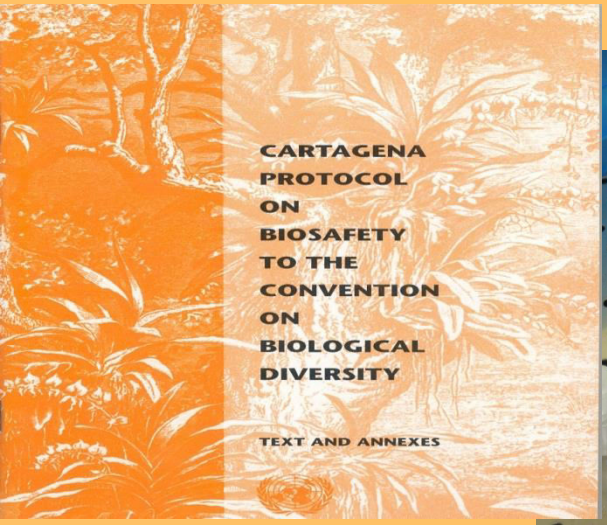
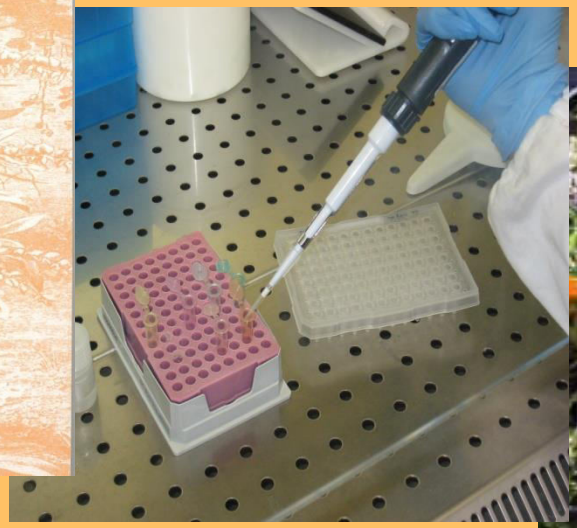
EXPERIENCE OF THE REPUBLIC OF BELARUS IN THE FIELD OF SAFETY OF GENETIC ENGINEERING ACTIVITY

GALINA MOZGOVA

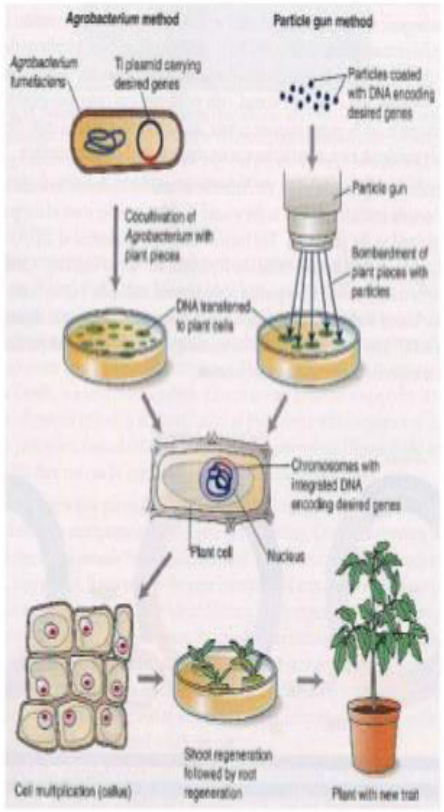
NATIONAL CO-ORDINATION BIOSAFETY CENTRE
STATE SCIENTIFIC INSTITUTION
«INSTITUTE OF GENETICS AND CYTOLOGY
AT THE NATIONAL ACADEMY OF SCIENCES OF BELARUS»





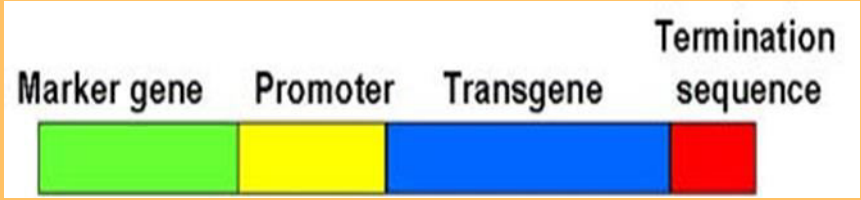
Creation of transgenic plants

Schematic representation of the two main ways to create transgenic plants



Agrobacterium Method

Particle Gun Method

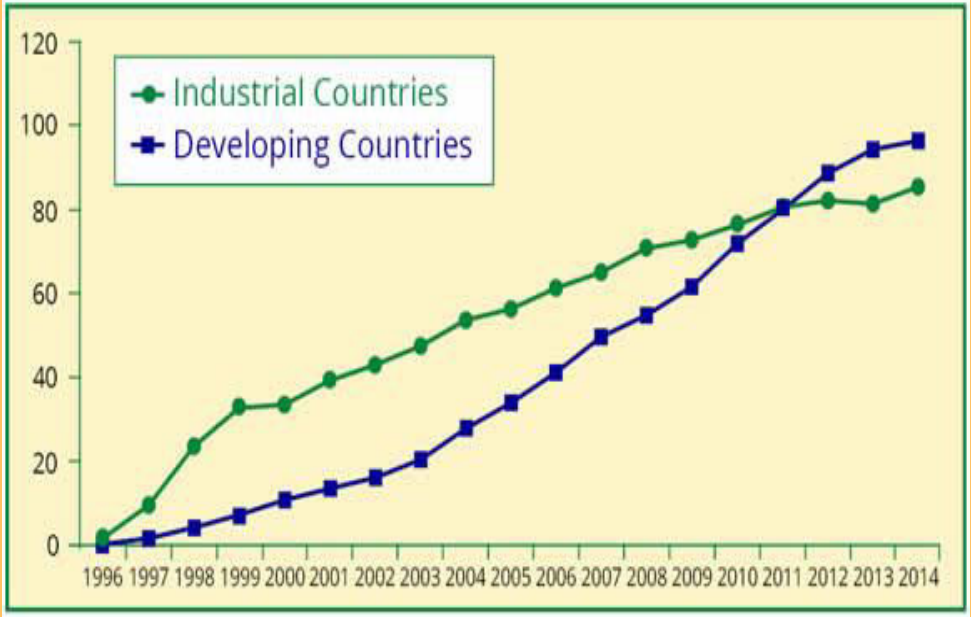


Plant varieties on the World Market

320 varieties developed from 25 transgenic plants are permitted to use

- Soybean
- Corn
- Polish canola
- Argentine canola
- Cotton
- Tomatoes
- Potatoes
- Rice
- Sugar beet
- Flax
- Turneps
- Melons
- Beans
- Sweet pepper
- Tobacco
- Chicory
- Papaya
- Carnations
- Wheat
- Lucerne
- Creeping bentgrass
- Plum
- Sunflower
- Rose
- Poplar

Figure 2. Global Area of Biotech Crops, 1996 to 2014: Industrial and Developing Countries (Million Hectares)



Source: Clive James, 2014.

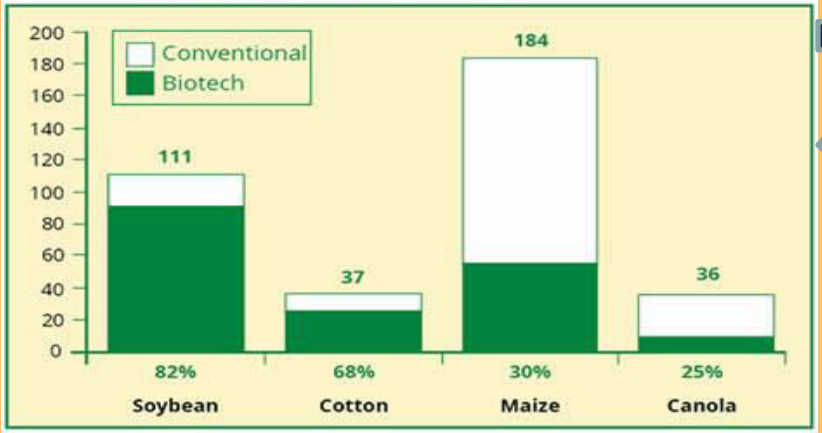
Table 2. Global Area of Biotech Crops in 2013 and 2014: by Country (Million Hectares**)

Country	2013	2014
USA*	70.1	73.1
Brazil*	40.3	42.2
Argentina*	24.4	24.3
India*	11.0	11.6
Canada*	10.8	11.6
China*	4.2	3.9
Paraguay*	3.6	3.9
Pakistan*	2.8	2.9
South Africa*	2.9	2.7
Uruguay*	1.5	1.6
Bolivia*	1.0	1.0
Philippines*	0.8	0.8
Australia*	0.6	0.5
Burkina Faso*	0.5	0.5
Myanmar*	0.3	0.3
Mexico*	0.1	0.2
Spain*	0.1	0.1
Colombia*	0.1	0.1
Sudan*	0.1	0.1
Honduras	<0.1	<0.1
Chile	<0.1	<0.1
Portugal	<0.1	<0.1
Cuba	<0.1	<0.1
Czech Republic	<0.1	<0.1
Romania	<0.1	<0.1
Slovakia	<0.1	<0.1
Costa Rica	<0.1	<0.1
Bangladesh	--	<0.1
TOTAL	**175.2**	**181.5**

Source: Clive James, 2014.

* Biotech mega-countries which grew more than 50,000 hectares, or more.
** Rounded-off to the nearest hundred thousand.

Figure 3. Biotech Crop Area as % of Global Area of Principal Crops, 2014 (Million Hectares)



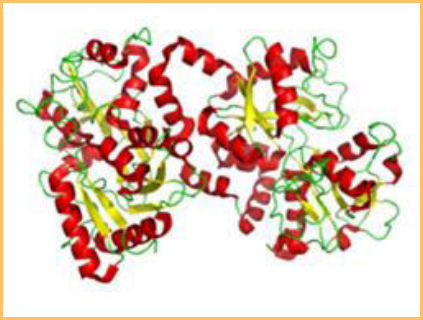
Source: Clive James, 2014.

Transgenic trait	Crops
Insect resistance	Corn, Cotton, Potato, Tomato
Herbicide tolerance	Corn, Soybean, Cotton, Canola, Sugarbeet, Rice, Flax
Virus resistance	Papaya, Squash, Potato
Altered oil composition	Canola, Soybean
Delayed fruit ripening	Tomato
Male sterility and restorer system (used to facilitate plant breeding)	Chicory, Corn, Canola
Modification of food and technological properties	Rice, Canola, Flax, etc.
New features of ornamental plants, animals	Rose, Petunia, GloFish

Research Areas of Genetic Engineering in Belarus

Culture	Trait	Organization
Potato	Y-virus resistance	RPC NAS Belarus for Potato, Fruit and Vegetable Growing
	Resistance to several fungal diseases	IGC NAS Belarus IBCI NAS Belarus
	Insect resistance	IGC NAS Belarus
	Synthesis of antimicrobial peptides	IBCI NAS Belarus RPC NAS Belarus for Potato, Fruit and Vegetable Growing
Canola	Synthesis of chicken interferon protein	BSU IBCI NAS Belarus
	Glyphosate resistance	BSU IGC NAS Belarus
Fiber Flax	Cell wall modification	IGC NAS Belarus RPC Institute of Flax NAS Belarus
Cranberries	Synthesis of antimicrobial peptides	CBG NAS Belarus
Tobacco Arabidopsis	Resistance to heavy metals and petroleum products	IGC NAS Belarus
Tobacco	Accelerated development and increased productivity	IGC NAS Belarus

Research Areas of Genetic Engineering in Belarus



lactoferrin

Scientific and Practical Center on Animal Husbandry NAS Belarus

CBD

Domestic goat modified to produce human lactoferrin

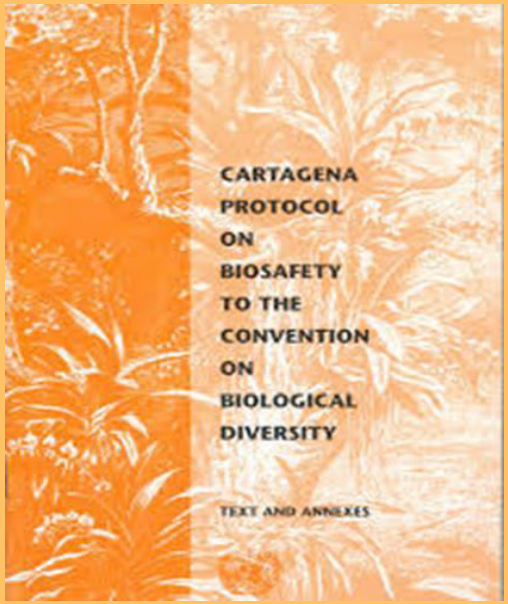
http://bch.cbd.int/database/record.shtml?documentid=108045

Read barcode or type above URL into internet browser to access information on this LMO in the Biosafety Clearing-House © SCBD 2012

Twin aspects of modern biotechnology

Modern biotechnology is recognized as having a great potential for the promotion of human well-being, particularly in meeting critical needs for food, agriculture and health care.

The concept of biosafety refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology.



The Parties shall ensure that the development, handling, transport, use,
transfer and release of any living modified organisms are undertaken in a
manner that prevents or reduces the risks to biological diversity, taking also into
account risks to human health

Republic of Belarus has acceded 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
Одобрен Советом Республики — 23 апреля 2002 года

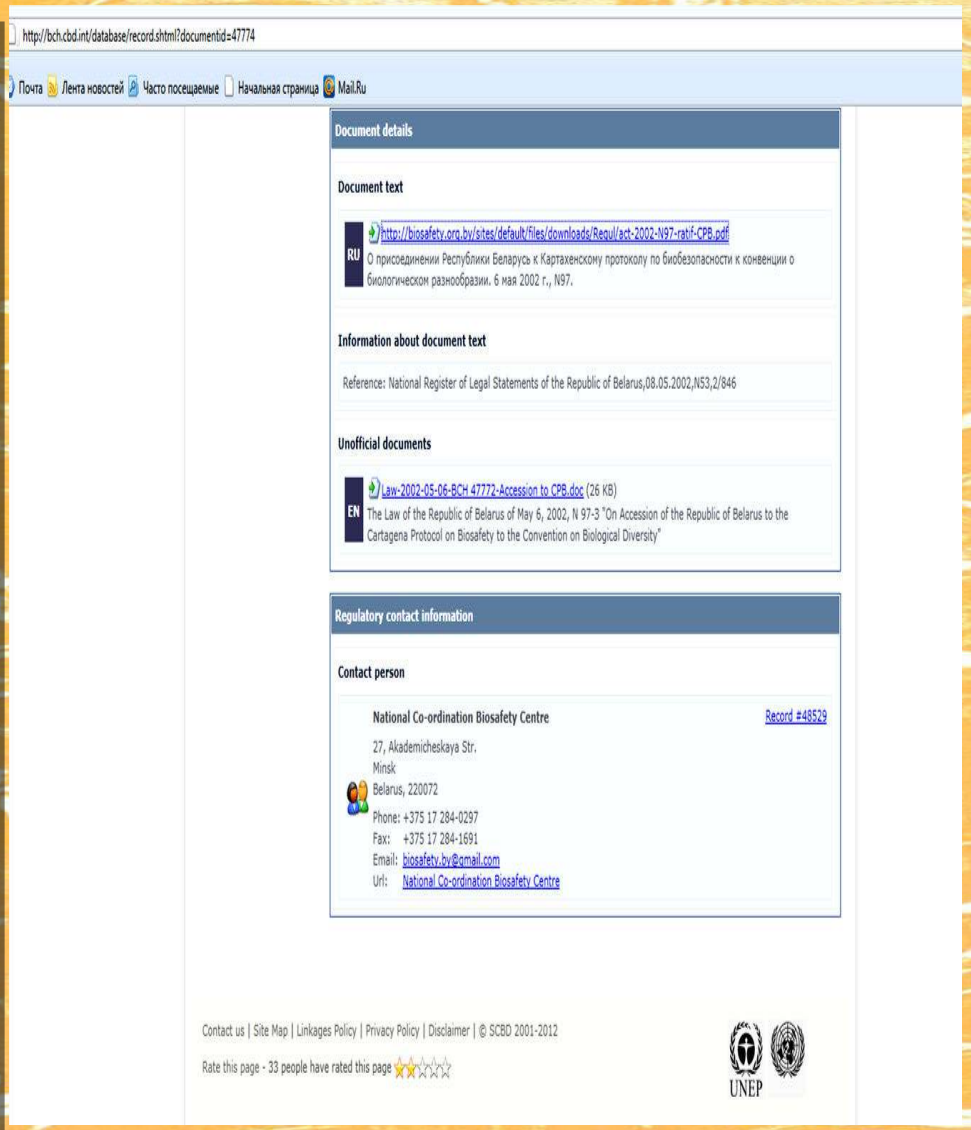
Статья 1. Присоединиться к Картахенскому протоколу по биобезопасности к Конвенции о биологическом разнообразии, принятому Конференцией Сторон Конвенции о биологическом разнообразии 29 января 2000 года в г. Монреале.

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

Президент
Республики Беларусь — **А.Лукашенко**

ПРАТАКОЛЬНЫ СЕКТАР

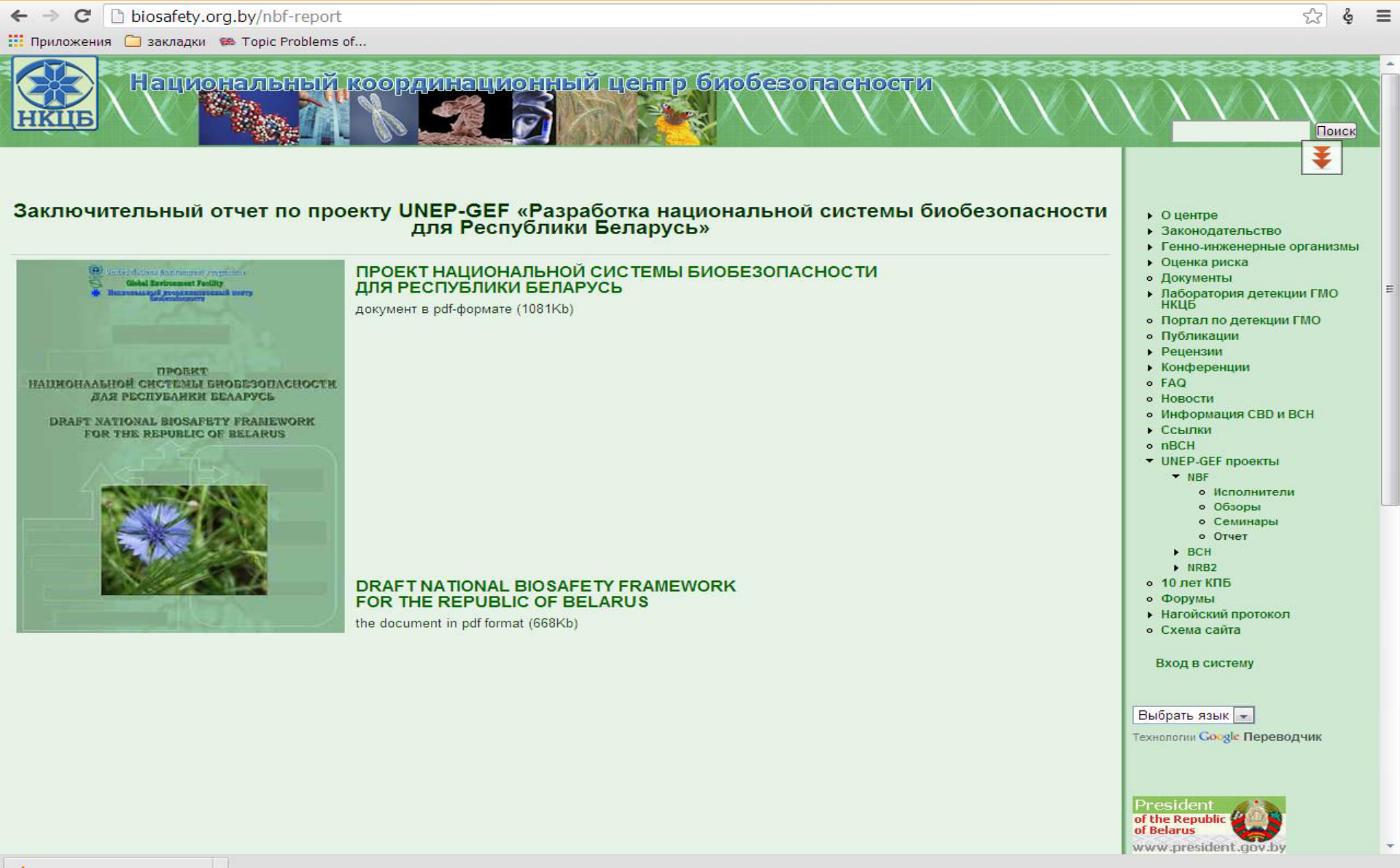
6 мая 2002 г., г.Минск
№ 97-З



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

47774	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	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"**

The National Biosafety System was developed in Belarus by 2006 by support of the United Nations Environment Programme.



Biosafety System of the Republic of Belarus

Administrative system

Ministry of Natural Resources and Environmental Protection

competence:

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

Ministry of Agriculture and Food

competence:

- 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).

National Co-ordination Biosafety Centre

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).

Legislation system

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

2002– The Law of the Republic of Belarus "On Joining to the Cartagena Protocol on Biosafety to the Convention of Biological Diversity" (97/2002)

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;

Stages of LMO biosafety estimation

Import of LMO

For contained use

For release into environment (AIA procedure)

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

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

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)

Release into environment for field trials

Biosafety studies of LMO — Reporting about field trials of LMO

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

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

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)

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- About the Protocol
- Text of the Cartagena Protocol
- Strategic Plan

Key Protocol Issues
- Assessment and Review
- Capacity Building
- Compliance
- Financial Mechanism
- Handling, Transport, Packaging and Identification
- Information sharing
- Liability and Redress
- Monitoring and Reporting
- Public Awareness and Participation
- Risk Assessment
- Risk Management
- Roster of Experts
- Sampling, Detection and Identification
- Socio-economic Considerations
- Unintentional Transboundary Movements

Parties
- List of Parties

Home | The Cartagena Protocol | Parties | List of Parties | Country Profile

Country Profile

Profile information and status	
Country	**Belarus**
Date of signature	-
Date of ratification	2002-08-26
Date of entry into force	2003-09-11
Profile revision	-
Profile status	Published
Profile last updated on	-

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Type of document	Number of records	Date of last update
Biosafety Expert	1	2015-05-04
Capacity Building Needs and Priorities	1	2012-08-06
Competent National Authority	4	2014-08-19
Country's Decision or any other Communication	1	2014-06-26
Law, Regulation or Guideline	23	2014-11-19
National Database or Website	1	2008-02-12
National Focal Point	3	2015-04-20
News	2	2015-09-29
Report on Assignment	0	-
Risk Assessment	4	2015-07-14
Reports on Implementation of the Protocol	2	2011-09-27
Total number of records	**43**	

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.

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

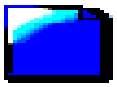
103667	On Safety Requirements for Trial Fields and Other Objects Provided for Testing Nonpathogenic Genetically Engineered Organisms under their First Release into the Environment
103668	On Approval of Instruction on Procedures of Testing Non-pathogenic Genetically Engineered Organisms under their Release into the Environment
103696	On Approval of Instructions on the Procedure of Risk Assessment of Possible Adverse Effects of Genetically Engineered Organisms on the Environment
103741	On approval of Regulations on the procedure for State Safety Examination of genetically engineered organisms and of approximate terms of contracts conduded for its carrying out, and issuing permits to release of non-pathogenic, genetically engineered organisms into the environment for testing
103872	On Approval of Regulations for State Registration Order of Genetically Engineered Plant Cultivars, Genetically Engineered Agricultural Breeds and Non-Pathogenic Genetically Engineered Microorganisms

HANDLING, TRANSIT, TRANSBOUNDARY MOVEMENT (IMPORT/EXPORT), CONTAINED USE

103139	On the Procedure of Registration of 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 Individual Entrepreneurs
103155	On the Procedure of Information Submission to the State Scientific Institution "Institute of Genetics and Cytology at the National Academy of Sciences of Belarus"
103683	On the Order of Notification of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus by the Carrier when Transit Through the Territory of the Republic of Belarus of Nonpathogenic, Genetically Engineered Organisms
103876	On Some Problems of Certain Commodity Transfer Across the Customs Border of the Republic of Belarus
103747	On Approval of Application Forms
103733	On Approval of Instructions on the Procedure of Issuing Permits to Seed Import to the Republic of Belarus and Seed Export from It

103684	**Belarus** **Contained use**	On Safety Requirements for Contained Use Systems During Performing Works of the First Risk Level of Genetic Engineering Activities

PUBLIC AWARENESS AND PARTICIPATION, INFORMATION SHARING



47772

The Law of the Republic of Belarus "On Safety in Genetic Engineering Activities"

103741

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

47776

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"

103214

On Some Issues of Providing Information for Consumers about Food Raw Materials and Foodstuffs

103598

On Quality and Safety of the Food Raw Materials and Foodstuffs for Human Life and Health

103736

Law of the Republic of Belarus "On Protection of Customers Rights"

SSI "Institute of Genetics & Cytology of NAS Belarus" functioning as the National Co-ordination Biosafety Centre in accordance with the Resolution of the Council of Ministers of the Republic of Belarus No. 963 of June, 19 1998.

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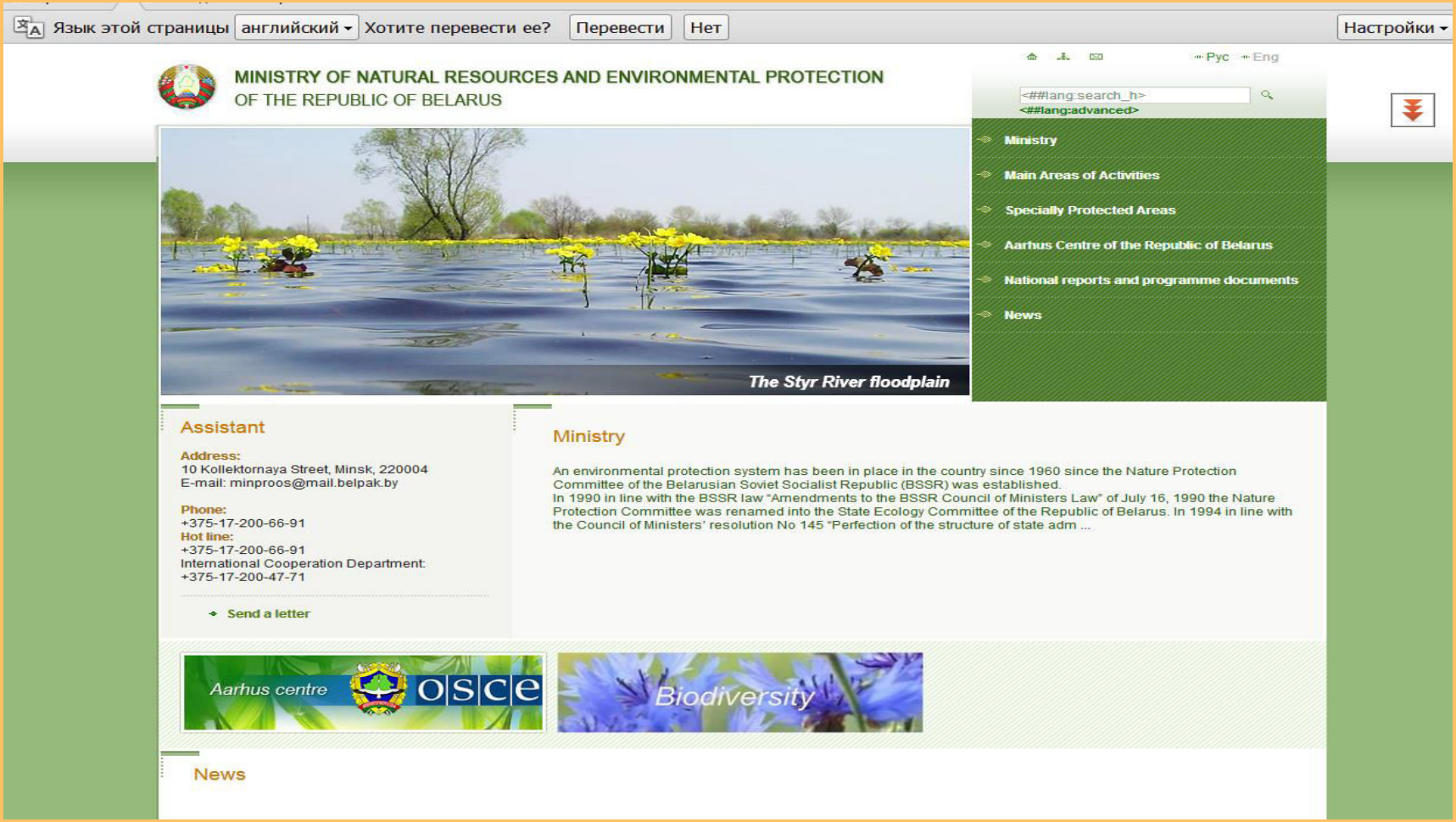
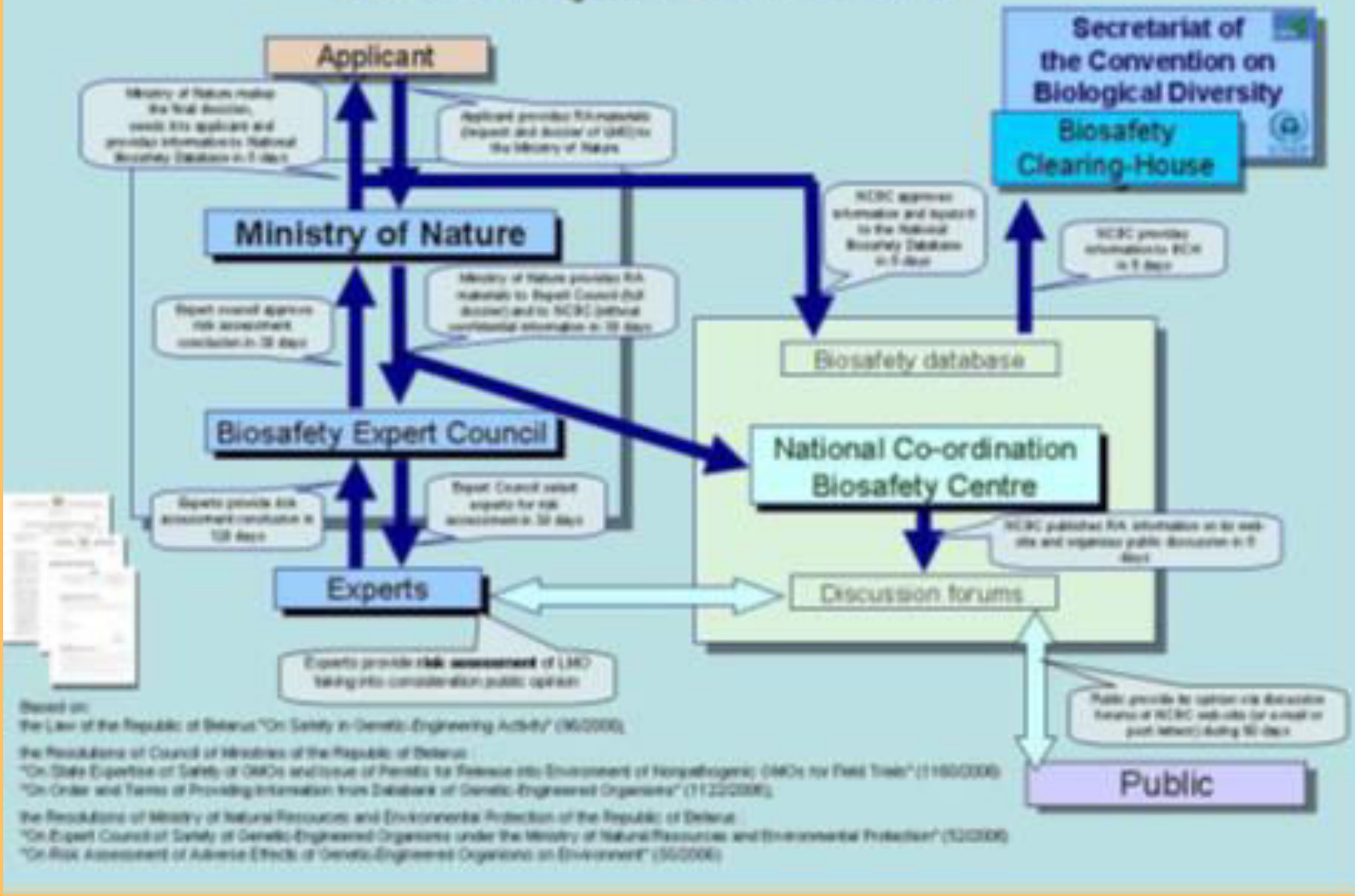
❖**Ministry of Natural Resources and Environmental Protection of the Republic of Belarus** coordinates activities in the field of safety of genetic engineering.

❖Under the leadership of the Ministry of Environment operates interdepartmental **Coordinating Council on safety of genetically engineered organisms.**

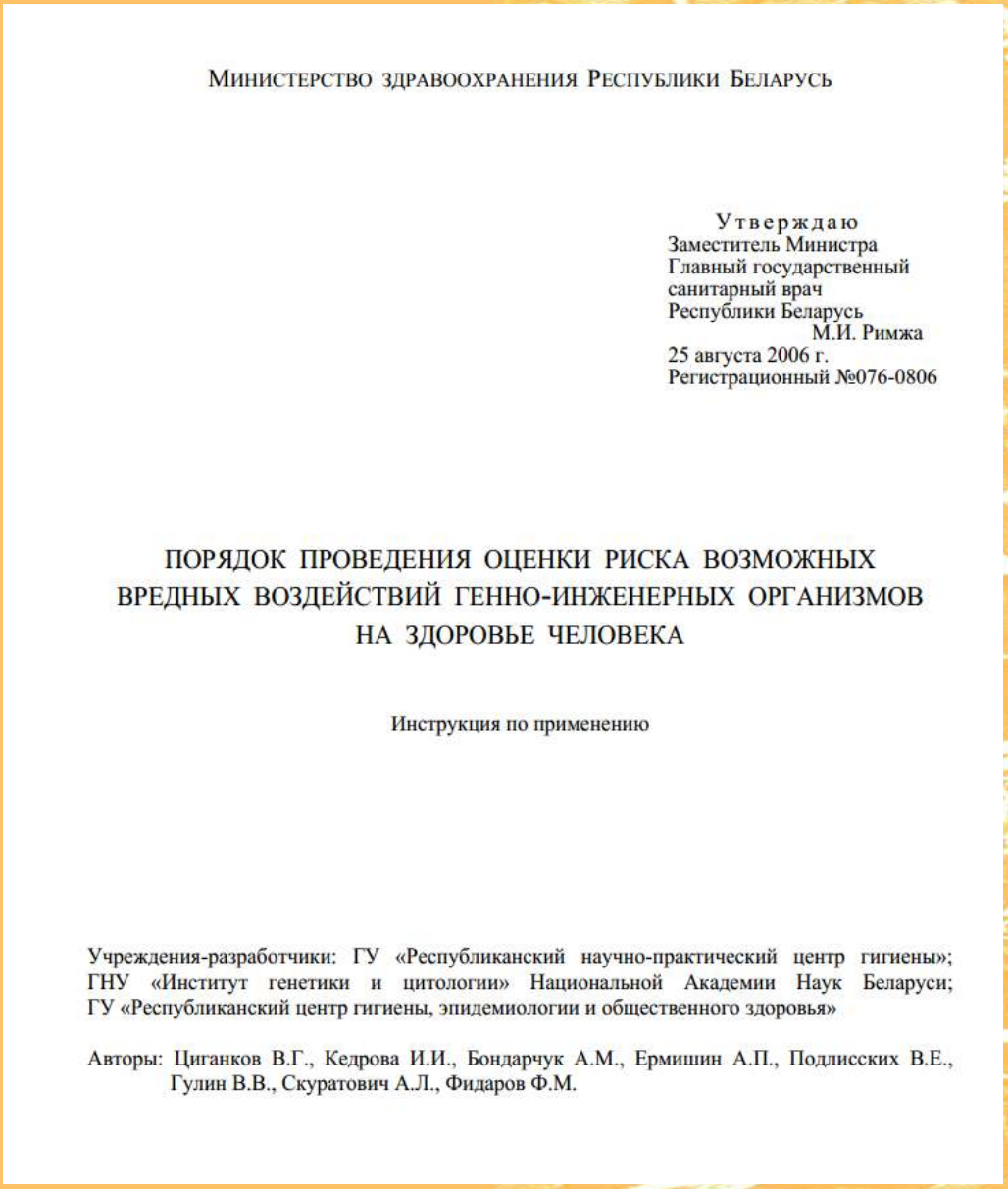
http://www.minpriroda.gov.by



National Biosafety Risk Assessment System of the Republic of Belarus



•**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

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

Laboratories on GMOs detection

In Belarus 18 laboratories on GMOs detection (LDGMO) that belongs to the Ministry of Health, State Commitee for Standartization, Ministry of Agriculture and Food and National Academy of Sciences were organised. They are placed in all regional centers of the Republic.

A list of laboratories accredited for GMO detection in Belarus

Ministry of Public Health

1. Republican Centre for Hygiene, Epidemiology and Public Health
2. Republican Scientific and Practical Centre for Hygiene
3. Minsk City Centre for Hygiene and Epidemiology
4. Brest Regional Centre for Hygiene, Epidemiology and Public Health
5. Gomel Regional Centre for Hygiene, Epidemiology and Public Health
6. Grodno Regional Centre for Hygiene, Epidemiology and Public Health
7. Mogilev Regional Centre for Hygiene, Epidemiology and Public Health
8. Vitebsk Regional Centre for Hygiene, Epidemiology and Public Health

State Committee for Standardization

9. Belarusian State Institute for Metrology
10. Brest Centre for Standardization, Metrology and Certification
11. Gomel Centre for Standardization, Metrology and Certification
12. Grodno Centre for Standardization, Metrology and Certification
13. Mogilev Centre for Standardization, Metrology and Certification
14. Vitebsk Centre for Standardization, Metrology and Certification

National Academy of Sciences

15. Institute of Genetics and cytology at NAS Belarus
16. Scientific and Practical Centre for Food, NAS of Belarus

Ministry of Agriculture and Food

17. Belarusian State Veterinary Centre
18. Central Research Laboratory of Bakeries



In LDGMO

genetically modified ingredients (GMO) in food raw materials and food products are checked

presence of GMO in agricultural products, forage and seed material is detected

The result of testing determines whether the seller has to place the goods etiquette "Contains GMO" or not.


The LIST of food raw materials and food products to be monitored for the presence of genetically modified constituents (components)

1. Soya
2 . Soya beans
3 . Soya plantlets
4 . Soya protein concentrates and textured shape
5 . Soya protein isolate
6. Soya protein hydrolyzate
7. Soya flour and its textured form
8. Milk replacer (soymilk)
9. Substitute milk powder (powdered soya milk)
10 . Canned soya
11. Boiled and roasted soya beans
12. Roasted soya flour
13. The products obtained from or with the use of soya protein isolate, soya protein concentrate , soya protein hydrolyzate , soya flour, powdered soya milk
14. Fermented soya products
15. Soya paste and the products including it
16. Soya sauce
17. Products derived from or using soya milk (tofu, fermented drinks, ice cream , mayonnaise , etc.)
18. Maize
19. Maize for immediate consumption (flour, grain , etc.)
20. Frozen and canned corn
21. Popcorn
22. Corn chips
23. Mixed flour comprising corn flour
24. Dietary supplements containing soya products and (or) corn
25. Baby food , produced using soya products and (or) corn

The result of testing determines whether the seller has to place the goods etiquette "Contains GMO" or not.

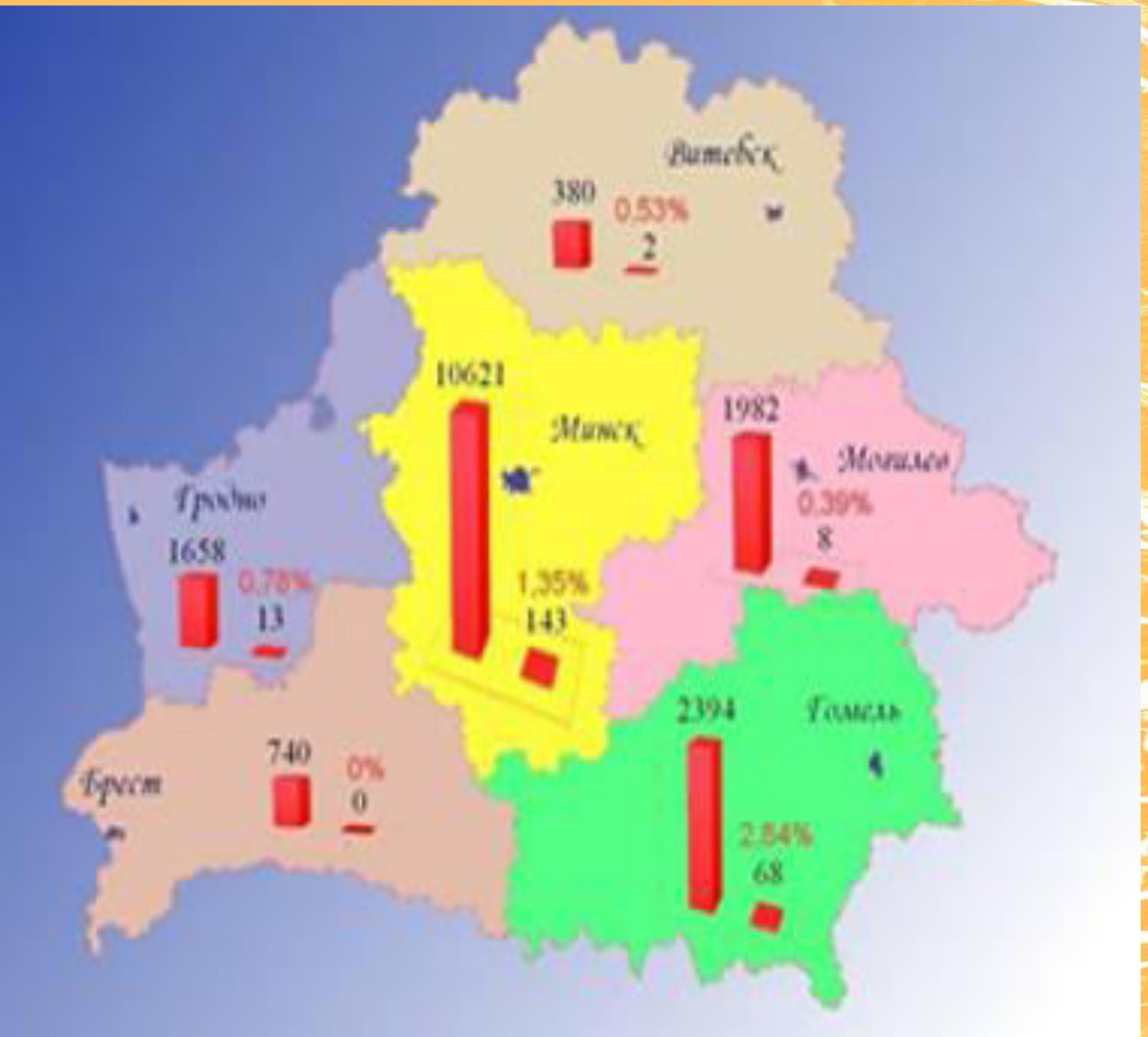
Until July 2013, accordingly to the Belarussian Law, a label had to be placed in all the cases of GMO detection, regardless of the amount (the principle - "present-not present"), so qualitative methods of GMO detection were the most commonly used.

In Belarus traders are required to post information about the presence or absence of GM-products, not only on the packaging, but also directly on price tags.

Methods and Standards of GMOs detection:

STB GOST R 52173-2005 "Raw materials and food products. **Method of genetically modified sources (GMO) plant origin identification**“
GOST ISO 21569-2009 "Food Products. Methods of analysis for the detection of genetically modified organisms and derived products. **Methods of qualitative detection based on the analysis of nucleic acids**"
GOST ISO 21570-2009 "-//- **Methods of quantitative detection based on the analysis of nucleic acids**"
GOST ISO 21571-2009 "-//-Nucleic acids` extraction"
GOST ISO 21572-2009 "-//-Methods based on protein“

Long term tests shown that on average nearly 1% of samples contained GMO.
GM-Maize has been found in single cases. Among products containing
GM- ingredients were Soybean meal, fish burgers, chicken legs (due to the breading).



The distribution of samples with GM-ingredients detected in LDGMOs (be regions) made during the preparation of the Second National Report on the implementation of the Republic of Belarus obligations under the Cartagena Protocol on Biosafety (2008-2010).

Accession of the Republic of Belarus to the the Customs Union has led to the adoption of technical regulations of the CU TR TC 021/2011 "On Food Safety“ (Decision of CU Commission № 880 «ON THE ADOPTION CU technical regulations "On Food Safety"»).

- 0.9% threshold for labeling of foodstuffs and food raw materials containing GMOs has been defined.
- The list of standards containing rules and methods (tests) including

  MUK 4.2.2304-07 "Methods for the identification and quantitative evaluation of GMOs plant origin";

  MU 2.3.2.2306-07. 23.2. Medical and biologic GMOs` plant origin safety assessment

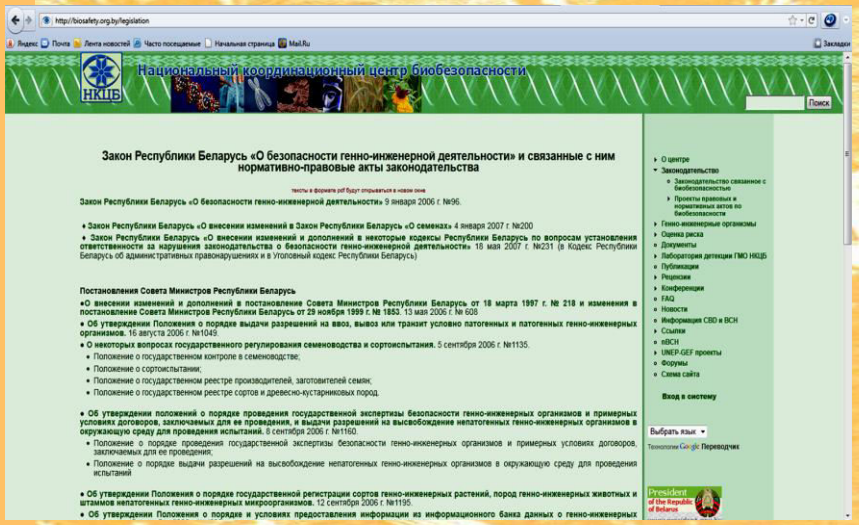
  has been added.

Republican Scientific & Practical Workshop
"**GMO Detection in the Republic of Belarus**", September, 21, 2015.
The workshop was held under the UNEP-GEF Project "Support to Preparation of the Third National Biosafety Reports to the Cartagena Protocol on Biosafety"

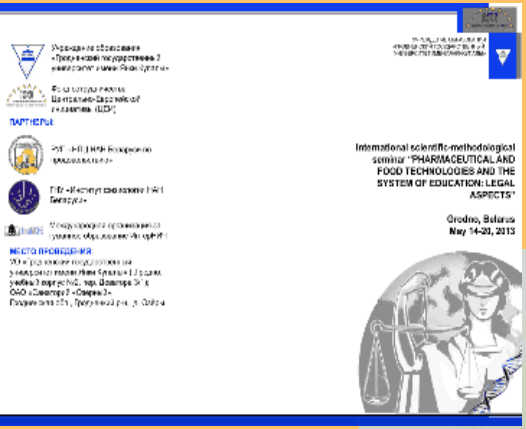
Public information and participation in decision-making process on GMOs

IGS NAS Belarus http://gens.by/

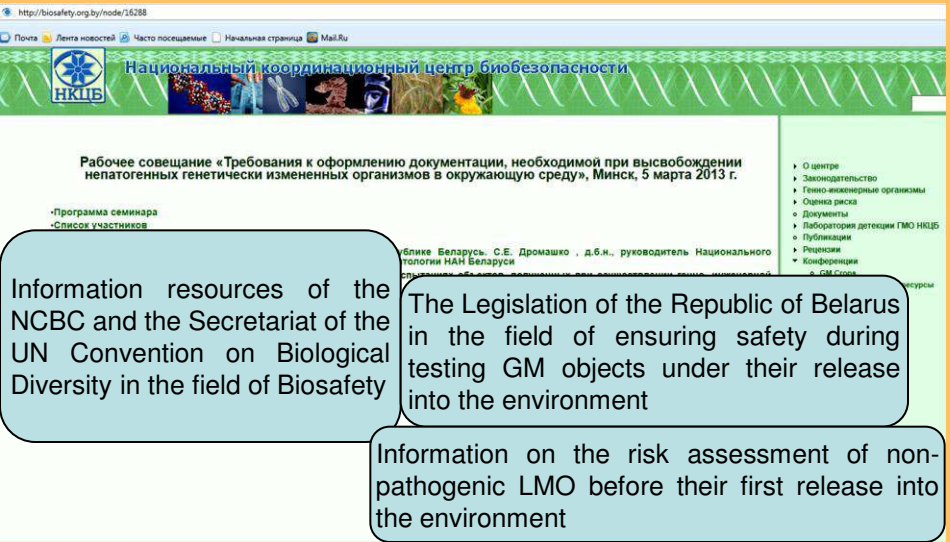
NCBC http://biosafety.org.by/



Aarhus Center http://www.aarhusbel.com/



The Workshop "Requirements for the the documentation necessary for the release of non-pathogenic genetically modified organisms into the environment", Minsk, 2013



Information resources of the NCBC 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 LMO before their first release into the environment

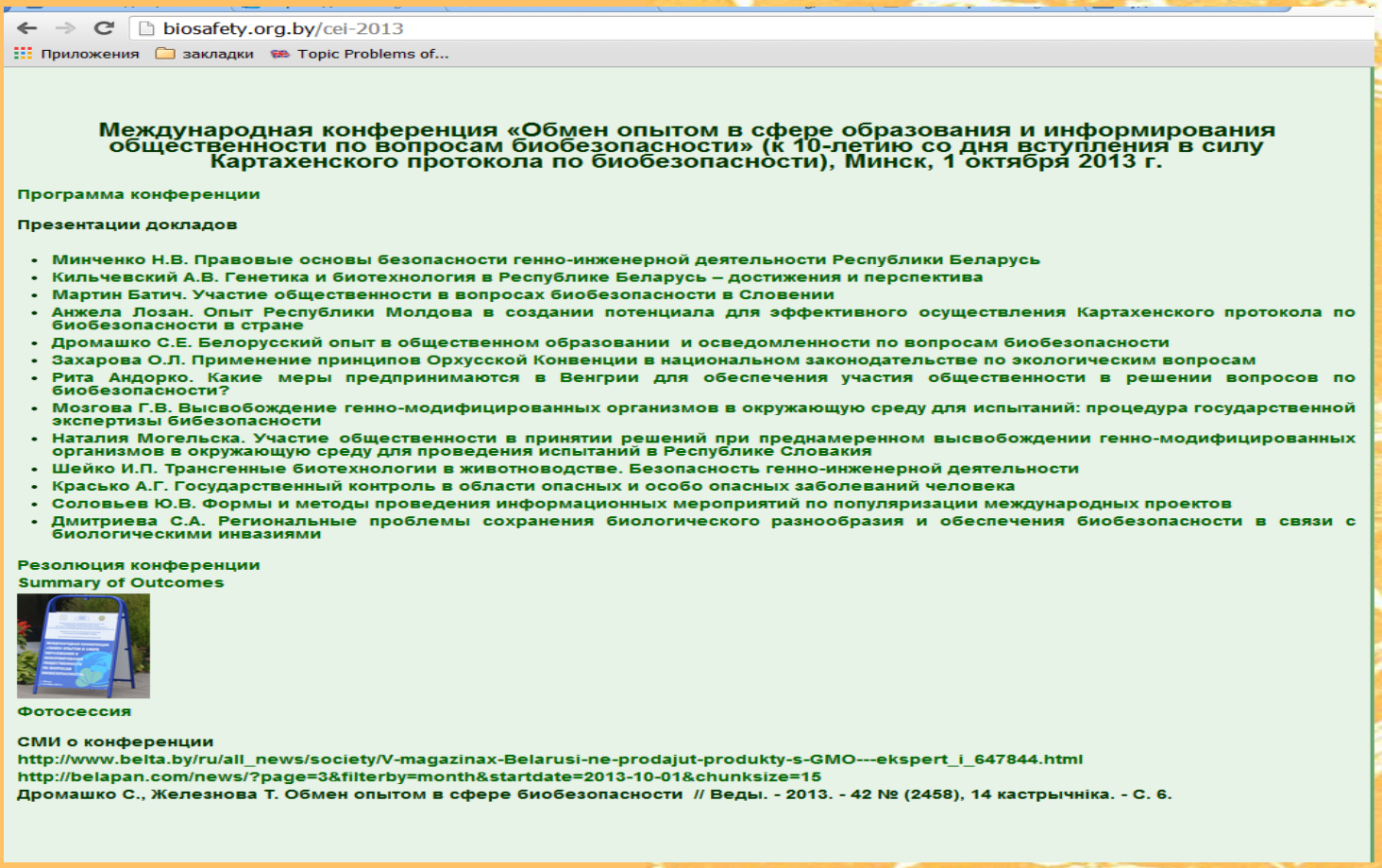
- NCBC personnel delivered lectures on GMOs and biosafety problems to University students and students of secondary schools.

- Courses of Lecturers in the field of GMOs and Biosafety are incorporated into the training programs on Biological Department and other relevant University Departments.

- NCBC holds workshops and seminars for Institutions, Public Organizations and citizens, GMOs developers.

- All the Documentation and Presentations available to the public concerned on the Website http://biosafety.org.by/conf.

INTERNATIONAL CONFERENCE
“EXPERIENCE SHARING IN PUBLIC EDUCATION AND AWARENESS OF BIOSAFETY ISSUES”
OCTOBER 1, 2013, MINSK, BELARUS



NCBC Publications

Thank you for your attention!