

the land-owner or land-user,

_____

its full name)

providing the compliance with the following risk management measures for possible adverse effects of such release:

_____

(risk management measures to be listed)

_____

_____

Deputy Minister _____ _____

(signature) (initials, surname)

Date of issue"__" _____ ____

**Annex III**
to the Provision on procedure
for issue of permits for release
of non-pathogenic genetically
engineered organisms into
the environment for testing

Form

REGISTRATION LOG
of permits for release of non-pathogenic
genetically engineered organisms into the environment for testing,
issued by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus

| Permit number | Issue date | Name of a legal entity, surname, initials and residence address of an individual entrepreneur | Genetically engineered organism species | Geographic and administrative field location, used for release of genetically engineered organisms | Permit validity date | Results of first release of a genetically engineered organism into the environment | Comment |
|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

## 1.6. USE OF GENETICALLY ENGINEERED ORGANISMS FOR ECONOMIC PURPOSES

In accordance with Article 16 of the Law of the Republic of Belarus "On Safety in Genetic Engineering Activity", use for economic purposes of potentially pathogenic and pathogenic genetically engineered organisms is not allowed.

Use of non-pathogenic genetically engineered organisms for economic purposes as genetically engineered plant varieties, 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 is executed, provided that there is 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 entering information, relating to registration of genetically engineered plant varieties, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms, into the State Register of genetically engineered plant varieties, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms. Confirmation of the State Registration of genetically engineered plant varieties, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms is their State Registration Certificate.

The Resolution of the Council of Ministers of the Republic of Belarus of 12 September 2006, №1195 establishes the Provision on procedures for the State Registration of genetically engineered varieties of plants, breeds of genetically engineered animals and strains of non-pathogenic genetically engineered microorganisms.

The State Registration of genetically engineered plants, animals and microorganisms used for economic purposes is carried out by the Ministry of Agriculture and Food of the Republic of Belarus.

For registration purposes of genetically engineered plants, animals and microorganisms in accordance with this Provision, legal entities and individual entrepreneurs, residing in the territory of the Republic of Belarus shall submit to the Ministry of Agriculture and Food of the Republic of Belarus the documents in line with a consolidated list of administrative procedures that are carried out by State bodies and other organizations with regard to legal entities and individual entrepreneurs, established by the Resolution of the Council of Ministers of the Republic of Belarus of 17 February 2012, № 156.

An applicant for the State Registration of new (newly-developed) genetically engineered plants, animals and microorganisms, developed by traditional breeding methods with use as an initial material of genetically engineered plants, animals and

microorganisms earlier included into the State Register of Genetically Engineered Varieties of Plants, Breeds of Genetically Engineered Animals and Strains of Non-pathogenic Genetically Engineered Microorganisms shall submit an application together with the documentation specified in the list.

The Register constitutes a Single Databank of genetically engineered varieties of plants, breeds of genetically engineered animals and strains of non-pathogenic genetically engineered organisms, used by legal entities and individual entrepreneurs for economic purposes and maintained by the Ministry of Agriculture and Food of the Republic of Belarus.

Condition for inclusion of genetically engineered plants, animals and microorganisms in the Register is a positive conclusion of the State Safety Expertise of genetically engineered plants, animals and microorganisms, as well as positive testing findings of genetically engineered plants, animals and microorganisms.

The Register includes the data as follows:

a registration number of the application submitted for the State Registration of genetically engineered plants, animals and microorganisms;

a name of genetically engineered plants, animals and microorganisms;

the State Registration code of genetically engineered plants, animals and microorganisms;

a registration number of the legal entity or individual entrepreneur, submitted an application for the State Registration of genetically engineered plants, animals and microorganisms, assigned by the Ministry of Agriculture and Food of the Republic of Belarus;

the Republic region, in the territory of which use of genetically engineered plants, animals and microorganisms is allowed in production for economic purposes;

a universal identifier of genetically engineered plants, animals and microorganisms;

genetic characteristic of genetically engineered plants, animals and microorganisms;

economic and biological characteristic of genetically engineered plants, animals and microorganisms.

Genetically engineered plants, animals and microorganisms shall be removed from the Register, provided that:

they have not been used for economic purposes for the last three years;

they have lost their economic value; data on their adverse effects on human health and the environment have been provided.

Removal from the Register shall be exercised in accordance with the Resolution of the Ministry of Agriculture and Food on representation of subordinating to it organizations and other State bodies.

Information on inclusion of genetically engineered plants, animals and microorganisms into the Register or their removal from the Register shall be provided to the State Scientific Institution "Institute of Genetics and Cytology of the National Academy of Sciences of the Republic of Belarus" within 5 days of the day of making a relevant decision.

The Register is published annually by the Ministry of Agriculture and Food.

A statement (application) is composed in the Russian (Belarusian) language and printed according to form, established by the Ministry of Agriculture and Food of the Republic of Belarus for representation of State organizations, entitled to carry out testing of genetically engineered plants, animals and microorganisms.

Proceedings in the application for the State Registration together with the supporting documentation shall be exercised by the Ministry of Agriculture and Food of the Republic of Belarus within 30 days of the day of its issuance.

The Ministry of Agriculture and Food independently demands:

for the State Registration of genetically engineered plants, animals and microorganisms:

a conclusion of the State Safety Expertise of Genetically Engineered Organisms;

recommendations of the Safety Expert Board for genetically engineered organisms of the Ministry of Natural Resources and Environmental Protection;

data on positive findings of the State testing of genetically engineered plants, animals and microorganisms;

data on positive findings of the State testing of genetically engineered plants, animals and microorganisms for the State Registration of new (newly-developed) genetically engineered plants, animals and microorganisms, developed by traditional breeding methods with use as an initial material of genetically engineered plants, animals and microorganisms previously included into the Register.

An applicant has a right to individual submission of the specified documents.

The Ministry of Agriculture and Food of the Republic of Belarus shall issue, within 5 days of the day of the relevant decision-making, the State Registration Certificate to an applicant according to form, approved by this Ministry.

Data on the State Registration of genetically engineered plants, animals and microorganisms are published annually by the Ministry of Agriculture and Food of the Republic of Belarus in the Register.

In case of alterations and (or) additions to the founding documents of a legal entity or the State Registration Certificate of an individual entrepreneur, a legal entity or individual entrepreneur shall, within 15 days of the day of the State Registration of these alterations and (or) additions, submit an application together with the documents specified in a list to the Ministry of Agriculture and Food of the Republic of Belarus

to introduce relevant alterations and (or) additions in the State Registration Certificate.

The Ministry of Agriculture and Food of the Republic of Belarus shall consider the documents, submitted for alterations and (or) additions to the State Registration Certificate and take a relevant decision according to the procedures, established for the State Registration.

In case of loss by a legal entity or individual entrepreneur of the State Registration Certificate, a duplicate document shall be issued within 15 days of the day of an application for a duplicate document to them.

The State Registration Certificate may be cancelled and genetically engineered plants, animals and microorganisms removed from the Register, provided that additional data on their adverse effects on human health and the environment have been received and confirmed by the State Expertise, initiated by State Administration bodies, NGOs and citizens.

The Ministry of Agriculture and Food of the Republic of Belarus shall inform the State Scientific Institution "Institute of Genetics and Cytology of the National Academy of Sciences of Belarus" on the fact of cancellation of the State Registration Certificate of genetically engineered plants, animals and microorganisms and their removal from the Register within 10 days of the day of taking a relevant decision.

## 1.7. INFORMATION EXCHANGE AND THE BIOSAFETY CLEARING-HOUSE, PUBLIC AWARENESS AND ITS PARTICIPATION IN DECISION-MAKING WITH REGARD TO SAFETY IN GENETIC ENGINEERING ACTIVITY

In accordance with Article 22 of the Law of the Republic of Belarus "On Safety in Genetic Engineering Activity", within a framework of information support in the field of genetic engineering activity, the following shall be implemented:

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

Databank development on genetically engineered organisms;

provision of information on safety issues in genetic engineering activity to interested legal entities and individuals;

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

Specially authorized Republican bodies of State Administration in the field of safety in genetic engineering activity within 5 days after issuance of a permit for release of non-pathogenic genetically engineered organisms into the environment for testing and a State Registration Certificate for genetically engineered plant varieties, 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 cargo with genetically engineered organisms, submit relevant information to the State Scientific Institution “Institute of Genetics and Cytology of the National Academy of Sciences of Belarus” with a view of Databank development on genetically engineered organisms and information exchange with Coordination Biosafety Centers of other states and international organizations. Information is submitted to the State Scientific Institution “Institute of Genetics and Cytology of the National Academy of Sciences of Belarus” according to forms, established by these State Bodies in consultation with the National Academy of Sciences of Belarus.

Procedure and conditions for information submission from the Databank on genetically engineered organisms to interested legal entities and individuals shall be established by the Resolution, approved by the Council of Ministers of the Republic of Belarus of 15 September 2006, № 1222.

The Databank forms a constituent part of the National Biosafety Database, developed in accordance with the Resolution of the Council of Ministers of the Republic of Belarus of 19 June 1998, № 963 “On Establishment of the National Co-ordination Biosafety Centre” and constitutes a specialized automated information system of electronic documents.

The Databank operates for the purposes of:

collection, analysis and systematization of information on the Republic of Belarus legislation with regard to safety in genetic engineering activity;

collection, systematization and analysis of information on genetically engineered organisms imported, developed and used for economic purposes in the Republic of Belarus;

delivery of information on genetically engineered organisms imported, developed and used for economic purposes in the Republic of Belarus to the concerned Republican bodies of State Administration;

fulfillment of international obligations by the Republic of Belarus for the Cartagena Protocol on Biosafety, relating to the provision of information to the international Database of the Biosafety Clearing-House;

assisting Coordination Biosafety Centers (Focal Points) of other countries and international organizations in providing and exchanging information in relation to the Cartagena Protocol on Biosafety;

exercising rights of citizens and NGOs to full and accurate information in the field safety in genetic engineering activity in the Republic of Belarus;

The Databank is a public information resource, administered by the State Scientific Institution "Institute of Genetics and Cytology of the National Academy of Sciences of Belarus" that exercises functions of the National Co-ordination Biosafety Centre (NCBC).

The NCBC collects and processes incoming information and provides:

smooth operation of software and hardware complexes of the Databank;

free access to information contained in the Databank;

storage of information and its protection against loss, distortion and unauthorized access.

Republican bodies of State Administration shall submit, in accordance with the legislation, data on safety in genetic engineering activity to the National Center through specially designated by them officials and according to the established procedures.

The Databank shall be updated with the provided data within 5 days of the day of information uptake by the NCBC.

The NCBC shall provide within 5 days of the day of data input into the Databank relevant information to the International Database of the Biosafety Clearing-House, in accordance with the recommendations of the Secretariat of the Convention on Biological Diversity.

Information shall be provided by the Databank in the form of electronic documents via the Internet computer network with use of standard data transfer protocols. Data access is free and unlimited for:

Republican bodies of State Administration, local executive and regulatory bodies, legal entities and citizens of the Republic of Belarus;

Coordination Biosafety Centers of other countries, international organizations, foreign legal entities and foreign citizens.

Information shall be provided from the Databank in print format and in the form of analytical reviews, reports and other documents; technical facilities for the Databank access shall be provided at the client's expense for such information according to the Agreement with the National Center.

At present, genetically engineered organisms are not used for economic purposes in the Republic of Belarus (growing (cultivation) and (or) breeding of genetically engineered varieties of plants, breeds of genetically engineered animals and strains of non-pathogenic genetically engineered microorganisms for the production of agricultural and microbiological products). At the same time, the research in the development of genetically engineered organisms with economically valuable biological characteristics (traits) is carried out at Scientific Research Laboratories of the National Academy of Sciences of the Republic of Belarus. As of 1 May 2016, the Databank contained information on 15 organizations involved or can be involved in genetic engineering activity, eight of them confirmed on official request of the NCBC the fact of such activity in self-contained systems and provided information on genetically engineered organisms that are used for research, 8 names (items) in total. Many of these works are in development stage.

The National Center Database contains information for years 1999 – 2001 on risk assessment of genetically modified sugar beetroot Edda and issuance of a decision on possibility of this variety testing under release into the environment but testing was not carried out, as at that time there were no registered trial fields for such activity in Belarus.

As of 1 May 2016, the NCBC Database has 3 field certificates destined for testing of genetically modified plants, that is trial fields of the State Scientific Institution "Central Botanic Garden of the National Academy of Sciences of Belarus" (registration date: 17.11.2010), the State Scientific Institution "Institute of Genetics and Cytology of the National Academy of Sciences of Belarus" (registration date: 03.12.2012) and the Scientific and Practical Center of the National Academy of Sciences of Belarus for Potato, Vegetable and Fruit Growing (registration date: 17.06.2014).

For the period of 2014 – 2016 four applications for risk assessment of genetically modified organisms were received: two applications were submitted in 2014 and two in 2015. Following the consideration of applications for years 2014-2015 and a full cycle of the State Expertise (risk assessment and consideration of protocols by the Biosafety Expert Board of genetically engineered organisms of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus) a permit to the State Scientific Institution "Institute of Genetics and Cytology of the National Academy of Sciences of Belarus for testing of potato plants with *Cy3aM* gene and the Belarusian State University for testing of rape plants with *aroA* gene in the trial field of the same Institute were issued. One application submitted in 2015 is at its consideration stage.

In accordance with Article 23 of the Law "On Safety in Genetic Engineering Activity", the citizens and NGOs are guaranteed with a right to full, up-to-date and accurate information in the field of safety in genetic engineering activity.

According to this Article, each individual application for release of genetically modified organisms into the environment shall undergo a procedure of public debates by placing on the information site of the National Co-ordination Biosafety Centre of the obtained from the Ministry of Natural Resources data on risk assessment of possible adverse effects of genetically engineered organisms on human health and the environment, as well as risk management measures. The discussion results of the above-mentioned applications are available to all concerned legal entities and individuals.

Alongside this, the NCBC website has sections "Biosafety News and Biotechnologies" and news on this subject, incoming by the RSS technology to enable all concerned individuals to make themselves aware of modern biotechnology techniques, as well as information for specialists in genetic engineering (sections

"Genetically Engineered Organisms and "Portal on Detection of Genetically Modified Organisms") is provided.

## 1.8. GMO DETECTION AND THE LABELLING RULES FOR PRODUCTS, CONTAINING GENETICALLY MODIFIED COMPONENTS

Of great significance is the activity carried out by 18 Laboratories for Detection of Genetically Modified Organisms (LDGMOs) in food products, raw materials used for their production and feeds and that are in departmental subordination to the Ministry of Health, the Ministry of Agriculture and Food and the National Academy of Sciences of Belarus. This activity is carried out with a view of exercitation of a consumer right to information.

The GMO label "Contains GMOs" is mandatory in the Republic of Belarus. The label "Contains No GMOs" is non-mandatory. The basis for a mark sign "Contains GMOs" or "No GMO-contained" is the documents that include laboratory research results in qualitative examination of food products on the GMO purity. The examination should be carried out in the accredited, in accordance with the Accreditation System of the Republic of Belarus, Laboratories. As of 1 May 2016, 18 laboratories located in different Regions of the Republic of Belarus were accredited to the right to carry out testing of alimentary raw materials and food products with a view of genetically modified component detection.

In accordance with the Laws of the Republic of Belarus "On Quality and Safety of Alimentary Raw Materials and Food Products for Human Life and Health" and "On Protection of Consumer Rights", a customer (buyer, purchaser) has a right to credible information on food products, including on the content of GMOs or their components in them. Normative legal acts that determine the labelling rules for products, containing genetically modified components, and that implement the above-mentioned right to the GMO-related information serve this objective. In addition, there is a list of agricultural crop and products mandatory for screening on a regular basis with a view of genetically modified components' identification in them (the Resolution of the Ministry of Health of the Republic of Belarus and the Committee for Standardization, Metrology and Certification at the Council of Ministers of the Republic of Belarus of 8 June 2005 No. 12/26 "On Approval of a List of the Production Raw Material and Food Products Subject to Control over the Presence of Genetically Modified Components). A list of products, subject to mandatory control, contains 25 names of soya and corn products. Labelling applies to food products subject to control in accordance with the legislation on control over presence of genetically modified components, developed by genetic engineering methods from genetically modified organisms on their presence or absence in these organisms.

By the Resolution of the Council of Ministers of the Republic of Belarus "On Some Issues of Information Provision to Consumers on the Production Raw Material and Food Products" of 28 April 2005 No. 434 related to the admissible level of GM-components, a nonthreshold system was established. The entire batch of produce is labelled provided that the GM admixture was detected in it as a result of random checks.

The label "Contains No GMOs" is non-mandatory, provided that GM-components have not been detected in the raw material and food products based on research of the GMO Detection Laboratories accredited in conformity with national standards. And at the buyer's request, the seller must provide the accredited laboratory findings to confirm that, in fact, no GMOs have been detected in the product. The food product with a mark "No GMO-contained" must not contain GMOs and should be produced with no use of genetic engineering methods. On 1 September 2008 the technical code of common practice 131-2008 came into effect in our Republic "Food products. Published "Labeling regulations with a mark "No GMO-contained". "General provisions". The document sets voluntary labeling regulations for food products with a designated mark and intended for use by producers, importers and authorized representatives of producers. The Ministry of Natural Resources and Environmental Protection, the Ministry of Health, the Ministry of Agriculture and Food, the National Centre of Legislation and Legal Research and the State Committee for Standardization were involved in the process. The document was approved by the State Committee for Standardization. The document revision and introduction of modifications shall be initiated by the State Committee for Standardization. According to the clarification of labeling regulations published on the website of the State Committee for Standardization of the Republic of Belarus, the main objective of food products labeling with a mark "No GMO-contained" is the execution of a consumer right to full and accurate information on food products, as well as ensuring consumer competency in their choice and competitiveness of food products.

Labelling is carried out by applying on the consumer packaging of a mark "Contains GMOs" or "No GMO-contained". A mark may also be applied on the tag, label, back label and colour label. The exact place for a mark shall be defined by the applicant.

Responsibility for the mark application propriety "No GMO-contained", conformity of the labeled food product with laboratory examination results lies on the applicant.

The National Co-ordination Biosafety Centre (NCBC) Database contains detailed information on the activity of the GMO Detection Laboratory of the State Scientific Institution "Institute of Genetics and Cytology of the National Academy of Sciences of Belarus", the data on the activity of other laboratories are shown in the

Second and Third National Reports on the Implementation of the Cartagena Protocol in the Republic of Belarus, published on the Internet portal of the Biosafety Clearing-House.

## 1.9. CONTROL IN THE FIELD OF SAFETY IN GENETIC ENGINEERING ACTIVITY AND LEGISLATION VIOLATION LIABILITY

The National legislation and the legal and regulatory framework of the Republic of Belarus were developed in accordance with the Cartagena Protocol requirements. Article 5 of the Law "On Safety in Genetic Engineering Activity" stipulates safety measures, including, among other things, the ones that establish responsibility for violation of legislative requirements with regard to safety in genetic engineering activity. Given that violations of safety regulations in handling with genetically engineered organisms are treated as actions related to the category of environmental abuses, the penalties were defined in the corresponding Articles of Administrative Violations and Criminal (Penal) Codes of the Republic of Belarus. Article 15.4. of the Administrative Violations Code "Violation of Safety Regulations in Handling with Genetically Engineered Organisms, Environmentally Hazardous Substances and Wastes" stipulates imposing of fines only on an individual entrepreneur and a legal entity and Article 278 "Violation of Safety Regulations in Handling with Genetically Engineered Organisms, Environmentally Hazardous Substances and Wastes" of the Criminal (Penal Code) stipulates stricter penalties both in the form of administrative punishments (a fine, public works, deprivation of right to hold specific posts) and limitation of freedom (up to 6 months) depending on a violation degree.

Main competent authorities that were involved in the mainstreaming process are the Ministry of Natural Resources and Environmental Protection, the Ministry of Health, the Ministry of Agriculture and Food, the National Academy of Sciences and its subordinated authorities (institutions) and the National Centre of Legislation and Legal Research.

The above-mentioned Articles of the Codes were adopted by the House of Representatives and, subsequently, approved by the Council of the Republic in 1999 and 2003. In the course of the legal and regulatory framework development, a number of consensus meetings among the concerned bodies were held to discuss the wording

of normative legal acts and Articles of both Administrative Violations and Criminal (Penal) Codes, taking into account related international practices.

Article 26 of the Law of the Republic of Belarus "On Safety in Genetic Engineering Activity" establishes that control (supervision) in the field of safety in genetic engineering activity shall be exercised to verify compliance with the requirements of standard legal acts, including mandatory ones, to comply with the requirements of technical standard legal acts, as well as the implementation of measures to ensure the safety of these activities.

Control over compliance with requirements to the legislation on environmental protection when carrying out genetic engineering activities is part of the control in the field of environmental protection, sustainable use of natural resources, hydrometeorological activities and exercised by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus and its territorial bodies, specified by the Council of Ministers of the Republic of Belarus.

Supervision over compliance with requirements in the field of sanitary-epidemiological well-being of the population when carrying out genetic engineering activities is part of the State Sanitary Inspection over compliance with the legislation in the field of sanitary-epidemiological well-being of the population by the audited entities and inspected by the bodies and institutions, exercising the State Sanitary Inspection specified by the Council of Ministers of the Republic of Belarus.

Supervision over compliance with requirements to the legislation in the field of breeding, veterinary activities, seed-growing and plant protection during genetic engineering activities is part of the State Inspection over breeding, supervision in the field of veterinary medicine, quality assurance of food raw materials and foodstuffs, grain, mixed fodder, seed-growing, quarantine and protection of plants, supervision over export, import and transit of cargo under the State Veterinary Inspection and exercised by the Ministry of Agriculture and Food of the Republic of Belarus, the Department of Veterinary and Food Supervision at the Ministry of Agriculture and Food of the Republic of Belarus, State organizations subordinated to the Ministry of Agriculture and Food of the Republic of Belarus and specified by the Council of Ministers of the Republic of Belarus.

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

Legal entities and individual entrepreneurs engaged in genetic engineering activity are obliged to organize and exercise production control in accordance with the established by them procedures to check the compliance with safety requirements in genetic engineering activity, established by normative legal acts, including technical normative legal acts.

The production control in the field of safety in genetic engineering activity shall be exercised at its sole cost and expense and other funding sources according to local normative legal acts, elaborated and approved by a legal entity or individual entrepreneur in accordance with the Instruction, approved by the Resolution of 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 of 3 April №19/23/14. The Instruction applies to legal entities and individual entrepreneurs engaged in genetic engineering activity of risk level I and State legal entities involved in genetic engineering activity of risk levels II, III and IV.

The local normative legal act shall be elaborated and established for an individual entrepreneur or legal entity as a whole and (or) for each separate division of a legal entity, exercising production control in the field of safety in genetic engineering activity.

The elaborated normative legal act shall be approved by order, direction of the Head of the legal entity or individual entrepreneur.

The local normative legal act includes the following sections:

"General information"

"Organization of production control"

"Production control objects"

"Planning and carrying out control"

"Planning, development and approval of activities directed at the protection of human health and the environment, their implementation monitoring"

"Accountability in the field of safety in genetic engineering activity"

"Mitigation and management of adverse effects on human health and the environment associated with the environmental pollution"

"Professional training, advanced training, retraining of employees of legal entities and individual entrepreneurs engaged in genetic engineering activity".

The "General information" section provides data on a legal entity or individual entrepreneur:

name of a legal entity;

registered address;

surname, name, patronymic (if any) of an individual entrepreneur;

place of residence;

place of genetic engineering activity;

State Registration details of a legal entity or individual entrepreneur.

The "Organization of production control" section includes:

activity arrangement procedures for an individual responsible for the production control, their functions, objectives, rights and duties;

procedures for the production control data provision and its results to the Head of the legal entity or individual entrepreneur.

The "Production control objects" section contains a list of production control objects, to which the following may be referred:

genetically engineered organisms, including non-pathogenic, potentially pathogenic and pathogenic genetically engineered organisms;

strains of non-pathogenic genetically engineered microorganisms;

genetically engineered varieties of plants;

breeds of genetically engineered animals;

other objects, which are used or may be used in genetic engineering activity.

This section includes information on a risk level of genetic engineering activity, requirements to transportation and storage of genetic engineering activity objects.

The section "Planning and carrying out control" includes the following subsections:

"Production control organization procedures", including:

activities directed at the production control implementation (scheduled plans, activity plants, etc.);

procedures for presentation of the production control results (drawing up production control acts on elimination of breaches (shortcomings) revealed, keeping their record, etc.) ;

organization procedures for elimination of breaches, revealed as a result of the production control;

"Organization and carrying out production control" includes:

procedures for elaboration and approval of activities aimed at the production control implementation;

a list of sampling sites and the sites for execution of measurements;

procedures for activity management and results of the production control implementation;

documentation maintenance procedures of the production control results .

The section "Planning, development and approval of activities directed at the protection of human health and the environment, their implementation monitoring" includes:

procedures for planning, development and approval of activities aimed at training of employees of legal entities and individual entrepreneurs on work with genetically engineered organisms, compliance with requirements of the sanitary-epidemic regime and to personal hygiene;

procedures for planning, development and approval of activities directed at prevention of emergency situations and remediation of consequences, when engaged in genetic engineering activity;

procedures for planning, development and approval of activities directed at the environmental protection for emergencies of natural and technogenic character that have harmful environmental effects;

control procedures on environmental protection activities.

The "Accountability in the field of safety in genetic engineering activity" section contains data on maintenance and submission of accounting records (documentation), stipulated by Article 25 of the Law of the Republic of Belarus "On Safety in Genetic Engineering Activity" and other legislative acts of the Republic of Belarus.

The section "Mitigation and management of adverse effects on human health and the environment associated with the environmental pollution" includes:

procedures for prevention and management of natural and technogenic emergencies and other unforeseen situations that may have adverse effects on human health and the environment;

procedures for investigation by employees of a legal entity or individual entrepreneur engaged in genetic engineering activity of accidental situation cases, natural and technogenic emergencies and other unforeseen situations that had harmful effects on human health and the environment.

The section "Professional training, advanced training, retraining of employees of legal entities and individual entrepreneurs engaged in genetic engineering activity" provides:

a list of employees, involved in organization and implementation of the production control subject to professional training, advanced training and retraining in the field of safety in genetic engineering activity, including the frequency of training courses;

a list of employees, involved in work with genetically engineered organisms subject to professional training, advanced training and retraining in the field of environmental protection, including the frequency of training courses;

an instruction (briefing) type, stipulated by the legislation, its programme, frequency, management of all required documentation on it.

Article 15.4 of the Administrative Violations Code of the Republic of Belarus establishes responsibility for violation of safety rules for handling of genetically engineered organisms, including violation of industrial safety rules, storage, use, transport, burial (disposal) and other handling of genetically engineered organisms subject to a fine of ten to fifty base values, for an individual entrepreneur a fine of fifty to one thousand base values.

Article 278 of the Criminal (Penal) Code of the Republic of Belarus establishes punishment for violation of industrial safety rules, rules for storage, use, transport, burial (disposal) and other handling of genetically engineered organisms, committed within a year after imposition of an administrative penalty for the same violation or

knowingly threatening to cause harm to human health or the environment in the form of community services, a fine or deprivation of right to hold specific posts or engage in specified activity or correctional works for up to one year or arrest. For violation of the same rules, committed in the environmentally neglected zone or resulted in willful damage or infliction of damage on a large scale, a guilty person shall be punished in the form of correctional works for up to two years or restriction of freedom for up to five years or deprivation of freedom for the same term, including deprivation of right to hold specific posts or engage in specified activity or with no deprivation; for violation of the same rules resulted in human death by recklessness or human diseases – restriction of freedom for up to five years or deprivation of freedom from one to seven years, including deprivation of right to hold specific posts or engage in specified activity or with no deprivation.

## 1.10. BIOSAFETY MAINSTREAMING IN BILATERAL AGREEMENTS AND HARMONIZATION OF THE NATIONAL LEGISLATION IN CONNECTION WITH THESE AGREEMENTS

In connection with the formation of the Eurasian Economic Community and the Eurasian Economic Union in 2014, which includes Belarus, Russia, Kazakhstan, Armenia and Kyrgyzstan, and adoption of principles of free movement of goods within the Union and single customs territory, it deemed necessary to develop a unified legal and regulatory framework for the movement of goods among member-states, as well as unified approaches and standards in the field of biosafety or their harmonization with the national standards of member-states. The Customs Union Technical Regulations TR CU 021/2011 "On Food Safety" and TR CU 022/2011 "Food Products in Terms of their Labelling", including 0.9% for GM products labelling, was elaborated in accordance with the Agreement on common principles and rules of the Technical Regulation in the Republic of Belarus, the Republic of Kazakhstan and the Russian Federation of 18 November 2010. The Customs Union Commission adopted a resolution on the distribution of the technical regulations on food products released into circulation in terms of their labelling for the single (uniform) Customs Union territory. The Customs Union Technical Regulation was adopted in 2011 in line with Article 13 of the Agreement on common principles and rules of the Technical Regulation in the Republic of Belarus, the Republic of Kazakhstan and the Russian Federation of 18 November 2010.

Technical Regulations TR CU 021/2011 "On Food Safety" establish:

- GMO safety requirements (including sanitary-epidemiological, hygienic and veterinary ones);
- GMO detection regulations;

- Forms and procedures for assessment (verification) of GMOs for conformity with the Technical Regulation requirements.

Objectives of TR CU 021/2011introduction (adoption):

1) protection of human life and (or) health;

2) prevention of actions, misleading of acquirers (consumers);

3) environmental protection.

In the course of the Technical Regulations TR CU 022/2011 adoption "Food Products in Terms of their Labelling", the Commission decided that

2.1. the Customs Union Technical Regulation “Food Products in Terms of their Labelling” (hereinafter referred to as “the Technical Regulation”) shall come into effect on 1 July 2013;

2.2. before 15 February 2015, the production and release into circulation of food products was allowed in conformity with mandatory requirements to food products in terms of their labelling, as established by either normative legal acts of the Customs Union or the Customs Union Member-State legislation prior to the day the Technical Regulation became effective;

2.3. the handling of products released into circulation in line with subparagraph 2.2 of this Decision is allowed for the product shelf life period established in accordance with the legislation of the Customs Union Member-State.

Scope of TR CU 022/2011 application

1. The Customs Union Technical Regulation applies to the food products released into circulation in the single (uniform) Customs Union territory in terms of their labelling;

2. The Customs Union Technical Regulation does not apply to food products being generated (produced) by catering organizations in the provision of catering services in the place of production, as well as food products being generated (produced) by individuals in private farm households not for entrepreneurial activity purposes;

3. The Customs Union Technical Regulation establishes requirements to food products in terms of their labelling to prevent actions misleading consumers with regard to implementation of consumers’ rights to reliable information on food products;

4. Additional requirements for the Customs Union Technical Regulations with regard to certain types of food products in terms of their labelling that do not contradict the existing Technical Regulation should be taken into account when applying the Customs Union Technical Regulation.

The Technical Regulations TR CU 022/2011 establish the requirements for indicating on the labelling of information on the presence in food products of components developed by use of genetically engineered organisms:

1. For food products developed by use of GMOs, including the products not containing deoxyribonucleic acid (DNA) and protein, the following information should be provided "genetically modified produce" or "the produce developed from genetically modified organisms", or "the produce containing components of genetically modified organisms".

Provided that the producer in the production of food products did not use genetically modified organisms that contain in food products of 0.9% or less, the GMO is an unintentional or technically irremovable admixture and such food products do not belong to the GMO-content food products. In labelling of such food products the data on the GMO presence is not indicated.

2. For the food products developed from genetically modified microorganisms (bacteria, yeast and filamentous fungi, the genetic material of which was modified by genetic engineering techniques) (hereinafter referred to as "GMMs") or with their use, the following information shall be mandatory provided on the food products:

- containing living GMMs - "The product contains living genetically modified microorganisms";

- containing inviable GMMs - "The product developed with use of genetically modified microorganisms";

- free of technological GMMs or developed with use of GMM free components – "The product contains components developed with use of genetically modified microorganisms".

Article 20 of TR CU 021/2011 states that "Methods of examination (testing) and measurement of food products are specified in the List of Standards, containing regulations and methods of examination (testing) and measurement, including the rules of sampling required for the application and enforcement of the requirements of these Technical Regulations and implementation of assessment (confirmation) of conformity of food products." For LMOs it is the Resolution of the Chief State Sanitary Inspector of RF of 30.11.2007 No. 80 "On Supervision over the Circulation of Food Products Containing GMOs" (together with "MR 2.3.2.2306-07.23.2. Food Products and Food Supplements. Biomedical Assessment of the Safety of Genetically Modified Organisms of Plant Origin. Methodological Guidelines", "MR 4.2.2304-07. Control Methods and Microbiological Factors. Food Products and Food Supplements. Methods of Identification and Quantification (Quantitative Determination) of Genetically Modified Organisms of Plant Origin. Methodological Guidelines", "MR 4.2.2305-07. 4.2.Control Methods. Biological and Microbiological Factors. Food Products and Food Supplements. Detection of Genetically Modified Microorganisms and Microorganisms Having Genetically Modified Analogues in Food Products by Real-Time Polymerase Chain Reaction (PCR) Methods and PCR with Electrophoretic Detection. Methodological Guidelines". The Regulation can be found in "Belarus" section on the website of the Biosafety Clearing-House.

The Technical Regulations was adopted in 2011 by a High-level Decision of the Customs Union Commission (Belarus, the Russian Federation and Kazakhstan) of 9 December 2011 and became effective on 15 December 2015. At present time, in connection with the Eurasian Economic Union (EAEU) formation in 2014 which, apart from the Republic of Belarus, Kazakhstan and the Russian Federation, includes Armenia and Kyrgyzstan, the Customs Union Commission powers have been delegated to the Eurasian Economic Commission.

Functioning and development of the Eurasian Economic Union (EAEU), the Customs Union (CU) and the Common Economic Space (CES) and proposals in the field of integration within these unions are ensured and implemented by the Eurasian Economic Commission (EEC) – the EAEU permanent supranational regulatory body (previously of the CU and CES). The Eurasian Economic Commission was established by the Decision of the Presidents of the Russian Federation, the Republic of Belarus and the Republic of Kazakhstan and operates on the basis of Treaties of 18 November 2011 "On the Eurasian Economic Commission" and "On the Rules and Procedures of the Eurasian Economic Commission". The Commission has a status of the supranational regulatory body subordinated to the Supreme Eurasian Economic Council. The Commission's Decisions are binding in the EAEU Member-States territory (previously – the CES and CU)

The Commission powers are laid down in Article 3 of the Treaty "On the Eurasian Economic Commission". The Commission has also been assigned with a number of additional functions, including:

- customs tariff and non-tariff regulations
- customs administration
- technical regulation
- sanitary, veterinary and phytosanitary measures.

Within the established scope of activity, the Commission may take decisions that are binding for the Parties and the recommendations of nonbinding nature. The Commission executive body that develops proposals on further integration within the Customs Union and the Common Economic Space is the Eurasian Economic Commission Board. The EEC Board includes 10 members (2 from each Party); one of them is a Chairperson of the EEC Board. The EEC Board takes decisions by voting. Every Board member has one vote. The EEC Board holds a meeting once in every week.

The platform (space) to discuss Technical Regulations TR CU 021/2011 "On Food Safety" and TR CU 022/2011 "Food Products in Terms of their Labelling" was created at the member-states' level. Member-states constantly hold discussions and deal with revision of laws, standards and harmonization of legislation. Any member-state may act as an initiator. The procedure is similar to the one that uses the above listed instruments for the national approval procedure. The legal and regulatory

framework and standards are reviewed and supplemented as and when required. The ministry or any other institution that comes with a proposal on the need to introduce changes in the document or the mechanism for its implementation may act as an initiator. Then a stage of the mechanism for proposals' consideration comes; it includes consultations with all authoritative bodies and involved institutions by sending the proposal (its text) to all institutions, collecting official responses and proposals from them, as well as holding of meetings to discuss the suggestions received. Further, a proposal for amendments is submitted for consideration and approval to the Eurasian Economic Commission.

On the part of the Republic of Belarus, the following competent authorities are involved with a view of draft normative legal acts' development and expertise related to biosafety issues within the Customs Union and the Common Economic Space formation and operation: the Ministry of Natural Resources and Environmental Protection, the Ministry of Health and its subordinated institutions (including the Republican Unitary Enterprise "Scientific and Practical Centre of Hygiene", the Republican Centre for Hygiene, Epidemiology and Public Health, at which the Customs Union Division was established on 1 January 2010, and the Republican Research and Practical Centre for Epidemiology and Microbiology), the Ministry of Agriculture and Food, the National Academy of Sciences and its subordinated establishments (institutions, including the Institute of Genetics and Cytology and the Institute of Microbiology), the National Centre of Legislation and Legal Research, and the State Customs Committee within its competence.

The Customs Union Technical Regulations were approved by the Customs Union Commission.

The Technical Regulations of the EAEU Customs Union in the field of LMOs circulation, as well as rules on GM products labelling are similar to the European Union Directives and Regulations on labelling and comply with the requirements in paragraph 1 of Article 14 of the Cartagena Protocol on Biosafety. The methodological base developed in the Customs Union is largely harmonized with the requirements of international organizations and the European Union and provides a level of protection not less than that defined in the Cartagena Protocol on Biosafety.

At the same time, during the Desk Study preparation and its discussion in course of the round table and seminar (see Appendix 1 and Appendix 2) it was found out that the harmonization process of national legislations, standards and methodological approaches of EAEU countries continues. In particular, a threshold of 0% for labelling of products, raw materials used for their production and feeds, containing GMOs or their components has not been cancelled in the Republic of Belarus by National Legislation yet, while the Customs Union has established a threshold of 0,9% for the permitted GMOs. At the same time, the meeting participants also note that the country has carried out work on the harmonization of normative

legal acts and technical regulations: the by-law “Sanitary Norms and Regulations” came into effect, which establishes a threshold of 0,9% and a new version of the Law “On Quality and Food Safety” that previously established a nonthreshold principle for food product labelling has been elaborated. A new version of the Law was brought in conformity with the TR CU and the EU legislation. The Law is at the initial stage of editing. The Republic of Belarus has also approved methodology guidelines "Procedures for Risk Assessment of Possible Harmful Effects of Genetically Engineered Organisms on Human Health. Instructions for Use." Following the entry into the Customs Union, a list of standards that includes principles and methods of research (testing) and measurements for a GM-component in food products and food supplements, methodology guidelines “Food Products and Food Supplements. Biomedical Safety Assessment of Genetically Engineered Modified Organisms of Plant Origin. Methodical Guidelines” was determined. With reference to the above, the meeting participants made recommendations to the designated authorities in the field of safety in genetic engineering activity (and the seminar participants supported them) to continue work on harmonization of the legislation of the EAEU member-states in terms of GMO labelling, GMO-containing products, derived from/or with use of GMOs, harmonization of interstate methodological approaches, standards and instructions with regard to the GMO detection and identification, risk assessment of GMOs and GMO-derived products. Concrete proposals are given in the Summary of the Round-table, Appendix 1, paragraphs 1.2., 2.1-2.4.

## 1.11. CONCLUSION ON BIOSAFETY MAINSTREAMING INTO GENERAL LAW, SECTORAL AND CROSS-SECTORAL LAWS AND POLICIES. GOOD PRACTICES, CHALLENGES, CAPACITY NEEDS, OPPORTUNITIES, AND LESSONS LEARNED

The Desk Study and analysis during the round-table and the seminar (PSA Appendix 1 and Appendix 2) revealed that the Republic of Belarus had developed legal, administrative and other measures highly harmonized with CPB provisions to fulfill obligations under CPB.

In the Republic of Belarus there are three State bodies responsible for implementation of the Cartagena Protocol and, respectively, the provision of safety in genetic engineering activity with regard to biosafety and human health: the Ministry of Natural Resources and Environmental Protection, the Ministry of Health and the Ministry of Agriculture and Food. They were the main developers of the Law “On Safety in Genetic Engineering Activity” and other normative legal acts that provide the fulfillment of this Law. Subordinated authorities (institutions, centers) of the Ministry of Natural Resources and Environmental Protection, the Ministry of Health, the Ministry of Agriculture and Food, the National Academy of Sciences as well as

the National Centre of Legislation and Legal Research were involved in the process of the Law and by-laws development. The national legislation is drawn up in such a way that as many specialists as possible of all areas related to this field are attracted to the process of such documents' development. In the course of the national legislation development in the field of biosafety, draft documents were sent to all competent organizations in this area (head organizations have a list of institutions competent in a particular area and messaging is done according to the list). In the course of the legal and regulatory framework development, a number of consensus meetings among the concerned bodies were held. In accordance with the legislation of the Republic of Belarus, draft Law and by-Laws were subject to public discussion. Information on the project approval was posted on the institution website responsible for the project development (the Ministry of Natural Resources and Environmental Protection, the Ministry of Health, the Ministry of Agriculture and Food or other organizations responsible for the particular project development) and within 30 days any public association or any individual could participate in the discussion.

Biosafety mainstreamed into the general Law "On Safety in Genetic Engineering Activity" (hereafter referred to as "Law") of 9 January 2006, No. 96, is mandatory for all organizations in the area of LMO biosafety and describes departments/institutions authorized and responsible for particular LMO safety activity, all necessary procedures, and interdepartmental coordination mechanisms. The Law provides that the State Administration in the field of safety in genetic engineering activity shall be exercised by the President of the Republic of Belarus, the Council of Ministers of the Republic of Belarus, specially authorized Republican bodies of State Administration in the field of safety in genetic engineering activity. Specially authorized Republican bodies of State Administration in the field of safety in genetic engineering activity are the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus, the Ministry of Health of the Republic of Belarus, the Ministry of Agriculture and Food of the Republic of Belarus. The Law establishes powers for each of the above-mentioned institutions in the following areas of safety in genetic engineering activity: work in self-contained systems; import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of GMOs; risk assessment of possible adverse effects of GMOs on the environment and human health before field trials and placement to the market; release of GMOs into the environment; use of GMOs for economic purposes; information exchange and the Biosafety Clearing-House; public awareness and its participation in decision-making with regard to safety in GEA; control in the field of safety in GEA; responsibility for violation of legislation on safety in GEA; GMO detection and identification. The Law also establishes responsibilities of individuals engaged in genetic engineering activity, powers of the Expert Safety Board for Genetically Engineered Organisms, risk assessment procedures preceding the release

of genetically engineered organisms into the environment for testing or use in economic activity.

The Law determines the role of the National Co-ordination Biosafety Centre (NCBC) of the Institute of Genetics and Cytology of the National Academy of Sciences of Belarus. In accordance with Article 22 of the Law, specially authorized Republican bodies of State Administration in the field of safety in genetic engineering activity shall, within 5 days following the issuance of a permit for release of nonpathogenic genetically engineered organisms into the environment for testing, the State Registration Certificate for genetically engineered varieties of plants, breeds of genetically engineered animals and strains of nonpathogenic genetically engineered microorganisms, as well as the State Customs Committee of the Republic of Belarus within 5 days following the crossing of a cargo with genetically engineered organisms of the customs border of the Republic of Belarus, submit relevant information to the State Scientific Institution "Institute of Genetics and Cytology of the National Academy of Sciences of Belarus" with a view of a Databank formation of genetically engineered organisms and information exchange with Coordination Biosafety Centers of other states and international organizations. NCBC exercises the Biosafety Clearing-House functions.

It should be noted, that the NCBC of the Institute of Genetics and Cytology was established in accordance with the Resolution of the Council of Ministers of the Republic of Belarus of 19 June 1998 No. 963 and fulfills its obligations in line with the Resolution. We would like to clarify that in Belarus the National Academy of Sciences (hereinafter referred to as "NAS of Belarus") has a special status and the State significant powers in accordance with the Charter approved by the Presidential Decree of the Republic of Belarus of 3 February 2003 No. 56 "On Some Issues of the National Academy of Sciences of Belarus". The Charter assigns that NAS of Belarus is the Supreme State Scientific Institution of the Republic of Belarus that organizes and coordinates fundamental and applied research performed by all subjects involved in scientific activity; carries out fundamental and applied scientific research and developments, provides organizational and technical support for the State Scientific Expertise, serves as the head organization of the Republic on methodological support in the field of information development; it also performs other authorities established by the legislative acts and this Charter, certain functions of the Republican Body of State Administration. The objective to ensure safety in genetic engineering activity is directly related to the functions of the National Academy of Sciences, particularly in the areas of organizational and technical support for the State Scientific Expertise, including the assessment of the risks posed by GMOs. Thus, the assignment of functions of the National Co-ordination Biosafety Centre on the Institute of Genetics and Cytology of NAS of Belarus is justified from both the State and scientific-practical standpoint (perspective), providing highly professional scientific approach to

biosafety in the country and the Cartagena Protocol effective implementation. Thus, taking into account the above-mentioned special aspects, the National Co-ordination Biosafety Centre in its direct comprehension as the "cross-sectoral institution" is not as such, but has the authority in accordance with paragraphs 2 and 3 of the Resolution of the Council of Ministers of the Republic of Belarus "On Establishment of the National Coordination Centre" of 19 June 1998 No. 963, as mentioned above.

Main functions of the NCBC are: development of the National Information Databank; collection, analysis and systematization of information on legislation and scientific research in the field of biosafety, field trials of genetically engineered objects, import / export, commercial use of GMOs and the products derived from them in the Republic of Belarus, as well as of the specified information on biosafety obtained from the International Information Network Databases; delivery of information on biosafety issues to the involved Ministries and other Republican bodies of State Administration and the mass media; provision of advisory services to the Ministries and other Republican bodies of State Administration in drafting legislative acts in biosafety area and in formulation of proposals on entry into bilateral and regional agreements, as well as drawing up international agreements (treaties) on biosafety issues; organization of the Scientific Safety Expertise of genetically engineered organisms and products derived from them, destined for use in the territory of the Republic of Belarus.

NCBC provides a number of biosafety educational resources, including online modules, biosafety courses and educational articles that are available on the website at the link: http://biosafety.org.by/ and initiates meetings related to the issues of GMO release for trials, as well as their placement at the market, a number of training workshops and seminars for any of the specialist groups engaged in biosafety activity (GMO developers, biosafety experts, staff members of the GMO Detection Laboratories, public associations) and the representatives of all country institutions engaged in biosafety of genetic engineering activity are invited to take part in them. Such activities (events) are organized at the Institute of Genetics and Cytology, as well as at other institutions in the form of issue-related (thematic) workshops. The officials of State bodies responsible for the implementation of biosafety at the country level in accordance with the Law "On Safety in Genetic Engineering Activity" (the Ministry of Nature, the Ministry of Agriculture and Food, the Ministry of Health), their subordinated establishments (institutions, scientific and practical centers), the Aarhus Centre specialists and public associations are invited on a regular basis.

In Belarus cross-sectoral, i.e. inter-departmental (inter-industry), functions are exercised by so-called Inter-agency Councils (Boards); in addition, there are Inter-agency Expert Councils (Boards). The Expert Board for Biosafety of Genetically Engineered Organisms of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus belongs to this type of Inter-agency Council

(Board). A list of Expert Board members on biosafety of genetically engineered organisms of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus, provided in Appendix 5, clearly shows that the Board includes representatives of the establishments subordinated to different agencies (institutions) and it ensures the representation of all involved and competent in the area of biosafety establishments and agencies (institutions). The work of the Expert Board for Biosafety allows, using the knowledge and experience of all country organizations competent in the issues of safety in genetic engineering activity, listed in Appendix 5, to decide on the admissibility of release of genetically engineered organisms into the environment for testing or their use for economic purposes; it also allows to identify risk management techniques of their release and monitoring methods.

Immediately following the Law adoption with a view of biosafety integration in the country, the steps were taken to elaborate local laws and normative legal acts that define safety mechanisms for genetic engineering activity at both sectoral (departmental) and cross-sectoral (interdepartmental) levels in the following areas: work in self-contained systems; import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of GMOs; risk assessment of possible adverse effects of GMOs on the environment and human health before field trials and placement to the market; release of GMOs into the environment; use of GMOs for economic purposes; information exchange and the Biosafety Clearing-House; public awareness and its participation in decision-making with regard to safety in GEA; GMO detection and identification, control in the field of safety in GEA as well as responsibility for violation of legislation on safety in GEA. Subordinated authorities (institutions, centers) of the Ministry of Natural Resources and Environmental Protection, the Ministry of Health, the Ministry of Agriculture and Food, the National Academy of Sciences, as well as the National Centre of Legislation and Legal Research were involved in the process, including other competent organizations on an as-needed basis.

Biosafety mainstreaming into sectoral and cross-sectoral laws and policies were thoroughly described on pages 4-99 of the Desk Study, including appendices of main administrative forms that should be used in organizations. Biosafety mainstreaming into laws, policies and institutional frameworks are incorporated herein and presented below in a concise table form.

**Biosafety Mainstreaming into Sectoral and Cross-sectoral Laws and Policies and other Relevant Instruments**

| Law, Policy | The body that adopted the instrument (tool) and the organization that approved the instrument (tool) | Level (sectoral and cross-sectoral) | Organizations/institutions it applies to | Integrated by means of an instrument related to the sphere of safety in genetic engineering activity into the institution (s) and the institution (s) responsibilities |
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| On Establishment of the National Co-ordination Biosafety Centre | Resolution of the Council of Ministers of the Republic of Belarus of 19 June 1998, No. 963 | Sectoral | State Scientific Institution "Institute of Genetics and Cytology of the National Academy of Sciences of Belarus" | Development of the National Information Databank<br>Collection, analysis and systematization of information on legislation and scientific investigations of the biosafety issues, field tests of gene engineering objects, import (export), commercial use of genetically (gene) engineered organisms and products on their basis in Belarus as well as biosafety information from the database of International Information Networks;<br>submission of biosafety information to ministries and other Republican |

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| | | | | governmental bodies and mass media concerned;<br>Exchange of information with coordination biosafety centers of other countries and international organizations;<br>Organization of scientific safety expertise for genetically engineered organisms and products on their basis, the use of which is intended in the Republic of Belarus;<br>Rending of consultative services to ministries and other Republican governmental bodies in working out draft legislative documents related to import (export) and safe use of genetically engineered organisms and products on their basis, manuals for assessment and prevention of risk to the environment and human health, safety engineering instructions for genetic engineering laboratories;<br>Rendering of consultative services to ministries and other Republican governmental bodies to prepare proposals on bilateral and regional agreements, development of |

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| | | | | international agreements, including international agreements on biosafety issues.<br><br>The National Co-ordination Biosafety Centre also exercises the Biosafety Clearing-House functions as the constant liaison with the Secretariat. |
| On Approval of Regulation on Terms and Conditions for the Provision of Information on Genetically Engineered Organisms from the Information Databank | Resolution of the Council of Ministers of the Republic of Belarus, of 15 September 2006, No. 1222 | Cross-Sectoral | National Co-ordination Biosafety Centre, legal and private entities and the public | It establishes procedure and conditions for information submission from the Databank on genetically engineered organisms to interested legal and private entities and the public |
| On Submission of Information to the Databank of Genetically Engineered Organisms | Resolution of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus | Cross-Sectoral | Ministry of Natural Resources, National Co-ordination Biosafety Centre | It establishes data submission procedures and the data to be provided by the Ministry of Natural Resources and Environmental Protection to the Databank of genetically engineered organisms of the National Co-ordination Biosafety Centre of the Institute of |

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| On Approval of Data Submission Procedures to the Databank of Genetically Engineered Organisms | Resolution of the Ministry of Health of the Republic of Belarus of 22 December 2006 No. 116 | Cross-Sectoral | Ministry of Health, National Co-ordination Biosafety Centre | It establishes data submission procedures to the Databank of genetically engineered organisms of the National Co-ordination Biosafety Centre of the Institute of Genetics and Cytology, NAS of Belarus. |
| On Procedure of Information Submission to the State Scientific Institution "Institute of Genetics and Cytology of the National Academy of Sciences of Belarus" | Resolution of the State Customs Committee of the Republic of Belarus of 16 February 2009 No. 9 (as worded in the Resolution of the State Customs Committee of 13 July 2010 No. 27) | Cross-Sectoral | State Customs Committee of the Republic of Belarus, National Co-ordination Biosafety Centre | It establishes both the data submission procedure and its form, including the data to be submitted by the State Customs Committee to the Databank of genetically engineered organisms of the National Co-ordination Biosafety Centre of the Institute of Genetics and Cytology, NAS of Belarus |
| On Approval of Regulations on | Resolution of the Council of | Cross-Sectoral | Legal entities (organizations) and | It establishes a risk assessment procedure to identify possible |

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| the Procedure for the State Safety Expertise of Genetically Engineered Organisms and Approximate Terms of Agreements Concluded to Carry it out and Issuance of Permits for Release of Non-pathogenic Genetically Engineered Organisms into the Environment for Testing | Ministers of the Republic of Belarus, of 8 September 2006 No. 1160 | | individual entrepreneurs engaged in genetic engineering activity, the Ministry of Natural Resources and Environmental Protection, Expert Board of the Ministry of Natural Resources and Environmental Protection (including expert organizations listed in Annex 6), National Co-ordination Biosafety Centre | adverse effects of genetically engineered organisms on the environment and human health before their release for field trials or intended use in economic activity. |
| On Approval of the Regulation on a Risk Assessment Procedure of Possible Adverse Effects | Resolution of the Council of Ministers of the Republic of Belarus, of 4 May 2006, No. 677 | Cross-Sectoral | Legal entities (organizations) and individual entrepreneurs engaged in genetic engineering activity, the Ministry of Natural Resources and | It establishes a risk assessment procedure to identify possible adverse effects of genetically engineered organisms on human health before their release for field trials or intended use in economic activity. |

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| of Genetically Engineered Organisms on Human Health | | | Environmental Protection of the Republic of Belarus, Expert Board of the Ministry of Natural Resources and Environmental Protection | |
| On Approval of Regulation on the State Registration Procedure for Genetically Engineered Plant Varieties, Genetically Engineered Breeds of Animals and Strains of Non-pathogenic Genetically Engineered Microorganisms | Resolution of the Council of Ministers of the Republic of Belarus of 12 September 2006 No. 599 | Cross-Sectoral | Legal entities and individual entrepreneurs, the Ministry of Agriculture and Food, the Ministry of Natural Resources and Environmental Protection, Expert Safety Board for Genetically Engineered Organisms of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus | It establishes the State Registration Procedure for genetically engineered plant varieties, genetically engineered breeds of animals and strains of nonpathogenic genetically engineered microorganisms. |
| On some Issues related to Sanitary and Epidemiological | Resolution of the Council of Ministers of the Republic of | Cross-Sectoral | In the area of sanitary and hygiene monitoring: the Ministry of Health jointly with the Ministry | It establishes procedures and conditions for the State Registration of products that pose potential danger for life and health of |

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| Welfare of Population | Belarus of 11 September 2006 No. 635 | | of Labour and Social Protection,<br>the Ministry of Natural Resources and Environmental Protection, the Ministry of Agriculture and Food, the Ministry of Trade, the Ministry of Education, the Ministry of Housing and Communal Services, the Ministry of Defense, the Ministry of Internal Affairs, the State Security Committee, the State Border Committee, the Department of Presidential Affairs of the Republic of Belarus, the National Statistical Committee, local executive and administrative bodies.<br>In the area of sanitary and epidemiological audit: bodies and establishments that exercise state sanitary | population; approves a list of products subject to the State Sanitary and Hygienic Expertise; determines the authorities to perform sanitary supervision, socio-hygienic monitoring, sanitary-epidemiological audit. |

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| | | | supervision, included by the Ministry of Health into a list of organizations authorized to perform sanitary and epidemiological audit.<br>Bodies and establishments that exercise State sanitary supervision authorized to carry out the State Registration of products (as worded in the Resolution of the Ministry of Health of 10 June 2015 No. 82):<br><br>1. Baranovichi Zonal Centre of Hygiene and Epidemiology<br>2. Brest Regional Centre for Hygiene, Epidemiology and Public Health<br>3. Vitebsk Regional Centre for Hygiene, Epidemiology and Public Health | |

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| | | | 4. Gomel Regional Centre for Hygiene, Epidemiology and Public Health<br>5. Grodno Regional Centre for Hygiene, Epidemiology and Public Health<br>6. Minsk City Centre for Hygiene and Epidemiology<br>7. Minsk Regional Centre for Hygiene, Epidemiology and Public Health<br>8. Mogilev Regional Centre for Hygiene, Epidemiology and Public Health<br>9. Polotsk Zonal Centre of Hygiene and Epidemiology<br>10. Republican Centre for Hygiene, Epidemiology and Public Health | |

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| Provision on Procedures and Conditions for the State Registration of Products that Constitute a Potential Danger for Life and Health of Population | Approved by the Resolution of the Ministry of Health of the Republic of Belarus of 17 July 2012 No. 101 | Cross-Sectoral | Bodies and establishments that exercise State sanitary supervision and authorized to carry out the State Registration of products (as worded in the Resolution of the Ministry of Health of 10 June 2015 No. 82). | It establishes procedures and conditions for the State Registration of Products that constitutes a potential danger for life and health of population, including procedures and conditions for issuance, change, reissuance, suspension, renewal, termination of the Certificate for State Registration |
| On Some Issues Related to Commodity Transfer Across the Customs Border of the Republic of Belarus (Regulation on Order and Terms of Issue by the Ministry of Health of Conclusions | The Resolution of the Council of Ministers of the Republic of Belarus of 11 July 2012 No. 635 | Cross-Sectoral | Ministry of Health of the Republic of Belarus, Republican Research and Practical Center for Epidemiology and Microbiology of the Ministry of Health, State Customs Committee of the Republic of Belarus | It establishes a procedure for the organization and performance of a range of works on acceptance and consideration of documents, submitted by the declarant with a view of receiving a decision (authorization documents). It establishes a list of potentially pathogenic and pathogenic genetically engineered organisms, limited for conveyance through the State border of the Republic of Belarus during their import and (or) export on non-economic grounds, |

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| (Permits) to Import and (or) Export of Potentially Pathogenic and Pathogenic Genetically Engineered Organisms, Restricted for Transit through the State Border of the Republic of Belarus Based on Noneconomic Reasons) | | | | the import and (or) export of which shall be allowed upon availability of a permit (an authorization document), issued by the Ministry of Health of the Republic of Belarus. |
| On Safety Requirements for Self-contained Systems when Performing Works of Risk Level I in Genetic Engineering Activity and | Resolution of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of 17 August 2006 No. 50 | Cross-Sectoral | Legal entities (organizations) that carry out works in self-contained systems of Risk Level I of genetic engineering activity; territorial bodies of the Ministry of Natural Resources and Environmental Protection of the Republic of | It establishes procedures for carrying out of works; safety requirements to self-contained systems when exercising works of Risk Level I in genetic engineering activity; procedures for waste neutralization |

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| Individuals Involved in the Development of Genetically Engineered Organisms | | | Belarus | |
| On Some Issues Related to Safety in Genetic Engineering Activity | Resolution of Ministry of Health of the Republic of Belarus of 25 August 2006 No. 65 | Cross-Sectoral | Legal entities (organizations) that exercise works in self-contained systems of Risk Levels II, III and IV in genetic engineering activity.<br>Commissions that carry out accreditation of self-contained systems:<br>the Commission for Control over Compliance with Biological Safety Requirements and Epidemiological Regime of the Ministry of Health of the Republic of Belarus, the Commission for Control over Compliance with Biological Safety Requirements and | It establishes:<br>- safety requirements to self-contained systems to carry out works of Risk Levels II, III and IV in genetic engineering activity;<br>- accreditation procedures for self-contained systems to carry out works of Risk Levels II, III and IV in genetic engineering activity;<br>- safety requirements to transport of potentially pathogenic and pathogenic genetically engineered organisms;<br>- record procedures for legal entities of developed, imported into the Republic of Belarus and exported from the Republic of Belarus and conveyed in transit through its territory of potentially pathogenic and pathogenic genetically engineered organisms |

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| | | | Epidemiological Regime of Regional Centers for Hygiene, Epidemiology and Public Health and the State establishment "Minsk City Centre for Hygiene and Epidemiology", the Republican Research and Practical Center for Epidemiology and Microbiology of the Ministry of Health. | |
| On Approval of Instruction on Procedure of Development and Approval by the Legal Entity or Individual Entrepreneur of Local Normative Legal Act on the Production Control in the Field of Safety | Resolution of 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 3 April | Cross-Sectoral | Legal entities (organizations) or individual entrepreneurs engaged in genetic engineering activity of Risk Level I and State legal entities engaged in genetic engineering activity of Risk Levels II, III and IV. | The approved instruction establishes a procedure for the development and approval by legal entities or individual entrepreneurs of the local normative legal act on the production control in the field of safety in genetic engineering activity |

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| of Genetic Engineering Activities | 2014 No. 19/23/14 | | | |
| On Approval of the Instruction on Risk Assessment Procedure of Possible Adverse Effects of Genetically Engineered Organisms on the Environment | Resolution of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of 29 August 2006 No. 57 | Cross-Sectoral | Legal entities and individual entrepreneurs engaged in genetic engineering activity, Experts of the Safety Expert Board for Genetically Engineered Organisms of the Ministry of Natural Resources and Environmental Protection, the experts that perform risk assessment. | It establishes a procedure for risk assessment of possible adverse effects of genetically engineered organisms on the environment. |
| On Approval of the Instruction Related to the Procedure for Conducting Risk Assessment of Possible Adverse Effects of Genetically | Resolution of the Chief Sanitary Doctor of the Republic of Belarus of 25 August 2006, No 076-086 | Cross-Sectoral | Legal entities and individual entrepreneurs engaged in genetic engineering activity, Experts of the Safety Expert Board for Genetically Engineered Organisms of the Ministry of Natural Resources and | The approved instruction establishes a procedure to perform risk assessment of possible adverse effects of genetically engineered organisms on human health. |

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| Engineered Organisms on Human Health | | | Environmental Protection, the experts that perform risk assessment. | |
| On Approval of the Provision on the Expert Safety Board for Genetically Engineered Organisms of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus | Approved by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of 17 August 2006 No. 52. | Cross-Sectoral | The Expert Safety Board is a collegial advisory body that incorporates a Chairperson, Deputy Chairperson, a Secretary and Board members from the officials of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus, other specially authorized bodies of the State Administration in the field of safety in genetic engineering activity and specialists in this field (Appendix 6), as well as citizens of the Republic of Belarus. | Organization of the State Safety Expertise of genetically engineered organisms;<br>recommendation of an agency (a laboratory, an institution, etc.) to carry out the State Safety Expertise of genetically engineered organisms;<br>consideration of the State Safety Expertise findings on genetically engineered organisms;<br>adoption of recommendations on release admissibility of genetically engineered organisms into the environment for testing or use for economic purposes and granting/nongranting of a Permit for Release. |
| Members of the Expert Safety Board for | Resolution of the Ministry of Natural | Cross-Sectoral | At present it includes representatives the following establishments: | It approves members of the Expert Safety Board for Genetically Engineered Organisms. |

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| Genetically Engineered Organisms of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus | Resources and Environmental Protection of the Republic of Belarus of 5 December 2012 No. 412-OD; amendments introduced by orders of 12 January 2015 No. 14-OD and 28 October 2015 No. 370-OD). | | the Ministry of Natural Resources, the Belarusian Research Centre "Ecology"; the Ministry of Agriculture and Food; subordinated institutions of the National Academy of Sciences of Belarus: the Institute of Genetics and Cytology, the Institute of Microbiology, the Institute of Biophysics and Cell Engineering, the Institute of Experimental Botany, the Institute of Forest, the Scientific and Practical Centre for Potato, Vegetable and Fruit Growing, the Institute of Plant Protection; subordinated establishments of the Ministry of Health: the Republican Research and Scientific Centre for Epidemiology and Microbiology, the | |

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| | | | Scientific and Practical Centre of Hygiene; the Belarusian State Institute of Metrology (see Annex 6 for details). | |
| On Cooperation of the Republic of Belarus and International Organizations | The Resolution of the Council of Ministers of the Republic of Belarus of 30 October 2002 No. 1504 | Sectoral | Ministry of Natural Resources and Environmental Protection of the Republic of Belarus | It establishes that the Ministry of Natural Resources and Environmental Protection shall provide a liaison with the Secretariat of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety to the Convention and that it has been entrusted with powers of the National Competent Body and the Coordination Centre. |
| On the Notification Procedure of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus by the Carrier Conveying in | Ministry of Natural Resources and Environmental Protection of the Republic of Belarus, of 17 August 2006 No. 49 | Cross-Sectoral | Legal entities (organizations) and individual entrepreneurs that carry out the transport of nonpathogenic, genetically engineered organisms, the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus | It establishes the notification procedure of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus by the carrier conveying in transit through the territory of the Republic of Belarus of nonpathogenic genetically engineered organisms. |

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| Transit through the Territory of the Republic of Belarus of Nonpathogenic Genetically Engineered Organisms | | | | |
| On Approval of Permit and Application Forms for Import, Export or Transit of Potentially Pathogenic or Pathogenic Genetically Engineered Organisms | Resolution of the Ministry of Health of the Republic of Belarus, of 21 September 2006 No. 73 | Cross-Sectoral | State legal entities engaged in genetic engineering activity of Risk Levels II, III and IV, the Republican Research and Practical Center for Epidemiology and Microbiology of the Ministry of Health. | It establishes permit forms for import, export and transit of potentially pathogenic and pathogenic genetically engineered organisms and applications for import (export, transit) of potentially pathogenic and pathogenic genetically engineered organisms |
| On Registration Procedure of Nonpathogenic, Genetically Engineered Organisms Developed, Imported into | Ministry of Natural Resources and Environmental Protection of the Republic of Belarus, of 17 August 2006 | Cross-Sectoral | Legal entities (organizations) and individual entrepreneurs that carry out the transport of nonpathogenic genetically engineered organisms, the Ministry | It establishes the registration procedure for nonpathogenic, genetically engineered organisms developed, imported into the Republic of Belarus, exported from the Republic of Belarus and conveyed as transit goods through its territory by legal entities and |

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| the Republic of Belarus, Exported from the Republic of Belarus and Conveyed as Transit Goods through its Territory by Legal Entities and Individual Entrepreneurs | No. 51 | | of Natural Resources and Environmental Protection of the Republic of Belarus | individual entrepreneurs. |
| On Safety Requirements for Trial Fields and Other Objects Provided for Testing of Nonpathogenic Genetically Engineered Organisms under their First Release into the Environment | Resolution of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of 29 August 2006 No. 56 | Cross-sectoral | Organizations/institutions that have trial fields at their disposal destined for GMO testing, territorial bodies of the Ministry of Nature | It establishes requirements for trial fields and other objects provided for testing of nonpathogenic genetically engineered organisms under their first release into the environment |
| The Trial Field Certificate for | Approved by the Director of the | Sectoral | Institute of Genetics and Cytology, NAS of | It establishes the requirements and procedures the trial field use, safety |

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| testing of nonpathogenic genetically engineered organisms under their first release into the environment в | Institute of Genetics and Cytology of the National Academy of Sciences of Belarus, coordinated with Minsk City Committee of Natural Resources and Environmental Protection (2012 ) | | Belarus | regulations of genetic engineering activity under release of nonpathogenic genetically engineered organisms for testing in the trial field, the responsibilities for individuals engaged in this activity. |
| Procedures for use of specially prepared (equipped) trial field of the Institute of Genetics and Cytology of NAS of Belarus to test transgenic plants under their first | Approved by the Director of the Institute of Genetics and Cytology of the National Academy of Sciences of Belarus (2015) | Sectoral | Institute of Genetics and Cytology, NAS of Belarus | Developed to ensure the compliance with the National biosafety legislation on testing of genetically engineered plants under their first release into the environment. It provides regulations on the trial field use for release of genetically engineered plants. |

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| release into the environment | | | | |
| The Trial Field Certificate for testing of nonpathogenic genetically engineered organisms under their first release into the environment. | Approved by the Director of the Central Botanic Garden, coordinated with Minsk City Committee of Natural Resources and Environmental Protection | Sectoral | Central Botanic Garden, NAS of Belarus | It establishes requirements to the trial field and safety regulations of genetic engineering activity under release of nonpathogenic genetically engineered organisms into the trial field that satisfy the established safety requirements. |
| The Trial Field Certificate for testing of nonpathogenic genetically engineered organisms under their first release into the environment. | Approved by the Director General of the Scientific and Practical Centre for Potatoes, Vegetable and Plant Growing of NAS of Belarus, coordinated with Uzda Regional Inspection of the Ministry of Natural | Sectoral | Scientific and Practical Centre for Potatoes, Vegetable and Plant Growing of NAS of Belarus | It establishes requirements to the trial field and safety regulations of genetic engineering activity under release of nonpathogenic genetically engineered organisms for testing into the trial field that complies with the established requirements. |

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| | Resources and Environmental Protection of the Republic of Belarus (2014 ) | | | |
| Raw materials and food products. The detection technique for genetically modified sources (genetically modified components) | STB GOST P 52173-2005 | Cross-Sectoral | Eighteen Republican LDGMOs | It establishes the State Laboratory Standard for detection of genetically modified sources (genetically modified components of plant origin. |
| On some issues of provision of information to consumers on food raw material and food products | Resolution of the Council of Ministers of the Republic of Belarus of 28 April 2005 No. 434 | Cross-Sectoral | For all bodies that ensure safety in genetic engineering activity, the State Customs Committee and 18 Republican LDGMOs | A nonthreshold system established – the entire batch of produce, in which as a result of random checks the GM admixture detected is labelled with a mark “Contains GMOs”. |
| On establishment of sanitary norms | Resolution of the Ministry of Health of the | Cross-Sectoral | For all bodies that ensure safety in genetic engineering activity, the | It establishes sanitary-epidemiological requirements to the production raw material and food |

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| and regulations “Requirements to the production raw material and food products” and и the sanitary-hygienic standard “Safety indicators and data for a man of the production raw material and food products” | Republic of Belarus of 21 June 2013 No. 52 | | State Customs Committee and 18 Republican LDGMOs | products, their safety, the handling process and labelling. Adopted after the accession to the Customs Union and sets labelling regulations in accordance the Customs Union standards. |

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| On approval of veterinary and sanitary regulations to ensure safety of feeds, feed additives and the raw materials for the combined feed production. | Resolution of the Ministry of Agriculture and Food of the Republic of Belarus of 10 February 2011 No. 10 | Cross-Sectoral | For all bodies that ensure safety in genetic engineering activity, the State Customs Committee and 18 Republican LDGMOs | It establishes veterinary and sanitary regulations to ensure safety of feeds, feed additives and the raw materials for the combined feed production.<br><br>It established that the content of genetically modified organisms exceeding 0,9% of each of the components is allowed in feeds containing soya and corn of the approved lines, specified in Annex 2 to this Regulation, on condition of mandatory declaration by the producer on the fact of their presence in the Quality Certificate or in the Quality and Safety Certification. Adopted after the accession to the Customs Union and sets labelling regulations in accordance the Customs Union standards. |

Thus, the legislation that fully embraces all safety spheres in genetic engineering activity was elaborated in the Republic of Belarus, biosafety was mainstreamed into main sectoral and cross-sectoral laws and policies, integration safety mechanisms into sectoral and cross-sectoral activity of institutions were worked out .

At the same time in connection with formation of the Eurasian Economic Community and the Eurasian Economic Union in 2014, which includes Belarus, the Russian Federation, Kazakhstan, Armenia and Kyrgyzstan, and adoption of principles of free movement of goods within the Union and common customs territory, in particular adoption of the Customs Union Technical Regulations TR CU 021/2011 "On Food Safety" and TR CU 022/2011 "Food Products in terms of their Labelling", the harmonization process of national legislations, standards and methodological approaches of EAEU countries continues. With reference to the above, the meeting participants made recommendations to the designated authorities in the field of safety in genetic engineering activity (and the seminar participants supported them) to continue work on harmonization of the legislation of the EAEU member-states in terms of GMO labelling, GMO-containing products, derived from/or with use of GMOs, harmonization of interstate methodological approaches, standards and instructions with regard to the GMO detection and identification, risk assessment of GMOs and GMO-derived products. Concrete proposals are given in the Summary of the Round-table, Appendix 1, paragraphs 1.2., 2.1-2.4.

Also, in the course of the seminar and the round-table, the participants laid emphasis on the fact that at present a number of newly-developed GMOs, as well as GMOs at various stages of release into the environment and already commercialized GMOs is increasing and this, in its turn, leads to an increase in the number of GMOs that cannot be identified by generally accepted for the moment methods, such as the detection by 35S promoter and Nos-terminator since they do not allow to detect new transgenic events, for the development of which other sequences are used. Also, commonly used methods do not allow to detect transgenic animals and their products that may be potentially realized in the market. As an example, we can mention a rapidly developing new direction - transgenic fish, developed in aquacultures, such as fast-growing Atlantic salmon, disease-resistant American catfish and White Amur, resistant to cold silver carp, as well as disease-resistant oysters and crustaceans with modified productivity indicators. These organisms are at various stages of testing, however, the Atlantic salmon has recently been approved by the Food and Drug Administration (US FDA), making it the first genetically modified animal, intended for human consumption.

This reality leads to an increase in the number of events to be detected in the Laboratory for the GMO Detection (LDGMOs). The presence of unapproved GMOs in the potential market results in the situation when the laboratories face with the need

to detect a large number of GM events, some of which may have been approved, while the others have not been allowed for use yet and some are used illegally and in case of packaged genetically modified plants (GMPs) (that is the GMPs developed as a result of the crossing of one or more GMPs or by the several gene cassette transformation, the retransformation of GMPs or simultaneous transformation by various cassettes or vectors). The situation may be strongly complicated by the presence of all these factors in a single sample. In connection with the above-mentioned, the participants of the round-table and the seminar laid emphasis that there is a need for training and counseling in new methods of GMO detection and identification, including theoretical and practical courses and counseling with regard to administrative and legal requirements (both at EAEU and international levels) to LDGMOs specialists of the Republic of Belarus (Appendix 1, Appendix 2).

## 2. BIOSAFETY MAINSTREAMING INTO NATIONAL STRATEGIES. ACTIVITIES ACROSS VARIOUS MINISTRIES AND SECTORS AND NATIONAL LEVEL PROJECTS IN THE FIELD OF BIOSAFETY. GOOD PRACTICES, CHALLENGES, CAPACITY NEEDS, OPPORTUNITIES, AND LESSONS LEARNED

On 26 December 2012 the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus adopted a Strategic Plan on the implementation of the Cartagena Protocol on Biosafety in the Republic of Belarus. The plan covers the period up to 2020.

The Strategic Plan is the key instrument for stimulation of effective implementation of the Protocol by the subjects responsible for its implementation in the Republic of Belarus on the basis of a strategic approach that includes a joint concept, mission and objectives to ensure clear understanding of targets and responsibility, as well as a plan including a name of events, responsible performers and deadlines. The plan was developed by the Expert Safety Board for Genetically Engineered Organisms of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus based on the Decision BS-V/16 of the Conference of the Parties to the Cartagena Protocol on Biosafety with regard to the approval of the Strategic Plan on the Protocol implementation. The Strategic Plan shows that the activity on the Protocol implementation in the Republic of Belarus is held at the level of ministries and executive institutions and by the National Co-ordination Biosafety Centre of the Institute of Genetics and Cytology of NAS of Belarus. The Strategic plan concept is to ensure the proper protection level for biological diversity of the Republic of Belarus from any adverse impact of genetically modified organisms (GMOs).

The Strategic plan indicates that the basis for the Strategic Plan development was the necessity to prepare additional guidelines and (or) explanations to the procedures and processes related to the implementation of a number of Protocol Provisions, including the application of the prior informed consent procedure (Article 7); the procedure application with regard to living modified organisms destined for direct use as foodstuffs or feeds or for handling purposes (Article 11), risk assessment and regulation (Articles 15 and 16); handling, packaging and identification (Article 18), capacity building (Article 22); mechanisms for raising public awareness and public participation (Article 23); responsibility and indemnification mechanisms (Article 27); procedures and organizational mechanisms to promote the Protocol Provisions compliance (Article34) and etc.

The Strategic Plan was developed within a framework of the State programme "Innovation Biotechnology" for 2010-2012 and for the period up to 2015, approved by the Resolution of the Council of Ministers of the Republic of Belarus of 23 October 2009 23 No. 1386, including analytical materials collected in the Preparation of the Second National Report on the Cartagena Protocol on Biosafety implementation. The Strategic Plan also takes account of the Provisions of the Strategy on the Conservation and Sustainable Use of Biological Diversity for 2011-2020 in the Republic of Belarus.

The Strategic Plan shows that funding of events included in the Strategic Plan is carried out at the expense of the State budget and international funds' financing provided that the financing for projects' implementation has been received from the International Technical Assistance.

The Strategic Plan includes 5 strategic objectives. Each strategic objective includes a name of events, responsible officers and deadlines. Setting strategic objectives and priority identification is carried out according to their contribution to the Protocol implementation, taking into account the specific areas of its application:

*Strategic objective 1*. Further development and enhancement of efficiency of the National biosafety system with a view of the Protocol implementation in the Republic of Belarus as the Customs Union Member-State.

*Strategic objective 2*. Capacity building to implement obligations on the Protocol.

*Strategic objective 3*. The Protocol compliance and assessment of effectiveness of its implementation.

*Strategic objective 4*. Information exchange.

*Strategic objective 5*. Expanded access to the Protocol and collaboration.

The plan implementation that covers the entire period and all institutions involved in realization of each strategic objective is available on the Ministry of Nature website at the link http://minpriroda.gov.by/ru/new_url_1070651998-ru/.

The Strategic Plan shows that coordinators on the Strategic Plan implementation may vary depending on the issues, actions and events specified in the Plan. Some of the actions may be carried out by the ministries and NCBC responsible for the implementation of Protocol Provisions, or other organizations involved to perform certain objectives. The sources of information are the information reports of the main executors and other sources that are relevant to biosafety and available to receive the data required for analysis. The Strategic Plan can be amended and supplemented as required on the basis of annual assessment results on its implementation and decisions that affect the course of its implementation, or other grounds.

The Strategic Plan also indicates that NCBC should timely submit to the Biosafety Clearing-House Mechanism of information in accordance with Article 20 of the Protocol (adopted laws and normative acts, decisions on living modified organisms, etc.). It should be noted that NCBC implements the plan. This work is carried out on an on-going basis by a specially authorized person – Head of the National Co-ordination Biosafety Centre. As of 30 September 2016, all major normative legal acts on the Biosafety regulation in the Republic of Belarus, reports on Risk Assessment, Country's Decision or any other Communication, Reports on Implementation of the Protocol and other relevant documents were published on the Internet portal of the Biosafety Clearing-House, 50 documents in total. NCBC also on a constant basis makes registration on the BCH website of living modified organisms developed in the country to assign a unique identification number to them in order to trace these organisms in future. The State risk assessment procedure is not possible without the assigned registration number to them.

Among the priority directions of scientific research of the Republic of Belarus for 2011-2015, approved by the Resolution of the Council of Ministers of 19 April 2010 №585 and aimed at development of biosafety system, the conservation and sustainable use of genetic resources are the following:

*3. "Physico-chemical bases of Biology. Biotechnologies, bioenergy and biofuels:*

*3.3. genetics and genomics of plants, animals, microorganisms and humans, including the conservation of genetic resources;*

*3.4. biosafety of transgenic plants, microorganisms and their components to human health, animals and environment;*

*3.5. Bioinformatics, Nanobiology;*

*3.6. gene identification and mapping; certification, marking, identification, breeding and development of agricultural plants, animals and microorganisms by DNA-technologies; DNA-technologies and genetic engineering techniques in the diagnosis and treatment of human and farm animal diseases;*

*3.11. metabolomics of living systems, detection of metabolic markers for plant, human and animal diseases, metabolic engineering.*

*9. Production, storage and processing of agricultural products:*

*9.1. theory and methodology of the effective functioning of agro-industrial complex;*

*9.2. restoration, rational use and protection of soil resources and agricultural lands;*

*9.3. theory and methodology for improving the breeding process, using the latest biotechnologies and genetic engineering mechanisms in plant growing and animal breeding;*

*9.4. technologies and methods for the development of high-yielding and resistant varieties and hybrids of agricultural crops, taking into account the targets and zonal characteristics;*

*9.5. technologies and methods to improve the species composition, husbandry, feeding, reproduction, veterinary protection and targeted use of farm animals;*

*10. Ecology, natural resources, resource conservation, sustainable environmental management and protection from emergency situations:*

*10.4. geoecologic assessment and management of environmental quality, conservation and rational use of natural resources potential of aquatic and terrestrial ecosystems;*

*10.5. dynamics of biological and genetic diversity of native and introduced flora and fauna;*

*10.6. problems of migration and accumulation of pollutants in landscapes and trophic chains;*

*10.7. regeneration of forests on the basis of genetic and breeding methods, tools and technologies for forest growing, conservation and protection of forests, multipurpose forest management;*

*10.8. technologies and tools for the restoration and use of disturbed natural ecosystems;*

*10.9. innovation technologies for use and reproduction of populations of animal and plant resource species, DNA-technology assessment of the gene pool state of animal and plant natural populations;*

*10.10. monitoring methods and technologies, information and analysis forecasting systems of natural environment state as a result of economic activity and emergency situations, the Earth surface remote sensing with a view of environmental management and ecological safety monitoring;*

*10.11. innovation tools and technologies for prevention and liquidation of emergency situations, methods and devices for the product and material testing to ensure the compliance with safety requirements.*

Scientific activities across various subordinated authorities (institutions, centers, academic departments) belong to the National Academy of Sciences and State Universities and the implementation of scientific projects in the field of

biosafety is mainly carried out within a framework of state programs. In 2011-2015 the state program "Innovative Biotechnologies" was implemented, years 2010-2012 and the period for up to 2015 (the Resolution of the Council of Ministers of the Republic of Belarus of 23.10.2009 N 1386). The key State program objective was the establishment of the biotechnological sector of economy in the Republic of Belarus, conforming to modern international standards, as well as ensuring its legal, scientific and human resource support.

Out of 47 implemented assignments within a framework of subprogram "Agricultural Biotechnology (plant growing) of the State program "Innovative Biotechnologies" with a view of ensuring the biosafety system development, the following ones should be noted:

"Biosafety assessment of transgenic potato plants for human health, animals and the environment", carried out by the State Scientific Institution "Institute of Genetics & Cytology", the State Scientific Institution "Institute of Biophysics & Cell Engineering", and the State Unitary Enterprise "Scientific & Practical Centre for Potato, Vegetable and Fruit Growing of the National Academy of Sciences of Belarus".

"The field creation to perform transgenic plant testing under their first release into the environment" at the State Scientific Institution "Institute of Genetics & Cytology of the National Academy of Sciences of Belarus", carried out by the State Scientific Institution "Institute of Genetics & Cytology of the National Academy of Sciences of Belarus" in 2014.

"The completion of the field creation to perform transgenic plant testing under their first release into the environment at the Republican Unitary Enterprise "Scientific & Practical Centre for Potato, Vegetable and Fruit Growing", carried out by the Republican Unitary Enterprise "Scientific & Practical Centre for Potato, Vegetable and Fruit Growing" in 2015.

"The establishment of the DNA-biotechnology center for the DNA-marking and certification of plants, animals, microorganisms and a human, carried out by the State Scientific Institution "Institute of Genetics & Cytology of the National Academy of Sciences of Belarus".

"The role determination of a heterologous gene expression of thaumatin II protein in showing of antifungal activity and changes in the fruit taste of marsh cranberry (Oxycoccus macrocorpus). The technology development for laboratory and field trials of transgenic cranberry plants to select forms with increased resistance to pathogens and modified fruit palatability traits", carried out by the State Scientific Institution "Central Botanic Garden of the National Academy of Sciences of Belarus" in 2014.

Also, within Subprogram 2 " Genetic, physiological and biochemical bases for the adaptive crop breeding" of the State program "Innovative Technologies for the

Agroproduction Complex" for years 2011-2015, the Scientific & Practical Centre for Arable Farming alongside the State Scientific Institution "Institute of Genetics & Cytology of the National Academy of Sciences of Belarus" carried out the assignment "Study of molecular genetic biochemical and biological characteristics of transgenic rape plants with CYP11A1 gene encoding P450 cytochrome expression".

It should be noted that despite the framed by 2006 legislation in the field of biosafety, GMOs were examined only in closed laboratory conditions and, thus, implementation of State program assignments for years 2010-2015 enabled to create safe conditions to perform transgenic plant testing under their release into the environment, as well as ecological and genetic monitoring.

Other completed assignments were aimed at carrying out medical and biological assessment of developed GMOs, as well as elaboration of technologies for the laboratory and field testing of GMOs, necessary to pass all stages of the GMO assessment, intended for further use in economic activity.

An essential result of the implementation of assignments within the State program "Innovative Biotechnologies" was the establishment at the State Scientific Institution "Institute of Genetics & Cytology of the National Academy of Sciences of Belarus" of the "DNA-biotechnology Centre for the DNA-marking and Certification of Plants, Animals, Microorganisms and a Human" in October 2015 – International Research Centre for Genetic Engineering Safety.

In accordance with the Resolution of the Council of Ministers of the Republic of Belarus of 30 December 1999 № 2063 "On State Program "Establishment of National Genetic Fund of Economically Valuable Plants" in 2000-2005, and subsequently, in 2007-2010 the National Centre for Economically Valuable Plant Genetic Resources was established, which includes 11 field-specific organizations related to the Departments of Agricultural and Biological Sciences of the National Academy of Sciences of Belarus and 2 educational institutions of agricultural and biological profile. The gene pool, including more than 30 thousand specimens, has been collected, studied and is used in practical breeding and scientific research.

In the Resolution of the Council of Ministers of 28 March 2011 №385 "On State program "Establishment of the National Bank of Plant Genetic Resources for Breeding of New Varieties and Hybrids of Agricultural Crops, Preservation and Enrichment of Cultural and Natural Flora of Belarus, for years 2011-2015" it was planned to continue and expand activities carried out in 2000 - 2005 and 2007 - 2010. The program was aimed at the replenishment, maintenance, research and mobilization of genetic resources of economically valuable plants with a view of enriching and expanding the starting breeding material, promoting research in this field and accessibility to it of breeding institutions of the Republic of Belarus; operational use of the latest patterns of economically valuable plants, belonging to domestic and world collections; the optimization of existing system of plant resources utilization by

creating a network of sectorial branches of the genetic fund (hereinafter referred to as "the gene pool"); organization of operational and long-term storage of plant gene resources and their targeted use. The State program also provided the organization of scientific and technical basis for the identification of all the material, belonging to economically valuable plants and being submitted to the DNA bank of the Republic of Belarus. The program implementation is the key basis to ensure the respect for copyrights in the field of plant breeding in the Republic of Belarus. In addition, as part of the program implementation, the use of the collection fund and copyrights of breeding institutions of the Republic of Belarus and abroad was harmonized, as well as publication of reference, thematic and promotional material in the field of biosafety of economically valuable flora.

In the course of the program implementation, the gene bank of the Republic of Belarus (the National Bank of Plant Gene Resources of the Republic of Belarus) was established at the Republican Unitary Enterprise "Scientific & Practical Centre for Arable Farming" and stores the major seed stock (seed fund) of economically valuable plant genetic resources in the Republic of Belarus. As part of the same program implementation, the Republican DNA Bank of Plants, Animals, Microorganisms and a Human was formed at the State Scientific Institution "Institute of Genetics & Cytology of the National Academy of Sciences of Belarus".

Among the priority areas of research in 2010-2015, the research on the development of DNA-identification system for varietal belonging of crop seed material, the elaboration of DNA-marking techniques to identify breeding valuable traits of plants and animals was considered and implemented as part of various scientific research programs. In particular, during the implementation of the State program "Innovative Biotechnologies", the State program "Genomics" and the Interstate Special-purpose Program (ISPP) "EurAsEC" carried out a number of projects aimed at the development DNA-marking methods for most important, not modified agricultural plant varieties, animal breeds and strains of microorganisms. The lessons learned as a result of research activity, as well as procedures, elaborated research techniques and technological regulations for non-modified organisms may be further used to develop appropriate methods for GMOs.

Use of accumulated results in environmental studies on traditional cultures is also important for further research in the field of GMO safety. A number of such assignments were performed in 2011-2015. As part of Subprogram 2 "Biodiversity, Bioresources & Ecotechnologies", for example, of the State program "Scientific Basis for Integrated Use, Preservation and Reproduction of Natural Resource Potential and Environmental Enhancement (Natural Resource Potential)", the results of which may be used for strategy developments with a view of GMO risk management and monitoring, the following assignments should be noted:

"Identify the dynamics of invasive processes in the fauna and flora of the Republic, assess the environmental effects of aggressive alien species as a basis for the development of effective control measures and damage minimization". Implemented by the Scientific & Practical Centre for Bioresources, the Institute of Experimental Botany, the Central Botanic Garden and the Belarusian State University.

"The scientific basis for the organization of breeding genetic monitoring of forest seed production to ensure the unique gene pool preservation, the generation of sustainable and highly- productive forests."

"The assessment of structure-functional status of plant complexes of natural and urban environment to introduce a set of measures for the conservation, restoration and optimization of their environmental sustainability".

Implemented by the Central Botanic Garden, National Academy of Sciences of Belarus.

In 2016 by the Decree of the Council of Ministers of 12.03.2015 N 190 the priority directions of scientific research in the Republic of Belarus for 2016-2020 were established. They are as follows: biological systems and technologies, ecology and environmental management, as well as human, society and State safety.

As part of the State research program "Biotechnologies", Subprogram 2 "Structural & Functional Genomics" for 2016-2018, the State Scientific Institution "Institute of Genetics & Cytology of the National Academy of Sciences of Belarus" implements the following assignment: "Assessment of interspecies gene transfer among cultivated and wild species of the *Brassicaceae* family with a view of the biodiversity and biosafety monitoring".

The establishment of research centers aimed at the study of agronomic characters, the development of DNA-marking techniques, the study of GMOs, the establishment of a seed bank and DNA bank, the environmental research results obtained on plant varieties, animal breeds and traditional breeding microorganism stains will certainly promote the research development in the field of GMO biosafety, the observance of national and international principles of biological safety in use of plant material.

Thus, it should be noted that modern biotechnologies, including genetic engineering ones, are rapidly developing in the country. For example, as part of program "Innovative Biotechnologies" (years 2011-2015) 7 assignments were directed at the development of the genetically engineered organisms and 2 assignments at the biosafety assessment of newly-developed cultures (crops). However, biomedical assessment and environmental studies are mandatory steps for the GMO risk assessment and it should not be carried out by GMO developers, but at the institutions that have trial fields at their disposal to assess environmental risks

with the appropriate equipment and specially trained personnel to carry out biomedical safety assessment.

The scientific research on potential risk assessment, carried out by the GMO developer jointly with relevant organizations rendering services in such assessments, may be effectively conducted in the form of assignments within state research programs to provide that the further use of GMOs in the economic activity is attended with scientifically grounded recommendations to ensure the conservation of biological diversity.

Further improvement of regulations and protocols on the potential risk assessment of GMOs on human health is required and they should be scientifically grounded and presented in the simplest for the executor terms to ensure the traceability of results in the course of time to conduct analytical studies in organizations that perform such assessments.

It should be specially noted that an important step for the analysis of the National Biosafety System was the implementation of UNEP-GEF international technical assistance projects, carried out at the country level "Support to Preparation of the Second National Biosafety Report to the Cartagena Protocol on Biosafety" in 2011 and "Support to Preparation of the Third National Biosafety Report to the Cartagena Protocol on Biosafety" in 2015. The projects were carried out in the form of a consultative process, including the holding of seminars with the participation of the country organizations responsible for ensuring of biosafety. The analysis of the amendments in the national legislation for the period of 2008 -2015 allowed to identify the areas for further development in the field of biosafety. (http://biosafety.org.by/nrb2; http://biosafety.org.by/node/27789).

With a view of biosafety system development in Belarus and raising awareness of key persons and the public concerned among other activities of the National Co-ordination Biosafety Centre (NCBC), NCBC in collaboration with relevant organizations publish methodical recommendations, guidelines, books, training materials which are available on the website of the NCBC at the link http://biosafety.org.by/publications. A list of publications is in Appendix 4. The project implemented with the CEI financial support "Experience Sharing in Public Education and Awareness of Biosafety Issues" in 2013 was aimed at raising public awareness of GMO issues (http://biosafety.org.by/cei-2013). It was revealed that the priority part should be conducted by the National Co-ordination Biosafety Centre in close contact with the Aarhus Centre and that resulted in the increased cooperation and joint activities of two centers in the field of public education.

Thus, Belarus adopted a Strategic Plan on the implementation of the Cartagena Protocol on Biosafety for 2013-2020, which is the key instrument that stimulates effective implementation of the Protocol by the organizations responsible for its implementation in the Republic of Belarus. The strategic plan includes 5 strategic

objectives. Each strategic objective includes a name of events, responsible executing organizations and deadlines. Scientific research biosafety programmes are held in the country and this direction was included in a list of priority scientific research directions for 2011-2015 and 2016-2020.

Alongside this, the Desk Study and the round table revealed some issues:

**1 Issue.** GMO biosafety issues were not included into the "Strategy of the Republic of Belarus on the Conservation and Sustainable Use of Biodiversity" for 2011-2020. At the same time, this document is the basis for stimulation of the integrated implementation of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity at the national level. In this respect, the participants of the Round-table suggested and the seminar participants' supported that biosafety issues of genetic engineering activity should be included into the "Strategy of the Republic of Belarus on the Conservation and Sustainable Use of Biodiversity" and "National Strategy on Sustainable Social and Economic Development of the Republic of Belarus" with a view of biosafety projects' mainstreaming among the biodiversity ones.

At the seminar the desk study consultants introduced concrete proposals on the inclusion of the biosafety issues in National Strategies that regulate activity in the area of biological diversity conservation and its sustainable use (see the table below).

**NATIONAL STRATEGIES**
**that regulate activity in the area of biological diversity conservation and its sustainable use**

| No. | Name | State Authority & Document Approval Date | Objectives & Targets | Targets, biosafety issues to be included in |
|---|---|---|---|---|
| | **Elaboration of strategy for scientific, scientific and technological and innovation activity in the area of environmental protection and efficient use of natural resources for 2014-2015 and for the period up to 2025** | Board Decision of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of 26 November 2014, No. 112-P | **Priority objective:** sustainable development of the scientific field of the Republic of Belarus in the area of environmental protection and efficient use of natural resources to provide scientific support in tackling of ecological safety challenges of the State.<br>**Targets:**<br>elimination and prevention of threats to national security in the science and technology area **[including the area of modern biotechnology]** associated with risks to scientific resources alleviation and loss of existing scientific schools;<br><br>ensuring of program and targeted development with regard to scientific, scientific and technological and innovative activity in the area of environmental protection and efficient use of natural resources;<br>organization of complex high-level scientific research [**including the area of modern biotechnologies]** that allows us to | **including the area of modern biotechnology**<br><br>**including the area of modern** |

| | | | | |
|---|---|---|---|---|
| | | | address challenges in the area of environmental protection and efficient use of natural resources, and based on this, to develop a scientific baseline with a view of a permanent increase in the share of innovative products and services in their total production volume;<br><br>encouragement of innovation activity;<br><br>mainstreaming of research scientist profession prestige; a comprehensive system improvement with regard to material and moral incentives for personnel engaged in scientific research and developments; invention activities support;<br><br>development of new research forms and directions to preserve scientific and technological potential in conditions of cutbacks to budget funding for scientific research and developments.<br><br>The strategy implementation includes <u>three stages</u>:<br>stage I – short-term (years 2014-2015),<br>stage II – mid-term (years 2016-2020),<br>**stageIII** -- long-term (years 2021-2025 and onwards). | **biotechnology** |

| | | | | |
|---|---|---|---|---|
| | **Strategy for conservation and sustainable use of biological diversity for years 2011-2020 "On Some Issues in the Area of Conservation and Sustainable Use of Biological Diversity"** | Resolution of the Council of Ministers of the Republic of Belarus of 19 November 2010, No. 1707 | **<u>Activity priority directions</u>:**<br>- implementation of techniques for wildlife objects use in hunting, fishing and forestry management, which do not deplete them;<br>- system optimization for specially protected natural areas, establishment of the National Ecological Network and ensuring of its operation;<br>- announcement of biosphere reserves, including the cross-border ones;<br>- system optimization for management of specially protected natural areas, development of economic activity in specially protected natural areas, providing conditions for tourism development in these areas;<br>- development of cooperation between state nature management and educational establishments;<br>- development of a system to provide information and scientific support in the area of conservation and sustainable use of biological diversity<br>**[-development of information and scientific system in the area related to safety in genetic engineering activity]** | **development of information and scientific system in the area related to safety in genetic engineering activity,** |

| | | | | |
|---|---|---|---|---|
| | | | -mainstreaming and strengthening of international collaboration in the area of conservation and sustainable use of biological diversity **[as well as safety in genetic engineering activity].**<br><br>With a view of scientific support for conservation and efficient use of biological and landscape diversity to elaborate:<br>- action plans to preserve wildlife species included into the Red Book of the Republic of Belarus;<br>- integrated measures to preserve wildlife habitats of the species included into the Red Book of the Republic of Belarus;<br>- management plans for invasive wildlife species;<br>- integrated measures for ecological systems rehabilitation and restoration ;<br>- Geological Information Systems (GIS) for specially protected natural areas;<br>- recommendations and technologies to preserve biological and landscape diversity;<br>- new techniques to manage populations of wild animals;<br>- express methods to indicate changes in the species state and their resistance to ecological systems under conditions of anthropogenic changes of their habitats **[including in the territories adjacent to** | **as well as safety in genetic engineering activity**<br><br>**including in the territories adjacent to the fields used for testing of genetically modified plants and** |

| | | | | |
|---|---|---|---|---|
| | | | **the fields used for testing of genetically modified plants and the areas for keeping genetically modified live-stock animals used to pasture them, as well as in the instances of unintended release of GMOs into the environment during their transport].** | **the areas for keeping genetically modified live-stock animals used to pasture them, as well as in the instances of unintended release of GMOs into the environment during their transport** |

**2 Issue.** The desk study shows that critical few of scientific researches were directed at the safety assessment of newly developed GMOs in the Republic of Belarus.

To decide this issue the round table participants recommended request the Ministries, involved in safety issues in the field of genetic engineering activity, to include scientific projects on human health risk assessment of GMOs being developed in the country and the projects aimed at the development of effective screening techniques and DNA-marking of GMOs, GMO-contained products, derived from/or with use of GMOs into the State Research Programs. Support of such projects is a prerequisite to subsequent safe release of GMOs into the environment, their use in economic activity and transboundary movement.

**3 Issue.** Belarus has a big problem related to the maintaining and/or restoration of peat bogs as they are the most important places for wetland birds nesting, as well as keeping the required balance of underground water, which prevents the desertification process. Therefore all funds allocated for the country under GEF-6 financial program are directly used for the implementation of this huge program.

Based on the results of the Desk Study, which showed that in Belarus the issues related to safety in genetic engineering activity are discussed at the level of strategic security plans for the country and of great importance for the EAEU member-states, projects for the integrated implementation of targets (objectives) aimed at biodiversity conservation and biosafety should be considered within the framework of GEF-7 as the priority ones.

## SUMMARY OF THE DESK STUDY

### Key-issues identified as a result of the Desk Study

The desk study was presented before and during the round-table and the seminar for discussion, comments and clearance by participants. Detailed description is given in Appendix 1 and Appendix 2.

The desk study and analysis during the round-table and the seminar revealed that the Republic of Belarus (the CPB Party since 2002) had developed legal, administrative and other measures highly harmonized with CPB provisions to fulfill obligations under CPB.

The main law in GMO biosafety area is the Law “On Safety in Genetic Engineering Activity” (hereafter referred to as “the Law”) of 9 January 2006, No. 96, elaborated on the basis of the Cartagena Protocol on Biosafety and aimed at the implementation of this international commitment. A number of by-laws to ensure

safety in genetic engineering activity were elaborated in addition to this Law. The by-laws describe all necessary procedures, departments/institutions authorized and responsible for each activity and interdepartmental coordination mechanisms. Both the Law and by-laws cover the following areas of GMO biosafety:

- specially authorized bodies responsible for each sphere of genetic engineering activity (GEA);
- work in self-contained systems;
- import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of GMOs;
- risk assessment of possible adverse effects of GMOs on the environment and human health before field trials and placement to the market;
- release of GMOs into the environment;
- use of GMOs for economic purposes;
- information exchange and the Biosafety Clearing-House;
- public awareness and its participation in decision-making with regard to safety in GEA;
- control in the field of safety in GEA;
- responsibility for violation of legislation on safety in GEA;
- GMO detection and identification.

State Administration in the field of safety in genetic engineering activity is exercised by the President of the Republic of Belarus, the Council of Ministers of the Republic of Belarus, specially authorized Republican bodies of State Administration in the field of safety in genetic engineering activity.

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

The Resolution of the Council of Ministers of the Republic of Belarus of 30 October 2002, No. 1504 "On Cooperation of the Republic of Belarus and International Organizations" establishes that the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus shall provide a liaison with the Secretariat of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety to the Convention and that it has been entrusted with powers of the National Competent Body and Coordination Centre.

The National Co-ordination Biosafety Centre was established in accordance with the Resolution of the Council of Ministers of the Republic of Belarus of 19 June 1998, No. 963. The State Scientific Institution "Institute of Genetics & Cytology of the National Academy of Sciences of Belarus" was entrusted with functions of this Centre. The National Co-ordination Biosafety Centre exercises the Biosafety Clearing-House functions.

By Order of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of 5 December 2012, No. 412-OD (with amendments introduced by orders of 12 January 2015, No. 14-OD and 28 October 2015, No. 370-OD), the Expert Safety Board of Genetically Engineered Organisms of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus was established. The Biosafety Expert Board serves as a guarantee that the national legislation is in conformity with the clauses of the Cartagena Protocol on Biosafety and prevents unauthorized release of GMOs into the environment inside the country.

A list of national bodies and institutions involved in biosafety activity, including cross-sectoral bodies and coordination mechanisms and their respective roles and responsibilities in respect to biosafety is provided in Appendix 3.

The draft desk study revealed that biosafety of GMOs and their compounds to human health and the environment was emphasized among the priority directions of scientific research of the Republic of Belarus for 2011-2015, approved by the Resolution of the Council of Ministers of 19 April 2010, No. 585 and aimed at development of a biosafety system, conservation and sustainable use of genetic resources. In 2016, by the Decree of the Council of Ministers of 12 March 2015, No. 190, the priority directions of scientific research in the Republic of Belarus for 2016-2020 were established. They are as follows: biological systems and technologies, ecology and environmental management, as well as human, society and State safety. In 2011-2015 the implementation of scientific projects in the field of biosafety was mainly carried out within a framework of state programs (e.g. subprogram "Agricultural Biotechnology of the State program "Innovative Biotechnologies", subprogram "Genetic, physiological and biochemical bases for the adaptive crop breeding" of the State program "Innovative Technologies for the Agroproduction Complex"). Implementation of State program assignments for years 2010-2015 enabled to create safe conditions to perform transgenic plant testing under their release into the environment, as well as ecological and genetic monitoring.

Other completed assignments were aimed at carrying out medical and biological assessment of the developed GMOs, as well as elaboration of technologies for the laboratory and field testing of GMOs, necessary to pass all stages of the GMO assessment and intended for further use in economic activity.

An essential result with regard to assignments' implementation within the State program "Innovative Biotechnologies" was the establishment at the State Scientific Institution "Institute of Genetics & Cytology of the National Academy of Sciences of Belarus" of the "DNA-biotechnology Centre for the DNA-marking and Certification of Plants, Animals, Microorganisms and a Human" and in October 2015 – the International Research Centre for Safety in Genetic Engineering Activity.

In accordance with the Resolution of the Council of Ministers of the Republic of Belarus of 30 December 1999 No. 2063 "On State Program "Establishment of the

National Genetic Fund of Economically Valuable Plants" in 2000-2005, and subsequently, in 2007-2010 the National Centre for Economically Valuable Plant Genetic Resources was established, which includes 11 field-specific organizations related to the Departments of Agricultural and Biological Sciences of the National Academy of Sciences of Belarus and 2 educational institutions of agricultural and biological profile. In continuation of the activities in 2011-2015, the National Bank of Plant Genetic Resources of the Republic of Belarus was established at the Republican Unitary Enterprise "Scientific & Practical Centre for Arable Farming." It stores the major seed fund of economically valuable plant genetic resources of the Republic of Belarus. The Republican DNA Bank of Plants, Animals, Microorganisms and a Human was formed at the State Scientific Institution "Institute of Genetics & Cytology of the National Academy of Sciences of Belarus."

Among the priority areas of research in 2010-2015, the research on the development of DNA-identification system for varietal belonging of crop seed material, the elaboration of DNA-marking techniques to identify breeding valuable traits of plants and animals was considered and implemented as part of various scientific research programs (e.g. the State program "Innovative Biotechnologies", the State program "Genomics" and the Interstate Special-purpose Program (ISPP) "EurAsEC").

The establishment of research centers aimed at the study of agronomic characters, the development of DNA-marking techniques, the study of GMOs, the establishment of the National Bank of Plant Genetic Resources and the Republican DNA Bank, the environmental research results obtained on plant varieties, animal breeds and traditional breeding microorganism stains will certainly promote the research development in the field of GMO biosafety, the observance of national and international principles of biological safety in use of a plant material.

It should be specially noted that an important step for the analysis of the National Biosafety System was the implementation of UNEP-GEF international technical assistance projects, carried out at the country level "Support to Preparation of the Second National Biosafety Report to the Cartagena Protocol on Biosafety" in 2011 and "Support to Preparation of the Third National Biosafety Report to the Cartagena Protocol on Biosafety" in 2015. The projects were carried out in the form of a consultative process, including the holding of seminars with the participation of the country organizations responsible for ensuring of biosafety. The analysis of the amendments in the national legislation for the period of 2008 - 2015 allowed to identify the areas for further development in the field of biosafety.

The project implemented with the CEI financial support "Experience Sharing in Public Education and Awareness of Biosafety Issues" in 2013 was aimed at raising public awareness of GMO issues (http://biosafety.org.by/cei-2013). It was revealed that the priority part should be conducted by the National Co-ordination Biosafety

Centre in close contact with the Aarhus Centre and that resulted in the increased cooperation and joint activities of two centers in the field of public education.

With a view of biosafety system development in Belarus and raising awareness of key persons and the public concerned among other activities of the National Co-ordination Biosafety Centre (NCBC), NCBC in collaboration with relevant organizations published methodical recommendations, guidelines, books, training materials which are available on the website of the NCBC at the link http://biosafety.org.by/publications. A list of publications is in Appendix 4 to the Project Report.

The International Centre for Safety in Genetic Engineering Activity was established at the Institute of Genetics and Cytology of the National Academy of Sciences of Belarus in 2015 to develop professional skills of specialists involved in genetic engineering activity.

**Project results and lessons learnt and difficulties encountered in mainstreaming of biosafety in the national context, including an analysis of replicability of such experiences**

The important biosafety areas needed for improvement were revealed during the desk study and consultation process with stakeholders in preparation and during the round-table and the seminar:

1. Due to increasing GMO variety being developed by the global community, it was stressed on the necessity to consider by competent authorities the proposed amendments to the Law "On Safety in Genetic Engineering Activity" to fulfill obligations under CPB. Concrete proposals contained in the Resolution of the round-table meeting (paragraphs 1.1.-1.6.).

2. In connection with the accession to the Customs Union, EurAsEC (from 2014 onwards – Eurasian Economic Union, EAEU) continuation of the harmonization process of national legislations, standards and methodological approaches of EAEU countries in the field of GMO safety is needed (paragraph 2 of the Resolution of the Round-table Meeting).

3. GMO biosafety issues were not included into the "Strategy of the Republic of Belarus on the Conservation and Sustainable Use of Biodiversity" for 2011-2020.

4. The desk study shows that critical few of scientific researches were directed at the safety assessment of newly developed GMOs in the Republic of Belarus.

5. Belarus has a big problem related to the maintaining and/or restoration of peat bogs as they are the most important places for wetland birds nesting, as well as keeping the required balance of underground water, which prevents the desertification process. At the same time, all funds allocated for the country under GEF-6 financial program are directly used for the implementation of this huge program.

## National capacity needs and skill gaps and strengths

The analysis of the desk study shows that proper legislative, administrative and methodological bases for risk assessment of GMOs before field trials, as well as the LDGMOs system that includes 18 laboratories in regional centers of the Republic, have been developed in Belarus.

At the same time, important national capacity needs for the proper fulfilment of obligations in connection with an increasing number of developing new complex GMOs and harmonization of the National legislation, standards and methodological approaches are as follows:

1. Continue work on harmonization of the legislation of the EAEU member-states in terms of GMO labelling, GMO-containing products derived from/or with use of GMOs, harmonization of interstate methodological approaches, standards and instructions with regard to the GMO detection and identification, risk assessment of GMOs and GMO-derived products.

2. Need on training and counseling in new methods for GMO detection and identification, including theoretical and practical courses, counseling with regard to administrative and legal requirements (at the level of EAEU and international level) of LDGMOs specialists of the Republic of Belarus, as well as counseling on accreditation of national LDGMOs in conformity with international standards requirements.

3. Development of clear national and EAEU instructions on risk assessment of possible harmful effects of GMOs to human health with clearly established standard procedures for toxicity and allergenicity assessment of GMOs to be used in the national laboratories responsible for risk assessment of GMOs to human health.

4. In connection with the above mentioned difficulties encountered in mainstreaming of biosafety in the national context pointed in the paragraph "Lessons learnt and difficulties encountered in mainstreaming of biosafety in the national context, including an analysis of replicability of such experiences" and in paragraph "National capacity needs and skill gaps and strengths", there is a need that Biosafety issues should be taken into consideration in preparation of projects supported by GEF-7 and projects for the integrated implementation of targets (objectives) aimed at biodiversity conservation and biosafety should be considered within the framework of GEF-7 as the priority ones.

## Recommendations to further improve mainstreaming of biosafety

1. Include biosafety issues of genetic engineering activity into the "National Strategy on Sustainable Social and Economic Development of the Republic of

Belarus" and the "Strategy of the Republic of Belarus on the Conservation and Sustainable Use of Biodiversity" with a view of mainstreaming of biosafety projects among the biodiversity ones.

2. Biosafety issues should be taken into consideration in preparation of projects supported by GEF-7 and projects for the integrated implementation of targets (objectives) aimed at biodiversity conservation and biosafety should be considered within the framework of GEF-7 as the priority ones.

3. Development of a system to monitor wildlife in local points used for GMO testing in special fields (GM plant testing) or for GMO keeping in special chambers or pastures (transgenic goats) is required. Two types of monitoring can be used: ecological monitoring (by currently used methods of species composition registration) and genetic monitoring (by modern techniques for transgenic elements identification, including methodological approach of population genetics). The latter approach can be used for genetic resources inventory, as well as long-term genetic monitoring of biodiversity, based on investigation in the genetic structure of populations inside species and paying strict attention to the detection of genetically modified events. The research starting target can be insects or soil microorganisms as being more mobile organisms, which contact with other organisms, including GMOs.

4. Promote the effectiveness of the interdepartmental information exchange in area of biosafety (steps to be implemented are pointed out in paragraphs 3.1. -3.2. of the seminar).

5. Hold seminars on a regular basis for the individuals that determine a strategic course and involved in decision-making, as well as professionals of departmental institutions engaged in biosafety and biodiversity conservation issues to inform on the implementation of activities included in National Strategies and Programs, and if necessary adjusting them.

6. Take measures to encourage public involvement in the discussion of issues related to the environmental protection in the part of biosafety.

**Appendix 1**

# RESOLUTION AND RESULTS OF THE ROUND-TABLE WITH PROPOSALS ON THE DESK STUDY AND DISCUSSION OF THE APPROPRIATE ACTIONS AND MODALITIES FOR INTEGRATED IMPLEMENTATION OF THE CBD AND THE CARTAGENA PROTOCOL, AS WELL AS LESSONS LEARNT FROM NATIONAL EXPERIENCE

## Introduction

With a view of the Desk Study analysis of the existing national policies, strategies and activities in the field of biosafety, on 25 May 2016 the Institute of Genetics and Cytology of the National Academy of Sciences of Belarus, vested with functions of the National Co-ordination Biosafety Centre with support of the Secretariat of the Convention on Biological Diversity and the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus hosted a round-table meeting "Capacity-building to Promote Integrated Implementation of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity at the National Level". 40 representatives of different institutional subordinations, the activity of which is related to biosafety issues in the Republic of Belarus took part in the round-table meeting. Members of the Expert Advisory Board on Safety of Genetically Engineered Organisms of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus were among the participants of the meeting, as well as representatives of the involved ministries and other National government agencies that hold responsibility for the decision-making in regard to the release of GMOs into the environment, the GMO registration and their transportation (movement); representatives of the National Aarhus Center of the UN Convention to promote public participation in the discussion of environmental issues, including the biosafety ones and NGOs, engaged in environmental activities in the Republic of Belarus, representatives of Institutions, involved in genetic engineering activity and ensuring safety of genetic engineering activity in the self-contained systems.

## Stages of Activity

1. Advance of a round-table meeting, the participants were provided with the desk study "Analysis of the Implementation in the Republic of Belarus of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity".

2. In the course of the round-table session, the desk study results, including analysis of the National legislation of the Republic of Belarus in the field of safety in genetic engineering activity (GEA)*, the administrative and legal regulation of the activity, standards and methodology guidelines in the field of detection and

identification of genetically engineered organisms, the analysis of practical activities and implementation of international projects at the national level that ensure the safety in genetic engineering activity, were heard.

3. The participants held a discussion of the desk study, including:

- coverage by the National legislation of biosafety areas within a framework of implementation of the Cartagena Protocol on Biosafety at the country level;

- other National, International, Multilateral (the Eurasian Economic Union, EAEU) Agreements (Treaties) that ensure safety in genetic engineering activity, including safety in use of genetically engineered organisms in economic activity: handling of food raw materials and food products, animal feeds, derived from GMOs or their components, medicinal products; mechanisms of the concerned public participation in decision-making in relation to GMOs;

- institutional and inter-institutional mechanisms to control and coordinate safety in genetic engineering activity; means of building and strengthening of National Inter-institutional Coordination Mechanisms to provide a coordinated approach to implementation of Provisions of the Convention and the Protocol;

- degree of involvement and integration of biosafety mechanisms into National Biodiversity Strategies and Action Plans (NBSAPs) and other relevant agency and Inter-agency plans, strategies and programs, national budgets, bilateral and multilateral cooperation programs (projects) at the national and international levels;

- mainstreaming biosafety issues among other projects / activities to obtain support from GEF funds, allocated for countries which are Parties to the Convention on Biological Diversity, with a view of biodiversity conservation.

**Summary**

1. The meeting participants noted that legislative, administrative and legal systems of the Republic of Belarus, related to GMO safety, are very effective. The main law in this area of activities is the Law "On Safety in Genetic Engineering Activity" of 9 January 2006, №96 (hereinafter – the Law), elaborated on the basis of the Cartagena Protocol on Biosafety and aimed at the implementation of this international commitment. A number of by-laws to ensure safety in genetic engineering activity were elaborated in addition to this Law. At the same time, due to the increasing diversity of GMOs being developed by the global community and in the Republic of Belarus, it seems necessary to introduce changes and amendments in

** Pursuant to the Law «On Safety in Genetic Engineering Activity", the genetic engineering activity is the activity, associated with the development of genetically engineered organisms, their release into the environment for testing, their use for commercial 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.*

the Law "On Safety in Genetic Engineering Activity" and, where appropriate, in by-laws. The suggestions made are as follows:

1.1. In connection with the emergence of new methods in genetic engineering activity, to clarify the definition of the "genetically engineered organism" (GEO). The Law provides the following definition "a genetically engineered organism (genetically changed (modified, transgenic organism)) is a living organism containing a new combination of genetic material, produced by genetic engineering". At the same time, new areas in genetic engineering activity, which do not imply the introduction of new genes into genome, are being developed. The genetic engineering event leads to a change in the combination of genetic material (e.g., gene knockout, protein engineering). The participants noted that it determines the need to clarify the definition.

1.2. The participants noted that Paragraph I of 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" determines that "Import into the Republic of Belarus and transit through its territory of genetically engineered organisms is allowed, provided that the exporter (the country, performing transit) is a Party to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, adopted in Montreal 29 January 2000." The Republic of Belarus is the EAEU member-state, but some Parties to this Treaty (e.g. the Russian Federation) are not Parties to the Cartagena Protocol that causes a legal problem in the implementation of Article 18 and the safe transboundary movement of GMOs. The participants were invited to approach the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus with a proposal to tackle the issue from the standpoint of eliminating contradictions in Article 18 of the Law with regard to the EAEU country membership and prepare a draft of respective alterations and/or additions to the Law and other normative legal acts.

1.3. Paragraph II of Article 15 of the Law "Safety Requirements for Release of Genetically Engineered Organisms into the Environment for Testing" defines that the "Release of non-pathogenic genetically engineered organisms into the environment for testing is carried out upon availability of 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".

Paragraph II of Article 16 "Safety Requirements for Use of Genetically Engineered Organisms for Economic Purposes" defines that "Use for economic purposes of non-pathogenic genetically engineered organisms in the form of genetically engineered varieties of plants, genetically engineered breeds of animals and strains of non-pathogenic genetically engineered microorganisms is allowed upon the State Registration in the Ministry of Agriculture and Food of the Republic of

Belarus. The State Registration is carried out upon a positive conclusion (positive findings) of the State Safety Expertise of genetically engineered organisms and positive test findings of genetically engineered organisms after their release into the environment by making entry with regard to registration-related genetically engineered varieties of plants, genetically engineered breeds of animals and strains of non-pathogenic genetically engineered microorganisms to the National Register of Genetically Engineered Varieties of Plants, Genetically Engineered Breeds of Animals and Strains of Non-Pathogenic Genetically Engineered Microorganisms. Availability of a State Registration Certificate confirms the fact of a State Registration of genetically engineered varieties of plants, genetically engineered breeds of animals and strains of non-pathogenic genetically engineered microorganisms.

The participants brought into focus that not all GMOs, intended for use in economic activity, are released into the environment. For example, non-pathogenic microorganisms, some transgenic animals – producers, contained and used in self-contained systems. Thus, it seems necessary to determine and make a distinction between State Registration procedures and risk assessment of GMOs, released and not released into the environment, determine testing procedures for the GMOs with no release into the environment, intended for use in economic activity. Remove from line 2 of Paragraph II, Article 16 the wording "on their release into the environment".

1.4 It was noted that the Law does not sufficiently delineate and clearly determine the registration procedure for different varieties of GMOs (plants, animals, microorganisms; non-pathogenic, potentially pathogenic, pathogenic organisms). It deems it necessary to more clearly define in Articles 9,10, 11 Ministerial functions in relation to registration procedures for plants, animals, microorganisms, including potentially pathogenic and pathogenic ones.

1.5 In order to improve the State Expertise and for the purpose of further safe use of GMOs in economic activity, it is necessary to determine in the Law the importance of expert verification for the presence of new genetic material insertion during the State Safety Expertise. For example, make additions to Paragraph III of Article 20 "Objects of the State Safety Expertise of Genetically Engineered Organisms are as follows: new inserted sequences".

1.6 Paragraph V of Article 3 of the Law "access to information in the field of safety in genetic engineering activity" shall be inserted the words "and public participation in decision-making".

2. The participants particularly noted that on 10 October 2008 the Treaty on the Single Customs Territory and the Customs Union of the Republic of Belarus, the Republic of Kazakhstan and the Russian Federation (the Eurasian Economic Community, EurAsEC) came into effect. Thus, following the entry into the Customs Union, EurAsEC member-states approved Technical Regulations of the Customs

Union TR CU 021/2011 “On Safety of Food Products” and TR CU 022/2011 “Food Products in Terms of their Labeling”, as well as a set of standards and methodology guidelines in the field of GMO safety. Now this Technical Regulation operates within a framework of Technical Regulations of the EAEU Customs Union. The experts, involved in the elaboration of the Technical Regulations and present at the round-table meeting, noted that this legislation is in line with European approaches in the field of GMO safety.

It was pointed out that the harmonization process of national legislations, standards and methodological approaches of EAEU countries continues. In particular, a threshold of 0% for labeling of products, raw materials used for their production and feeds, containing GMOs or their components has not been cancelled in the Republic of Belarus yet, while the Customs Union has established a threshold of 0,9% for the permitted GMOs. The meeting participants also note that the country has carried out work on the harmonization of normative legal acts and technical regulations: the by-law “Sanitary Norms and Regulations” came into effect, which establishes a threshold of 0,9% and a new version of the Law “On Quality and Food Safety” that previously established a non-threshold principle for food product labeling has been elaborated. A new version of the Law was brought in conformity with the TR CU and the EU legislation. The Law is at the initial stage of editing. The Republic of Belarus has also approved methodology guidelines "Procedures for Risk Assessment of Possible Harmful Effects of Genetically Engineered Organisms on Human Health. Instructions for use." Following the entry into the Customs Union, a list of standards that includes principles and methods of research (testing) and measurements for a GM-component in food products and food supplements, methodology guidelines “Food Products and Food Supplements. Biomedical Safety Assessment of Genetically Engineered Modified Organisms of Plant Origin. Methodical Guidelines” was determined.

With reference to the above, the meeting participants recommend to the designated authorities in the field of safety in genetic engineering activity:

2.1. Continue work on harmonization of the legislation of the EAEU member-states in terms of GMO labeling, GMO-containing products, derived from/or with use of GMOs, harmonization of interstate methodological approaches, standards and instructions with regard to the GMO detection and identification, risk assessment of GMOs and GMO-derived products.

2.2. Make additions to the Instruction "Procedures for Risk Assessment of Possible Harmful Effects of Genetically Engineered Organisms to Human Health" (Registration №076-0806) with clearly established standard procedures for toxicity and allergenicity assessment of GMOs with regard to their effects on human (and animal) health.

2.3. Put forward a proposal for elaboration of an interstate standard for the Customs Union member-states in accordance with the established in the Republic of

Belarus Instruction "Procedures for Risk Assessment of Possible Harmful Effects of Genetically Engineered Organisms to Human Health", methodical guidelines (MU 2.3.2.2306-07. 23.2.), introduced in the EAEU, as well operational guidelines of relevant international organizations (FAO). It is proposed to establish clear testing procedures and standards to risk assessment of GMOs for human health with a view of their use in the laboratories of accredited organizations that carry out testing. This work should be done at the interstate level of the Customs Union member-states.

2.4. There is a recommendation to the National Co-ordination Biosafety Centre to initiate work on the joint meeting between the Expert Safety Board for Genetically Engineered Organisms of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus and the Eurasian Economic Commission experts to determine standards and regulations for the Customs Union.

3. In the course of the project analysis carried out at the national level, it was established that biosafety issues had been included into priority directions of scientific research in the Republic of Belarus for 2011-2015. The projects were aimed at arranging safe test conditions for plant release into the environment, ecological and genetic monitoring, as well as scientific research in the biomedical assessment of the produced GMOs. At the same time, GMO biosafety issues were not included into the "Strategy of the Republic of Belarus on the Conservation and Sustainable Use of Biodiversity" for 2011-2020. In addition, the desk study shows that critical few of scientific research activities were directed at the safety assessment of newly developed GMOs.

In this regard, it is recommended to:

3.1 Include biosafety issues of genetic engineering activity into the "National Strategy on Sustainable Social and Economic Development of the Republic of Belarus" and the "Strategy of the Republic of Belarus on the Conservation and Sustainable Use of Biodiversity" with a view of mainstreaming biosafety projects among the biodiversity ones.

3.2 Include biosafety issues of genetic engineering activity into priority directions of scientific research. Request the Ministries, involved in safety issues in the field of genetic engineering activity, to include scientific projects on human health risk assessment of GMOs being developed in the country and the projects aimed at the development of effective screening techniques and DNA-marking of GMOs, GMO-contained products, derived from/or with use of GMOs into the State Research Programs. Support of such projects is a prerequisite to subsequent safe release of GMOs into the environment, their use in economic activity and transboundary movement.

**Appendix 2**

# RESOLUTION

## Seminar on the International Technical Assistance Project of the Secretariat of the Convention on Biological Diversity "Capacity-building to Promote Integrated Implementation of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity at the National Level"

**Minsk, 22 July 2016**

## INTRODUCTION

**The project objective** "Capacity-building to promote integrated implementation of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity at the national level" is **to strengthen capacity** of 10 countries that participate in the pilot project, including the Republic of Belarus to elaborate practical measures on the integrated implementation of the Cartagena Protocol on Biosafety (hereinafter referred to as "the Protocol") and the Convention on Biological Diversity (hereinafter referred to as "the Convention) and formulate proposals to the State Bodies responsible for the fulfillment of commitments on the Protocol and the Convention. The project is implemented at the national level by the State Scientific Institution "Institute of Genetics & Cytology of the National Academy of Sciences of Belarus" that exercises functions of the National Co-ordination Biosafety Centre and the International Research Center for Safety in Genetic Engineering Activities.

In the discussion of issues related to legislative regulations and activity efficiency in the area of Safety in Genetic Engineering Activity, as well as on raising awareness of individuals involved in establishing of a strategic course and decision-making, the representatives of organizations that belong to different departmental subordinations and the activity of which is related to biosafety issues in the Republic of Belarus, took part: House of Representatives of the National Assembly of the Republic of Belarus, the Ministry of Natural Resources and Environmental Protection, the Ministry of Agriculture and Food, the Ministry of Foreign Affairs, the State Customs Committee, the Republican Research Unitary Enterprise "Belarusian Research Center "Ecology", the Republican Research and Practical Center for Epidemiology and Microbiology of the Ministry of Health, the Belarusian State Institute of Metrology, the Aarhus Center, the National Academy of Sciences of Belarus and subordinate Research and Development Institutions, including the Institute of Microbiology, the Republican Unitary Enterprise "Research and Practical Center of the National Academy of Sciences of Belarus for Arable Farming", the Republican Unitary Enterprise "Research and Practical Center of the National

Academy of Sciences of Belarus for Animal Breeding", the State Scientific and Production Amalgamation of the National Academy of Sciences of Belarus "Scientific and Practical Center for Bioresources", V.F. Kuprevich Institute of Experimental Botany, the State Scientific Institution "Central Botanic Garden", the State Scientific Institution "Institute of Genetics and Cytology".

The seminar participants noted that the Republic of Belarus had accumulated some experience in Genetic Engineering Activity and in ensuring of its safety and a full-fledged National Biosafety System that provides legal regulation of Genetic Engineering Activity and use of its findings in the scientific field and their practical application had been developed.

A multistakeholder dialogue identified a number of practical steps towards the integration of biosafety issues both into National Strategic Plans and State Scientific Research Plans, as shown in the seminar summary below.

## WORK STAGES

1. In the course of the seminar the following reports were heard: "Establishment of Biosafety System in the Republic of Belarus" by V.A. Lemesh, Director of the State Scientific Institution "Institute of Genetics and Cytology of the National Academy of Sciences of Belarus", "Sustainable Development of Agriculture and Biodiversity: contemporary state, issues" by S.B. Melnov, Director of the Republican Research Unitary Enterprise "Belarusian Research Center "Ecology", "Biosafety State and the Cartagena Protocol Status at the National Level. Key Data and Desk Study Findings " by G.V. Mozgova, Head of the "National Co-ordination Biosafety Centre", "Genetically Engineered Organisms as the Nagoya Protocol Objects" by E.N. Makeyeva, Head of the "National Coordination Center on Access to Genetic Resources & Benefit-Sharing".

2. The participants held a discussion of the reports and desk study findings in relation to legislative regulation of the activity carried out within a framework of implementation of the Cartagena Protocol on Biosafety by our country; the information on the Republic of Belarus participation in other National, International and Multilateral (the Eurasian Economic Union, EAEU) Agreements that ensure the provision of Safety in Genetic Engineering Activity, including safety in use of genetically modified organisms (GMOs) in economic activity: in handling of food raw materials, foodstuffs and animal feeds derived from GMOs or their ingredients (components), medicinal products; implementation of a mechanism for the interested public participation in the decision-making with regard to GMOs, as well as departmental and interdepartmental mechanisms for management and coordination of Safety in Genetic Engineering Activity; tools for establishing and strengthening of National Interdepartmental Coordination Mechanisms to ensure an integrated approach to implementation of the Convention and Protocol Provisions; a degree of

involvement and biosafety integration mechanisms in National Biodiversity Strategies and Action Plans and other appropriate departmental and interdepartmental plans, strategies and programs, national budgets, bilateral and multilateral collaboration programs (projects) at the national and international levels; raising importance of biosafety issues in projects to obtain support within GEF funds allocated to countries - Parties to the Convention with a view of biodiversity conservation. During the seminar the consultants suggested that GMO biosafety paragraphs should be included into the national strategies that regulate activity in the area of biological diversity conservation and its sustainable use (Appendix 5).

## SUMMARY

1. The seminar participants noted that the Republic of Belarus has an effectively operating legislative and administrative legal system in the field of Safety in Genetic Engineering Activity. The basic law in this area is the Law "On Safety in Genetic Engineering Activity" of 9 January 2006, No. 96 (hereinafter referred to as "the Law") elaborated on the basis of the Cartagena Protocol on Biosafety and aimed at implementation of the given international commitment. A number of by-laws were elaborated as an addition to this Law to ensure Safety in Genetic Engineering Activity.

2. Due to increasing GMO variety being developed by the global community and in the Republic of Belarus, the participants confirm that some changes and adjustments should be introduced to the Law "On Safety in Genetic Engineering Activity" and if necessary to the by-laws.

*3. To promote the effectiveness of the interdepartmental information exchange in area of biosafety, the following steps should be implemented:*

3.1. Make use of the National Co-ordination Biosafety Centre (NCBC) potential, providing the requested information within the NCBC functions established in the Resolution of the Council of Ministers of the Republic of Belarus of 19 June 1998, №963;

3.2. Establish a constant liaison of the State Institutions engaged in Genetic Engineering Activity and responsible for taking decisions on GMO release into the environment, GMO registration, GMO detection and identification, GMO use in the production, GMO circulation within the country, including the Institutions (establishments) that provide import, export and / or transit of GMOs in the territory of the Republic of Belarus, with NCBC, providing information on contact persons;

4. Hold seminars on a regular basis for the individuals that determine a strategic course and involved in decision-making, as well as professionals of departmental institutions engaged in biosafety and biodiversity conservation issues to inform on the implementation of activities included in National Strategies and Programs, and if necessary adjusting them (by NCBC);

5. Take measures to encourage public involvement in the discussion of issues related to the environmental protection in the part of biosafety (NCBC with the assistance of the Ministry of Natural Resources and Environmental Protection and in collaboration with the National Center for the Aarhus United Nations Convention and NGOs).

6. The participants back up the recommendations given in the course of the Round-table Meeting at 2nd stage of the International Technical Assistance Project, which was held on 25 May 2016, on the necessity to consider by competent authorities of the proposed amendments to the Law "On Safety in Genetic Engineering Activity", including the recommendations related to Safety in Genetic Engineering Activity contained in the Resolution of the round-table meeting (paragraphs 1.1-1.6), as well as proposed recommendations on harmonization of the EAEU legislation, methods and standards (paragraph 2 of the Round-table Resolution) and inclusion of biosafety issues of genetic engineering activity into the National Strategies and priority directions of scientific research (paragraph 3 of the Round-table Resolution).

## Appendix 3

### List of National bodies and institutions involved in biosafety activity, including inter-sectoral bodies and coordination mechanisms and their respective roles and responsibilities in respect to biosafety

| No. | **Title of Ministries, Institutions, etc.** |
|---|---|
| 1. | The Ministry of Natural Resources and Environmental Protection of the Republic of Belarus.<br>National Government Body responsible for the implementation of the Cartagena Protocol in the Republic of Belarus. |
| 2. | The Ministry of Agriculture and Food of the Republic of Belarus.<br>National Government Body responsible for the implementation of the Cartagena Protocol in the Republic of Belarus. |
| 3. | The Ministry of Health of the Republic of Belarus.<br>National Government Body responsible for the implementation of the Cartagena Protocol in the Republic of Belarus. |
| 4. | State Customs Committee of the Republic of Belarus. |
| 5. | State Scientific Institution "Institute of Genetics and Cytology of the National Academy of Sciences of Belarus".<br>Entrusted by the Government of the Republic of Belarus with functions of the National Co-ordination Biosafety Centre. |
| 6. | State Scientific Institution "Institute of Forest of the National Academy of Sciences of Belarus".<br>The Institute has a Laboratory of Biotechnology. The laboratory conducts scientific research in the field of investigation and development of genetically modified organisms. |
| 7. | Republican Unitary Enterprise "State Scientific and Practical Centre for Arable Farming of the National Academy of Sciences of Belarus"<br>Development and research of genetically modified organisms is conducted in the Centre. |
| 8. | State Scientific Institution "Central Botanical Garden of the National Academy of Sciences of Belarus".<br>Development and scientific research of genetically modified organisms is conducted in the Central Botanical Garden. |
| 9. | State Scientific Institution "Institute of Biophysics and Cell Engineering of the National Academy of Sciences of Belarus".<br>Development and scientific research of genetically modified organisms is conducted at the Institution. |
| 10. | State Scientific Institution "Institute of Microbiology of the National Academy of Sciences of Belarus".<br>Development and scientific research of genetically modified microorganisms is conducted at the Institution. |
| 11. | Republican Unitary Enterprise "Belarusian State Institute of Metrology of the |

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| | National Academy of Sciences of Belarus".<br>The Enterprise conducts regulatory and control activities over Laboratories for GMO Detection and provides them with proper regulations, standards and methodological information related to the activities in biosafety. |
| 12. | Belarusian State University (Department of Molecular Biology, Biology Faculty).<br>Development and scientific research of genetically modified organisms is conducted at the Department of Molecular Biology. |
| 13. | State Scientific Institution "Institute of Experimental Botany named after V.F. Kuprevich of the National Academy of Sciences of Belarus".<br>Specialists of the Institute are involved in the ecological monitoring of plants growing in the area around the field used for trial of genetically modified plants. |
| 14. | State Scientific and Production Amalgamation "Scientific and Practical Center for Bioresources of the National Academy of Sciences of Belarus".<br>Specialists of the Institute are involved in the ecological monitoring of wildlife animals inhabiting the area around the field used for trial of genetically modified plants. |
| 15. | State Institution "Republican Scientific and Practical Centre of Epidemiology and Microbiology of the Ministry of Health of the Republic of Belarus".<br>There is a collection of pathogenic microorganisms, including genetically modified ones in the Center. |
| 16. | Republican Scientific Subsidiary Unitary Enterprise "Institute of Plant Protection of the National Academy of Sciences of Belarus".<br>Specialists of the Enterprise conduct consulting services on biosafety issues related to reagents and technologies for plant protection. |
| 17. | State Institution "Republican Scientific and Practical Center of Hygiene of the Ministry of Health of the Republic of Belarus".<br>There is a Laboratory for GMO Detection in this Centre. |
| 18. | Republican Unitary Enterprise "Scientific and Practical Centre for Potato, Vegetable and Fruit Growing of the National Academy of Sciences of Belarus".<br>Research of genetically modified potato is conducted at the Enterprise. |

## Appendix 4

# Publications on biosafety issues

| № | Authors, titles, size |
|---|---|
| 1. | S.E.Dromashko, E.N.Makeyeva, A.M.Lebedeva, G.V. Mozgova, O.G.Babak, A.V.Kilchevsky, T.V.Zheleznova, M.O.Kholmetskaya. Biosafety. New methodological approaches to quality assessment of food, pharmaceutical and agricultural products. – Minsk: Belaruskaya Navuka, 2015. – 219 p. |
| 2. | G.V.Mozgova. Risk assessment of GMO impacts on conservation and sustainable use of biodiversity, taking into account risks to human health: Methodological Guidelines. – Minsk: Law & Economics, 2014. – 58 p. |
| 3. | S.E.Dromashko. Genetically modified organisms. Development of genetically modified plants, their use and biosafety issues. – Saarbrücken, Germany: LAP LAMBERT Academic Publishing, 2014. – 142 p. |
| 4. | A.P.Yermishin. Genetically modified organisms and biosafety. – Minsk: Belaruskaya Navuka, 2013. – 171 p. |
| 5. | E.N.Makeyeva, S.E.Dromashko. Modern technologies for genomic DNA study. – Minsk: Researchers Training Institute, 2013. – 66 p. |
| 6. | S.E.Dromashko, A.P.Yermishin, E.N.Makeyeva, E.G.Popov, M.O.Kholmetskaya. Genetically modified organisms and biosafety issues. – Minsk, Researchers Training Institute, 2011. – 70 p. |
| 7. | A.P.Yermishin. 2008. On the status of legislative and regulatory framework for issues of biotechnological science, biotechnological production and biosafety in the Republic of Belarus (Analytical note). – 15 p. |
| 8. | A.P. Yermishin. 2008. On advisability of use of genetically engineered plants in the agricultural industry (Analytical note). – 6 p. |
| 9. | A.P. Yermishin. 2008. Some aspects of legal protection and use of genetically engineered plants in breeding. – 2 p. |
| 10. | A.P. Yermishin. 2008. Ethical aspects in use of modern biotechnology achievements. – 7 p. |
| 11. | A.P. Yermishin. 2006 State regulation on safety in genetic engineering activity in the Republic of Belarus. – 10 p. |
| 12. | A.P.Yermishin, V.E. Podlisskikh, E.V. Voronkova, B.Y. Anoshenko, V.M.Zarkov. Biotechnology. Biosafety. Bioethics. (Under the editorship of A.P.Yermishin). – Minsk: Technalohija, 2005. – 430 p. |
| 13. | A.P. Yermishin. Genetically modified organisms: myths and reality. – Minsk: "Technalohija", 2004. – 51 p. |
| 14. | G. Mozgova, E. Makeyeva, S. Dromashko. Biomedical assessment of LMO safety in the Republic of Belarus // Bulletin of National Agrarian University of Armenia. 2014, No. 2 (46). – P. 67-70. |
| 15. | S.E. Dromashko. Genetically modified plants (ecological and medical issues of use) // Vestsi NAS Belarus. Agricultural sciences . 2014, No.3. – P. 104-111. |
| 16. | S.E. Dromashko. Natural products and GMOs // Biology & Chemistry. 2014, No. 6 (18). |

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| | – P. 41-46. |
| 17. | S.E. Dromashko. Genetically modified organisms and biosafety system in the Republic of Belarus // Vestnik, Tver State University. Series: "Biology & Ecology". 2014, No. 1. – P. 179-195. |
| 18. | N. Minchenko, A. Kilchevsky, S. Dromashko, E. Makeyeva. Cartagena Protocol on Biosafety in the Republic of Belarus // Nauka & Innovatsii. 2013, No. 10(128). – P. 70-72. |
| 19. | S.E Dromashko. GMOs, Ecology, Health: myths and reality // Biology & Chemistry. 2013, No. 8(8) – P. 52-62. |
| 20. | S.E. Dromashko. Modern biotechnology: environmental and health consequences // Pharmaceutical and food biotechnologies and education system: Legal Aspects: a collection of scientific articles – Grodno: Yanka Kupala State University of Grodno, 2013, P. 16-21. |
| 21. | E.N. Makeyeva, G.V. Mozgova, M.O. Kholmetskaya, S.E. Dromashko. 10 years of the Cartagena Protocol in Belarus: from GMO detection to risk assessment // Pharmaceutical and food biotechnologies and education system : Legal Aspects: a collection of scientific articles – Grodno: Yanka Kupala State University of Grodno, 2013. – P. 92-98. |
| 22. | S.E. Dromashko. GMO impact on health: myths and reality // Contemporary issues of science and education. Materials of 13th International scientific and practical conference school, 26 April – 5 May 2013, Odessa. – Kharkiv, 2013. – P.35-41. |
| 23. | S.E. Dromashko. National biosafety system and GMO detection in the Republic of Belarus// Quality and ecological safety of food products and production. – Tver: Tver State University, 2013. – P. 8-11. |
| 24. | S.E. Dromashko. Genetically modified organisms and biosafety issues // 9th Kurdyum Readings «Synergetics in social and natural sciences»: materials of the International interdisciplinary scientific conference with elements of scientific school for the youth. – Tver: Tver State University, 2013. – P. 5-8. |
| 25. | S.E. Dromashko, E.N. Makeyeva, M.O. Kholmetskaya, E.G. Popov, L.S. Sidor, N.A. Balashenko. Labeling of GMO-content food products in Belarus // Biology: Teaching Issues. 2012, No. 2 (75). – P. 3-11. |
| 26. | S.E. Dromashko, E.N. Makeyeva, M.O. Kholmetskaya. Labeling of GMO-content food products // Nauka & Innovatsii. 2012, No. 7 (113). – P. 28-30. |
| 27. | N. Minchenko, S. Dromashko, E. Makeyeva. Engaging and empowering the media to promote awareness of biosafety issues: the experience of Belarus // Biosafety Protocol News. September, 2012. Issue 10. – P. 6-7. Internet Resource: http://www.cbd.int/doc/newsletters/bpn/bpn-10-en.pdf. |
| 28. | S.E. Dromashko, E.N. Makeyeva, M.O. Kholmetskaya, L.S. Sidor, S.O. Vdovenko, N.N. Belko. Control of genetically modified ingredients in food products in the Republic of Belarus// Vesti, NAS Belarus, Series: Agrarian Sciences, 2012. No. 4. – P. 108-112. |
| 29. | S.E. Dromashko. Regulation of genetic engineering activity: experience of the Republic of Belarus // Materials of the International Youth Conference "Animal and plant genetics |

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| | – fundamental issues and contemporary experimental approaches" within a framework of Science Festival", Tomsk, 24-27 September, 2012 – Tomsk, 2012. – P. 51-61. |
| 30. | S. Dromashko, A. Yermishin. Genetic Engineering Biosafety Framework of Belarus // Curso de Bioseguridad. 21–24 febrero 2011. Maracay [Electronic resource]: electronic presentations of lectures on Biosafety courses. – Electronic data and programming (348 MB). – Maracay, Venezuela, 2011. – 1 electronic optical disk (CD-ROM): colour., 9,4 MB. |
| 31. | A. Yermishin. Experience of the Republic of Belarus in the field of biosafety // Curso de Bioseguridad. 21–24 febrero 2011. Maracay [Electronic resource]: electronic presentations of lectures on Biosafety courses. – Electronic data and programming (348 MB). – Maracay, Venezuela, 2011. – 1 electronic optical disk (CD-ROM): colour. – 1,7 MB. |
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| 33. | S.E. Dromashko, M.O. Kholmetskaya, L.S. Sidor, S.O. Vdovenko, N.N. Belko. Detection of genetically modified components in foodstuffs: research experience of the Laboratory for GMO Detection at the National Biosafety Co-ordination Centre // Ecological, legal and medical aspects of Bioethics and Biosafety: a collection of scientific articles – Grodno: Grodno State University, 2011. – P. 45-49. |
| 34. | S.E. Dromashko, E.N. Makeyeva, E.G. Popov. Biosafety system in the Republic of Belarus and National legislation (comparative analysis in the European dimension // Nauka & Innovatsii. – 2011. – No. 7 (101). – P. 70–72; – No. 8 (102). – P. 71-72. |
| 35. | S.E. Dromashko, E.G. Popov, E.N. Makeyeva. Are transgenic plants needed for Agriculture? // Biology: Teaching Issues. – 2011, No. 6 (73). – P. 3-10. |
| 36. | S.E. Dromashko, E.N. Makeyeva, E.G. Popov. National Biosafety System of the Republic of Belarus in European dimension// Contemporary issues of administrative humanization and harmonization. Materials of 10$^{th}$ International scientific and practical conference school, 3–10 November, 2010, Kharkiv. – Kharkiv, 2010, P.20-34. |
| 37. | Review and assessment of existing international treaties of the Republic of Belarus on genetic engineering activity issues / State Scientific Institution "Institute of Genetics and Cytology of the National Academy of Sciences of Belarus" – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |
| 38. | Review and assessment of the existing legislation of the Republic of Belarus in relation to woks with microorganisms of different risk groups in self-contained systems / Scientific Institution "Republican Research and Practical Centre for Epidemiology and Microbiology" of the Ministry of Health of the Republic of Belarus – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |

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| 39. | Review and assessment of the existing legislation of the Republic of Belarus in relation to woks with microorganisms of different risk groups in self-contained systems / Scientific Institution "Republican Research and Practical Centre for Epidemiology and Microbiology" of the Ministry of Health of the Republic of Belarus – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |
| 40. | Review and assessment of the existing legislation of the Republic of Belarus in the field of food product safety / the Republican Centre for Sanitation and Hygiene of the Ministry of Health of the Republic of Belarus – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |
| 41. | Review and assessment of the existing legislation of the Republic of Belarus in the field of environmental protection: Analysis of the Republic of Belarus legislation regulating relations in the field of environmental protection, recommendations on legislation improvement in relation to release of genetically modified organisms (GMOs) into the environment (the review was made on the basis of the Republic of Belarus existing legislation for 15 July 2003) / Public association "Ecopravo" – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |
| 42. | Review and assessment of the existing legislation of the Republic of Belarus in the field of testing and registration of new plant varieties / Institute of Genetics and Cytology of the National Academy of Sciences of the Republic of Belarus – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |
| 43. | Review and assessment of the existing legislation of the Republic of Belarus on phytosanitary issues / Institute of Plant Protection of the National Academy of Sciences of the Republic of Belarus – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |
| 44. | Review and assessment of the existing legislation of the Republic of Belarus in the field of animal breeding and veterinary activity / Institute of the Animal Breeding of the National Academy of Sciences of the Republic of Belarus – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |
| 45. | (a) Review and assessment of the existing legislation of the Republic of Belarus in the field of accountability, storage, testing and registration of microorganisms / Institute of Microbiology of the National Academy of Sciences of the Republic of Belarus -- Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |

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| 46. | (b) Review and assessment of the existing legislation of the Republic of Belarus in the field of testing and registration of new pesticides and fertilizers / Institute of Microbiology of the National Academy of Sciences of the Republic of Belarus -- Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |
| 47. | Review and assessment of the existing legislation of the Republic of Belarus on procedures for import and export of living organisms: Analysis of the Republic of Belarus legislation regulating relations in the field of import / export of living organisms, organization of ecological, sanitary, customs control over this process, recommendations for the legislation improvement in the field of import / export of genetically engineered organisms (review was made on the basis of the Republic of Belarus existing legislation for 15 July 2003) / Public association "Ecopravo" – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |
| 48. | Review on release of genetically engineered organisms into the environment in the Republic of Belarus / Institute of Genetics and Cytology of the National Academy of Sciences of the Republic of Belarus – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003) |
| 49. | Review and analysis of the State scientific and practical programme "Infections and Medical Biotechnologies" / Scientific Institution "Republican Research and Practical Center for Epidemiology and Microbiology" of the Ministry of Health of the Republic of Belarus – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |
| 50. | Review and analysis of the State scientific and technical programme "Industrial Biotechnology" / Institute of Genetics and Cytology of the National Academy of Sciences of Belarus together with the specialists of the concern "Belbiofarm" and the Institute of Microbiology of the National Academy of Sciences of Belarus – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |
| 51. | Review and analysis of the State fundamental research programme "Development of scientific basis for biotechnological processes: breeding and establishment of a collection of non-pathogenic microorganisms as biotechnological objects; genetic and cell engineering of plants and microorganisms; microbial synthesis of biologically active compounds and use of microorganisms in industry, agriculture and environmental protection ("Biotechnology") / Institute of Microbiology of the National Academy of Sciences of the Republic of Belarus – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |
| 52. | Review and analysis of the State fundamental research programme "Development and use of genetic engineering biotechnologies for the benefits of agriculture and medicine |

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| | "Genetic Engineering for 2002-2006" / Institute of Genetics and Cytology of the National Academy of Sciences of the Republic of Belarus – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |
| 53. | Review and analysis of the joint research programme with the Russian Federation "Development of highly effective biologically safe medicinal products of new generation on the basis of human proteins received from transgenic animal milk" ("Belrostransgen") / Institute of Animal Breeding of the National Academy of Sciences of the Republic of Belarus – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |
| 54. | Review of the existing biosafety structure of the Russian Federation / Institute of Genetics and Cytology of the National Academy of Sciences of Belarus – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |
| 55. | Review of the existing biosafety structure of the Ukraine and Moldova / Institute of Genetics and Cytology of the National Academy of Sciences of Belarus – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |
| 56. | Review of the existing biosafety structure of EU pre-accession countries from Belarus subregion / Institute of Genetics and Cytology of the National Academy of Sciences of Belarus – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |
| 57. | Review of the existing biosafety structure of the US / Institute of Genetics and Cytology of the National Academy of Sciences of Belarus – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |
| 58. | Review of the existing biosafety structure of Canada / Institute of Genetics and Cytology of the National Academy of Sciences of Belarus – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |
| 59. | Review of existing mechanisms for risk assessment / risk management of possible adverse effects of genetic engineering activity in the Russian Federation, the Ukraine and Moldova / Institute of Genetics and Cytology of the National Academy of Sciences of Belarus – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003) |
| 60. | Review of existing mechanisms for risk assessment / risk management of possible adverse effects of genetic engineering activity in EU pre-accession countries from Belarus subregion / Institute of Genetics and Cytology of the National Academy of |

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| | Sciences of Belarus – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |
| 61. | Biosafety system assessment of the Republic of Belarus in mass consciousness / Institute of Genetics and Cytology of the National Academy of Sciences of Belarus – Common project of the Republic of Belarus Government and the United Nations Environment Programme (UNEP) "Elaboration of the National Biosafety System in the Republic of Belarus" (2003). |

**Appendix 5**

**Members of the Expert Board on biosafety of genetically engineered organisms of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus (order of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of 12 January 2015 No. 14-OD)**

| Full Name | Position | Specialization | Place of Employment |
|---|---|---|---|
| Igor M. Kachanovskiy | Deputy Minister (Expert Board Chairperson) | environmental protection | Ministry of Natural Resources and Environmental Protection of the Republic of Belarus |
| Tatyana V. Zheleznova | Adviser, Department of Biological Diversity, Biological and Landscape Diversity Division (Expert Board Secretary) | biological diversity | Ministry of Natural Resources and Environmental Protection of the Republic of Belarus |
| Zinaida M. Aleshchenkova | Head of Laboratory | microbiology, biotechnology | Institute of Microbiology, National Academy of Sciences of Belarus |
| Oleg M. Belanovskiy | Head, Seed Department, Main Plant Growing Division | plant growing | Ministry of Agriculture and Food of the Republic of Belarus |
| Tamara A. Gapeyeva | Senior Researcher | molecular genetics | Institute of Biophysics and Cell Engineering, National Academy of Sciences of Belarus |
| Sophia A. Dmitriyeva | Senior Researcher | botany | Institute of Experimental Botany, National Academy of Sciences of Belarus |

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| Olga L. Zakharova | Head, the Aarhus Centre of the Republic of Belarus | environmental protection | Ministry of Natural Resources and Environmental Protection of the Republic of Belarus |
| Dmitriy I. Kagan | Senior Researcher | biotechnology | Institute of Forest, National Academy of Sciences of Belarus |
| Anatoliy G. Krasko | Head of Laboratory | virology | Republican Scientific and Practical Centre for Epidemiology and Microbiology |
| Valiantsina A. Lemesh | Director | genetics, biotechnology | Institute of Genetics and Cytology, National Academy of Sciences of Belarus |
| Elena S. Lebedik | Category 2 engineer, Department of Food and Agricultural Products Testing | metrology, GMO detection | Belarusian State Institute of Metrology |
| Elena N. Makeyeva | Head of ABS NCC* and **Lead Researcher of NCBC | genetics, molecular biology, biosafety | National Coordination Centre on Access to Genetic Resources and Benefit-sharing (ABS NCC)*, **National Coordination Biosafety Centre (NCBC), Institute of Genetics and Cytology of the National Academy of Sciences of Belarus |
| Sergey B. Melnov | Director, Belarusian Scientific and Practical Centre | genetics, molecular biology, | Belarusian Scientific and Practical Centre “Ecologiya” |

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| | “Ecologiya” | biosafety | |
| Galina V. Mozgova | Head, National Coordination Biosafety Centre | genetics, molecular biology, biosafety | National Coordination Biosafety Centre, Institute of Genetics and Cytology of the National Academy of Sciences of Belarus |
| Galina I. Novik | Head of Laboratory | microbiology, biotechnology | Institute of Microbiology, National Academy of Sciences of Belarus |
| Vladimir E. Padutov | Head of Laboratory | genetics, biotechnology | Institute of Forest of the National Academy of Sciences of Belarus |
| Lyudmila I. Trepashko | Head of Laboratory | plant protection | Institute for Plant Protection |
| Ekaterina V. Fedorenko | Head of Laboratory | sanitary and hygiene, epidemiology, GMO detection | Republican Scientific and Practical Centre of Hygiene |
| Viya A. Shukevich | Head, Food Hygiene Division | medical and preventative care | Republican Centre for Hygiene, Epidemiology and Public Catering (Nutrition) |