



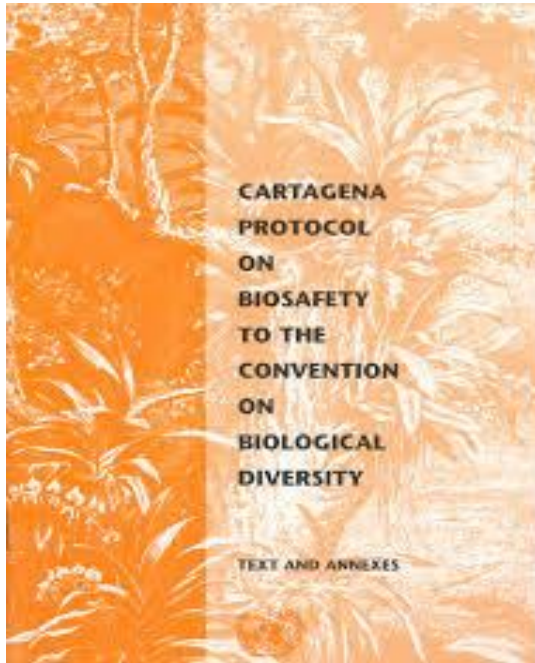
**STATE SCIENTIFIC INSTITUTION
«INSTITUTE OF GENETICS AND CYTOLOGY
AT THE NATIONAL ACADEMY OF SCIENCES OF BELARUS»
NATIONAL COORDINATION BIOSAFETY CENTRE**

***Release of Genetically Modified Organisms into the
Environment for Testing:
Biosafety State Examination Procedure***

GALINA MOZGOVA

**INTERNATIONAL CONFERENCE
“EXPERIENCE SHARING IN PUBLIC EDUCATION AND AWARENESS OF
BIOSAFETY ISSUES”**

**October 1, 2013
Minsk, Belarus**

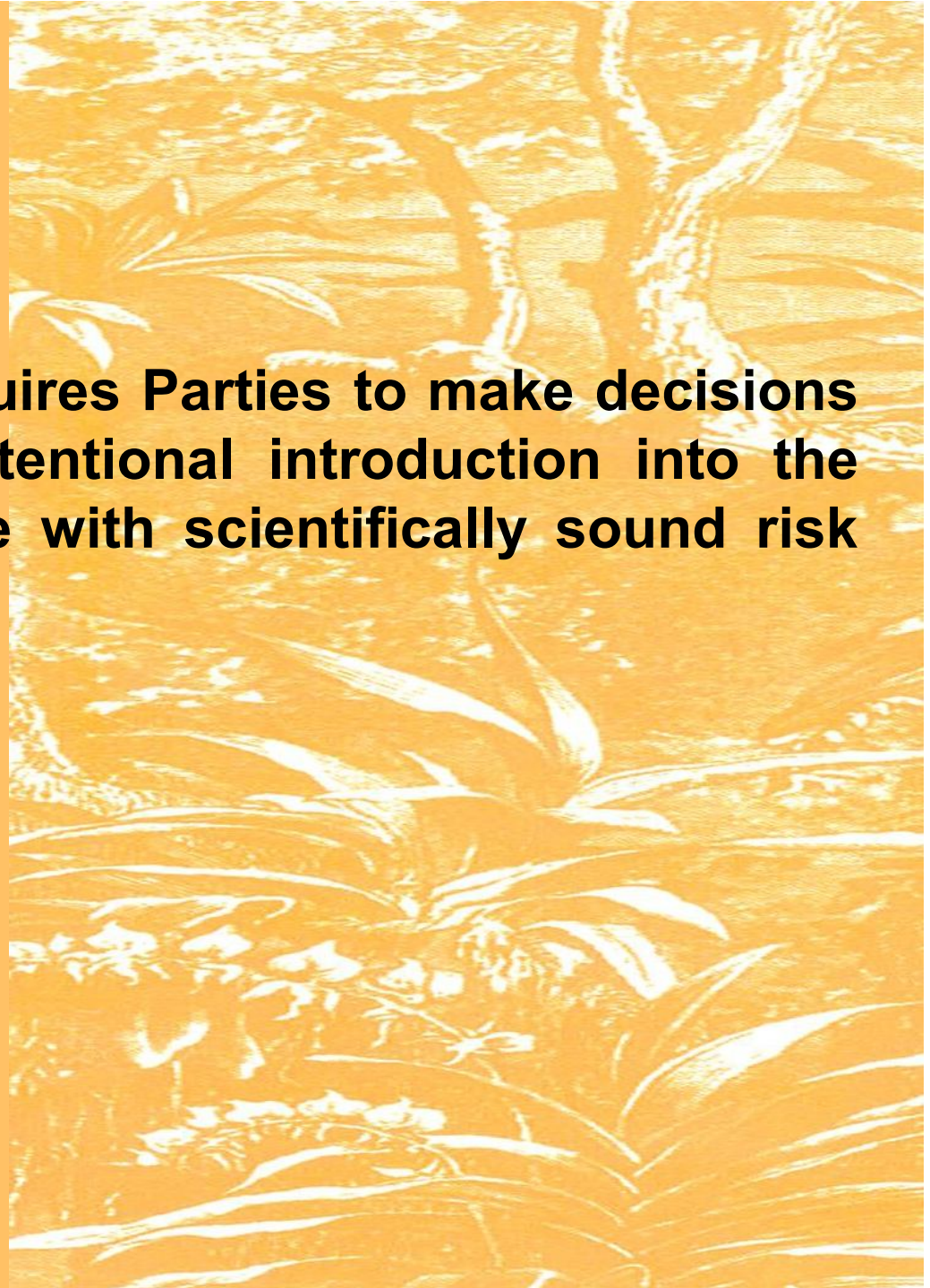


The **Cartagena Protocol on Biosafety to the Convention on Biological Diversity** is an international treaty governing the movements of living modified organisms resulting from modern biotechnology from one country to another. It was adopted on January, 29 2000 as a supplementary agreement to the Convention on Biological Diversity and **entered into force on September 11, 2003.**

THE OBJECTIVE OF THE *KARTAGENA PROTOCOL* is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.


▪

The Biosafety Protocol requires Parties to make decisions on import of LMOs for intentional introduction into the environment in accordance with scientifically sound risk assessments ([Article 15](#)).



Republic of Belarus joined to the Cartagena Protocol on May 6, 2002. September 11, 2003 – Date of entry into force.




**ЗАКОН
РЕСПУБЛИКИ БЕЛАРУСЬ**


О присоединении Республики Беларусь к Картахенскому протоколу по биобезопасности к Конвенции о биологическом разнообразии

Принят Палатой представителей 3 апреля 2002 года
Одобен Советом Республики 23 апреля 2002 года

Статья 1. Присоединиться к Картахенскому протоколу по биобезопасности к Конвенции о биологическом разнообразии, принятому Конференцией Сторон Конвенции о биологическом разнообразии 29 января 2000 года в г. Монреале.

Статья 2. Совету Министров Республики Беларусь принять необходимые меры по реализации положений Картахенского протокола по биобезопасности.

Президент
Республики Беларусь **А.Лукашенко**




6 мая 2002 г., г. Минск
№ 97-З

http://bch.cbd.int/database/record.shtml?documentid=47774

Почта Лента новостей Часто посещаемые Начальная страница Mail.Ru

Document details


Document text

 <http://biosafety.org.by/sites/default/files/downloads/Rcu/act-2002-197-ratf-CPB.pdf>
О присоединении Республики Беларусь к Картахенскому протоколу по биобезопасности к конвенции о биологическом разнообразии. 6 мая 2002 г., 197.

Information about document text





Reference: National Register of Legal Statements of the Republic of Belarus, 08.05.2002, NS3,2/846


Unofficial documents


 [Law-2002-05-06-BCH-47772-Accession to CPB.doc](#) (26 KB)
The Law of the Republic of Belarus of May 6, 2002, N 97-З "On Accession of the Republic of Belarus to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity"

Regulatory contact information

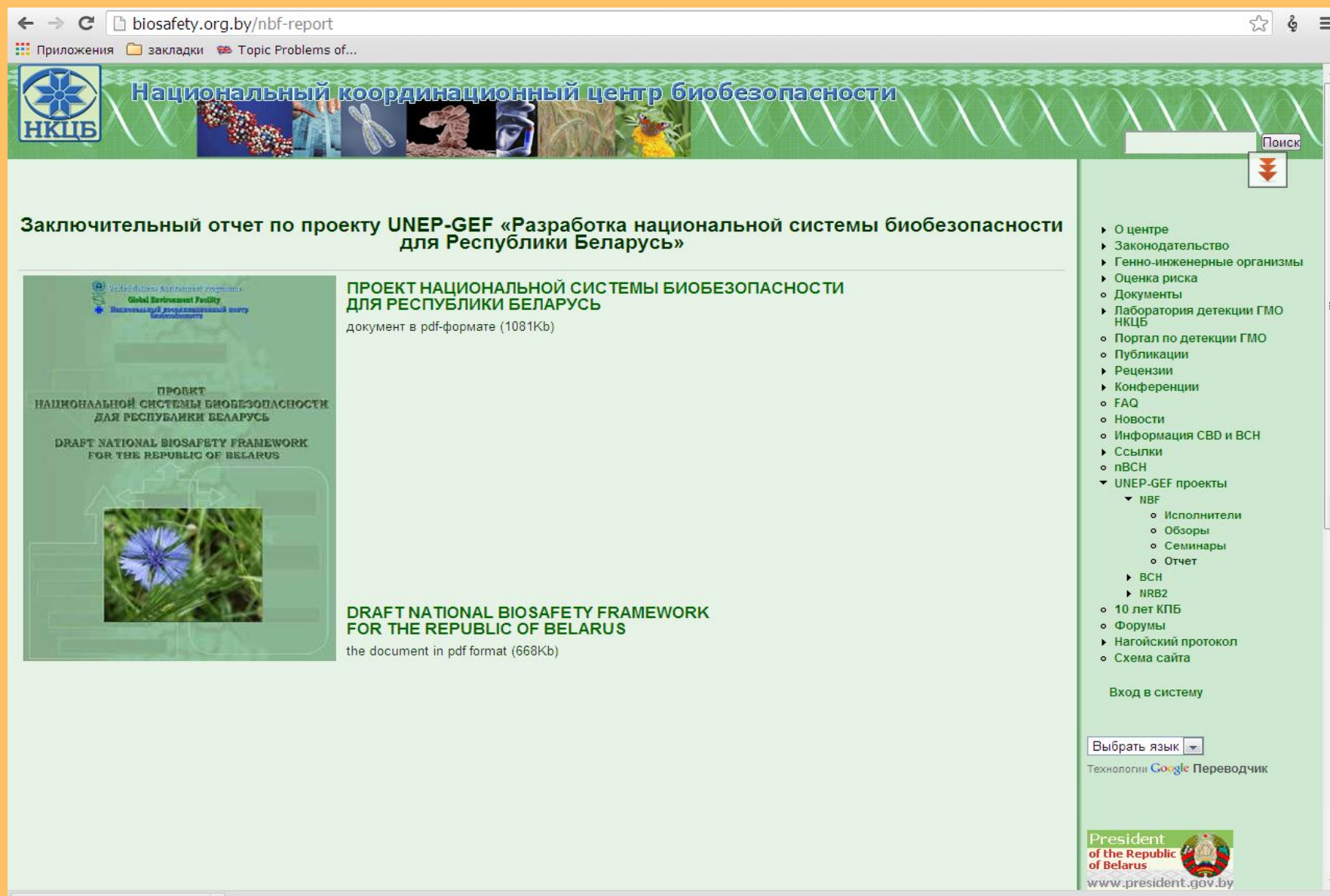
Contact person

National Co-ordination Biosafety Centre [Record #48572](#)
27, Akademicheskaya Str.
Minsk
Belarus, 220072
 Phone: +375 17 284-0297
 Fax: +375 17 284-1691
 Email: biosafety.by@gmail.com
 Url: [National Co-ordination Biosafety Centre](#)

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The National Biosafety System was developed in Belarus by 2006 by support of the United Nations Environment Programme. Basic Laws governing Biosafety State Examination Procedure came into force that year.



The screenshot shows a web browser window with the address bar displaying "biosafety.org.by/nbf-report". The browser's address bar also shows "Приложения", "закладки", and "Topic Problems of...". The website header features the logo of the National Center for Biosafety (НКЦБ) and the text "Национальный координационный центр биобезопасности". Below the header, there is a search bar with the text "Поиск" and a dropdown arrow. The main content area is titled "Заключительный отчет по проекту UNEP-GEF «Разработка национальной системы биобезопасности для Республики Беларусь»". Below this title, there are two document links: "ПРОЕКТ НАЦИОНАЛЬНОЙ СИСТЕМЫ БИОБЕЗОПАСНОСТИ ДЛЯ РЕСПУБЛИКИ БЕЛАРУСЬ" (document in pdf-format (1081Kb)) and "DRAFT NATIONAL BIOSAFETY FRAMEWORK FOR THE REPUBLIC OF BELARUS" (the document in pdf format (668Kb)). The right sidebar contains a navigation menu with items such as "О центре", "Законодательство", "Генно-инженерные организмы", "Оценка риска", "Документы", "Лаборатория детекции ГМО НКЦБ", "Портал по детекции ГМО", "Публикации", "Рецензии", "Конференции", "FAQ", "Новости", "Информация CBD и ВСН", "Ссылки", "nBCH", "UNEP-GEF проекты", "NBF", "Исполнители", "Обзоры", "Семинары", "Отчет", "ВСН", "NRB2", "10 лет КПБ", "Форумы", "Нагойский протокол", and "Схема сайта". At the bottom of the sidebar, there is a "Вход в систему" link, a language selection dropdown, and a "Технологии Google Переводчик" link. The footer of the website includes the logo of the President of the Republic of Belarus and the website address "www.president.gov.by".

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

ЗАКОН РЕСПУБЛИКИ БЕЛАРУСЬ О БЕЗОПАСНОСТИ ГЕННО-ИНЖЕНЕРНОЙ ДЕЯТЕЛЬНОСТИ № 96 от 9 января 2006 г.

Article 20. State expertise of safety of genetically engineered organisms

Expertise shall be mandatory in case of the first release of genetically engineered organism into the environment for trials and state registration of genetically engineered varieties of plants, breeds of animals and strains of microorganisms designed for use in economic activities.

Objects of expertise:


- samples of genetically engineered organisms;
- materials containing data on the assessment of risk of potential harmful impact of genetically engineered organisms on human health and the environment, as well as on measures for prevention of such risk.

Legislation governing activities in the field of safety in genetic engineering activities can be found on the Website of the **National Coordination Biosafety Centre (NCBC)**

<http://biosafety.org.by/legislation>

biosafety.org.by/legislation

заклады Topic Problems of...

 Национальный координационный центр биобезопасности

Поиск

Закон Республики Беларусь «О безопасности генно-инженерной деятельности» и связанные с ним нормативно-правовые акты законодательства

тексты в формате pdf будут открываться в новом окне

Закон Республики Беларусь «О безопасности генно-инженерной деятельности» 9 января 2006 г. №96.

- Закон Республики Беларусь «О внесении изменений в Закон Республики Беларусь «О семенах» 4 января 2007 г. №200
- Закон Республики Беларусь «О внесении изменений и дополнений в некоторые кодексы Республики Беларусь по вопросам установления ответственности за нарушения законодательства о безопасности генно-инженерной деятельности» 18 мая 2007 г. №231 (в Кодекс Республики Беларусь об административных правонарушениях и в Уголовный кодекс Республики Беларусь)

Постановления Совета Министров Республики Беларусь

- О внесении изменений и дополнений в постановление Совета Министров Республики Беларусь от 18 марта 1997 г. № 218 и изменения в постановление Совета Министров Республики Беларусь от 29 ноября 1999 г. № 1853, 13 мая 2006 г. № 608
- Об утверждении Положения о порядке выдачи разрешений на ввоз, вывоз или транзит условно патогенных и патогенных генно-инженерных организмов. 16 августа 2006 г. №1049.
- О некоторых вопросах государственного регулирования семеноводства и сортоиспытания. 5 сентября 2006 г. №1135.
 - Положение о государственном контроле в семеноводстве;
 - Положение о сортоиспытании;
 - Положение о государственном реестре производителей, заготовителей семян;
 - Положение о государственном реестре сортов и древесно-кустарниковых пород
- Об утверждении положений о порядке проведения государственной экспертизы безопасности генно-инженерных организмов и примерных условиях договоров, заключаемых для ее проведения, и выдачи разрешений на высвобождение непатогенных генно-инженерных организмов в окружающую среду для проведения испытаний. 8 сентября 2006 г. №1160.
 - Положение о порядке проведения государственной экспертизы безопасности генно-инженерных организмов и примерных условиях договоров, заключаемых для ее проведения;
 - Положение о порядке выдачи разрешений на высвобождение непатогенных генно-инженерных организмов в окружающую среду для проведения испытаний
- Об утверждении Положения о порядке государственной регистрации сортов генно-инженерных растений, пород генно-инженерных животных и штаммов непатогенных генно-инженерных микроорганизмов. 12 сентября 2006 г. №1195.
- Об утверждении Положения о порядке и условиях предоставления информации из информационного банка данных о генно-инженерных организмах. 15 сентября 2006 г. №1222.

Постановления Министерства здравоохранения Республики Беларусь

- О некоторых вопросах безопасности генно-инженерной деятельности. 25 августа 2006 г. №65
 - Инструкция о требованиях безопасности к замкнутым системам при осуществлении работ второго, третьего и четвертого уровней риска генно-инженерной деятельности;
 - Инструкция о порядке проведения аккредитации замкнутых систем для осуществления работ второго, третьего и четвертого уровней риска генно-инженерной деятельности;
 - Инструкция о требованиях безопасности при транспортировке условно-патогенных и патогенных генно-инженерных организмов;

Вход в систему

Выбрать язык

Технология Google Переводчик

President of the Republic of Belarus
www.president.gov.by

Government of the Republic of Belarus
www.government.by

11 сентября 2013

National Coordination Biosafety Centre

<http://biosafety.org.by/legislation>

← → ↻ biosafety.org.by/legislation

закладки Topic Problems of...

Google Переводчик Переведено на **английский** Показать исходный текст Настройки

 **Национальный координационный центр биобезопасности**

Law of the Republic of Belarus "On the safety of genetic engineering" and related regulations legislation

texts in pdf will open in a new window

Law of the Republic of Belarus "On the safety of genetic engineering," January 9, 2006 number 96.

- ♦ **Law of the Republic of Belarus "On Amending the Law of the Republic of Belarus" On Seeds "** January 4, 2007 № 200
- ♦ **Law of the Republic of Belarus "On amendments and additions to some codes of the Republic of Belarus on the establishment of liability for violations of the legislation on the safety of genetic engineering,"** May 18, 2007 number 231 (the Code of Administrative Offences and the Criminal Code of the Republic of Belarus)

Resolution of the Council of Ministers of the Republic of Belarus

- **On the Introduction of Amendments and Additions to the Council of Ministers on 18 March 1997 number 218 and the changes in the resolution of the Council of Ministers on 29 November 1999 number 1853 .** May 13, 2006 № 608
- **Approval of the Regulations on the procedure for issuing permits for the import, export or transit of opportunistic pathogens and genetically engineered organisms.** Aug. 16, 2006 number 1049.
- **On some issues of state regulation of seed and variety trials.** September 5, 2006 number 1135.
 - Regulation on State control of seed;
 - The position of the variety trials;
 - Statement on the State Register of manufacturers, packers seeds;
 - Statement on the State Register of varieties and trees and shrubs.
- **Approval of the Procedure of state expertise safety of genetically engineered organisms and sample conditions of contracts for its execution, and permits the release of non-pathogenic genetically engineered organisms into the environment for testing.** September 8, 2006 number 1160.
 - Regulation of public safety review of genetically engineered organisms and sample terms of the agreement to carry it out;
 - Regulation on the procedure for issuing permits for the release of non-pathogenic genetically engineered organisms into the environment for testing
- **Approval of the Regulations on the procedure of state registration of genetically engineered plants, breeds of genetically engineered animals and non-pathogenic strains of genetically engineered microorganisms.** September 12, 2006 number 1195.
- **Approval of the Regulations on the procedure and conditions for the provision of information from the data bank of genetically engineered organisms.** September 15, 2006 number 1222.

Ordinance of the Ministry of Health of the Republic of Belarus

- **On some issues of the safety of genetic engineering.** Aug. 25, 2006 number 65
 - Instruction on safety requirements for closed systems during handling of the second, third and fourth levels of the risk of genetic engineering;
 - Guidelines for the Accreditation of closed systems for the implementation of the work of the second, third and fourth levels of the risk of genetic engineering;
 - Instruction on safety requirements for transport of opportunistic pathogens and genetically engineered organisms;
 - Instructions regarding the accounting for government entities created imported into the Republic of Belarus exported from the Republic of Belarus and transported in transit through its territory of opportunistic pathogens and genetically engineered organisms

▶ About the Center
▼ Legislation

- Legislation related to biosafety
 - ▶ Draft laws and regulations of the Biosafety
- ▶ Genetically engineered organisms
- ▶ Risk assessment
- ▶ Documentation
- ▶ Laboratory detection of GMOs NSC
- The portal for the detection of GMOs
- Publications
- ▶ Reviews
- ▶ Conference
- FAQ
- News
- Information CBD and BCH
- ▶ References
- nBCH
- ▶ UNEP-GEF projects
- 10 years CFS
- Forums
- ▶ The Nagoya Protocol
- Scheme website

Log in

английский

Технологии Google Переводчик

President of the Republic of Belarus
www.president.gov.by

Government of the Republic of Belarus

or on the Website of the Biosafety Clearing-House

<http://bch.cbd.int/about/countryprofile.shtml?country=by>

The screenshot shows a web browser window displaying the Biosafety Clearing-House website. The browser's address bar shows the URL `bch.cbd.int/database/results?searchid=585621`. The website header includes the Biosafety Clearing-House logo and the Convention on Biological Diversity logo. The main navigation menu includes Home, The BCH, The Protocol, Finding Information, Registering Information, Resources, and Help. The left sidebar contains sections for Finding Information and Compiled Information. The main content area displays search results for Belarus, with 23 records found. The results are listed in a table with columns for ID and Description. Each record includes a document icon, the ID number, the country name (Belarus), a brief description, and a set of icons for document actions.

Language: [العربية](#) | [中文](#) | [english](#) | [español](#) | [français](#) | [русский](#) | [My Profile](#) | [Sign Out](#)

Biosafety Clearing-House

Convention on Biological Diversity

Home The BCH The Protocol Finding Information Registering Information Resources Help Country Profiles...

Finding Information

- National Contacts
- Laws and Regulations
- Country's Decisions and other Communications
- Risk Assessments
- Roster of Experts
- LMOs, Genes or Organisms
- National Reports
- Capacity-Building
- Organizations
- The BCH Virtual Library
- Advanced Search --

Compiled Information

- National Contacts
- LMO Registry
- Organism Registry
- Gene Registry

Go to record ID:

Home | Finding Information | Search results

Search results

Group records by: Display Type: Listing

Sort records by: Results per page: 25

[Export results to CSV file](#)
[Subscribe to RSS feed updates for this search](#)

ID	Description
47772	Belarus All functions pursuant to the Cartagena Protocol on Biosafety The Law of the Republic of Belarus "On Safety in Genetic Engineering Activities"
47773	Belarus Capacity Building, Competent National Authorities and National Focal Points, Information Sharing, Confidential Information The Resolution of Council of Ministers of the Republic of Belarus "On Establishment of the National Co-ordination Biosafety Centre"
47774	Belarus All functions pursuant to the Cartagena Protocol on Biosafety 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"
47775	Belarus All functions pursuant to the Cartagena Protocol on Biosafety The Resolution of the Council of Ministers of the Republic of Belarus "On Measures for Implementation of the Provisions of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity"
47776	Belarus Public awareness and participation, Information Sharing The Resolution of the Council of Ministers of the Republic of Belarus "On Approval of the Provision on Order and Condition of Providing Information from Information Data Bank of Genetically Engineered Organisms"

► Resolution of Council of Ministers of the Republic of Belarus of September 8, 2006 N1160

"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"

The screenshot shows a web browser window with the URL <http://bch.cbd.int/database/record.shtml?documentid=103741>. The browser's address bar and navigation buttons are visible. The main content area displays document information for a resolution dated 2006-09-08.

Document details

Document text

RU [res-2006-SovMin-N1160-RA.doc](#) (456 KB)
Постановление Совета Министров Республики Беларусь от 8 сентября 2006 г., № 1160 «Об утверждении Положений о порядке проведения государственной экспертизы безопасности генно-инженерных организмов и примерных условиях договоров, заключаемых для ее проведения, и выдачи разрешений на высвобождение непатогенных генно-инженерных организмов в окружающую среду для проведения испытаний»

Information about document text

Registered in the National Register of Legal Statements of the Republic of Belarus on September 18, 2006, N151, 5/22922

Unofficial documents

EN [RES-CouncilMin-08-09-2006-N1160-RA-release-perm-issue.doc](#) (116 KB)
Resolution of Council of Ministers of the Republic of Belarus of September 8, 2006 N1160 "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"

Regulatory contact information

Contact person

National Co-ordination Biosafety Centre [Record #48529](#)
27, Akademicheskaya Str.
Minsk
Belarus, 220072
Phone: +375 17 284-0297
Fax: +375 17 284-1691
Email: biosafety.by@gmail.com
Url: [National Co-ordination Biosafety Centre](#)



ПАСТАНОВА
ПОСТАНОВЛЕНИЕ

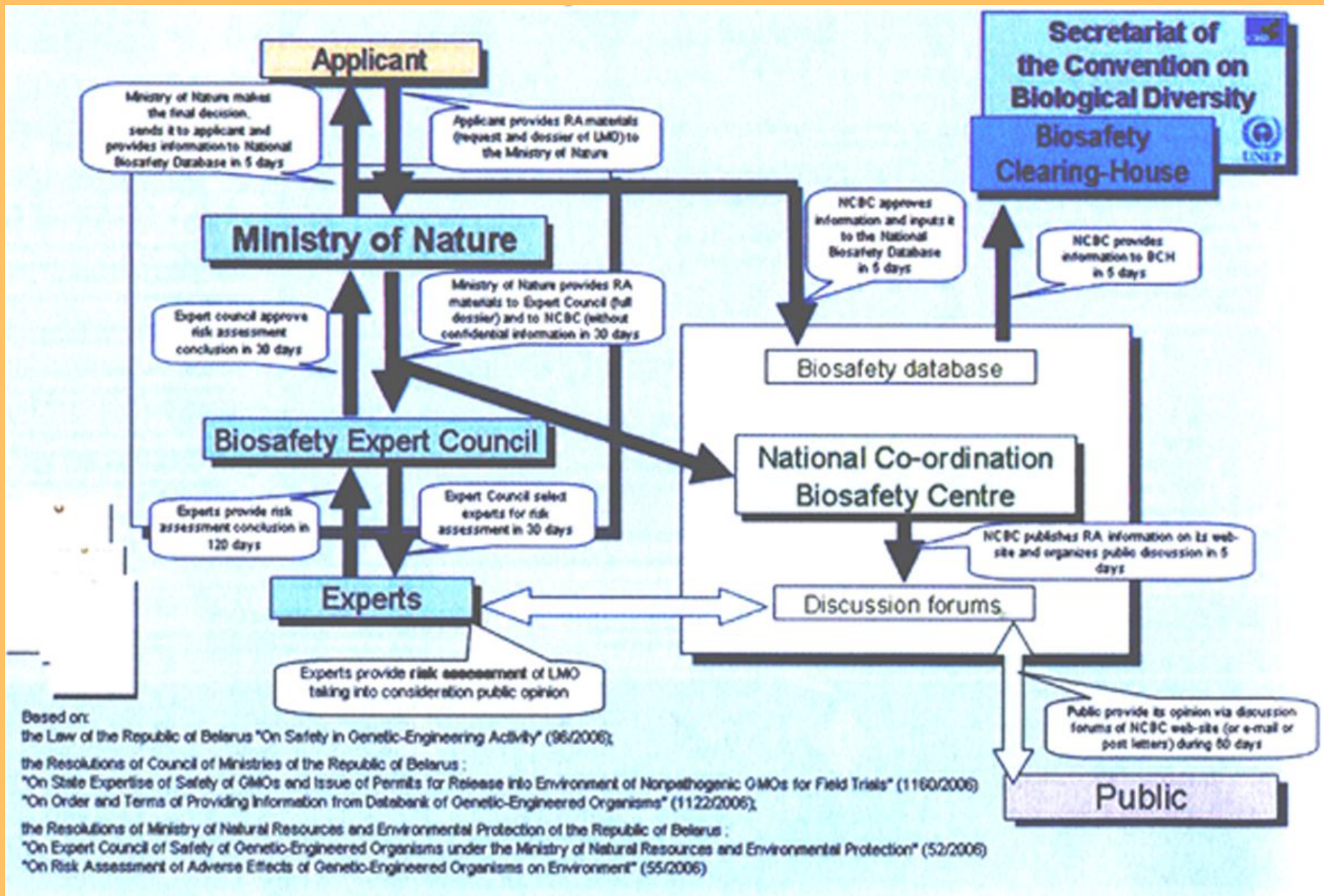
г. Минск
г. Минск

8 сентября 2006 г. № 1160

Об утверждении положений о порядке проведения государственной экспертизы безопасности генно-инженерных организмов и примерных условиях договоров, заключаемых для ее проведения, и выдачи разрешений на высвобождение непатогенных генно-инженерных организмов в окружающую среду для проведения испытаний

**REGULATIONS
ON ORDER OF CARRYING OUT THE PROCEDURE OF
STATE SAFETY EXAMINATION OF GENETICALLY
ENGINEERED ORGANISMS AND ON APPROXIMATE
TERMS OF CONTRACTS CONCLUDED FOR ITS CARRYING OUT**

National Biosafety Risk Assessment System of the Republic of Belarus



For carrying out Examination and obtaining a conclusion of this Examination, an interested Legal Entity or an Individual Entrepreneur being an initiator of its carrying out submits to the Ministry of Natural Resources and Environmental Protection documents :

➤An application for carrying out State Safety Examination of genetically engineered organisms is represented in due form according to Annex 1.

APPLICATION
for State Safety Examination of Genetically Engineered Organisms

Applicant: _____
(Name of Legal Entity or Family name and initials of Individual Entrepreneur,
regular mail, telephone, fax, e-mail)

in the person of: _____
.....(Position, Family name, initials of the Corporation Main Manager)

asks the Ministry of Natural Resources and Environmental Protection of the Republic of
Belarus to carry out the State Safety Examination of genetically engineered organisms.

1. Information on genetically engineered organisms.

1.1. Recipient organism:

→ Family _____

→ Genus _____

→ Species _____

.....Sub-species _____

1.2. Variety/breeding line _____

1.3. Code of the genetically engineered organism _____

2. Description of traits and features which have been introduced or changed as a result of
genetically engineered modification.....

3. Purpose of the State Safety Examination of genetically engineered organisms*.

Hereby I certify that information presented by me to State Safety Examination of
genetically engineered organisms, is complete and true. I am aware of the responsibility for
withholding information about the alleged adverse effects of genetically engineered organisms
on human health and the environment according to the legislation.

Annex of sheet(s) in _____ copy(ies) is(are) enclosed.

.....
(Applicant signature) → → → → → → (Initials, Family name)
Place of stamp

Date « _____ » _____ . _____

.....(day-month-year)

* Getting permission to release nonpathogenic genetically engineered organisms into the environment for testing
and certificate of state registration of genetically engineered varieties of plants, breeds of genetically engineered
animals, nonpathogenic strains of genetically engineered microorganisms.

➤ Information about the risk of possible adverse effects of genetically engineered organisms on human health and the environment, as well as on measures to prevent such a risk for genetically engineered organisms belonging to higher plants is reported according to the information list under **Annex 2**, for genetically engineered organisms belonging to other organisms, other than higher plants - in accordance with the information list under **Annex 3**

LIST

of information about risk assessment of possible adverse effects of genetically engineered organisms belonging to higher plants (Gymnosperms and Angiosperms) on human health and the environment, as well as on measures to prevent such a risk.

1. Information on biological characteristics of the recipient organism:
 - 1.1. Full name:
 - Family;
 - Genus;
 - Species;
 - Sub-species;
 - Variety/breeding line;
 - Common (routine) name;
 - 1.2. Information concerning the characteristics of propagation:
 - Type(s) of reproduction;
 - Specific factors affecting reproduction;
 - The time of procreation;
 - Sexual compatibility with other cultivated or wild species;
 - 1.3. Survival in the environment;
 - The ability to form structures for survival or go into a resting state; specific factors affecting the survival rate;
 - 1.4. Dissemination;
 - Dissemination ways and degree;
 - Specific factors affecting dissemination;
 - 1.5. Geographical dissemination;
 - 1.6. Description of natural habitat, including information on natural predators, parasites, competitors and symbionts;
 - 1.7. Potentially significant interactions with organisms other than plants, in ecosystems typical of normal growth, including information on toxicity to humans, animals or other organisms.
2. Information about biological features of donor organisms;
 - 2.1. Full name:
 - Family;
 - Genus;
 - Species;
 - Sub-species;
 - Variety/breed/strain;
 - Common (routine) name;
 - 2.2. Origin of donor organisms;

- 2.3. Biological characteristics of donor organisms;
3. Biological features of vector:
 - 3.1. The nature and origin of the vector, its natural habitat and the relevant safety features;
 - 3.2. Structure of transposons, promoters and other non-coding genetic segments used to develop the genetic structure necessary for its transfer and functioning in the recipient organism;
 - 3.3. The frequency of inserted vector mobilization (the ability to acquire mobility) or transfer it to other organisms;
 - 3.4. Factors that may affect the ability of vectors to adapt to other host-organisms.
4. Information relating to the nature of genetic engineering modifications:
 - 4.1. The methods used in the development, transfer of transgenic construction and in selection of transgenic organisms;
 - 4.2. Description of DNA fragment inserted into genome (plasmon) of the recipient organism (size and origin, that is name of donor organism(s) and expected function of each constituent element or location of inserted DNA, including regulatory and other elements that affect transgene functioning), structure (sequence) and functional conformity of inserted DNA fragment, the presence of known potentially harmful sequences in it;
 - 4.3. The presence of any unknown sequences in the inserted DNA, and available information about the extent of insertion restriction by DNA which is required for implementation of the expected function;
 - 4.4. Characteristics of site modification of the recipient genome (plasmon), localization of insertion (incorporated into chromosome, chloroplasts, mitochondria or it is in the unintegrated state);
 - 4.5. Stable state of DNA inserted into genome (plasmon) of the recipient organism;
 - 4.6. Number of transgene copies;
 - 4.7. Description of the method for detection and identification of internal DNA fragment, sensitivity, reliability and specificity of this technique.
5. Information relating to biological characteristics of genetically engineered organisms:
 - 5.1. Description of genetic traits or phenotypic characteristics, especially of the new features and characteristics that became apparent or stopped to be apparent in genetically engineered organisms in comparison with the recipient organism;
 - 5.2. Genetic stability of genetically engineered organisms;
 - 5.3. The degree and level of transgene(s) expression. The method for assessment of transgene expression, its sensitivity;
 - 5.4. The activity and properties of the protein(s) encoded by the transgene(s);
 - 5.5. Parts of plants, in which transgenes are expressed (roots, leaves, pollen, etc.);
 - 5.6. History of previous modifications of genetically engineered organisms.
 - 5.7. Characteristic of genetically engineered organisms in relation to safety for human health: toxic or allergenic effects of genetically engineered organisms and/or products derived from genetically engineered organisms;

5.8. Methods suggested for the detection and identification of genetically engineered organisms; their precision, sensitivity and reliability;

6. Information on the potential receiving environment:

6.1. Location of the plot where the release will be conducted (region, district, locality, Landlord or Land Renter with their full names);

6.2. The proximity to the National Natural Reserves, Wildlife Sanctuary and other conservation facilities and territories;

6.3. Description of the plot: size and cultivation; climatic, geological and soil scientific characteristics; flora and fauna;

6.4. Comparison of the natural habitats of the recipient organisms with the expected location of the release of genetically engineered organisms;

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

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

7.1. Biological characteristics of genetically engineered organisms (as compared with intact recipient organisms) that may affect survival, reproduction and dissemination in the potential receiving environment;

7.2. Known and predicted conditions of the potential receiving environment, which may have an impact on survival, reproduction and dissemination of genetically engineered organisms;

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

7.4. The probability of undesirable characteristic manifestation of genetically engineered organisms in the potential receiving environment;

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

7.6. The ability of genetic information transfer: the presence of wildlife or cultural related species capable for hybridization with genetically engineered organisms in the potential receiving environment; the probability of transgene transfer from genetically engineered organisms into those organisms;

7.7. Identification and description of target-organisms for transgenic products;

7.8. The assumed mechanism and the result of the interaction between genetically engineered organisms and the target-organisms;

7.9. Identification and description of the organisms that are not targeted by the transgene products, which can be influenced by genetically engineered organisms;

7.10. Other potentially possible interactions of genetically engineered organisms with the environment;

7.11. Information regarding the intended use of genetically engineered organisms, including new or changed use compared to the recipient organism.

8. Information on the implementation of the release of genetically engineered organisms into the environment, monitoring, control, territory clean up and emergency operations during the release and testing:

8.1. Information on release of genetically engineered organisms:

Description of the supposed release of genetically engineered organisms and its purpose;

Supposed start and end dates of release and the schedule of experiments related to the release, including the number and duration of the experiments;

Supposed quantity of the released genetically engineered organisms; quantity of the genetically engineered organisms per plot square unit;

The distance from the landing plot to planting of wild and cultivated plants of related species capable for hybridization with genetically engineered organisms;

Information on the availability and the results of previous releases of genetically engineered organisms into the environment;

8.2. Monitoring techniques;

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

The specificity, that is, possibility to identify the genetically engineered organisms that are distinguished from organism of the recipient, as well as sensitivity and reliability of monitoring methods for genetically engineered organisms;

Identification methods of transgene transfer into other organisms;

Duration and frequency of monitoring;

8.3. Monitoring of genetically engineered organisms release;

Measures that will be used to prevent the dissemination of pollen, seeds and genetically engineered organisms;

Methods and procedures aimed at protecting the release area from trespassing of the unauthorized persons;

Methods and procedures designed to protect the area from unwanted visits of other organisms;

8.4. The plot cleaning up:

The procedure for plot processing at the end of the release;

Methods for removal of genetically engineered organisms at the end of the experiments;

8.5. The plan of action in emergency situations involving unexpected dissemination of genetically engineered organisms:

Methods and procedures for monitoring genetically engineered organisms in the case of accidental releases;

Methods for disposal or recovery of plants, animals, etc. that were exposed to genetically engineered organisms during or after their accidental releases;

Strategy for protecting human health and the environment in case of revealing undesirable impacts of genetically engineered organisms on them.

(Applicant signature)

(Initials, Family name)

Place of stamp

Points to consider under Risk Assessment (Annex III of the Cartagena Protocol)

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

- (a) Recipient organism or parental organisms. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;
- (b) Donor organism or organisms. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;
- (c) Vector. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;
- (d) Insert or inserts and/or characteristics of modification. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;
- (e) Living modified organism. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;
- (f) Detection and identification of the living modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability;
- (g) Information relating to the intended use. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and
- (h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

The Ministry of Nature register the application and enter into a contract with the Applicant to conduct the Examination within 30 days from the date of its filing

Within 5 days after signing the Contract the Ministry of Nature submit

A copy of the application with enclosed copies of the Documents (Annex 2 or 3) to the Expert Council for genetically engineered organisms at the Ministry of Nature for carrying out Examination

Information on risk assessment to the NCBC of the Institute of Genetics and Cytology for submitting the stated information for consideration to everybody concerned

The Expert Council recommend experts for carrying out Examination to the Ministry of Nature within 10 days

Within 5 days after receiving information on risk assessment, the National Co-ordination Biosafety Centre locate it at its information site

The Ministry of Nature choose experts, who will carry out Examination, and conclude a contract with them for carrying out Examination within 30 days

Interested Legal Entities or Individual Entrepreneurs may look through the stated information within 60 days after location of information and send their remarks and proposals to the NCBC which summarizes obtained remarks and proposals after the expiry of the stated date and within 10 days submits them for consideration to the Expert Council

The Examination shall be carried out within 120 days

In cases when it is impossible to assess risk admissibility of possible adverse effects of LMO on the recommendation of Experts within 5 days the Ministry of Nature shall send written notification to the Applicant on the necessity to provide additional information within 30 days

The Ministry of Nature submit the Final report prepared by Experts to the Expert Council

Within 30 days after receiving the Final Report, the Expert Council consider it, take recommendations of admissibility of releasing genetically engineered organisms into the environment for testing or using for economic purposes and send it and the Final Report to Republican governmental authority in the field of genetic engineering activity as well as to the Applicant

LMO Risk Assessment General Principles / Annex III of the Cartagena Protocol

- Risk assessment should be carried out in a scientifically sound and transparent manner.
- Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.
- Risks should be considered in the context of risks posed by the non-modified recipients or parental organisms.
- Risks should be assessed on a case-by-base basis.

•On August 25, 2006 the Ministry of Health of the Republic of Belarus approved instruction №076-0806 on assessing the risks of GMO potential adverse effects on human health.

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ БЕЛАРУСЬ

Утверждаю
Заместитель Министра
Главный государственный
санитарный врач
Республики Беларусь
М.И. Римжа
25 августа 2006 г.
Регистрационный №076-0806

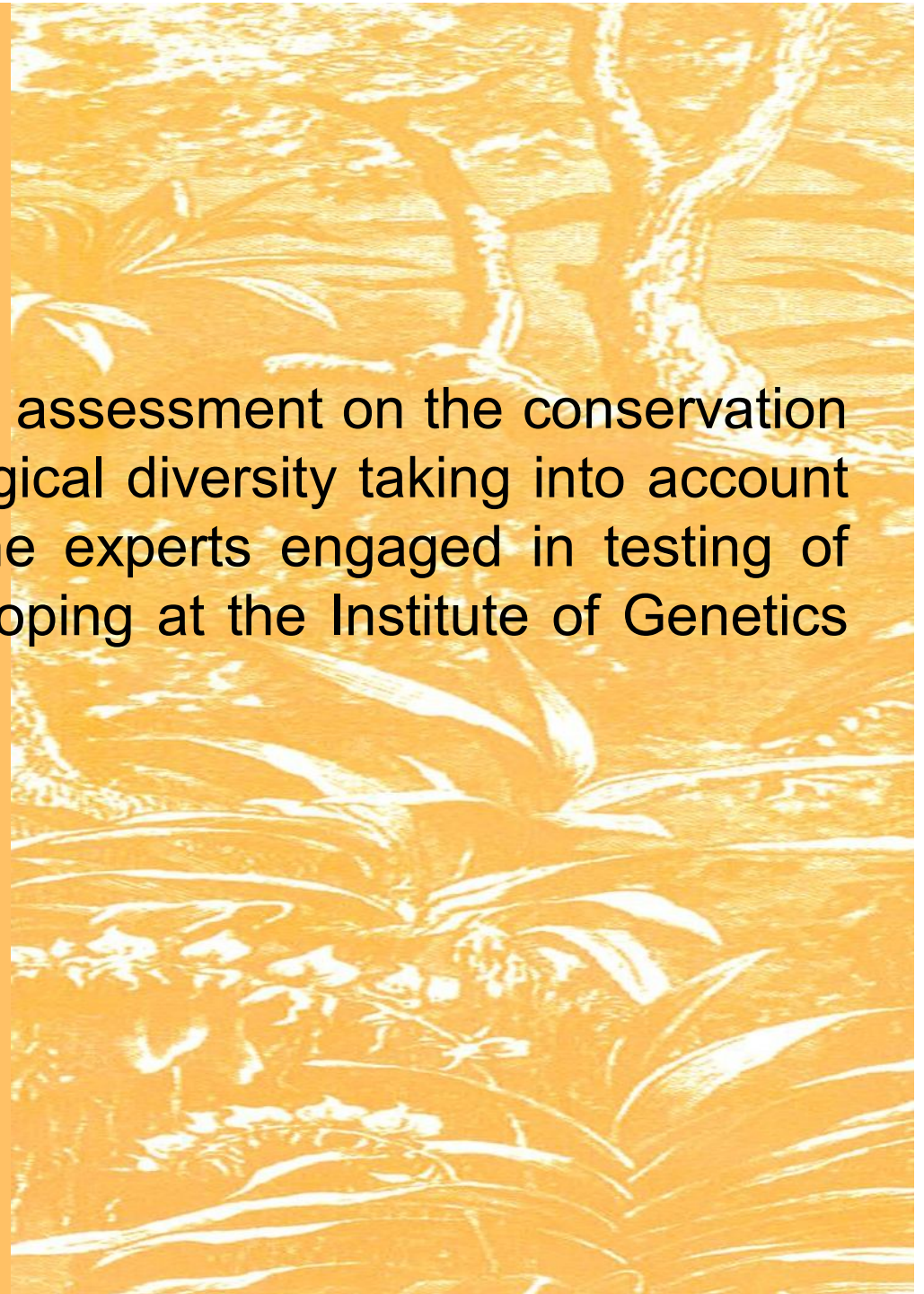
ПОРЯДОК ПРОВЕДЕНИЯ ОЦЕНКИ РИСКА ВОЗМОЖНЫХ
ВРЕДНЫХ ВОЗДЕЙСТВИЙ ГЕННО-ИНЖЕНЕРНЫХ ОРГАНИЗМОВ
НА ЗДОРОВЬЕ ЧЕЛОВЕКА

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., Подлиских В.Е.,
Гулин В.В., Скуратович А.Л., Фидаров Ф.М.

The guidance for LMOs risks assessment on the conservation and sustainable use of biological diversity taking into account risks to human health for the experts engaged in testing of LMOs is under way of developing at the Institute of Genetics and Cytology NAS Belarus



National Coordination Biosafety Centre

<http://biosafety.org.by>

The main objectives of the National Coordination Biosafety Center of the Republic of Belarus are the timely awareness of Public Institutions, Public Organizations and citizens of the measures taken by the State to ensure the safety of genetic engineering for the environment and human health.

A field for testing GM plants meeting the requirements of biosafety was established at the Institute of Genetics and Cytology in 2013. In connection with the supposed restricted LMOs release for field experiments under controlled conditions NCBC works actively in the field of Public education on the issues of genetic engineering activity, risk assessment, public participation in it and the awareness of the Public of the main Websites for the actual information (BCH and NCBC).

The screenshot displays the website of the National Coordination Biosafety Centre (NCBC) of Belarus. The header features the NCBC logo and the text "Национальный координационный центр биобезопасности". The main content area is titled "Закон Республики Беларусь «О безопасности генно-инженерной деятельности» и связанные с ним нормативно-правовые акты законодательства". Below this, there is a list of legislative acts, including the Law of the Republic of Belarus of 9 January 2006, No. 96, and the Law of the Republic of Belarus of 4 January 2007, No. 200. The website also includes a sidebar with navigation links such as "О центре", "Законодательство", "Проекты правовых и нормативных актов по биобезопасности", and "Вход в систему".

The Workshop

"Requirements for the the documentation necessary for the release of non-pathogenic genetically modified organisms into the environment"

Minsk, March 5, 2013

Information resources of the NCCB and the Secretariat of the UN Convention on Biological Diversity in the field of Biosafety

The Legislation of the Republic of Belarus in the field of ensuring safety during testing GM objects under their release into the environment

Information on the risk assessment of non-pathogenic LMOs before their first release into the environment



Информационные ресурсы по вопросам биобезопасности Секретариата Конвенции о биологическом разнообразии

The screenshot displays the website interface for the Biosafety Clearing-House. At the top, there is a navigation bar with language options (العربية | 中文 | english | español | français | русский) and user options (Создать учетную запись | Войти в систему). The main header features the 'Biosafety Clearing-House' logo and the 'Convention on Biological Diversity' logo, accompanied by an image of hands holding a globe.

The navigation menu includes: Домашняя страница, МПБ, **Протокол**, Поиск информации, Регистрация информации, Ресурсы, and Помощь. The 'Протокол' menu is expanded, showing a comprehensive list of links categorized under 'Картахенский протокол', 'Ключевые вопросы Протокола', 'Стороны Протокола', 'Лиability and Redress', 'Мониторинг и отчетность', 'Информирование общественности и ее участие', 'Оценка рисков', 'Регулирование рисков', 'Регистр экспертов', 'Социально-экономические соображения', 'Стороны Протокола', 'Национальные контакты', and 'Национальные доклады'. Other categories include 'КС-СС (руководящий орган)', 'Мероприятия и документация', 'Ресурсы', 'Публикации', and 'Nagoya - Kuala Lumpur Supplementary Protocol on Liability and Redress'.

On the left side, there is a 'Добро пожаловать' (Welcome) section and a 'Последние новости' (Latest News) section with a list of recent events and workshops. On the right side, there are several promotional boxes: '10th Anniversary Cartagena Protocol Biosafety', 'COP-MOP 6 Decision booklets', 'Survey to gather information corresponding to indicators in the Strategic Plan', 'TESTING Guidance on Risk Assessment of LMOs', and 'Open-ended Online Expert Forum on Risk Assessment and Risk Management'.

The bottom of the page features a footer with the URL 'bch.cbd.int/protocol/' and two main sections: 'Risk Assessment:' and 'Guidance on Risk Assessment:'. The Windows taskbar is visible at the very bottom of the image.

Добро пожаловать на Центральный портал МПБ

Механизм посредничества по биобезопасности (МПБ) представляет собой механизм, учрежденный [Картахенским протоколом по биобезопасности](#) с целью содействия обмену информацией о живых измененных организмах (ЖИО) и оказания помощи Сторонам в соблюдении, наилучшим образом, обязательств в рамках Протокола. Глобальный доступ к различной научной, технической, природоохранной, правовой информации и данным по созданию потенциала предоставляется на всех 6 языках ООН.

Владельцы учетных записей МПБ могут создавать записи и управлять ими в МПБ, выполнив вход в разделе [Центр управления](#) ([Регистрация информации](#)).

Последние новости

- 2013-09-11 [10th anniversary of the entry into force of the Cartagena Protocol on Biosafety...](#)
- 2013-09-10 [Беларусь - 11 СЕНТЯБРЯ 2013 г. ИСПОЛНЯЕТСЯ 10 ЛЕТ СО ДНЯ ВСТУПЛЕНИЯ В СИЛУ КАРТАХЕНСКОГО ПРОТОКОЛА ПО БИОБЕЗОПАСНОСТИ КОНВЕНЦИИ О БИОЛОГИЧЕСКОМ РАЗНООБРАЗИИ...](#)
- 2013-08-26 [Гватемала - Taller "Diseño del Sistema Nacional de Monitoreo de Organismos Vivos Modificados \(OVMs\) en Guatemala"...](#)
- 2013-07-22 [Иран \(Исламская Республика\) - "Executive Regulation of Iran Biosafety law" came in to force...](#)
- 2013-07-12 [Перу - Primer Taller Nacional CIISB/BCH del 2013...](#)
- 2013-07-11 [Taller Nacional BCH Peru I -2013...](#)
- 2013-06-28 [Эквадор - Capacitación en Biotecnología, Bioseguridad y OVMs a comunicadores sociales del Ministerio del Ambiente...](#)
- 2013-06-25 [Лесото - Biosafety Clearing House District Training Workshop...](#)

[Еще новости...](#)

Последние дополнения [\[Еще дополнения...\]](#)

- 2013-09-23 [Измененный организм](#)
- 2013-09-23 [Колумбия - Компетентный национальный орган](#)
- 2013-09-23 [Измененный организм](#)
- 2013-09-20 [Турция - Национальный координационный центр](#)
- 2013-09-20 [Информационный ресурс по биобезопасности](#)

Последние обновления

- 2013-09-25 [Измененный организм](#)
- 2013-09-25 [Последовательность генов и ДНК](#)
- 2013-09-24 [Последовательность генов и ДНК](#)
- 2013-09-24 [Последовательность генов и ДНК](#)
- 2013-09-24 [Последовательность генов и ДНК](#)

Online Training on Risk Assessment:



[Training Manual](#)



[E-training](#)

Guidance on Risk Assessment:



[Guidance on RA of LMOs](#)

Оставайтесь с нами:



[МПБ](#)



[КПБ](#)



[YouTube](#)



COP-MOP 6 Decision booklets:

[Ar](#) | [En](#) | [Es](#) | [Fr](#) | [Ru](#) | [Zh](#)
[Meeting report](#) / [Webpage](#)

Survey

to gather information corresponding to indicators in the Strategic Plan



TESTING

Guidance on Risk Assessment of LMOs



Open-ended Online Expert Forum on Risk Assessment and Risk Management

Regional Networks on PAEP



[Protocol on Biosafety](#)

BCH on BCH

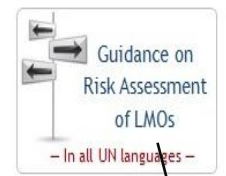


focal points' forum



Text of the Guidance

- Guidance on Risk Assessment of Living Modified Organisms
- Preface
- Objective and Scope of this Guidance
- Part I: Roadmap For Risk Assessment of Living Modified...
- Part II: Specific Types of LMOs and Traits
- Part III: Monitoring of Living Modified Organisms Released in...
- Use of Terms



- Ar | En | Es | Fr | Ru | Zh
- Ar | En | Es | Fr | Ru | Zh

Guidance on Risk Assessment of Living Modified Organisms

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- Objective and Scope of this Guidance >

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 - Identification and consideration of uncertainty >
- Planning phase of the risk assessment >
 - Establishing the context and scope >
 - The choice of comparators >
- Conducting the risk assessment >
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PART II: SPECIFIC TYPES OF LMOs AND TRAITS >

- A. Risk Assessment of Living Modified Plants with Stacked Genes or Traits >
 - Introduction >
 - Objective and scope >
 - Planning phase of the risk assessment >



Учреждение образования
«Гродненский государственный
университет имени Янки Купалы»



Фонд сотрудничества
Центрально-Европейской
инициативы (ЦЕИ)

ПАРТНЕРЫ:



РУП «НПЦ НАН Беларуси по
продовольствию»



ГНУ «Институт физиологии НАН
Беларуси»



Международная организация за
гуманное образование ИнтерНИЧ

МЕСТО ПРОВЕДЕНИЯ:

УО «Гродненский государственный
университет имени Янки Купалы» (г.Гродно,
учебный корпус №2, пер. Доватора 3/1);
ОАО «Санаторий «Озёрный»,
Гродненская обл., Гродненский р-н, д. Озёры

УЧРЕЖДЕНИЕ ОБРАЗОВАНИЯ
«ГРОДНЕНСКИЙ ГОСУДАРСТВЕННЫЙ
УНИВЕРСИТЕТ ИМЕНИ ЯНКИ КУПАЛЫ»



**International scientific-methodological
seminar "PHARMACEUTICAL AND
FOOD TECHNOLOGIES AND THE
SYSTEM OF EDUCATION: LEGAL
ASPECTS"**

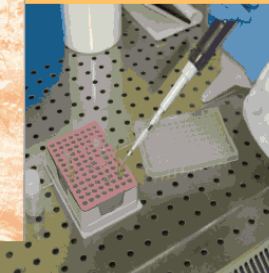
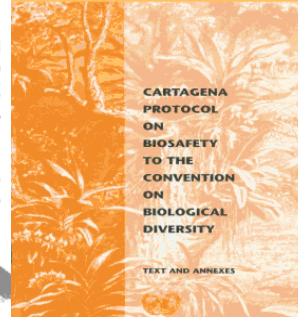
**Grodno, Belarus
May 14-20, 2013**



Institute of Genetics and Cytology NAS Belarus National Coordination Biosafety Centre

**10 YEARS OF KARTAGENA PROTOCOL ON BIOSAFETY IN BELARUS:
FROM GMO DETECTION TO RISK ASSESSMENT**

MOZGOVA G.V.



Thank you for attention