





### THE CENTRAL AND EASTERN EUROPEAN TRAINING COURSE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS 24-28 SEPTEMBER 2018, MINSK, BELARUS

### RISK ASSESSMENT EXPERIENCES IN THE REGION: EXPERIENCE OF BELARUS WITH RISK ASSESSMENT AND THE REGULATORY SYSTEM FOR LIVING MODIFIED ORGANISMS

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http://www.biosafety.by/

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



In accordance with Article 20 of the Law of January 10, 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 the compliance of the Republic of Belarus legislation with them.

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 January 9, 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; it also ensures the fulfillment of international obligations by the Republic of Belarus in the field of safety in genetic engineering activity.



http://bch.cbd.int/database/results?searchid=596866

<u>47774</u>

The Law of the Republic of Belarus "On Accession of the Republic of Belarus to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity"

- The Resolution of the Council of Ministers of the Republic of Belarus
- 47775 "On Measures for Implementation of the Provisions of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity"

#### LEGISLATION / GMOs REGULATORY FRAMEWORK

#### ► THE LAW OF THE REPUBLIC OF BELARUS "ON SAFETY IN GENETIC ENGINEERING ACTIVITIES" №96, January 9, 2006

➤The Law establishes legal and organisational principles for ensuring safety in genetic engineering activities and regulates relations in this field.

Does not cover relations related to the use of genetic engineering to human beings, their organs and tissues, handling of pharmaceutical preparations, as well as the production and use of raw and finished food products and animal fodder produced from genetically engineered organisms or their components. The Republic of Belarus has 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,

the Ministry of Agriculture and Food.

## **Biosafety System of the Republic of Belarus**

#### Administrative system

## Ministry of Natural Resources and Environmental Protection

#### compelence.

- Biosafety measures for contained use of LMOs;
- Risk assessment of LMOs for release into environment:
- Permissions for release of LMOs into environment for field trials:
- Biosafety measures and risk management for field trials of LMOs;
- Risk assessment of LMOs for placing in the market;
- Registration of created, imported and exported LMOs;
- Notification about transit of LMOs:
- State control of biosafety measures (release LMOs into environment).

#### Ministry of Health

#### competence:

- Biosafety measures for contained use of pathogenic and opportunistic pathogenic LMOs;
- Permissions for import, export and transit pathogenic and opportunistic pathogenic LMOs;
- Registration of created, imported and exported pathogenic and opportunistic pathogenic LMOs;

National Co-ordination Biosafety Centre

- Order of risk assessment of LMOs on human health:
- State control of biosafety measures (human health).

## Ministry of Agriculture and Food

#### compelence

 Registration of LMOs for placing in the market (growth, cultivation, propagation, etc.);

 State control of biosafety measures (animal health, agricultural activities, social and economical considerations).

#### Legislation system

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1998 - Resolution of Council of Ministries of the Republic of Belarus "On Establishing the National Co-ordination Biosafety Centre" (963/1998)



2006 - The Law of the Republic of Belarus "On Safety in Genetic-Engineering Activity" (96/2006); 28 resolutions of Council of Ministries and Ministries of the Republic of Belarus covering:

Biosafety measures for contained use of LMOs;

- Requirements for import, export and transit LMOs (including AIA procedure):
- Registration created, imported and exported LMOs:

 Decision making process for release LMOs into environment including risk assessment of field trials:

- Biosafety measures for field trials of LMOs;
- · Decision making process for placing LMOs in the market including risk assessment of LMOs for placing in the market;
- Registration of LMOs for placing in the market;
- Risk management and monitoring of LMOs used in economical activities:
- National biosafety database and information sharing with BCH:
- Public awareness and participation in decision making process;
- · Penalties for breach of biosafety measures:

#### competence:

- Liaison with the SCBD on biosafety aspects (CPB National Focal Point, BCH Focal Point);
- Maintain National biosafety web-site and database;
- Consulting and advising National Competent Authorities and institutions on biosafety aspects;
- Information sharing with National Biosafety Centers of other countries and International Organizations;
- Public awareness in biosafety and genetic-engineering;
- Provision of public participation in risk assessment of LMOs and decision making process (via web-site).

#### Stages of LMO biosafety estimation



Contained use

Planning of LMO Creation (import) of LMO Laboratory studies of LMO

- 1. Biosafety estimation of future LMO and creation of LMO dossier;
- 2. Registration of created (imported) LMO; 3. Biosafety studies of created LMO and replenishment of LMO dossier;

Under the control of the institutional biosafety council (manufacturing inspection)

**Risk assessment** of LMO for release into environment for field trials and issuing the permission by Ministry of Nature

Release into environment for field trials

**Biosafety studies of LMO** 

- 1. Biosafety studies of released LMO in special fields;
- 2. Reporting about field trials of LMO and replenishment of LMO dossiel";

Under the control of the institutional biosafety council (manufacturing inspection) and Ministry of Nature (State inspection)

Reporting about field trials of LMO

**Risk assessment** of LMO for placing in the market by Ministry of Nature and state registration of LMO by Ministry of Agriculture

#### Placing in the market

Risk management and biosafety monitoring of LMO

1. Biosafety monitoring possible effect of LMO on human health and biological diversity and social and economical investigations of LMO placed in the market;

Under the control of Ministries of Nature, Health and Agriculture (State inspections)

The Law, by-laws and regulations define concepts and describerequirements and procedures, which contribute to fulfill obligationsregardingGMOsundertheCPB.

#### E.g.

Article 13. Risk Levels of Genetic Engineering Activity

Article 14. Safety Requirements for Genetic Engineering Activity in the Self-Contained System Article 15. Safety Requirements for Release of Genetically Engineered Organisms into the Environment for Testing

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

Article 17. Safety Requirements for Transport of Genetically Engineered Organisms 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 **Article 20. State Safety Expertise of Genetically Engineered Organisms** Article 24. Requirements to Information on Safety of Genetically Engineered Organisms during their Transport and Storage

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

and others

A number of by-laws to ensure safety in genetic engineering activity (GEA) were elaborated in addition to this Law:

http://www.biosafety.by/zakony-respubliki-belarus/

http://bch.cbd.int/database/results?searchid=716002

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 GEA;
- work in self-contained systems;
- import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of Genetically Engineered Organisms (GEOs);
- risk assessment of possible adverse effects of GEOs on the environment and human health before field trials and placement to the market;
- release of GEOs s into the environment;
- use of GEOs for economic purposes;
- information exchange and the Biosafety Clearing-House;
- public awareness and its participation in decision-making with regard to safety in genetic engineering activity;
- control in the field of safety in genetic engineering activity;
- responsibility for violation of legislation on safety in genetic engineering activity;
- GEO detection and loss if eation.

#### LMO definition in Belarus:

#### LAW OF THE REPUBLIC OF BELARUS "ON SAFETY IN GENETIC ENGINEERING ACTIVITY", January 9, 2006 No. 96-3 (the Law)

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

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

"Genetic engineering activity" means the activity associated with the development of genetically engineered organisms, their release into the environment for testing, use for economic purposes, import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of genetically engineered organisms, their storage and deactivation.

RISK ASSESSMENT AND MANAGEMENT, INTENTIONAL INTRODUCTION INTO THE ENVIRONMENT, STATE REGISTRATION OF THE GENETICALLY ENGINEERED ORGANISMS



On Safety Requirements for Trial Fields and Other Objects Provided for Testing Nonpathogenic Genetically Engineered Organisms under their First Release into the Environment



On Approval of Instruction on Procedures of Testing Non-pathogenic Genetically Engineered Organisms under their Release into the Environment



On Approval of Instructions on the Procedure of Risk Assessment of Possible Adverse Effects of Genetically Engineered Organisms on the Environment



On approval of Regulations on the procedure for State Safety Examination of genetically engineered organisms and of approximate terms of contracts concluded for its carrying out, and issuing permits to release of non-pathogenic, genetically engineered organisms into the environment for testing



On Approval of Regulations for State Registration Order of Genetically Engineered Plant Cultivars, Genetically Engineered Agricultural Breeds and Non-Pathogenic Genetically Engineered Microorganisms



"On Risk Assessment of Adverse Effects of Genetic-Engineered Organisms on Environment" (55/2006)

By order of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of December 5, 2012 No. 412-OD (with amendments introduced by orders of January 12, 2015 No. 14-OD and of October 28, 2015 No. 370-OD), the Safety Expert Board for Genetically Engineered Organisms at the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus was established in the Republic of Belarus. The work of the Biosafety Expert Board allows, using the knowledge and experience of all the country organizations competent in the issues of safety in genetic engineering activity, 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.

List of members: <u>http://www.biosafety.by/otsenki-</u> <u>riskov/ekspertnyj-sovet/</u> •On August 25, 2006 the Ministry of Health of the Republic of Belarus approved instruction №076-0806 on assessing the risks of LMO potential adverse effects on human health.

Министерство здравоохранения Республики Беларусь

У т в ер ж да ю Заместитель Министра Главный государственный санитарный врач Республики Беларусь М.И. Римжа 25 августа 2006 г. Регистрационный №076-0806

ПОРЯДОК ПРОВЕДЕНИЯ ОЦЕНКИ РИСКА ВОЗМОЖНЫХ ВРЕДНЫХ ВОЗДЕЙСТВИЙ ГЕННО-ИНЖЕНЕРНЫХ ОРГАНИЗМОВ НА ЗДОРОВЬЕ ЧЕЛОВЕКА

Инструкция по применению

Учреждения-разработчики: ГУ «Республиканский научно-практический центр гигиены»; ГНУ «Институт генетики и цитологии» Национальной Академии Наук Беларуси; ГУ «Республиканский центр гигиены, эпидемиологии и общественного здоровья»

Авторы: Циганков В.Г., Кедрова И.И., Бондарчук А.М., Ермишин А.П., Подлисских В.Е., Гулин В.В., Скуратович А.Л., Фидаров Ф.М.  Assessment of the risks of GMOs impact on the conservation and sustainable use of biological diversity, taking into account risks to human health: methodological recommendations.

Developed by the NCBC and agreed with the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus (22.10.2014 No. 3-2-11 / 1124 ext.)

цено www.biosafety.by/publikatsii/



<u>Г.В.Мозгова Оценка рисков воздействия ГМО на сохранение и устойчивое использование биологического</u> разнообразия, с учетом рисков для здоровья человека: методические рекомендации.

– Минск: Право и экономика, 2014. – 58 с.

В методических рекомендациях описывается процесс оценки экологического риска и риска здоровью человека, проводимый при выпуске генетически модифицированных организмов (ГМО) в окружающую среду. В основу рекомендаций положены основные положения и методические рекомендации, предложенные международными экспертами при Секретариате Конвенции о биологическом разнообразии, а также действующие в Республике Беларусь законодательные и нормативно-

правовые акты в области обеспечения безопасности генно-инженерной деятельности.

Методические рекомендации предназначены для использования экспертами, проводящими государственную экспертизу безопасности ГМО при их выпуске в окружающую среду для проведения испытаний и последующем коммерческом высвобождении, а также компетентными органами и лицами, принимающими участие в принятии решений относительно высвобождения ГМО.

	CBD	
UNEP	Distr. GENERAL	
Convention on Biological Diversity	UNEP/CBD/BS/COP-MOP/8/8/Add.1 14 September 2016* ORIGINAL: ENGLISH	
CONFERENCE OF THE PARTIES TO THE CONVENTI BIOLOGICAL DIVERSITY SERVING AS THE MEET THE PARTIES TO THE CARTAGENA PROTOCOL C BIOSAFETY Eighth meeting Cancun, Mexico, 4-17 December 2016 Item 11 of the provisional agenda <sup>**</sup>	FING OF N	
GUIDANCE ON RISK ASSESSMENT OF LIVING M IN THE CONTEXT OF R		
Note by the Executi	ve Secretary	
<ol> <li>In its decision BS-VII/12, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) welcomed the results of the testing of the Guidance on Risk Assessment of Living Modified Organisms, and invited Parties, other Governments and relevant organizations to test or use, as appropriate, the Guidance in actual cases of risk assessment and as a tool for capacity- building activities in risk assessment.</li> </ol>		
2 In the same decision, the Parties extended the ma	indate of the Open ended Online Expert Forum	

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 September 8, 2006 No. 1160.

#### 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
- 2. Information on biological features of a donor organism
- 3. Biological features of a vector
- 4. Information on genetic engineering modification character
- 5. Information on biological features of genetically engineered organisms
- 6. Information on the potentially receiving environment
- 7. Information on the interaction of genetically engineered organisms with the environment

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

#### 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", the following shall be implemented within a framework of information support in the field of genetic engineering activity:

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.



The National Coordination Biosafety Centre (NCBC) was established in accordance with the Resolution of the Council of Ministers of the Republic of Belarus of June 19, 1998 No. 963 at the Institute of Genetics and Cytology of the National Academy of Sciences of Belarus and fulfill all above mentioned functions.

The NCBC developed and maintains an information database on biosafety, access to which is provided through the website

## http://biosafety.by

#### LMO RA in Belarus

#### One RA before accession to the Cartagena Protocol

#### record.shtml?documentid=105072

G	eneral Information		
0	Country		
	• Belarus		
Title of risk assessment			
	Expert conclusion based on the results of the safety assessment for human health and the environment of genetically engineered organism - sugar beet resistant to the herbicide glufosinate ammonium (commercial name Liberty)		

#### Date of the risk assessment

1999-04-20

#### LMO RA in Belarus

## Seven RA after accession to the Cartagena Protocol

<b>2</b> 105663	<b>Belarus</b> Risk assessment of nonpatogenic potato (Solanum tuberosum, var. Skarb/ 38-4)	Potato Modified for insect resistance Potato, SOLTU	🎸 🏾 🕾 🖶 🖻 🥲
<b>2</b> 106348	Belarus Expert conclusion based on the results of the safety assessment for human health and the environment of transgenic potato plants expressing the genes for antimicrobial peptides of the cecropin and melittin type	Potato modified for antimicrobial activity Potato, SOLTU	♦ 1 2 4 6 0
<b>108249</b>	<b>Belarus</b> Transgenic rapeseed line with incorporeted gene sequence aroA, providing resistance to the herbicide glyphosate. The conclusion of the State expertise.	Canola modified for herbicide tolerance BRANA, Canola Plant, Oilseed Rape, Rape, Rapeseed, Turnip	◆『當寺 品で
<b>2</b> 110619	<b>Belarus</b> Transgenic canola with incorporated gene sequence, encoding chicken alpha-interferon. The conclusion of the State expertise.	Canola modified for the expression of chicken interferon alpha BRANA, Canola Plant, Oilseed Rape, Rape, Rapeseed, Turnip	♥ 1 2 0 0
<b>2</b> 112000	<b>Belarus</b> Expert conclusion based on the results of the safety assessment for human health and the environment of transgenic potato plants expressing the genes for antimicrobial peptides of the cecropin and melittin type. Re-examination	Potato modified for antimicrobial activity Potato, SOLTU	◆ 『 當 ⇔ 品 で
<b>2</b> 112540	<b>Belarus</b> Risk assessment of transgenic clover	Red Clover modified for cold tolerance and fungal resistance Peavine clover, Purple clover, Red clover, Rotklee, TRIPR	◆『當寺品で
<b>2</b> 113167	Belarus Expert conclusion based on the results of the safety assessment for human health and the environment of genetically engineered organism - Domestic goat modified to produce human lactoferrin	Domestic goat modified to produce human lactoferrin CAPHI, Domestic goat, Goat	◆『當幸旨で

## The examples of review and assessment of the biosafety law that government has conducted

In the Republic of Belarus all laws, by-laws and the legal and regulatory framework are reviewed and supplemented as and when required, taking into account practical experience in their application.

The survey and analysis of biosafety activity in the Republic of Belarus, including the experience gained in enforcement of the existing legal and regulatory framework, identified the need to revise certain provisions of the Law of the Republic of Belarus "On Safety in Genetic Engineering Activity" and in particular:

- Its rectification and supplement with the main terms: "risk of possible adverse effects", "genetic engineering activity", "neutralization of genetically engineered organisms";
- Risk assessment procedures and conditions are being reviewed.
  - The relations are being specified with regard to:

Non-pathogenic genetically engineered microorganisms;

Import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of genetically engineered organisms;

Tracking and notification of transfer of genetically engineered organisms, and etc.

# In 2017-2018 the Law "On Safety in Genetic Engineering Activity" passes revision by the State Institutions in the field of safety in genetic engineering activity.

From 2014 onwards, 7 applications for State Expertise in safety of genetically engineered organisms were considered. Based on its results and the Expert Board recommendations, 3 permits were issued for release of non-pathogenic genetically engineered organisms into the environment for testing.



### **Trial Fields**





