



United Nations Environment Programme

Global Environment Facility

National Co-ordination Biosafety Centre

DRAFT NATIONAL BIOSAFETY FRAMEWORK FOR THE REPUBLIC OF BELARUS





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Joint project of the Government of the Republic of Belarus,
the United Nations' Environmental Program and the Global Environmental Facility
“Development of the National Biosafety Framework for the Republic of Belarus”

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ABBREVIATIONS

| | | |
|------------------|---|--|
| BCH | - | Biosafety Clearing House |
| GEF | - | Global Environmental Facility |
| GEO ¹ | - | Genetically Engineered Organism |
| GMO | - | Genetically Modified Organism |
| GM-products | - | Genetically Modified Products |
| LMO | - | Living Modified Organism |
| NAS | - | National Academy of Science |
| NBF | - | National Biosafety Framework |
| NCC | - | National Coordinating Committee |
| NEA | - | National Executing Agency |
| NGO | - | Nongovernmental Organization |
| NIS | - | Newly Independent States |
| NPC | - | National Project Coordinator |
| UNEP | - | United Nations Environmental Programme |
| UNON | - | United Nations Office at Nairobi |

¹ The term "Genetically Engineered Organism" (GEO) is using in the National Biosafety Framework, which is correspond with the terms LMO and GMO cited in the text of this report during consideration of international legislation as they used in the originals.

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INTRODUCTION

The project document “Development of the National Biosafety Framework for the Republic of Belarus” was signed by the UNEP representative E.F. Ortega, head of the UNON Budgeting and Finance Department, and the Minister of Natural Resources and Environmental Protection of the Republic of Belarus L.I. Khoruzhik on October 31, 2002. Officially, the work on the project was started January 1, 2003 and was completed in December 7, 2004.

The Institute of Genetics and Cytology of the National Academy of Sciences (NAS) of Belarus, which earlier was granted the functions of the National Co-ordination Biosafety Centre under the Resolution No. 963 of June 19, 1998 of the Council of Ministers of the Republic of Belarus, was designated as the National Executing Agency (NEA). The NEA contact person shall be Dr. B.Yu. Anoshenko, leading research specialist of the Institute of Genetics and Cytology of the NAS of Belarus.

Institute of Genetics and Cytology of the NAS of Belarus formed a National Coordinating Committee (NCC) of 13 members:

1. Kartel Nikolai Alexandrovich, Director of the Institute of Genetics and Cytology of the NAS of Belarus, academician of the NAS of Belarus (chair).
2. Yermishin Alexander Petrovich, Head of the National Co-ordination Biosafety Centre, Ph.D, Dr. Sci. (Biology), (secretary).
3. Volotovskii Igor Dmitriyevich, Academician-Secretary of the Biology Department of the NAS of Belarus, Academician of the NAS of Belarus.
4. Lobanok Anatoli Georgiyevich, Director of the Institute of Microbiology of the NAS of Belarus, Academician of the NAS of Belarus.
5. Ganush Gennadi Iosifovich, Consultant of the Presidium of the NAS of Belarus (Agrarian Science Department), Academician of the NAS of Belarus.
6. Yevtushenkov Anatoli Nikolayevich, Holder of the Chair of Molecular Biology of the Belarusian State University, Ph.D., Dr. Sci. (Biology), Professor.
7. Malishevskii, Valentin Ivanovich, Deputy Minister of Natural Resources and Environmental Protection of the Republic of Belarus.
8. Petkevich Alexander Sergeyeovich, Deputy Director for Research of the State Institution “Research Institute of Epidemiology and Microbiology”, Ph.D., Candidate of Medical Science.
9. Kotova Alla Konstantinovna, Chief Specialist of the Department of Melioration, Agricultural Radiology and Environmental Protection of the Ministry of Agriculture and Food of the Republic of Belarus.
10. Stelmakh Viktor Alexandrovich, Deputy Director General of the “Belbiofarm” Group.
11. Sinyak Eduard Pavlovich, Member of the Plenary Commission for the Problems of the Chernobyl Catastrophe, Ecology and Environmental Management of the Chamber of Representatives of the National Assembly of the Republic of Belarus.
12. Shirokov Evgeni Ivanovich, National Committee for Development of Residential Areas of the Republic of Belarus (representative of non-governmental environmental organizations).
13. Patyko Dmitri Anatolyevich, observer for the newspaper “Respublika”.

A.P. Yermishin, Ph.D (Dr. Sci./ Biology) was appointed by the National Coordinating Committee to be the National Project Coordinator (NPC) (he performed his duties under the contact, signed with the UN Representative Office / Belarus, from 01.01.2003 till 30.06.2004).

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DRAFT NATIONAL BIOSAFETY FRAMEWORK FOR THE REPUBLIC OF BELARUS

1. Policy of the Republic of Belarus in the field of biosafety

The policy of the Republic of Belarus in the field of biosafety is part of its policy in the field of health care and environmental protection from the standpoint of the sustainable development concept. The state policy in these fields is based upon the fundamental principles, stated in a number of international agreements, which Belarus is a Party to, as well as upon the relevant national legislative acts.

The main objective of the Republic of Belarus in the field of biosafety is, on the one hand, to create an enabling environment for deriving maximum benefit from the achievements of modern biotechnology, to foster development of genetic engineering as one of the priority research areas of focus and, on the other hand, to ensure human and environmental health when carrying out genetic engineering activities, implementing new biotechnologies and consuming their products (Belarus' Strategy of Sustainable Development: Continuity and Renovation: Analytical Report. – Minsk: Unipak, 2003. Pages 103 – 109).

Considering the special importance of biotechnologies for sustainable development of the Republic of Belarus, they receive great attention from the State. Biotechnology and genetic engineering are on the list of priority research lines and technologies (Resolutions No. 139 of February 27, 1997 and No. 111 of January 29 2002 of the Council of Ministers of the Republic of Belarus) (the complete texts in Russian of legislative acts referred to in this Project are available at the web-site of the National Co-ordination Biosafety Centre <http://biosafety.org.by/rus/legislation.html>)

There have been three main directions of modern biotechnology formed in Belarus: (1) creation of new effective strains of microorganisms as biotechnological objects for microbial synthesis of biologically active compounds and for their use in industry, agriculture and environmental protection; (2) breeding genetically engineered varieties of agricultural and ornamental plants; (3) application of genetic engineering biotechnologies in medicine for diagnostics and treatment of diseases and creation of fundamentally new medical drugs.

In accordance with these directions, there have been developed and are being implemented such state-supported scientific and research programs as “Infections and Medical Biotechnologies” and “Industrial Biotechnology”, the State Fundamental Research Program of “Development of Scientific Fundamentals for Biotechnological Processes”. The State Program for 2002–2006 “Development and Use of Genetic Engineering Biotechnologies for the Benefit of Agriculture and Medicine (Genetic Engineering)”, along with conducting research activities, includes a set of organizational and human resource activities, intended to expedite development of this promising line of research. In the framework of the Union of Belarus and Russia there has been developed a research program “Creation of Highly Effective and Biologically Safe Medicinal Preparations of New Generation on the Basis of Human Proteins, Received from Milk of Transgenic Animals (BelRosTransGen)”.

Belarus has undertaken some important steps in the field of safe use of biotechnologies. Among the notable ones is, first of all, establishment of the National Co-ordination Biosafety Centre, which functions include full-scale monitoring of the development of this area of focus (Resolution No. 963 of June 19, 1998 of the Council of Ministers of the Republic of Belarus). In May 2002 Belarus acceded to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. In April 2004 the Parliament of Belarus adopted in the first reading the Draft Law “On Safety in Genetic Engineering Activities”. Continuous work is carried out on improving the current legislation and developing new regulatory legal acts in the field of biosafety.

2. International commitments of the Republic of Belarus in the field of biosafety

The Republic of Belarus is a Party to a number of international conventions, related to safe use of achievements of modern biotechnology. The most important of them are the following:

1. **Convention on Biological Diversity**. Adopted in 1992 in Rio de Janeiro. It was ratified by the Resolution of the Supreme Council of the Republic of Belarus of June 10, 1993 and entered into force 29 December 1993.

The problem of ensuring safety in the field of biotechnology is regarded in the Convention on Biological Diversity in subparagraphs g and h of Article 8, paragraph 1 of Article 14 and in paragraphs 3 and 4 of Article 19. In particular, subparagraph g of Article 8 contains an appeal to the Parties to establish or support means of regulating, controlling or limiting risks related to use and release of living modified organisms (LMO), resulting from modern biotechnology which may have adverse effect on the conservation and sustainable use of biological diversity. In accordance with paragraph 1 of Article 14, each Party shall introduce relevant procedures, calling for environmental expertise of the proposed projects which may produce significant adverse effect on biological diversity, with the purpose of preventing or minimizing such consequences, and, if it is expedient, provide for public participation in such procedures. Paragraph 3 of Article 19 proposes to the Parties to the Convention to consider the necessity and conditions of adopting the protocol in the field of the safe transfer, handling and use of living modified organisms. Paragraph 4 of the same article states that each Party shall directly provide and require from any natural person or legal entity under its jurisdiction, who provides such LMO, to share any available information on the rules of their use and safe handling, as well as any available information on potential adverse effects of the relevant particular LMO to the Party of Import.

2. **Cartagena Protocol on Biosafety to the Convention on Biological Diversity**. Adopted January 29, 2000 in the city of Montreal at the extraordinary meeting to the Conference of the Parties to the Convention on Biological Diversity. It entered into force 11 September 2003. Belarus ratified the Cartagena Protocol May 5, 2002 by adopting the Law of the Republic of Belarus “On Belarus Accession to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity”.

The Cartagena Protocol is the main international instrument for regulating transboundary movement of living modified organisms. Along with that, the Protocol contains most important provisions, which deal with ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMOs, assessing and preventing risks to human and environmental health related to living modified organisms, collection and exchange of information, promoting public awareness and public participation in the decision making process in the biosafety field.

In order to directly perform their obligations under the Protocol, each Party must designate a national focal point to be responsible on its behalf for liaison with the Secretariat of the Protocol, and one or several competent national authorities which shall be responsible for performing administrative functions required by the Protocol. In accordance with the Resolution No. 734 of 5 June 2002 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 Institute of Genetics and Cytology of the NAS of Belarus, performing the functions of the National Co-ordination Biosafety Centre, was designated as the national focal point, responsible for liaison with the Secretariat of the Protocol. The Ministry of Natural Resources and Environmental Protection (in the part of the functions related to release of living modified organisms into the environment) and the Ministries of Health Protection and Agriculture and Food (for the issues of using living modified organisms in economic activities) were designated as competent authorities.

3. **The International Convention for the Protection of New Varieties of Plants**. Adopted 2 December 1961, revised in Geneva 10 November 1972, 23 October 1978 and 19 March 1991. It was ratified pursuant to the Law of the Republic of Belarus of 24 June 2002 “On the Accession of the Republic of Belarus to the International Convention for the Protection of New Varieties of Plants”.

In Article 14 of the Convention, which designates “Scope of Plant Breeder’s Rights” paragraph (5), on “derived and some other varieties”, deals with, among others, varieties of agricultural plants, which to a significant degree inherit traits of other varieties, including those received by genetic engineering methods. This provision is also secured in Article 7 of the Law of

the Republic of Belarus “On Patents for Varieties of Plants” under the title “Varieties, inheriting to a significant degree traits of another variety, and some other varieties”.

Thus, the International Convention for the Protection of New Varieties of Plants and our national legislation do not regard genetic engineering as something extraordinary. From the scientific standpoint, it is a method of breeding, which allows for introducing particular non-significant alterations into the genotype of a variety (for adding or altering individual traits).

4. **Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (the Aarhus Convention)**. Adopted 25 June 1998 in Aarhus (Denmark) at the Ministerial Conference – “Environment for Europe” (approved by the Decree No. 726 of 14 December 1999 of the President of the Republic of Belarus).

The main provisions of the Aarhus Convention are in line with Article 23 of the Cartagena Protocol on Biosafety. In particular, it says that “Each Party shall ensure that ... public authorities in response to a request for environmental information make such information available to the public, within the framework of international legislation, including... copies of actual documentation containing or comprising such information” (Article 4). The Parties to the Convention shall provide for public participation in the decisions on whether to permit activities which may have a significant effect on the environment (Article 6). This article contains a commitment, directly related to genetically modified organisms, “Each Party shall, within the framework of its national law, apply, to the extent feasible and appropriate, provisions of this article to decisions on whether to permit the deliberate release of genetically modified organisms into the environment” (paragraph 11 of Article 6).

The Convention on Biological Diversity, the Cartagena Protocol to the Convention on Biological Diversity, the International Convention for the Protection of New Varieties of Plants and the Aarhus Convention, after their ratification by the Parliament (approval by the decrees of the President of the Republic of Belarus) made part of the national legislation of the Republic of Belarus in accordance with the Law of the Republic of Belarus “On Regulatory Legal Acts”. However, for meeting the international commitments, contained in these international agreements, it is necessary to issue domestic regulatory legal acts.

Compliance with the commitments of the Republic of Belarus, contained in the above mentioned international agreements, is one of the most important legislative requirements in the field of biosafety.

3. Selecting the model of the state governing of safety in genetic engineering activities in the Republic of Belarus

For selecting the model of the state governing of safety in genetic engineering activities it is critical to adequately assess benefits and possible adverse effects of using the achievements of modern biotechnology. Under- or overestimation of the latter may result in a significant reduction of the effectiveness of the model.

The authors proceeded from the scientifically grounded and well proven idea of genetic engineering as of a new method of breeding, which allows for significant expansion of the possibilities of traditional breeding through using the whole variety of valuable genes that exist in nature. With the help of genetic engineering technique it is possible to add concrete genes in a plant variety, an animal breed or a strain of microorganisms, without altering the rest of their genetic characteristics. The risks to human health and the environment related to genetic engineering activities basically do not differ from those of using traditional breeding technologies (UNEP International Technical Guidelines for Safety in Biotechnology, point 6 of Introduction. UNEP. 1995. P. 2). They can be identified and assessed at early phases of the breeding process or even at the planning stage of experiments. It provides for a possibility to avoid or minimize possible adverse effects of genetic engineering activities.

When developing the model of state governing of the safety in genetic engineering activities, the following requirements were kept in mind:

First, it should ensure protection of human health and the environment in the process of carrying out genetic engineering activities and using their results, and simultaneously create favorable conditions for development of genetic engineering as a priority research area of focus.

Second, when forming the biosafety system, the State should avoid major amendments to the current legislation and establishment of new state bodies, which are going to become an additional burden on the national budget and ordinary tax payers. It is necessary to use currently available bodies, granting them, if need be, proper authority.

Third, it is important for the new legislation in the field of biosafety to include regulations and procedures, which can be implemented with minimum resources and funds. The procedures themselves should be simple and clear to people.

Fourth, the society has the right to receive full and true information on the results of genetic engineering activities and to exercise community control. Therefore, the evolving biosafety framework should envisage a mechanism for promoting public awareness and participation in the decision making in this field.

The concept of state governing the safety in genetic engineering activities in the Republic of Belarus is based on the available expertise of several leading nations, the current legislation of the Republic of Belarus and the existing national system of state governing, and Belarus' commitments under international agreements. In the process of implementing this Project, there was completed the Draft Law of the Republic of Belarus "On Safety in Genetic Engineering Activities" (Annex 1), which has been approved by the national Parliament in the first reading. This Law establishes legal and organizational principles for ensuring safety in genetic engineering activities in the Republic of Belarus. Together with current legislative acts and a number of legal acts, drafted for the purpose of its development in the course of implementation of the project, makes the basis of the regulatory and legal framework of the evolving national biosafety system. Its main components are discussed below.

4. Legislation of the Republic of Belarus in the field of biosafety

4.1. Legislation of the Republic of Belarus in the field of safety in genetic engineering activities in contained use

4.1.1. Current legislation of the Republic of Belarus in the field of safety in genetic engineering activities in contained use

The fundamental Laws in this field are the following:

1. The Law "On Health", which determines the state policy in the field of health protection of citizens of the Republic of Belarus, and legal, socio-economic and organizational base of the health care system.

2. The Law "On Sanitary and Epidemic Well-Being of the Population", which regulates public relations in the field of provision of sanitary and epidemic well-being of the people of the Republic of Belarus, preserving and improving people's health, their physical and spiritual growth and long and active life. The Law designates competencies of national and local enterprises, institutions, organizations and other economic entities regardless of their substitution and form of ownership, public associations, officials and citizens in complying with sanitary regulations, rules, and hygienic norms and carrying out sanitary and hygienic, preventive, anti-epidemic and anti-radiation activities; the state control and surveillance system; and penalties for violations of sanitary legislation.

In order to provide continuous control over observance of the requirements of biological safety and conditions of handling microorganisms, which are pathogenic to humans, including genetically engineered microorganisms, the laboratories in the institutions under the Ministry of Health use 15 various regulatory and legal acts and methodological guidelines (See Table 1). This list includes a number of regulatory documents, developed in the Soviet Union, which are not in conflict with the legislation of the Republic of Belarus. They will remain effective in this country until national regulatory and legal acts, developed on their basis, are adopted in this field.

Table 1. List of legislative acts of the Republic of Belarus, regulating safety of work with microorganisms of various pathogenicity groups in contained use²

- 1 The Law of the Republic of Belarus “On Health” of 18.06.1993 (amended and supplemented: 03.05.1996; 03.03.1997; 11.01.2002).
- 2 The Law of the Republic of Belarus “On Sanitary and Epidemic Well-Being of the Population” of 23.11.1993 (amended and supplemented: 15.07.1997; 09.07.1999; 23.05.2000).
- 3 The Law of the Republic of Belarus “On Safety in Genetic Engineering Activities”(the draft law adopted in the first reading by the Chamber of Representatives of the National Assembly of the Republic of Belarus 29 April 2004).
- 4 Resolution No. 25 of 25.11.1997 by the Chief State Sanitary Physician of the Republic of Belarus “On Committee for Control over Compliance with the Requirements of Biological Safety and Anti-Epidemic Conditions (Control Committee)”.
- 5 Sanitary rules for safe handling of microorganisms. Part 1. Procedure of issuing permits for work with microorganisms of pathogenicity groups I - IV and recombination DNA molecules (SR 1.2.006-93).
- 6 Sanitary and epidemiological rules “Safe handling of recombination DNA molecules”, 1989.
- 7 Sanitary rules “Safe handling of microorganisms of pathogenicity groups I - II” (SR 1.2.011-94).
- 8 Specific features of techniques of handling causative agents of human infectious diseases of pathogenicity groups I - II of bacterial etiology (manual). 1989.
- 9 Regulations on the order of accounting, storing, handling, release and transfer of cultures of bacteria, viruses, rickettsia, fungi, protozoa, mycoplasma, bacterial toxins, poisons of biological origin. 1980.
- 10 Instructions for handling aerosols of causative agents of especially dangerous and other bacterial infections. 1977.
- 11 Rules of organization, occupational safety, industrial sanitation, anti-epidemic conditions and personal hygiene for work in laboratories (divisions, departments) of sanitary and epidemiological institutions of the Ministry of Health. 1981.
- 12 Rules of occupational safety, industrial sanitation, and anti-epidemic conditions for enterprises producing bacterial and viral preparations. 1980.
- 13 Guidelines for observance of anti-epidemic conditions in laboratories for AIDS testing. 1991.
- 14 Guidelines for sanitary and epidemic control of the ventilation systems in industrial premises. 1973.
- 15 Guidelines for using air conditioning in communicative disease units. 1986.
- 16 Methodological recommendations for determining the penetrability factors of filters by bacterial aerosols. 1988.
- 17 Guidelines on anti-epidemic conditions of handling antibiotic-resistant cultures of special danger infections. 1979.
- 18 General organizational principles and medical and technical requirements to design of maximum protection laboratories for virologic studies. 1987.

In particular, Resolution No. 25 of 25.11.1997 by the Chief State Sanitary Physician of the Republic of Belarus “On Committee for Control over Compliance with the Requirements of Biological Safety and Anti-Epidemic Conditions (Control Committee)” is unified with the effective Russian regulatory documents. This Resolution approves:

- Composition of the Republican Committee for control over compliance with the requirements of biological safety and anti-epidemic conditions (Control Committee) in the laboratories of the institutions under the Ministry of Health of the Republic of Belarus and of other agencies, working with microorganisms of pathogenicity groups I and II;
- Regulations on the Republican Control Committee;

² The texts of the legislative acts in Russian are presented at the web-site of the National Co-ordination Biosafety Centre <http://biosafety.org.by/rus/legislation.html>

- Regulations on the Regional Control Committee;
- Regulations on the procedure of issuing permits for conducting work with microorganisms of pathogenicity groups I and II;
- List of currently effective policy papers on compliance with the requirements of biological safety and anti-epidemic conditions in the process of handling microorganisms, which are pathogenic to humans.

Pursuant to the Chief State Sanitary Physician's Resolution, the Republican Control Committee is a controlling and advisory body of the Ministry of Health of the Republic of Belarus on the issues of compliance with the requirements of biological safety and anti-epidemic conditions in the laboratories of the institutions under the Ministry of Health of the Republic of Belarus and of other government agencies, working with microorganisms of pathogenicity groups I and II. Members of the Control Committee are approved by the Deputy Minister of Health – the Chief State Sanitary Physician, to whom it is directly subordinate. This regulatory act designated a unified procedure of issuing permits for work with microorganisms of pathogenicity groups I and II in the process of experimental and diagnostic studies and the manufacturing of immunobiological preparations and products of microbial synthesis.

All the above mentioned work may be performed only if the institution holds a permit for such work, issued by a state sanitary control body or institution on the basis of the conclusion of the Control Committee. The permit is issued for every microorganism type, used in the work, and officially confirms that this institution has provided proper sanitary and hygienic conditions, enabling compliance with the requirements of biological safety and anti-epidemic conditions, as well as protection of the population and of the environment. The permit for work with microorganisms of pathogenicity groups I and II is issued for 5 years. The permit may be cancelled in case of violation of the requirements of biological safety and anti-epidemic conditions and is regarded invalid in case of unauthorized alteration of layout and functions of the premises. Institutions, dealing with microorganisms of pathogenicity groups I and II form committees for control over compliance with the requirements of biological safety and anti-epidemic conditions (control committees).

4.1.2. Directions of improvement of the legislation of the Republic of Belarus in the field of safety in genetic engineering activities in contained use

The fundamental instrument of improving legislation in this field is the Draft Law of the Republic of Belarus “On Safety in Genetic Engineering Activities” (adopted in the first reading by the Chamber of Representatives of the National Assembly of the Republic of Belarus; its elaboration and preparation for review by the committees of the Parliament took place in the course of implementing the UNEP–GEF project) (<http://biosafety.org.by/rus/legislation.html>).

The Draft Law has a number of important provisions, regarding safety in genetic engineering activities in contained use. First of all, the Draft Law establishes four levels of risk related to genetic engineering activities:

- the first level of risk refers to working with non-pathogenic genetically engineered organisms;
- the second level of risk refers to working with opportunistic pathogenic genetically engineered organisms;
- the third level of risk refers to working with genetically engineered organisms capable of inducing dangerous infectious diseases and spreading infection for which effective prevention and treatment measures are available;
- the fourth level of risk refers to working with genetically engineered organisms inducing especially dangerous infectious diseases which can be rapidly spread and for which no effective prevention and treatment measures are known.

Genetic engineering activities of the second, third and fourth levels of risk shall be performed exclusively by state-owned organizations for contained use only. Implementation of these activities is allowed only if there is a permit for exercise of genetic engineering activities issued by the Ministry of Health of the Republic of Belarus. The procedure for determination of the levels of risk

of genetic engineering activities, as well as the requirements to contained use for performing work of the second, third and fourth levels of risk shall be determined by the Ministry of Health of the Republic of Belarus.

A contained use system in which genetic engineering activities are performed shall be subject to mandatory accreditation. Accreditation of contained use for implementation of genetic engineering activities of the second, third and fourth levels of risk shall be made by the Ministry of Health of the Republic of Belarus according to procedures specified by this ministry.

The Republic of Belarus has established an effectively functioning system of ensuring biosafety when working with microorganisms, including genetically engineered microorganisms of various pathogenicity groups. Evidently, this system may be fully employed with regard to work with pathogenic and opportunistic pathogenic genetically engineered microorganisms. An important peculiarity of such work as compared to regular ones is the correct identification of the pathogenicity group of a particular genetically engineered microorganism, since it may have elements of organisms of different groups in its genome. For this purpose there have been prepared “Methodological Guidelines for Risk Assessment of Genetic Engineering Activities”.

It is inexpedient to use the above described biosafety system, practiced within the Ministry of Health, for genetic engineering activities involving non-pathogenic genetically engineered organisms (plants and animals) in contained use, as such work does not pose a considerable threat for human health. At the same time, this work may involve certain environmental risks. Therefore, state governing of such activities should consist of provision of measures preventing undeliberate release of genetically engineered organisms into the environment.

The Draft Law of the Republic of Belarus “On Safety in Genetic Engineering Activities” envisages a procedure of accreditation of contained use systems intended for performing genetic engineering activities of the first level of risk (with non-pathogenic genetically engineered organisms), which should be implemented by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus in the order, specified by this ministry.

The procedure of accreditation of contained use systems intended for performing work with non-pathogenic genetically engineered organisms and safety rules for such work are laid down in relevant regulatory and legal acts, developed in the process of implementing this project (Table 2).

Table 2. List of legislative acts of the Republic of Belarus, regulating safety of work with non-pathogenic genetically engineered organisms in contained use³

- 1 The Law of the Republic of Belarus “On Safety in Genetic Engineering Activities”(the draft law adopted in the first reading by the Chamber of Representatives of the National Assembly of the Republic of Belarus 29 April 2004).
- 2 Procedure of Accreditation of Contained Use Systems where Genetic Engineering Activities are Performed (the draft document has been developed in the process of implementing the UNEP–GEF project).
- 3 Safety Rules for Work with Genetically Engineered Organisms in Contained Use (the draft document has been developed in the process of implementing the UNEP–GEF project).
- 4 “Methodological Guidelines for Risk Assessment of Genetic Engineering Activities“(the draft document has been developed in the process of implementing the UNEP–GEF project).

4.2. Legislation of the Republic of Belarus in the field of safety in genetic engineering activities involving release of genetically engineered organisms into the environment for trials

4.2.1. Current legislation of the Republic of Belarus in the field of biosafety of releasing genetically engineered organisms into the environment

The new revision of the Law of the Republic of Belarus “On Environmental Protection” (Version of the Law of 17 July 2002) contains Article 49, entitled “Requirements in the field of environmental conservation to the activities that have or may have an adverse biological effect on the environment”, pursuant to which “Introduction, acclimatization, cultivation, breeding and use of plants and animals, which are not native to the natural ecosystems, and of those created by artificial

³ The texts of the legislative acts in Russian are presented at the web-site of the National Co-ordination Biosafety Centre <http://biosafety.org.by/rus/legislation.html>

means, without developing measures for preventing their harmful impact on the natural ecosystems, obtaining positive conclusions of relevant expertise and (or) permits in accordance with the legislation of the Republic of Belarus, are prohibited...” As we can see, this provision is fully applicable to genetically engineered organisms. Nevertheless, this article contains a reference to the special legislative act, regarding release of genetically engineered organisms into the environment, in which the described requirements should be detailed.

4.2.2. Directions of improvement of the legislation of the Republic of Belarus in the field of biosafety related to release of genetically engineered organisms into the environment

Most legislative acts, regulating safety in the process of release of genetically engineered organisms into the environment for trials (Table 3) are currently in the process of drafting.

Table 3. List of legislative acts, regulating safety in the process of release of genetically engineered organisms into the environment for trials⁴

- 1 The Law of the Republic of Belarus of 6 May 2002 “On Accession of the Republic of Belarus to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity”
- 2 The Law of the Republic of Belarus “On Environmental Protection” (in the revision of 17 July 2002).
- 3 The Law of the Republic of Belarus “On Safety in Genetic Engineering Activities”(the draft law adopted in the first reading by the Chamber of Representatives of the National Assembly of the Republic of Belarus 29 April 2004).
- 4 The Resolution No. 734 of the Council of Ministers of the Republic of Belarus of 5 June 2002 “On Measures for Implementing Provisions of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity”
- 5 The Resolution No. 963 of the Council of Ministers of the Republic of Belarus of 19 June 1998 “On Establishment of the National Co-ordination Biosafety Centre”
- 6 “Procedure of Issuing Permits for Release of Genetically Engineered Organisms into the Environment for Trials” (the draft document has been developed in the process of implementing the UNEP–GEF project).
- 7 “Procedure of Accreditation of Sites for Controlled Release of Genetically Engineered Organisms into the Environment”. (The draft document has been developed in the process of implementing the UNEP–GEF project).
- 8 “Regulations on Procedure of Organization and Performing State Expertise of the Safety of Genetically Engineered Organisms”. (The draft document has been developed in the process of implementing the UNEP–GEF project).

The above mentioned legislative act (draft of “Procedure of issuing permits for release of genetically engineered organisms into the environment for trials”) designates the following types of releases of genetically engineered organisms into the environment for trials:

- controlled release refers to restricted field trials of genetically engineered organisms (including trials for biosafety) in enclosed guarded sites (testing sites) with taking special risk limitation measures. The site, intended for controlled release of genetically engineered organisms into the environment, should be accredited with the Ministry of Natural Resources and Environmental Protection pursuant to the drafted “Procedure of Accreditation of Sites for Controlled Release of Genetically Engineered Organisms into the Environment”.
- planned release refers to release of genetically engineered organisms into the environment without taking special risk limitation measures (including state crop variety trials).
- repeated release refers to controlled or planned release of genetically engineered organisms, which have been previously released, provided that previously issued relevant permits are available.

Only non-pathogenic genetically engineered organisms shall be allowed for release into the environment for trials. Any first time release of genetically engineered organisms into the

⁴ The texts of the legislative acts in Russian are presented at the web-site of the National Co-ordination Biosafety Centre <http://biosafety.org.by/rus/legislation.html>

environment is allowed by a permit issued by the Ministry of Natural Resources and Environmental Protection. No permit from the Ministry of Natural Resources and Environmental Protection is needed for release into the environment for trials of genetically engineered organisms, received by traditional breeding methods from the genetically engineered initial materials such as varieties of plants, breeds of animals and strains of microorganisms, which have undergone the procedure of state registration in the Republic of Belarus.

Article 17 of the Law of the Republic of Belarus “On Safety in Genetic Engineering Activities” envisages that trials of genetically engineered organisms during their first-time release into the environment must be performed in specially equipped testing sites designed for testing of genetically engineered organisms (controlled release). Safety requirements to sites for testing of genetically engineered organisms shall be determined by regulatory and legal as well as technical regulatory legal acts, adopted by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus in coordination with the National Academy of Sciences of Belarus, in particular, with “Procedure of Accreditation of Sites for Controlled Release of Genetically Engineered Organisms into the Environment”.

In accordance with the draft of “Procedure of Issuing Permits for Release of Genetically Engineered Organisms into the Environment for Trials” in order to receive a permit for controlled or planned release, the interested legal entity submits an application to the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus. Enclosed to the application are materials, containing information on the genetically engineered organisms to be released, the potential receiving environment and the goals and modalities of the release.

The Ministry of Natural Resources and Environmental Protection registers the submitted application within a 10-day period, assigns a registration number to it, notifies the applicant thereof, and submits it to expertise. Simultaneously, the application materials go to the National Co-ordination Biosafety Centre.

The State expertise of the safety of genetically engineered organisms is carried out pursuant to “Regulations on Procedure of Organization and Performing State Expertise of the Safety of Genetically Engineered Organisms”. In their work experts are guided by “Methodological Guidelines for Risk Assessment of Genetic Engineering Activities“(the draft documents have been developed in the process of implementing the UNEP–GEF project).

On the basis of the expert opinion of the safety of genetically engineered organisms, the Ministry of Natural Resources and Environmental Protection issues a permit for release of genetically engineered organisms into the environment. The permit is valid for all subsequent release of concrete genetically engineered organisms (genotypes) if there has been no change in the release modalities (receiving environment, safeguards, etc.). It may be specified in a permit for controlled release of genetically engineered organisms into the environment may specify that it is also valid for planned releases, if it is indicated in the expert opinion that release of these genetically engineered organisms is safe in the context of both controlled and planned releases.

A permit for release of genetically engineered organisms into the environment may be cancelled or suspended in case of violation of the legislation of the Republic of Belarus in the field of biosafety by legal entities, as well as in case of receiving additional reliable information on the adverse effect of these genetically engineered organisms on human and environmental health. The resolution on suspension or cancellation of the permit for release of genetically engineered organisms into the environment is communicated to the applicant in the written form.

In case the Ministry of Natural Resources and Environmental Protection refuses to issue to the applicant a permit for release of genetically engineered organisms into the environment, circumstantial reasons for the refusal should be provided. The applicant has the right to appeal the negative resolution of the Ministry of Natural Resources and Environmental Protection regarding release of genetically engineered organisms into the environment in the order, established by the legislation of the Republic of Belarus.

4.3. Legislation of the Republic of Belarus in the field of biosafety of using genetically engineered organisms in economic activities

4.3.1. Current legislation of the Republic of Belarus in the field of biosafety of using genetically engineered organisms in economic activities.

Pursuant to the Draft Law of the Republic of Belarus “On Safety in Genetic Engineering Activities”, the term “use of genetically engineered organisms in economic activities” means “breeding and (or) cultivating genetically engineered varieties of plants, breeds of animals, and strains of microorganisms for production of agricultural and microbiological products as well as for other economic purposes”.

The list of legislative acts of the Republic of Belarus, regulating safety of using genetically engineered varieties of plants in economic activities is presented in Table 4.

Table 4. List of legislative acts of the Republic of Belarus regulating safe use of genetically engineered varieties of plants in economic activities⁵

- 1 The Law of the Republic of Belarus “On Patents for Varieties of Plants” of 13 April 1995 (amended and supplemented 14 July 2004).
- 2 The Law of the Republic of Belarus “On Seeds” of 14 February 1997.
- 3 The Law of the Republic of Belarus of 6 May 2002 “On Accession of the Republic of Belarus to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity”
- 4 The Law of the Republic of Belarus of 24 June 2002 “On Accession of the Republic of Belarus to the International Convention on Protection of New Varieties of Plants”.
- 5 The Law of the Republic of Belarus “On Safety in Genetic Engineering Activities”(the draft law adopted in the first reading by the Chamber of Representatives of the National Assembly of the Republic of Belarus 29 April 2004).
- 6 Resolution of the Council of Ministers of the Republic of Belarus of 11 August 1997 “On Organizational and Legal Measures for Implementing the Law of the Republic of Belarus “On Seeds”.
- 7 Resolution No. 2 of the Ministry of Agriculture and Food of the Republic of Belarus of 15 March 2002 “On the Procedure of Import, Sale and Application of Means of Plant Protection and Plant Growth Regulators in the Republic of Belarus”.
- 8 Resolution No. 734 of the Council of Ministers of the Republic of Belarus of 5 June 2002 “On Measures for Implementing Provisions of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity”
- 9 Resolution No. 1288 of the Council of Ministers of the Republic of Belarus of 18 September 2002 “On Measures for Implementing Provisions of the International Convention on Protection of New Varieties of Plants”.
- 10 Regulations on the State Control in Seed Industry of 11.08.1997.
- 11 Regulations on State Crop Variety Trials of 11.08.1997.
- 12 Procedure and Conditions of Maintaining the State Register of Varieties of Plants and Wood and Shrub Species of 11.08.1997.
- 13 Order No. 128 of the Ministry of Agriculture and Food of the Republic of Belarus of 14 April 2003 “On the Approval of the Regulations on the State Inter-Agency Committee for Testing and Registration of Chemical and Biological Means of Plant Protection, Plant Growth Regulators and Fertilizers”.

Genetically engineered varieties of plants, in accordance with the Law of the Republic of Belarus “On Patents for Varieties of Plants” of 13 April 1995 (amended and supplemented 14 July 2004), belong to the category of varieties, which to a significant degree inherit traits of another variety (Article 7). Due to this, any genetically engineered variety, which is of interest for breeding, must undergo the registration procedure pursuant to the above mentioned Law, in order to be entered on the State Register of Protected Varieties of Plants of the Republic of Belarus and, thus, to be legally protected.

⁵ The texts of the legislative acts in Russian are presented at the web-site of the National Co-ordination Biosafety Centre <http://biosafety.org.by/rus/legislation.html>

Pursuant to the Law of the Republic of Belarus “On Seeds” of 14 February 1997, seeds of varieties of plants and woods and shrub species can be used for cultivation only after they have been entered into the State Register of Varieties of Plants and Woods and Shrub Species or recognized as having potential except as otherwise provided by this Law and other legislative acts of the Republic of Belarus.

In order to determine economically valuable and other traits of varieties of plants and woods and shrub species for the purpose of recommending them for use in production in the Republic of Belarus state variety trials are carried out. Implementation of the state variety trials in the Republic of Belarus is rests with the Inspectorate for State Trials and Protection of Varieties of Plants under the Ministry of Agriculture and Food of the Republic of Belarus, which carries out trials in accordance with the Regulations on Crop Variety Trials, approved by the Council of Ministers of the Republic of Belarus. The results of the state variety trials are taken into account, on the one hand, while performing patent expertise of the application for a variety, and, on the other hand, they make the basis for including or not including varieties of plants into the State Register of Varieties of Plants and Woods and Shrub Species of the Republic of Belarus.

Special attention should be given to the problem of state registration and circulation of genetically engineered varieties of plants intended for direct use as raw or processed food products, fodder or for processing (that is, imported seeds of plant varieties which are not intended for release into the environment). The current legislation does not envisage a special registration procedure for such varieties. Due to this, their import into the Republic of Belarus is exercised in accordance with the requirements of Article 11 of the Cartagena Protocol on Biosafety and requirements of the current legislation, regulating import of raw or processed food products and fodder.

For carrying out the state testing and registration of new most effective means of plant protection, the State Committee for Testing and Registration of Chemical and Biological Means of Plant Protection and Plant Growth Regulators (GosKhimKomissia)” was established under the Ministry of Agriculture and Food and it was granted the following main functions:

- compiling assortment of new chemical and biological means of plant protection and biologically active substances (preparations), which are safe to human and environmental health;
- organization of the state testing of new preparations and preparative forms produced in the NIS (countries of the former USSR) and other foreign countries;
- registration of preparations, produced in the NIS and other foreign countries, which have undergone state testing and have been allowed for application in the NIS countries.

April 14, 2003 the Ministry of Agriculture and Food of the Republic of Belarus issued the Order No. 128, approving the new composition of the GosKhimKomissia and “Regulations on the State Inter-Agency Committee for Testing and Registration of Chemical and Biological Means of Plant Protection, Plant Growth Regulators and Fertilizers”. Technical support of the work of the GosKhimKomissia is provided by the state-owned institution “Chief State Inspectorate for Seed Industry, Quarantine Policy and Plant Protection” (Paragraph 3 of the Order).

It is indicated in the new Regulations on the State Inter-Agency Committee for Testing and Registration of Chemical and Biological Means of Plant Protection, Plant Growth Regulators and Fertilizers that “it aims to provide State control over the unified procedure of state registration trials and registration of chemical and biological means of plant protection, plant growth regulators and fertilizers” (Chapter 2, Paragraph 4).

“...All chemical and biological means of plant protection, plant growth regulators and fertilizers, produced and used in the Republic of Belarus, including those imported from abroad, are subject to state registration” (Chapter 2, Paragraph 5).

"The “Catalogue of Pesticides and Fertilizers, Permitted for Application in the Territory of the Republic of Belarus” includes chemical and biological means of plant protection, plant growth regulators and fertilizers, which have undergone, according to the procedure specified by the legislation of the Republic of Belarus, state registration trials and have proper documents (Certificate of State Registration of Chemical and Biological Means of Plant Protection, Plant Growth Regulators and Fertilizers issued by the Ministry of Agriculture and Food and Certificate of State Hygienic Registration issued by the Ministry of Health)” (Chapter 2, Paragraph 6).

It can be seen that the Republic of Belarus has a well-defined system of ensuring safe use of biopesticides and biofertilizers, which can be used to the full extent with regard to biopesticides and biofertilizers on the basis of strains of microorganisms, produced by genetic engineering methods.

4.3.2. Directions of improvement of the legislation of the Republic of Belarus in the field of biosafety of using genetically engineered organisms in economic activities

The current legislation of the Republic of Belarus permits the use in economic activities of only those varieties of plants, which have undergone the state registration procedure (have been included in the State Register of Varieties of Plants and Wood and Shrub Species) upon the results of the state crop variety trials. This provision is applicable to both varieties of plants, bred by traditional breeding methods and genetically engineered varieties. Specific features of the state registration procedure for the latter are stated in Article 18 of the Draft Law of the Republic of Belarus “On Safety in Genetic Engineering Activities”: “State registration shall be made after performance of state expertise of safety of genetic engineering activities and when positive results of testing of genetically engineered organisms released into the environment are obtained”.

Thus, if positive results, obtained in the course of the state crop variety trials, are sufficient for the state registration of traditionally bred varieties of plants, the following additional documents are required for the registration of genetically engineered varieties.

First, it is a permit from the Ministry of Natural Resources and Environmental Protection for release of concrete genotypes of genetically engineered organisms into the environment for trials, which is issued on the basis of positive results of the state expertise of their biosafety.

Second, it is a report on the results of the testing of these genotypes of genetically engineered organisms for biosafety, which indicates that no significant adverse effects on the environment have been detected in the process of trials of the genetically engineered organisms.

Third, it is a positive expert opinion of the safety of these genetically engineered organisms to human health.

Procedure of the state registration of genetically engineered varieties of plants is described in the draft of “Regulations on the Procedure of the State Registration of Genetically Engineered Varieties of Plants, Breeds of Animals and Strains of Microorganisms”, which has been developed in the process of implementing the UNEP–GEF project. Decisions on inclusion of a genetically engineered variety is taken by the Inspectorate for State Trials and Protection of Varieties of Plants under the Ministry of Agriculture and Food of the Republic of Belarus, which carries out trials in accordance with the Regulations on Crop Variety Trials, on the basis of the results of the state crop variety trials and the review of the above listed documents.

On the basis of the resolution on the state registration of a genetically engineered variety the Inspectorate for State Trials and Protection of Varieties of Plants under the Ministry of Agriculture and Food of the Republic of Belarus within a 10-day period from the day of adopting the specified resolution issues a state registration certificate for the variety to the applicant and enters information on it into the State Register of Varieties of Plants and Woods and Shrub Species of the Republic of Belarus. Next, within a 10-day period from the day of issuing the certificate, the Inspectorate submits the required information to the National Co-ordination Biosafety Centre, its form of presentation cleared with the Centre.

The principles of the state governing of biosafety of using genetically engineered varieties of plants in economic activities may be applied to the full extent to means of plant protection and fertilizers, produced on the basis of microorganisms.

The Draft Law of the Republic of Belarus “On Safety in Genetic Engineering Activities” does not envisage a special state registration procedure for genetically engineered varieties of plants intended for direct use as raw or processed food products, fodder or for processing. However, if such a necessity arises in the process of development of the national biosafety framework, it will be done through introducing amendments and supplements into the current legislation. This function may be vested in the Ministry of Agriculture and Food, which is responsible for maintaining the State Register of Varieties of Plants and Wood and Shrub Species and ensuring food safety of this country.

4.4. Legislation of the Republic of Belarus in the field of safety and quality of edible raw materials and foodstuffs

4.4.1. Current legislation of the Republic of Belarus in the field of safety and quality of edible raw materials and foodstuffs

The list of legislative acts of the Republic of Belarus in the field of safety and quality of edible raw materials and foodstuffs is presented in Table 5.

The right of Belarusian citizens to protection of their health with regard to consumption of foodstuffs is stated in the Law of the Republic of Belarus “On Health”, which determines the state policy in the field of health care. The Law maintains the citizens’ right to health protection, which is provided by protection of the environment, creation of favorable conditions for work, domestic life and recreation, hygienic education, production and marketing of good quality foodstuffs, and creation of conditions for fitness and sports.

The Law of the Republic of Belarus “On Sanitary and Epidemic Well-Being of the Population” establishes legal and organizational fundamentals for prevention and elimination of adverse effects of factors of the human habitat (foodstuffs make an integral part of this habitat) on the human organism and regulates activities of state bodies, legal entities and natural persons related to ensuring sanitary and epidemic well-being of the population, which is closely linked to the quality and safety of consumed foodstuffs.

Table 5. List of legislative acts of the Republic of Belarus in the field of safety and quality of raw and processed food products⁶

- 1 The Law of the Republic of Belarus “On Health” of 18 June 1993 (in the version of 11.01.2002).
- 2 The Law of the Republic of Belarus “On Sanitary and Epidemic Well-Being of the Population” of 23 November 1993 (in the version of 23.05.2000).
- 3 The Law of the Republic of Belarus “On Protection of Consumers’ Rights” of 9 January 2002.
- 4 The Law of the Republic of Belarus of 29 June 2003 “On Quality and Safety of Edible Raw Materials and Foodstuffs to Human Life and Health” (as amended and supplemented 5 July 2004)
- 5 The Law of the Republic of Belarus of 5 January 2004 “On Assessment of Compliance with Requirements of Technical Regulatory Legal Acts in the Field of Norm Setting and Standardization”.
- 6 Resolution No. 1807 of the Council of Ministers of the Republic of Belarus of 14 December 2001 “On Improving the State System of Hygienic Regulation and Registration of Chemical and Biological Substances, Materials and their Derivative Products, Products for Industrial and Technical Purposes, Products for Personal (Household) Purposes and Foodstuffs”.
- 7 Resolution No. 116 of 2 September 2003 by the Chief State Sanitary Physician of the Republic of Belarus “On the State Hygienic Regulation and Registration of Edible Raw Materials and Foodstuffs, Produced from Genetically Modified Sources”
- 8 Resolution No. 14/2 of 10 March 1993 of the Ministry of Health of the Republic of Belarus and the Committee for Standardization, Metrology and Certification of the Republic of Belarus “On Regulation of Control over Safety Factors of Edible Raw Materials and Foodstuffs”.
- 9 Sanitary Rules “Hygienic Requirements to Quality and Safety of Edible Raw Materials and Foodstuffs” (SanPiN 11 63 RB 98).

The requirements, stipulated by the Law, are aimed at preventing arrival of potentially hazardous foodstuffs. Mandatory coordination with the state sanitary surveillance bodies of new types and samples of foodstuffs, implementation of new technologies and equipment, new types of edible raw materials and foodstuffs is a pre-requisite for ensuring safety of foodstuffs at the planning stage of their production. Regulatory technical documents for edible raw materials,

⁶ The texts of the legislative acts in Russian are presented at the web-site of the National Co-ordination Biosafety Centre <http://biosafety.org.by/rus/legislation.html>

products, technological processes and equipment are also subject to approval. The Law guarantees people's right to receive objective information on the quality and safety of foodstuffs.

In order to prevent use of hazardous products in the Republic of Belarus, legislative and other regulatory legal acts provide for the state hygienic registration and regulation of the locally produced and imported chemical and biological substances, materials and their derivative products, which are potentially hazardous to human health, as well as of products intended for industrial and technical purposes and personal purposes, including foodstuffs.

For the purpose of further elaboration of the Law "On Sanitary and Epidemic Well-Being of the Population" there has recently been adopted the Law of the Republic of Belarus "On Quality and Safety of Edible Raw Materials and Foodstuffs to Human Life and Health" (hereinafter referred to as the Law on Quality of Foodstuffs), which details provisions and requirements to ensuring safety of nutrition. The quality and safety of edible raw materials and foodstuffs are ensured through: 1) the state regulation (technical norm setting and standardization, the state hygienic registration and regulation, the licensing of certain activities, certification, state control and surveillance); 2) implementation by legal entities and natural persons of organizational, agrochemical, veterinary, technological, sanitary, antiepidemic and phytosanitary measures on compliance with the requirements of the Republic of Belarus to edible raw materials and foodstuffs; 3) enforcement by legal entities and natural persons of the in-process control over the quality and safety of edible raw materials and foodstuffs, their manufacturing and circulation conditions and implementation of the quality control management systems; 4) application of measures on preventing and precluding violations of the legislation of the Republic of Belarus in the field of ensuring quality and safety of foodstuffs; 5) application of other measures aimed at ensuring quality and safety of foodstuffs.

The main state governing bodies, providing control over the safety of foodstuffs, include the Ministry of Health, the Ministry of Agriculture and Food, the Committee for Standardization, Metrology and Certification under the Council of Ministers of the Republic of Belarus and the Committee for State Control of the Republic of Belarus.

The above mentioned state authorities are also responsible for carrying out the monitoring of quality and safety of foodstuffs, which plays a fundamental part in determination of the main lines of the state policy in the field of ensuring quality and safety of edible raw materials and foodstuffs, protection of people's health and development of measures for prevention of the marketing of poor quality foodstuffs that are hazardous for human life and health.

The Law on Quality of Foodstuffs for the first time introduces the notion of "genetically modified edible raw materials and foodstuffs, derived by genetic engineering methods from genetically engineered organisms or with their use". Unfortunately, this definition is not tenable from the standpoint of either science or common sense. First, there are no special genetic engineering methods for producing edible raw materials or foodstuffs. Second, it does not apply to raw materials and foodstuffs, actually received from GEO, since they are produced by regular, traditional means. Third, it does not comply with the existing practice of regulating safety of foodstuffs derived from genetically modified sources in Western Europe and the USA. For instance, the EU legislation specifies that foodstuffs made with the use of genetically modified organisms do not require special regulation (see: Explanatory Memorandum (Scope) for "Proposal for a Regulation of the European Parliament and of the Council on Genetically Modified Food and Feed". Brussels, 2001).

As it has been noted above, the Law of the Republic of Belarus "On Sanitary and Epidemic Well-Being of the Population" guarantees the right to receive information on foodstuffs. The Law on Quality of Foodstuffs specifies concrete requirements to its contents. In particular, the information, quoted in cover documents, on the packaging should contain particulars of the regulatory documents, specifying quality and safety of edible raw materials or foodstuffs, on its nutritional and biological value, on presence of substance which may be harmful for the consumer's life and health, indications and contraindications, indication of the fact that the foodstuffs, raw materials and individual components have been derived from genetically modified sources (if this is the case), manufacturing date and shelf life, storage requirements, and information on the

consequences of non-compliance with the recommended actions if the product is used after the expiration of its shelf life.

Work on ascertaining compliance of the products (including food products) with the requirements stated by regulatory acts and concrete standards is performed in accordance with the Law of the Republic of Belarus “On Assessment of Compliance with Requirements of Technical Regulatory Legal Acts in the Field of Norm Setting and Standardization”. One of the primary goals of product certification is to ensure its safety to human life and health. For this purpose, the Law provides for carrying out mandatory certification for products, which are subject to safety requirements with regard to human life and health, specified in regulatory documents. It is illegal to market in the territory of the Republic of Belarus and import products, which are subject to mandatory certification, without a certificate of conformity, proving the compliance of the products with the specified requirements.

The consumer’s rights to purchase commodities of proper quality, which are safe to human life and health, and to receive information on the commodities and their manufacturers, are stated in the Law of the Republic of Belarus “On Protection of Consumers’ Rights”. Pursuant to this Law in the field of safety of food products the consumer has the right to purchase safe products and to receive full information on them (with regard to food products the requirements are in line with the provisions of the Law on Quality of Foodstuffs). In particular, according to Paragraph 2.4 of Article 5 of the Law on Protection of Consumers’ Rights, information on commodities (work or services) must contain, among other things, indication of the fact that the food product is genetically modified or that it contains genetically modified components. The information must be presented in the state languages of the country.

In order to control quality and safety to human life and health of substance and materials, used in the national economy and households, the State System of Hygienic Regulation and Registration of Chemical and Biological Substances, Materials and Products was established by the Council of Ministers of the Republic of Belarus in 1993. The state hygienic regulation and registration of products (chemical and biological substances, materials and products thereof, products for industrial and technical purposes, products for personal (household) purposes, and domestic or foreign-made foodstuffs) is implemented for the purpose of exposing the traits of the products, which may be hazardous to human life and health and assessing the compliance of the products with the requirements of sanitary rules, norms and hygienic standards, preventing adverse effects of the products on human health in the process of their manufacturing and use. All substances, materials and products, manufactured and used in the Republic of Belarus, including imported ones, are subject to registration and regulation. The state hygienic registration should be preceded by regulation, exercised on the basis of special research or the available data, which are sufficient for tenable scientific substantiation of permissible concentrations or levels of harmful substances in various environmental objects, including food products.

Coordination of the work, expert assessment of the results of toxicological and hygienic studies, responsibility for the quality and reliability of the findings, and performance of registration and regulation rests with the Ministry of Health. It is entitled to approve the list of chemical and biological substances, materials and products, which are subject to registration.

The Resolution No. 1807 of the Council of Ministers of the Republic of Belarus of 14 December 2001 “On Improving the State System of Hygienic Regulation and Registration of Chemical and Biological Substances, Materials and Products Thereof, Products for Industrial and Technical Purposes, Products for Personal (Household) Purposes and Foodstuffs” specified the scheme of performing registration and regulation, the procedure of carrying out laboratory trials and selection of samples of products for laboratory trials. With regard to a number of international agreements on mutual recognition of documents (hygienic certificates, conclusion, etc.), signed by the Republic of Belarus, the new resolution stated that the aforementioned documents are recognized in accordance with the international commitments of this country.

The currently effective Resolution No. 54 of the Chief State Sanitary Physician of the Republic of Belarus “On the Approval of the Regulations on the Procedure of Performing the State Hygienic Regulation and Registration of Chemical and Biological Substances, Materials and Products Thereof, Products for Industrial and Technical Purposes, Products for Personal

(Household) Purposes and Foodstuffs in the Territory of the Republic of Belarus and the List of Products, Which Are Subject to the State Hygienic Registration” was adopted 13 November 2000. In particular, the List of Products, Which are Subject to the State Hygienic Registration includes the following categories: fats, biologically active nutritional supplements, flavoring agents, food supplements, fish products and seafood, concentrated products, starter cultures, alcoholic and alcohol-free beverages, fruit and vegetable products, dairy and meat products, sugar and confectionery products, flour and cereals flour-and-cereals and pulse plant products, coffee, tea, mate and others (diet and special products). Thus, the list includes practically the full range of food products. Beside, all substances and materials that come in immediate contact with foodstuffs in the process of their preparation, production, transportation and consumption are also subject to the registration. However, pursuant to the Regulations, edible raw materials and food products with limited shelf life (less than 1 month) and/or requiring special storage conditions ($+6^{\circ}\text{C}$ and below) are exempt from the state hygienic regulation and registration. Control over the quality and safety of such products is exercised in the framework of regular sanitary surveillance by the relevant competent authorities.

September 2, 2003 the Chief State Sanitary Physician of the Republic of Belarus adopted the Resolution No. 116 “On the State Hygienic Regulation and Registration of Edible Raw Materials and Foodstuffs, Derived from or with the Use of Genetically Modified Sources”. Pursuant to this Resolution, starting from 1 January 2004 edible raw materials and foodstuffs and components (fragments) used for their manufacturing, derived from or with the use of genetically modified sources, if they contain 2% or more of the latter, must undergo mandatory state hygienic regulation and registration. The approved list of such edible raw materials and food products, which are subject to *mandatory* laboratory tests for presence of genetically modified sources (components), is presented in Table 6. It has been established, that this Resolution is not applicable to edible raw materials and food products derived from or with the use of genetically modified sources, which do not contain DNA or proteins.

Pursuant to the Resolution, the mandatory document, which gives the right to produce and market such raw materials and food products, is a certificate of their state hygienic registration. The institutions under the Ministry of Health of the Republic of Belarus, performing the state hygienic registration, are instructed to ensure their state hygienic regulation and registration. Until laboratory tests for presence of genetically modified sources (components) are organized, the certificates of the state hygienic registration are to be issued on the basis of the cover documents, provided by the manufacturer (applicant) of the products. The Resolution prohibits circulation of edible raw materials and foodstuffs, as well as components for their production, derived from or with the use of genetically modified sources with no proper labeling.

A large group of documents, providing regulatory and legal control over safety and quality of food products, consists of regulatory acts of national state governing bodies, which are responsible for prevention of threats to human health from poor quality and potentially hazardous foods, such as the Ministry of Health, the Ministry of Agriculture and Food, the Committee for Standardization, Metrology and Certification, etc.

Among the fundamental documents that aim at ensuring quality and safety of food products are Sanitary Rules “Hygienic Requirements to Quality and Safety of Edible Raw Materials and Foodstuffs” (SanPiN 11 63 RB 98), which prescribe hygienic norms for quality and safety of edible raw materials and food products and meals for people, as well as requirements for compliance with the prescribed norms in the process of handling food, which are the same for all products and raw materials, regardless of use or no use of genetically modified sources.

The state hygienic registration of edible raw materials and food products derived from or with the use of genetically modified sources, envisages only carrying out molecular and genetic analyses in order to identify fragments of transgenic DNA in raw materials and food products. The results of the analyses are used to label the above named raw materials and products with a view to indicate the content of components from genetically modified sources. The draft of the guidelines for medical and biological assessment of food, produced from genetically modified sources, has been prepared and is currently at the approval stage.

Table 6. List of edible raw materials and foodstuffs, which are subject to mandatory laboratory trials for presence of genetically modified sources (components) (Annex 1 to Resolution No. 116 of 02.09.2003 of the Chief State Sanitary Physician of the Republic of Belarus).

| Edible Raw Materials | Foodstuffs |
|---|--|
| Soya | <ol style="list-style-type: none"> 1. Soy beans 2. Soy sprouts 3. Concentrate of soy protein and its texturized forms 4. Isolate of soy protein 5. Hydrolizate of soy protein 6. Soy flour and its texturized forms 7. Milk substitute (soy milk) 8. Sublimated milk substitute (sublimated soy milk) 9. Canned soya 10. Boiled soy beans 11. Fried soy beans 12. Fried soy flour 13. Products received from or with the use of isolate of soy protein, concentrate of soy protein, hydrolizate of soy protein, soy flour, and sublimated soy milk. 14. Fermented soy products 15. Soy paste and products thereof 16. Soy sauce 17. Products received from or with the use of soy milk (tofu, fermented beverages, ice-cream, mayonnaise, etc.) |
| Corn | <ol style="list-style-type: none"> 1. Corn for immediate consumption (flour, cereal, etc.) 2. Frozen and canned corn 3. Popcorn 4. Corn chips 5. Mixed flour, containing corn flour |
| Potatoes | <ol style="list-style-type: none"> 1. Potatoes for immediate consumption 2. Prepared potato products 3. Sublimated mashed potatoes 4. Potato flakes 5. Potato chips 6. Potato crackers (prepared products) 7. Potato products, fried : <ul style="list-style-type: none"> - potato crisps - slices - French fries 8. Potato concentrate: <ul style="list-style-type: none"> - flour for pancakes - ravioli with potato filling (prepared products) - instant mashed potatoes 9. Potato products, quick cooking: <ul style="list-style-type: none"> - dried potatoes, fast restorable - dried potatoes, fast cooked 10. Canned potatoes 11. Molasses |
| Tomatoes | <ol style="list-style-type: none"> 1. Tomatoes for immediate consumption (natural, whole-canned) 2. Tomato paste 3. Mashed tomatoes 4. Tomato juice, beverages 5. Tomato sauces, ketchups |
| Marrows | <ol style="list-style-type: none"> 1. Natural marrows 2. Products made from or with marrows |
| Melon | <ol style="list-style-type: none"> 1. Natural melon 2. Products made from or with melon |
| Papaya | <ol style="list-style-type: none"> 1. Natural papaya 2. Products made from or with papaya |
| Chicory | Products, containing chicory |
| Dietary supplements | Produce from or with the use of genetically modified sources |
| Biologically active dietary supplements | Produce from or with the use of genetically modified sources |
| Food products for children, healthful and dietary meals | Produce from or with the use of genetically modified sources |

Besides those described above, the range of documents, which are currently effective in the territory of the Republic, includes 41 regulatory and methodological documents regulating requirements to enterprises of the food processing industry (technological process and raw materials) and 11 documents on compliance with the sanitary and epidemic conditions at enterprises, which sell food products. The general methods of inspection and analysis of food

products, technical specifications of their manufacturing and quality requirements are contained in over 200 Standards of Belarus, 1,000 National Standards (GOSTs) and Technical Specifications.

4.4.2. Directions of legislation improvement in the field of safety and quality of edible raw materials and foodstuffs in the Republic of Belarus

The system of ensuring quality and safety of edible raw materials and foodstuffs, which currently exists in the Republic of Belarus, generally meets modern requirements. However, its provisions related to raw materials and food products, received from genetically engineered organisms, call for further improvement. In particular, due to the adoption of the Law of the Republic of Belarus “On Safety in Genetic Engineering Activities” it will be necessary to revise the definition of “genetically modified edible raw materials and foodstuffs”, which is contained in the effective Law of the Republic of Belarus “On Quality and Safety of Edible Raw Materials and Foodstuffs to Human Life and Health”.

In the process of implementing the Resolution No. 116 of the Chief State Sanitary Physician of the Republic of Belarus “On the State Hygienic Regulation and Registration of Edible Raw Materials and Foodstuffs, Derived from or with the Use of Genetically Modified Sources” it has become evident that it is impossible to fully implement paragraph 6, which regards mandatory laboratory testing of an extensive list of raw materials and food products for presence of genetically modified sources (components). Since these tests have no relation to safety of raw materials and food products and pertain to the field of consumers’ right to receiving information, this norm should be revised towards replacing total control over the raw materials and food products, which are on the list, with random control.

4.5. Legislation of the Republic of Belarus regulating import and export of genetically engineered organisms

4.5.1. Current legislation of the Republic of Belarus regulating import and export of genetically engineered organisms

The list of legislative acts of the Republic of Belarus regulating import, export and transit of genetically engineered organisms is presented in Table 7.

From the standpoint of legal regulations, living organisms are movable assets and are regarded as commodities in accordance with the provisions of the Civil Code of the Republic of Belarus of 7 December 1998 and Article 18 of the Customs Code of the Republic of Belarus of 6 January 1998 (as amended and supplemented). In the latter regulatory legal act, import and export are defined as actual transfer of commodities through the customs frontier of the Republic of Belarus.

Pursuant to Article 19 of the Customs Code, all persons are on the equal basis legally entitled to import and export commodities; restrictions of the implementation of this fundamental principle may be stated in this Code or in other legislative acts of the Republic of Belarus. In particular, import and export of certain commodities may be prohibited “for the purpose of ensuring the state security ... human life and health, protection of animals and plants, protection of the environment ... of the Republic of Belarus and foreign countries, protection of the property right, including the intellectual property right, protection of the interests of Belarusian consumers, imported commodities and proceeding from other interests of the Republic of Belarus on the basis of legislative acts of the Republic of Belarus and international agreements of the Republic of Belarus”. In their turn, restrictions of import and export of commodities may be imposed for the purpose of compliance with international commitments of the Republic of Belarus and for other reasons of sufficient importance in accordance with the legislation of the Republic of Belarus and international agreements of the Republic of Belarus.

On the other hand, pursuant to Article 133 of the Customs Code, when live animals, perishable commodities... and other similar commodities are imported or exported, they undergo a simplified procedure of customs clearance and are subject to preferential treatment. The cases and conditions of application of a simplified procedure of customs clearance are specified by the State Customs Committee of the Republic of Belarus.

Thus, the Customs Code secures the principle of freedom of exports and imports, including

those of living organisms, and bans for and restrictions of implementation of such activities are stated in other acts of the customs legislation and in another special legislation.

Table 7. List of legislative acts of the Republic of Belarus regulating imports, exports and transits of genetically engineered organisms⁷

- 1 The Customs Code of the Republic of Belarus of 6 January 1998
- 2 The Law of the Republic of Belarus “On Veterinary Medicine” of 2 December 1994
- 3 The Law of the Republic of Belarus “On Seeds” of 14 February 1997
- 4 The Law of the Republic of Belarus of 9 November 1999 “On Ratification of the Protocol on the Unified Procedure of Application of Technical, Medical, Pharmaceutical, Sanitary, Veterinary, Phytosanitary and Environmental Standards, Norms, Rules and Requirements with Regard to Commodities Imported into the States Parties to the Agreement on Customs Union”.
- 5 The Law of the Republic of Belarus of 6 May 2002 “On Accession of the Republic of Belarus to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity”
- 6 The Law of the Republic of Belarus “On Safety of Genetic Engineering Activities”(the draft law adopted in the first reading by the Chamber of Representatives of the National Assembly of the Republic of Belarus 29 April 2004).
- 7 Regulations on Quarantine of Plants of the Republic of Belarus. Approved by the Resolution of the Council of Ministers of the Republic of Belarus of 29 July 1993 “On Measures for Improvement of Quarantine of Plants in the Republic of Belarus”.
- 8 The Resolution of the Council of Ministers of the Republic of Belarus of 18 March 1997 “On Establishment of Bans for and Restrictions of Transfer of Items through the Customs Frontier of the Republic of Belarus” (as amended and supplemented 21 April 2000).
- 9 Resolution No. 734 of the Council of Ministers of the Republic of Belarus of 5 June 2002 “On Measures for Implementing Provisions of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity”
- 10 The Resolution of the State Customs Committee of the Republic of Belarus and the Ministry of Agriculture and Food of the Republic of Belarus of 5 July 2002 “On Conditions of Customs Regulations for the Categories of Goods, Which are Subject to Control by the Belarusian State Inspectorate for Quarantine of Plants”.
- 11 The Resolution of the Ministry of Agriculture and Food of the Republic of Belarus of 27 November 2001 “On Approval of the Regulations on the Procedure of Import into and Export from the Republic of Belarus of Seeds”.
- 12 Veterinary and Sanitary rules of Import into the Republic of Shipments of Animal Origin and Fodder (the Resolution of the Ministry of Agriculture and Food of the Republic of Belarus of 31 July 2002).
- 13 Regulations on the Procedure of Issuing Permits for Import into the Republic of Belarus or Transit through its Territory of Genetically Engineered Organisms (the draft document has been developed in the process of implementing the UNEP–GEF project).

The Resolution of the Council of Ministers of the Republic of Belarus of 18 March 1997 “On Establishment of Bans for and Restrictions of Transfer of Items through the Customs Frontier of the Republic of Belarus” (as amended and supplemented) approved a list of items, which are prohibited for transfer through the customs frontier of the Republic of Belarus. The items belong to the category of those prohibited for transfer through the customs frontier of the Republic of Belarus or restricted for transfer through the customs frontier of the Republic of Belarus only after they have been included into the relevant list, approved by the aforementioned Resolution. The list of items, prohibited for transfer through the customs frontier of the Republic of Belarus encompasses plants and animals of the species, which are included in the Red Book of the Republic of Belarus, as well as their parts and derivatives (with the exception of those that have been cultivated or grown in captivity). The list of items, restricted for transfer through the customs frontier of the Republic of Belarus encompasses plants and animals, their parts and derivative, which fall under the Convention

⁷ The texts of the legislative acts in Russian are presented at the web-site of the National Co-ordination Biosafety Centre <http://biosafety.org.by/rus/legislation.html>

on International Trade in Endangered Species of Wild Fauna and Flora.

Certain legal restrictions and bans have also been formulated with regard to import and export of seeds and farm livestock. For instance, the Law of the Republic of Belarus “On Seeds” of 14 February 1997 deals with special rules of export and import of seeds, pursuant to which seeds may be imported into the Republic of Belarus from other countries on condition that the State Quarantine Inspectorate of the Republic of Belarus has granted a permit for their import into the territory of the Republic; the seeds have a phytosanitary certificate, issued by the state bodies for quarantine of plants of the country of export; the seeds belong to the variety, which has undergone the state crop variety trials and has been included in the State Register of Varieties of Plants and Woods and Shrub Species or recognized as having potential.

The seeds of varieties, which have not been included in the State Register of Varieties of Plants and Woods and Shrub Species or have been recognized as unpromising, may be imported into the Republic of Belarus from other countries only for the purpose of research work, state crop variety testing and exhibition; if their proliferation is envisaged under an international agreement for the purpose of marketing outside of the Republic of Belarus; if a special resolution has been passed with regard to this crop variety or woods and shrub species by a relevant ministry or another national state governing body, which has the competency to deal with the issues of production, harvesting, circulation, and use of seeds.

Export of seeds is exercised in accordance with another legislation of the Republic of Belarus. Along with that, the seed imported into or exported from the territory of the Republic of Belarus for the purpose of research and state crop variety trials are exempt from customs duties, customs levies and taxes. Control over the import (export) of seeds is enforced by the Main Department for Crop Products, the Belarusian State Inspectorate for Quarantine of Plants (the BelGosKarantin), the State Inspectorate for Seeds pursuant to the Law of the Republic of Belarus “On Seeds”, Regulations on Quarantine of Plants of the Republic of Belarus, approved by the Resolution of the Council of Ministers of the Republic of Belarus of 29 July 1993 “On Measures for Improvement of Quarantine of Plants in the Republic of Belarus”, and the Resolution of the Ministry of Agriculture and Food of the Republic of Belarus of 27 November 2001 “On Approval of the Regulations on the Procedure of Import into and Export from the Republic of Belarus of Seeds”.

On the basis of the Law of the Republic of Belarus “On Veterinary Medicine” of 2 December 1994 the Resolution of the Ministry of Agriculture and Food of the Republic of Belarus of 31 July 2002 approved Veterinary and Sanitary rules of Import into the Republic of Shipments of Animal Origin and Fodder. They lay out special conditions for import of the listed items, including such living organisms as farm livestock, domestic animals, zoo and circus animals, as well as fur-bearing animals, birds, fish, bees and other faunal forms, in the territory of the Republic, requirements to the organization of quarantine, containers and packaging, the contents of certificates and other cover documents; regulate the procedure and conditions of issue of the permit for import of commodities to the importer by the Main Veterinary Department of the Ministry of Agriculture and Food of the Republic of Belarus. It is specially noted that the inspection control over the possibility of supplying the listed commodities to the Republic of Belarus is exercised by the Main Veterinary Department of the Ministry of Agriculture and Food of the Republic of Belarus.

Paragraph 315 of the Veterinary and Sanitary Rules contains a mandatory provision, under which fodder of vegetable origin, imported into the Republic of Belarus (fodder grain, soy beans, tapioca, and peanut and soy solvent cakes) “must not contain *crude materials, produced by genetic engineering methods or other genetically modified sources*”.

Over the past decade the import of foodstuffs into the Republic has dramatically grown. The findings of laboratory research testify to the fact, that in some cases concentrations of hazardous substances (mycotoxins, nitrates, microorganisms, etc.) in the imported foodstuffs exceed permissible limits. It was one of the reasons for ratifying the Protocol on the Unified Procedure of Application of Technical, Medical, Pharmaceutical, Sanitary, Veterinary, Phytosanitary and Environmental Standards, Norms, Rules and Requirements with Regard to Commodities Imported into the States Parties to the Agreement on Customs Union”. The Protocol establishes standard requirements to the application of standards, norms and rules in the field of import of commodities as a measure fostering protection of the life and health of citizens and the environments. The unified

procedure of application of the standards and requirements extends to both imported and exported commodities. The Law specifies the list of ministries and agencies, which shall be responsible for precluding imports of poor quality commodities, including food products. Pursuant to the Law, the national requirements to the procedure of import and circulation of commodities, which are subject to the mandatory standardization and hygienic registration, shall be applicable to the products, imported from the states, which are not parties to the Agreement of the Customs Area. The list of commodities, which are subject to the mandatory standardization and hygienic registration, the state sanitary surveillance, veterinary and phytosanitary control, includes a range of food products, crude materials for their production, dietary supplements, equipment use for production, preparation and consumption of food products, and other materials and substance which come in contact with food products (packaging, containers, etc.) and is sufficiently broad and well-grounded to ensure safety to human health.

A prerequisite for import of food products, as well as crude materials for their production and contacting materials is availability of documents confirming their safety to health, issued by the state sanitary surveillance bodies and of information on the origin of the product (with regard to genetically modified raw and processed food products). However, the Law envisages implementation of additional state control (expertise, testing, etc.), where appropriate. The Law prohibits import of commodities that do not meet the requirements, which are effective in the territory of this country. The commodities, which are prohibited for import by the state surveillance bodies, shall be immediately removed off the territory of the State.

In this context, the legal norms of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, which was ratified by Belarus in 2002, providing for a mandatory advance informed agreement procedure prior to the first intentional transboundary movement of genetically engineered organisms, intended for intentional introduction into the environment of the Party of import, are of vital importance for securing biosafety.

4.5.2. Directions of legislation improvement in the field of biosafety of imports and exports of genetically engineered organisms in the Republic of Belarus

Pursuant to the Draft Law of the Republic of Belarus “On Safety of Genetic Engineering Activities”, import into the Republic of Belarus of non-pathogenic genetically engineered organisms designed for release into the environment for trials shall be allowed if there is a permit for import and release of genetically engineered organisms into the environment for trials, issued according to Article 17 of this Law. As it has been previously noted, it is intended to release non-pathogenic genetically engineered organisms into the environment for trials if and only if there is a permit for release of genetically engineered organisms into the environment for trials, issued by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus.

Import into the Republic of Belarus of non-pathogenic genetically engineered organisms intended for economic activities shall be allowed if there is a state registration certificate for genetically engineered varieties of plants, breeds of animals and strains of microorganisms, issued according to Article 18 of this Law (“Genetically engineered varieties of plants, breeds of animals and strains of microorganisms, including those imported into the Republic of Belarus, can be used for economic activities only after their state registration by the Ministry of Agriculture and Food of the Republic of Belarus or the Ministry of Health of the Republic of Belarus in conformity with their competence according to the procedure established by the Council of Ministers of the Republic of Belarus. State registration shall be made after performance of state expertise of safety of genetic engineering activities and when positive results of testing of genetically engineered organisms released into the environment are obtained”).

Transit through the territory of the Republic of Belarus of non-pathogenic genetically engineered organisms shall be allowed after the carrier notifies the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus.

Import into the Republic of Belarus and transit through its territory of opportunistic pathogenic and pathogenic genetically engineered organisms shall be allowed exclusively for scientific research if there is a permit for import, issued by the Ministry of Health of the Republic of Belarus according to the procedure specified by the Council of Ministers of the Republic of Belarus.

In case of unauthorized import of genetically engineered organisms, the person who imports them shall remove them from the territory of the Republic of Belarus according to the customs legislation.

Export from the Republic of Belarus of genetically engineered organisms shall be allowed if there is a permit for export issued by a specially authorized body of the country of destination according to international agreements of the Republic of Belarus. Export from the Republic of Belarus of opportunistic pathogenic and pathogenic genetically engineered organisms shall be allowed if there is a permit for import issued by a specially authorized body of the country of destination according to international agreements of the Republic of Belarus and if there is a permit for export issued according to the procedure specified by the Ministry of Health of the Republic of Belarus.

Description of the procedure of receiving the above mentioned permits is contained in the draft of “Regulations of the Procedure of Issuing Permits for Import into the Republic of Belarus or Transit through its Territory of Genetically Engineered Organisms”, which has been developed in the process of implementing the UNEP–GEF project.

5. System of state governing bodies in the field of biosafety

5.1. Existing administrative system of the Republic of Belarus in the field of biosafety

The system of state governing bodies in the field of biosafety is currently in the process of development.

Pursuant to the Resolution of the Council of Ministers of the Republic of Belarus of 5 June 2002 “On Measures for Implementation of the Provisions of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity”, the Ministry of Natural Resources and Environmental Protection (in the part of the functions related to release of living modified organisms into the environment) and the Ministries of Health and Agriculture and Food (for the issues of using living modified organisms in economic activities) were designated as competent authorities for complying with the international obligations of this country under the Cartagena Protocol.

The Institute of Genetics and Cytology of the NAS of Belarus, which earlier performed the functions of the National Co-ordination Biosafety Centre, was designated as the national focal point, responsible for liaison with the Secretariat of the Cartagena Protocol. (Fig. 1)

The National Co-ordination Biosafety Centre has been created in accordance with the Resolution of the Council of Ministers of the Republic of Belarus No 963 of 19 June 1998 “for the purpose of ensuring effective participation of the Republic of Belarus in conservation of biological diversity and providing nation-wide coordination of the activities in the framework of the Convention on Biological Diversity, adopted in Rio-de-Janeiro 5 June 1992 and regarding the issues of the safe use of the achievements of modern biotechnology”. Its main tasks have been specified as following:

- to collect, analyze and systematize information on legislation and research in the field of biosafety, field trials of genetically engineered organisms, import (export) and commercial use in Belarus of genetically engineered organisms and products made on their basis, as well as the above mentioned information on biosafety from databases of international information networks, and to create a national biosafety database;
- to provide information on biosafety issues to the concerned ministries and other national state governing bodies and mass media;
- to share information with biosafety focal points of other countries and international organizations;
- to organize scientific expertise of the safety of genetically engineered organisms and products of genetically engineered organism origin, which are intended for use in the territory of the Republic of Belarus;
- to provide advisory support to the ministries and other national governing bodies in the drafting of legislative acts, dealing with imports (exports) and safe use of genetically engineered organisms and products of genetically engineered organism origin, guidelines

for assessment and prevention of risks to human and environmental health, and occupational safety guidelines for genetic engineering laboratories;

- to provide advisory support to the ministries and other national governing bodies in the preparation of proposals on conclusion of bilateral and regional agreements and in the development of international agreements on biosafety issues.

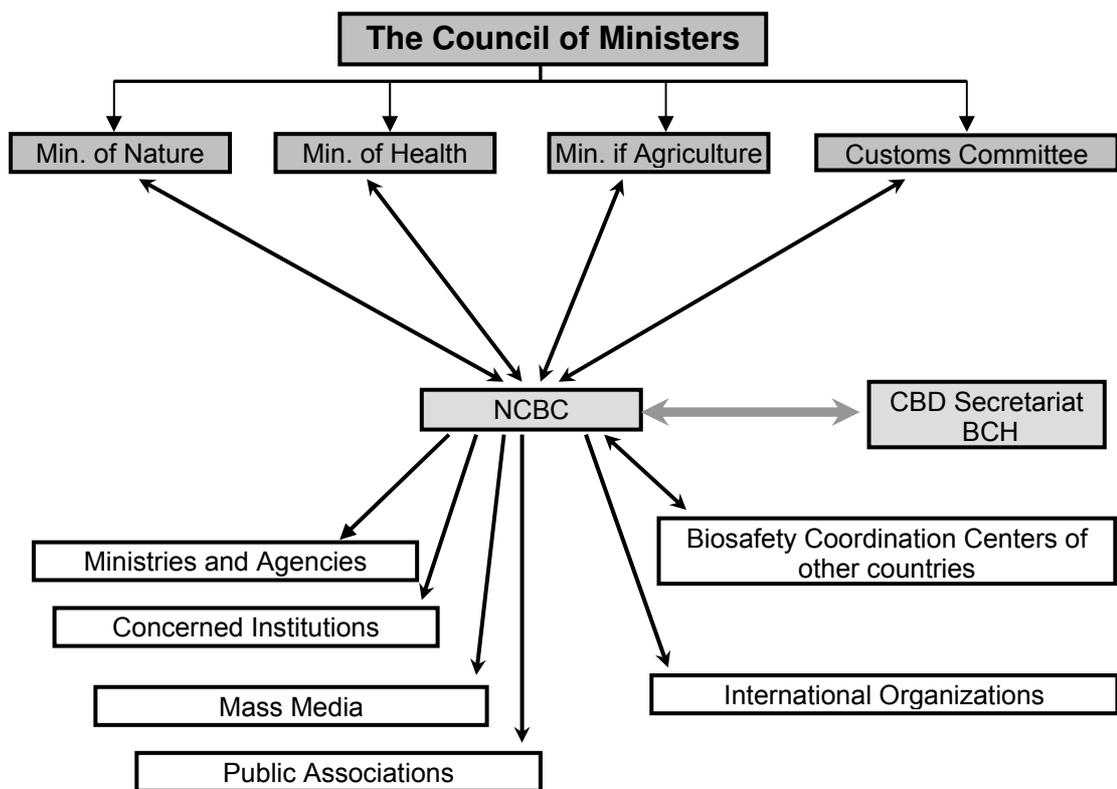


Figure 1. Structure of the administrative biosafety system of the Republic of Belarus.
 Min. of Nat. Res. – Ministry of Natural Resources and Environmental Protection of the Republic of Belarus;
 Min. of Health – Ministry of Health of the Republic of Belarus;
 Min. of Agriculture – Ministry of Agriculture and Food of the Republic of Belarus;
 Customs Committee – State Customs Committee of the Republic of Belarus;
 NCBC – National Co-ordination Biosafety Centre;
 CBD Secretariat - Secretariat of the Convention on Biological Diversity;
 BCH- Biosafety Clearing-House

5.2. Specific features of development of the administrative system of biosafety in the Republic of Belarus

Formation of the national biosafety system of the Republic of Belarus does not envisage establishment of a new state governing body the competence of which would encompass the whole range of issues related to this field. According to the Draft Law of the Republic of Belarus “On Safety in Genetic Engineering Activities”, state governing in the field of safety of genetic engineering activities is exercised by the President of the Republic of Belarus, the Council of Ministers of the Republic of Belarus, as well as special authorized national state governing bodies in the field of safety of genetic engineering activities: the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus, the Ministry of Health of the Republic of Belarus, the Ministry of Agriculture and Food of the Republic of Belarus and their territorial bodies.

The Government of the Republic of Belarus shall have the following powers in the field of regulating genetic engineering activities:

- adopt regulatory and legal acts in the field of safety of genetic engineering activities;
- determine the procedure of issuing permits for import into the Republic of Belarus, export out of the Republic of Belarus or transit through its territory of genetically engineered organisms, as well as permits for release of genetically engineered organisms into the environment for trials;

- approve regulations on the procedure of organization and performance of state expertise on safety of genetically engineered organisms;
- approve regulations on the State Register of Experts in the field of safety of genetic engineering activities;
- determine legal status and procedure of operations of the National Co-ordination Biosafety Centre;
- determine the procedure of state registration of genetically engineered varieties of plants, breeds of animals and strains of microorganisms;
- determine the procedure of issuing permits for import into the Republic of Belarus or transit through its territory of genetically engineered organisms;
- determine the procedure of state control in the field of safety of genetic engineering activities.

Under the legislation, the Government may exercise other powers.

The Ministry of Natural Resources and Environmental Protection of the Republic of Belarus shall have the right to:

- adopt regulatory and legal acts and technical regulatory acts in the field of safety of genetic engineering activities related to release of genetically engineered organisms into the environment for trials;
- issue, according to the specified procedure, permits for release of non-pathogenic genetically engineered organisms into the environment for trials;
- establish safety requirements for sites for trials of genetically engineered organisms in coordination with the National Academy of Sciences of Belarus;
- determine the procedure of the trials of genetically engineered organisms released into the environment;
- establish the procedure for risk assessment of potential adverse impacts of genetically engineered organisms on the environment;
- issue, according to the specified procedure, permits for import into the Republic of Belarus and release into the environment for trials of non-pathogenic genetically engineered organisms;
- establish safety requirements for contained use for performing genetic engineering activities of the first risk level;
- exercise state control in the field of safety of genetic engineering activities within its competence; and
- exercise other powers according to the legislation.

The Ministry of Health of the Republic of Belarus within its competence shall:

- adopt regulatory and legal acts and technical regulatory acts in the field of safety of genetic engineering activities of the second, third and fourth risk levels, performed for contained use;
- issue, according to the specified procedure, permits for implementing genetic engineering activities of the second, third and fourth risk levels, exercised in contained use;
- issue, according to the specified procedure, permits for import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of opportunistic pathogenic and pathogenic genetically engineered organisms;
- establish safety requirements to transportation of opportunistic pathogenic and pathogenic genetically engineered organisms;
- establish procedure of risk assessment of potential adverse effects of genetically engineered organisms on human health;
- exercise state registration of genetically engineered strains of microorganisms;
- exercise state control in the field of safety of genetic engineering activities and exercise other powers according to the legislation.

The authorities of the Ministry of Agriculture and Food of the Republic of Belarus shall encompass the following:

- adopting regulatory and legal acts and technical regulatory acts in the field of safety of genetic engineering activities involving use of genetically engineered organisms in economic activities;
- exercising state registration of genetically engineered varieties of plants, breeds of animals and strains of microorganisms;
- exercising state control in the field of safety of genetic engineering activities and exercising other powers according to the legislation.

6. System of state expertise of the safety of genetic engineering activities

6.1. Current situation

In accordance with the Resolution of the Council of Ministers of the Republic of Belarus of 19 June 1998 “On Establishment of the National Co-ordination Biosafety Centre”, one of the functions of the coordination biosafety Centre is “organization of scientific expertise of the safety of genetically engineered organisms and products made on their basis, which are intended for use in the territory of the Republic of Belarus”.

The first official trials of genetically engineered organisms in Belarus, involving their release into the environment, took place in 1999. On request of the company AgrEvo (Germany) the Institute of Genetics & Cytology of the National Academy of Sciences of Belarus carried out scientific expertise of the safety of a transgenic variety of sugar beet, resistant to the herbicide Ammonia Glufosinate. For assessment of risks to human and environmental health the experts of the Institute applied the technique, adopted in the EU countries. On the basis of their conclusion of the safety of this transgenic variety to human and environmental health, the Ministry of Natural Resources issued a permit for its import and testing.

6.2. Directions of improving and development of the system of state expertise of the safety of genetic engineering activities

In accordance with Article 22 of the Draft Law of the Republic of Belarus “On Safety in Genetic Engineering Activities” state expertise of safety of genetic engineering organisms (hereinafter called expertise) shall be made for the purpose of their identification, determination of probability of potential adverse effects of genetically engineered organisms on human health and the environment, as well as determination of admissibility of their release into the environment or use in economic activities.

State expertise of safety of genetically engineered organisms is performed in case of:

- the first release of genetically engineered organisms into the environment for trials;
- state registration of genetically engineered varieties of plants, breeds of animals and strains of microorganisms intended for use in economic activities.

The objects of the first-time release of genetically engineered organisms into the environment, which requires a permit from the Ministry of Natural Resources and Environmental Protection, may be the following:

1. individual breeding samples (primary transformants or their progeny), which are released into the environment in the testing site conditions (controlled release) for the purpose of testing their breeding value and biosafety and selecting the best genotypes;
2. genetically engineered varieties of foreign breeding, which are released into the environment in the context of the state variety trials (planned release) for their further state registration and use in economic activities.

In the course of the state expertise conducted as part of the first time release of genetically engineered organisms into the environment the main attention is paid to the assessment of the environmental safety of the released organisms. When breeding samples are tested, we deal with at least hundreds of genotypes, the overwhelming majority of which will be rejected upon the testing results.

The aspects of the safety of genetically engineered organisms to human health become the focus of attention of the state expertise of biosafety in the process of the state registration of genetically engineered varieties. On the one hand, at this stage it becomes topical whether it is permissible to use a particular genetically engineered variety in economic activities, since it has successfully undergone the state variety trials. On the other hand, a concrete genetically engineered variety can be thoroughly studied in relation with its safety to human health, by its essential equivalence parameters as well, while it can hardly be done in case of dozens and hundreds of genotypes.

State expertise shall be organized by expert councils on safety of genetically engineered organisms (hereinafter called expert councils) which shall be set by specially authorized national state governing bodies in the field of safety in genetic engineering activities. The expert council for the assessment of the biosafety of genetically engineered organisms at their first-time release into the environment is formed by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus. The expert council for the assessment of the biosafety of genetically engineered organisms intended for use in economic activities is formed by the Ministry of Health of the Republic of Belarus. Expert councils are formed from officials of state governing bodies in the field of safety in genetic engineering activities and leading experts in the field of biosafety. The composition of the expert councils shall be approved by the relevant national state governing authorities.

When preparing the Draft Law of the Republic of Belarus “On Safety in Genetic Engineering Activities” for the second reading at the Parliament, it is possible that establishment of a single inter-agency expert council – under the Ministry of Natural Resources and Environmental Protection – will be envisaged. The functions of this council will encompass organization of the two above described types of expertise.

For performing expertise, relevant special national state governing authorities in the field of safety in genetic engineering activities shall appoint state experts, on recommendation of expert councils. The state experts may be relevant leading research organizations of the Republic of Belarus, scientists and specialists which are nationals of the Republic of Belarus and are included into the register of state experts. The experts may not be interested persons, including employees of the legal entity which submitted an application for performance of expertise to the specially authorized national state governing body in the field of safety in genetic engineering activities. The state expert is personally liable for timely, objective and competent performance of expertise according to legislation.

In the process of implementing the UNEP–GEF project, the National Co-ordination Biosafety Centre requested a number of ministries and research institutes to provide their proposals on candidates and organizations, which can be included in the State Register of Biosafety Experts. The results of the performed work are presented at the web-site (<http://biosafety.org.by/rus/experts.html>). They can make a basis for compiling the official State Register of Biosafety Experts after the Law of the Republic of Belarus “On Safety in Genetic Engineering Activities” will come into force.

Upon the expertise results the state experts shall prepare a statement containing unambiguous conclusions on admissibility of release of concrete genotypes of genetically engineered organisms into the environment or their use in economic activities. Positive conclusion of the state experts shall be the ground for issuing a permit for release of genetically engineered organisms into the environment for trials, as well as for issuing a state registration certificate for genetically engineered varieties of plants, breeds of animals and strains of microorganisms.

The conclusion of the state experts shall be reviewed at a session of the expert council. Upon the results of the review of the state experts’ conclusion the expert council shall recommend to the relevant state governing authority to issue (not to issue) a permit for release of genetically engineered organisms into the environment for trials, issue (not to issue) a state registration certificate for genetically engineered varieties of plants, breeds of animals and strains of microorganisms or to perform a new expertise.

The procedure of organization and performance of expertise shall be determined by the Council of Ministers of the Republic of Belarus. The draft of “Regulations on Procedure of Organization and Performing State Expertise of the Safety of Genetically Engineered Organisms”

has been developed in the process of implementing the UNEP–GEF project (<http://biosafety.org.by/rus/legislation.html>).

After adoption of the Law of the Republic of Belarus “On Safety in Genetic Engineering Activities” significant efforts should be focused on to improving the educational level and special training of biosafety experts and upgrading material and methodological resources. For solving the former of the named tasks, the documents, developed in the process of implementing the UNEP-GEF project – “Methodological Guidelines for Risk Assessment of Genetic Engineering Activities” and a collective monograph “Biotechnology. Biosafety. Bioethics”, (Ed. A.P. Yermishin) – can be very useful.

7. Control and monitoring system in the field of safety in genetic engineering activities in the Republic of Belarus

7.1. Current situation

In accordance with the Draft Law of the Republic of Belarus “On Safety in Genetic Engineering Activities”, state control in this field is exercised, within their scope of competence, by the specially authorized national state governing bodies in the field of safety in genetic engineering activities: the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus, the Ministry of Health of the Republic of Belarus, the Ministry of Agriculture and Food of the Republic of Belarus and their territorial bodies and officials according to the procedure, specified by the Council of Ministers of the Republic of Belarus.

National state governing authorities, their territorial bodies and officials who are authorized to exercise state control in the field of safety of genetic engineering activities shall have the right, within their competence, to:

- issue mandatory instructions on correction of violations of legislation in the field of safety in genetic engineering activities, causes of such violations and contributory conditions;
- file lawsuits on indemnification for damage caused as a result of genetic engineering activities;
- take, according to the procedure established by legislation, decisions on restriction or suspension of genetic engineering activities exercised with violations of their safety requirements;
- exercise other rights according to the legislation.

Departmental control in the field of safety in genetic engineering activities shall be exercised by state authorities or organizations for ensuring the fulfillment by subordinate organizations of the requirements of legislation in the field of safety in genetic engineering activities and environmental protection.

The procedure of exercising departmental control in the field of safety in genetic engineering activities shall be specified by state governing authorities or organizations exercising such control in their subordinate organizations as agreed with the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus (for genetic engineering activities of the first risk level) and the Ministry of Health of the Republic of Belarus (for genetic engineering activities of the second, third and fourth risk levels).

Legal entities and individual entrepreneurs exercising genetic engineering activities shall organize and exercise in-process control for verification of compliance with requirements to safety of genetic engineering activities, as well as compliance with sanitary norms, rules, hygienic principles and environmental protection requirements.

The procedure of exercising in-process control in the field of safety in genetic engineering activities shall be specified by legal entities and individual entrepreneurs exercising genetic engineering activities, as agreed with the respective territorial bodies of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus (for genetic engineering activities of the first risk level), and of the Ministry of Health of the Republic of Belarus (for genetic engineering activities of the second, third and fourth risk levels).

Social control in the field of safety in genetic engineering activities shall be exercised by citizenry and public associations according to legislation.

The above mentioned state governing bodies are obliged to perform monitoring of effects of using genetically engineered organisms for economic activities within their competence.

Pursuant to the Draft Law of the Republic of Belarus “On Safety in Genetic Engineering Activities”, accounting of genetically engineered organisms and state statistical reports in the field of genetic engineering activities, as well as determination of potential impact of genetic engineering activities on human and environmental health shall be performed by legal entities and individual entrepreneurs dealing with genetic engineering activities, according to the procedure established by the Ministry of Statistics and Analysis of the Republic of Belarus as agreed with the Ministry of Health of the Republic of Belarus, the Ministry of Agriculture and Food of the Republic of Belarus, the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus and the National Academy of Science of Belarus. In the process of formation of the national biosafety system the procedure and reporting forms should be developed.

The Draft Law of the Republic of Belarus “On Safety in Genetic Engineering Activities” contains a list of violations of legislation in this field. Offences in the field of safety in genetic engineering activities shall include:

- violation of requirements to safety in genetic engineering activities;
- implementation by legal entities and individual entrepreneurs of economic activities without state registration certificates for genetically engineered varieties of plants, breeds of animals and strains of microorganisms;
- submission for state expertise of safety of genetically engineered organisms and for state registration of genetically engineered organisms, of documents containing knowingly false information about safety of genetically engineered organisms;
- failure to fulfill instructions of specially authorized national state governing bodies in the field of safety in genetic engineering activities, and of their territorial bodies and officials, for correction of identified violations of legislation on safety in genetic engineering activities;
- import in the Republic of Belarus, export from the Republic of Belarus, and transit through its territory of genetically engineered organisms, as well as their release into the environment without a proper permit;
- issue by officials of specially authorized national state governing body of permits for implementation of genetic engineering activities, permits for release of genetically engineered organisms into the environment for trials, as well as of state registration certificates for genetically engineered varieties of plants, breeds of animals and strains of microorganisms without positive conclusion of the state expertise of the safety of genetic engineering activities;
- performance by state experts of the state expertise of the safety of genetically engineered organisms in contravention of the legislation.

Legislative acts may also stipulate other offences in the field of safety in genetic engineering activities. The objective is to develop penalties for committed offences in the field of safety in genetic engineering activities and to include them in the existing legislation.

It should be noted that Belarus currently lacks functioning systems of control and monitoring, accounting and reporting, and prosecution for committed offences in the field of biosafety. There is no experience of solving particular problems in this field either.

Within the system of the Ministry of Health there have been founded two laboratories for identification of transgenic components in the DNA of raw and processed food products with the purpose of ensuring compliance with the legislation in the field of labeling GM-products and raw materials. Premises have been allocated, equipment has been purchased, and the personnel have undergone training in the relevant techniques. At present the efforts are aimed the official accreditation of the laboratories and certification of the techniques within the system of the State Standard (Committee for State Standards) of the Republic of Belarus. It is expected to create a few more such laboratories, under the National Academy of Sciences as well.

7.2. Objectives of the Republic of Belarus in the field of biosafety control and monitoring

After the Law of the Republic of Belarus “On Safety in Genetic Engineering Activities” enters into force, a significant amount of work will have to be done on establishment of relevant administrative bodies, adoption of subordinate regulatory legal acts, and on improvement of the educational level of biosafety experts.

8. Mechanism of promoting public awareness and public participation in the decision making process in the field of safety in genetic engineering activities

8.1. Current situation

The society will derive the maximum benefit through the use of the achievements of modern biotechnology if its every member is confident that the State is capable of ensuring the safety in genetic engineering activities.

With regard to this the legislation of the Republic of Belarus secures citizens’ right to receive information and the right to public participation in the decision making process. The aforementioned norms are included in a number of international agreements, ratified by the Republic of Belarus, in particular in the Cartagena Protocol on Biosafety (Article 23):

“1. The Parties shall:

- a) Promote and facilitate public awareness, education and participation concerning the safe transfer, use and handling of living modified organisms in relation to the conservation and sustained use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;
 - b) Endeavor to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.
2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.
3. Each Party shall endeavor to inform its public about the means of public access to the Biosafety Clearing-House”.

The Aarhus Convention, dedicated to mechanisms of informing the public and public participation in the decision-making process on issues of environmental importance, contains a separate clause regarding safety in genetic engineering activities (Article 6, par. 11): “Each Party shall, within the frameworks of its national law, apply, to the extent feasible and appropriate, provisions of this article to decisions on whether to permit the deliberate release of genetically modified organisms into the environment”.

Pursuant to Article 5 of the Law of the Republic of Belarus “On Protection of Consumers’ Rights” of 9 January 2002, the information on the goods (work or services) must contain, in particular, indication of the fact that the food product is genetically modified or contains genetically modified components. Such a requirement is contained in the Law of the Republic of Belarus “On Quality and Safety of Raw and Processed Food Products to Human Life and Health”. In particular, Article 10 of this Law rules that the information on the quality and safety of raw and processed food products should be indicated in cover documents, on the packaging or labels, or communicated to the people in another manner, and should include, in particular, indication of the fact that the raw or processed food products are genetically modified if they contain genetically modified components. Provision of compliance with these requirements is the aim of the Resolution No. 116 of 2 September 2003 of the Chief State Sanitary Physician of the Republic of Belarus “On the State Hygienic Regulation and Registration of Raw and Processed Food Products, Produced from or with the Use of Genetically Modified Sources”.

Under the Resolution No. 963 of 19 June 1998 of the Council of Ministers of the Republic of Belarus, the responsibilities of the National Co-ordination Biosafety Centre include provision of information on the issues of the safety in genetic engineering activities to the concerned national

state governing bodies, mass media, citizens and public associations. On the whole, the National Co-ordination Biosafety Centre is assigned an extremely important role in solving the discussed problem. A large piece of work has already been done. There have been conducted a number of workshops, dedicated to the issues of development of the biosafety system in the Republic of Belarus. Reports on topical issue of biosafety in Belarus have been presented at numerous national and international conferences and symposiums. The staff members of the Centre have given many interviews to the mass media and have prepared and published materials on biosafety in newspapers and journals. In 1998 there appeared an information web-site of the Centre (<http://biosafety.org.by/>), which contains extensive information on the national and international legislation in the field of biosafety and other topical problems of genetic engineering activities.

8.2. Directions of improving the mechanisms of promoting public awareness and public participation in the field of biosafety

The Draft Law of the Republic of Belarus “On Safety in Genetic Engineering Activities” contains a number of provisions, maintaining people’s rights to receive environment-related information and participate in taking decisions of environmental importance. In accordance with Article 24 of the Draft Law, citizens and civil associations shall be guaranteed the right to receive full, timely and true information in the field of safety in genetic engineering activities. Special national state governing authorities in the field of safety in genetic engineering activities, as well as legal entities and individual entrepreneurs exercising genetic engineering activities shall, on request of concerned citizens and public associations, provide information on issues of safety in genetic engineering activities according to legislation.

The Draft Law legally states the functions of the National Co-ordination Biosafety Centre in the field of collection, storage and dissemination of information in the field of biosafety. It is important to note, that the Draft Law obliges special authorized national state governing bodies to submit relevant information to the National Co-ordination Biosafety Centre. In particular, the information, which is referred to, regards issue of permits for implementation of genetic engineering activities for contained use; permits for release of genetically engineered organisms into the environment for trials; state registration certificates for genetically engineered varieties of plants, breeds of animals and strains of microorganisms; information on the crossing of the customs border of the Republic of Belarus by the persons who exercise import, export or transit of genetically engineered organisms (Article 27). The above information shall be submitted to the National Co-ordination Biosafety Centre within ten days after the issue of the listed permits.

It is intended that the process of development of regulatory legal documents, specifying the procedure of issuing permits for implementation of certain types of genetic engineering activities should envisage informing the community and public participation in making decisions with regard to issue of such permits. The informing the community and sharing information will probably be arranged through the above mentioned web-site of the National Co-ordination Biosafety Centre. (<http://biosafety.org.by/forum/>)

In particular, the draft of “Procedure of Issuing Permits for Release of Genetically Engineered Organisms into the Environment for Trials” (<http://biosafety.org.by/rus/legislation.html>) envisages that the National Co-ordination Biosafety Centre within 10 days from the arrival of the application materials for release of genetically engineered organisms into the environment for trials shall place the information (excluding confidential one), contained in the application, at the information web-site of the National Co-ordination Biosafety Centre for familiarization of the community. Comments and proposals from the community, related to the release of genetically engineered organisms into the environment, are accepted by the Centre within 60 days from the release of the application materials. The experts, performing the expertise of the application, are obliged to review and, where appropriate, take into account the comments and proposals submitted by the community. In case it is impossible to take into account particular comments and proposals of the community, the experts are obliged to provide written reasonable objections to the Centre. The comments and proposals submitted by the community and results of their review by the Expert Committee should be reflected in the expert opinion.

The results of the review of the application for release of genetically engineered organisms into the environment (the expert opinion and the resolution of the Ministry of Natural Resources) within 10 days after making a decision shall be placed at the information web-site of the National Co-ordination Biosafety Centre for familiarization of the community.

8.3. Practical examples of promoting public awareness, education and participation in the decision making process in the field of biosafety

In the process of implementing the UNEP-GEF project, an extensive scope of work was done on promoting public awareness, education and participation in the decision-making process in the field of biosafety. The various techniques used for this work included organization of workshops, news conferences, preparation of reviews and publications in the mass media, interviews in the mass media, preparation and publishing of special editions, designed for a broad audience and experts, and development and operation of the information web-site of the National Co-ordination Biosafety Centre.

Relevant materials have been published in such editions as newspapers “Respublika”, “Vedy” “Sovetskaya Belorussia”, “Argumenty i Fakty v Belarusi” (Arguments and Facts in Belarus), “Komsomolskaya Pravda v Belarusi” (Komsomolskaya Pravda in Belarus), “Natsionalnaya Ekonomicheskaya Gazeta” (National Economic Newspaper), “Nastaunitskaya Gazeta” (Teachers’ Newspaper), “Belorusskaya Delovaya Gazeta” (Belarusian Business Newspaper), “Belorusski Rynok” (Belarusian Market), “Vecherni Minsk”, “Minski Kurier”, “Znamia Yunosti”, and “Gastronom”, the magazine “Nauka i Innovatsii” (Science and Innovation), etc.

There have been organized the following workshops:

Workshop No. 1 “*On Status and Prospects of Development of Genetic Engineering Activities in the Republic of Belarus and Legal Framework in This Field*” (18 March 2003) was held with regard to the review of the Draft Law “On Safety in Genetic Engineering Activities” in the committees of the Chamber of Representatives of the National Assembly of the Republic of Belarus (Parliament). The workshop was primarily designed for the invited deputies of the Parliament, as well as representatives of the concerned ministries and agencies and the scientific community. The objective of the workshop was to give the attendees a general idea of genetic engineering, genetically engineered organisms, biosafety, and fundamentals of the state governing in this field. All of the above was supposed to contribute to a higher quality review of the Draft Law in the Parliament.

Workshop No. 2 “*Entry of the Cartagena Protocol into Force and Commitments of the Republic of Belarus in the Field of Biosafety: National Instruments of their Implementation*” (26 September 2003) was aimed at familiarizing the broader community, legislators and officials of the state bodies with the basic provisions of the Cartagena Protocol on Biosafety, international commitments of Belarus as a Party to the Protocol, and approaches to their implementation.

Workshop No. 3 “*Status and Prospects of Development of Biotechnologies in the Republic of Belarus. Guaranteeing Biosafety in the Current Legislation*” (28 October 2003) was dedicated to review and discussion of the information, collected in the course of the surveys in the format of the UNEP-GEF project. Among those who took part in its work, as well as in the previous workshops, there were deputies of the Parliament, representatives of the state governing bodies and NGOs, scientists and journalists.

Workshop No. 4 “*Risk Assessment of Potential Adverse Effects of Genetically Engineered Organisms on Human and Environmental Health: Theory and Experience*” (25 November 2003) was aimed at familiarizing the invited experts, who may be involved in performance of the biosafety expertise of genetically engineered organisms, with the fundamental principles and techniques of the biosafety expertise of genetically engineered organisms. Nevertheless, the program of the workshop was of great interest to representatives of the community and the authorities, who also participated in it.

Workshop No. 5 “*Biosafety System of the Republic of Belarus: Organizational and Legal Groundwork*” (26 March 2004) was dedicated to review and discussion of the fundamental provisions of the draft of the main legislative act in the field of biosafety. By that time the Draft Law had been finalized in the committees of the Parliament and prepared for review in the first

reading. The Draft Law was adopted 29 April 2004 in the first reading practically unanimously (only 4 deputies voted against its adoption).

Workshop No. 6 “*Securing the Rights of Citizens of the Republic of Belarus to Receive Information and Participate in the Decision Making Process in the Field of Biosafety*” (15 June 2004) was dedicated to one of the most important components of the modern biosafety system – promoting public awareness and public participation in the decision making in the field of biosafety. As expected, the workshop was of great interest. It gave a chance to prove their point to representatives of various environmentally focused organizations, including those which oppose any activities, related to the use of genetic engineering.

The attendees of the workshop showed a keen interest in the information on the findings of the sociological investigation “Assessment of the biosafety system of the Republic of Belarus in the mass consciousness”, conducted in the format of the project by the Institute of Sociology of the NAS of Belarus (presented in Russian at the web-site <http://biosafety.org.by/rus/gef.html>). The investigation represents opinions of residents of the City of Minsk and Minsk Oblast aged 16 and over. 768 persons altogether were surveyed by the individual standardized interview method (face to face). The survey has shown that people at large are *poorly aware or completely unaware* of the problem of using genetically engineered organisms – almost 80% of the respondents stated that they had only heard “something” or that it was the first time they heard about them. However, 2/3 of the respondents said that they wanted to know more about this issue. The peculiarity of this situation has to do with the fact that *the interest in GEOs has not yet reached the level of socially significant practical knowledge* (as, for instance, medical knowledge), i.e. it is caused by individual curiosity rather than need for possible application.

Among the possible sources of information on biosafety, TV, radio, and printed media, which are characterized by passive perception, are predominant; interpersonal communication holds an intermediate position. On the one hand, such a structure of the channels of informing on GEOs creates favorable conditions for circulation of unverified information, rumors, etc.; and on the other hand, it provides *an opportunity for pursuing an effective information policy and promoting interest to genetic engineering among the population through official mass media* (primarily, TV and printed media).

When developing the information and outreach strategy for legitimating genetic engineering activities, it should be taken into account that the people have the most trust for the information, broadcast in the name of scientists and physicians, and the least trust for that in the name of politicians and government officials. And this is a very delicate aspect to this – distrust in the opinions of politicians and officials on the biosafety issues does not deny the leading role of the State (as a social institution) in the control over the use of products that contain GEOs. It is comprehensive control – following comprehensive information on GM-products – that makes a prerequisite for their acceptance for the overwhelming majority of the respondents. And, as almost half of them believe, it is the primarily State, who has to enforce it. One of the instruments that provide a psychological compensation for the lack of knowledge on biosafety and ensure “the right of choice” to use or not to use GEOs for individuals, is special labeling of products, on which over half of the respondents (57,3%) rigidly insist. For the purpose of preventing possible social tensions, special labeling of GM-products should be definitely introduced even if it means an increase in the cost of the goods. At the same time, the requirement for labeling is caused by the need for psychological comfort, conditioned by the freedom of choice, rather than any rational considerations.

Workshop No.7 “*Problems of the Developing the National Biosafety Framework in the Republic of Belarus*” (22 July 2004) took place in the City of Gomel, which is the second important Belarusian region in the field of genetic engineering activities, and was aimed at familiarizing the community of this region with the process of developing the draft of the biosafety system for this country, its main provisions, and the tasks of the regional authorities in this field with regard to the accession of the Republic of Belarus to the Cartagena Protocol on Biosafety and adoption of the relevant legislation.

Workshop No. 8 “*Identification of Transgenes in Genetically Modified Organisms*” (2 September 2004) was organized for experts in the field of biosafety and was aimed at familiarizing

them with modern techniques of molecular and genetic analysis, including demonstration of the relevant equipment and experimental techniques.

Workshop No. 9 “*Draft of the National Biosafety System*” (24 September 2004) was the closing workshop, where the most important results of the implementation of the UNEP-GEF project were reported and discussed. The primary attention was given to the review of the draft of the national biosafety framework of the Republic of Belarus.

The news conference “Problems of the Developing the National System of Safety in Genetic Engineering Activities in the Republic of Belarus” (15 July 2004), at which representatives of the Ministry of Natural Resources and Environmental Protection, the Ministry of Health and the National Co-ordination Biosafety Centre answered the journalists’ questions on the topical issues of biosafety in the Republic of Belarus.

Presentation of the report “Genetically Modified Objects. Safety of Application” by Dr. A.P. Yermishin at the R&D conference “Nutrition and Health. Safety and Quality of Food Products” (Minsk, 31 August 2004). The conference was attended by approximately 300 experts in the field of nutrition hygiene from all the regions of Belarus. The information on the GEO-related risks to human health and methods of their assessment and prevention was quite useful for them.

At this conference, as well as at the above listed workshops No. 6-9 and the news conference, the popular science edition “Genetically Modified Organisms: Myths and Realities”⁸ (Author: A.P. Yermishin, Publishing House “Tekhnologia”, 7.8 printer’s sheets, circulation 2,550 copies), prepared and published in the process of implementing the UNEP-GEF project, was distributed. The book provides a popular presentation of the achievements of modern biotechnology, genetically engineered organisms and their difference from the organisms, created by conventional breeding methods. It discusses potential risks to human and environmental health, related to the use of genetically engineered organisms, and measures for elimination of these risks. Special attention is given to analysis of the large amount of unverified, distorted information on genetically engineered organisms, which often occurs in popular printed media. The objective information, presented in the book, will allow the readers to make a conscious choice with regard to genetic engineering as one of the most prominent scientific achievements of the past decades.

Among the important results of public participation the implementation of the UNEP-GEF project is preparation of 23 survey⁹ pertaining to the status and prospects of the development of modern biotechnology in Belarus, legislation related to the state governing of the safety in genetic engineering activities in Belarus, other countries of this region and a number of leading nations in the field of application of biotechnology achievements (<http://biosafety.org.by/rus/gef.html>). The surveys were performed by representatives of a broad range of scientific and research institutions and leading lawyers working in the field of environmental law (Table. 8)

In the process of implementing the UNEP-GEF project, the monograph “Biotechnology. Biosafety. Bioethics”⁸ (authors: A.P. Yermishin, V.E. Podlisskikh, E.V. Voronkova, B.Y. Anoshenko, V.M. Zarkov; Publishing House “Tekhnologia”, expected volume 34 printer’s sheets, circulation 500 copies) was prepared for publication. The monograph reflects the most significant results, achieved in the course of implementation of this project. In particular, the materials used for the writing of this book include those of the surveys, prepared by the Institute of Genetics and Cytology, the Institute of Microbiology, the Institute of Animal Husbandry, and the Institute of Plant Protection of the NAS of Belarus, the Institute of Microbiology and Epidemiology and the Republican R&D Centre for Hygiene under the Ministry of Health of the Republic of Belarus, the Public Association “EcoPravo”, the materials collected by the National Co-ordination Biosafety Centre in the process of construction of the information web page of this Centre, as well as the findings of the sociological survey, conducted by the Institute of Sociology of the NAS of Belarus. The book also includes the materials, contained in the reports, presented by the authors at the workshops, held in the format of the project. The authors decided to present the results of the project to the readers in a broader context. On the one hand, it will allow for a better assessment of

⁸ The electronic versions of the popular science edition and of the monograph are presented at the web-site of the National Co-ordination Biosafety Centre <http://biosafety.org.by/rus/publications.html>

⁹ The surveys are presented at the web-site of the National Co-ordination Biosafety Centre <http://biosafety.org.by/rus/gef.html>.

their significance and their role in the development of the biosafety system of this country. On the other hand, there is a large gap in the Russian-language scientific literature in the field of the safety in genetic engineering activities, their perception by the community, and ethical problems of the application of new biotechnologies. The monograph may be of interest to various population groups, who are interested in the achievements of genetic engineering and issues of the safety of genetic engineering activities: biologists, experts in agriculture and medicine, lawyers, government officials, college and high school students, etc.

Table 8. List of surveys performed in the course of implementing the UNEP-GEF project.

| Title | Performer |
|---|---|
| <i>Reviews of the current use of biotechnologies in the Republic of Belarus and the legislation regarding the safe use of biotechnologies</i> | |
| 1. Overview of the current use of conventional biotechnologies and prospects of further development of this field | Institute of Genetics and Cytology of the NAS of Belarus jointly with expert from the BelBioPharm Concern Institute of Microbiology of the NAS of Belarus |
| 2. Overview and assessment of the existing international agreements of the Republic of Belarus in the issues of genetic engineering activities | Institute of Genetics and Cytology of the NAS of Belarus |
| 3. Overview and assessment of the current legislation of the Republic of Belarus in the field of contained use of microorganisms of various risk levels | Institute of Microbiology and Epidemiology under the Ministry of Health of the RB |
| 4. Overview and assessment of the current legislation of the Republic of Belarus in the field of safety of foodstuffs | Republican Centre for Sanitation and Hygiene under the Ministry of Health of the RB |
| 5. Overview and assessment of the current legislation of the Republic of Belarus in the field of environmental protection | Public Association "EcoPravo" |
| 6. Overview and assessment of the current legislation of the Republic of Belarus in the field of testing and registration of new varieties of plants | Institute of Genetics and Cytology of the NAS of Belarus |
| 7. Overview and assessment of the current legislation of the Republic of Belarus on phytosanitary issues | Institute of Plant Protection of the NAS of Belarus |
| 8. Overview and analysis of the current legislation of the Republic of Belarus in the field of animal husbandry and veterinary medicine. | Institute of Animal Husbandry of the NAS of Belarus |
| 9 a). Overview and analysis of the current legislation of the Republic of Belarus in the field of accounting, storage, testing and registration of microorganisms | Institute of Microbiology of the NAS of Belarus |
| b). Overview and analysis of the current legislation of the Republic of Belarus in the field of testing and registration of new pesticides and fertilizers | |
| 10. Overview and assessment of the current legislation of the Republic of Belarus on the procedure of import and export of living organisms | Public Association "EcoPravo" |
| 11. Overview of the releases of genetically engineered organisms into the environment the Republic of Belarus | Institute of Genetics and Cytology of the NAS of Belarus |
| <i>Reviews of the existing national, bilateral, and multilateral cooperation programs on capacity building, research and application of biotechnologies</i> | |
| 12. Overview and analysis of the State Research and Development Program "Infections and Medical Biotechnologies" | Institute of Microbiology and Epidemiology under the Ministry of Health of the RB |
| 13. Overview and analysis of the State Research and Development Program "Industrial Biotechnology" | Institute of Genetics and Cytology of the NAS of Belarus jointly with expert from the BelBioPharm Concern Institute of Microbiology of the NAS of Belarus |

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| 14. Overview and analysis of the State Fundamental Research Program “Development of the scientific basis of biotechnological processes: selection breeding and creation of collection of non-pathogenic microorganisms as biotechnological objects; gene and cell engineering of plants and microorganisms; microbial synthesis of biologically active compounds and application of microorganisms in industry, agriculture and nature conservation” (“Biotechnology”) | Institute of Microbiology of the NAS of Belarus |
| 15. Overview and analysis of the State Fundamental Research Program “Development and application of genetic engineering biotechnologies for the benefit of agriculture and medicine “Genetic engineering” for 2002-2006 “ | Institute of Genetics and Cytology of the NAS of Belarus |
| 16. Overview and analysis of the Joint (Belarusian-Russian) Research Program “Development of highly effective and biologically safe medicinal preparations of the new generation on the basis of human proteins, received from the milk of transgenic animals” (“BelRosTransGen”) | Institute of Animal Husbandry of the NAS of Belarus |

Overviews of the existing biosafety structure of the countries of this subregion, and some leading nations in the field of biotechnology

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|---|--|
| 17. Overviews of the existing biosafety structure of the Russian Federation | Institute of Genetics and Cytology of the NAS of Belarus |
| 18. Overviews of the existing biosafety structure of Ukraine and Moldova | Institute of Genetics and Cytology of the NAS of Belarus |
| 19. Overviews of the existing biosafety structure of the EU Applicant countries from the subregion of Belarus | Institute of Genetics and Cytology of the NAS of Belarus |
| 20. Overviews of the existing biosafety structure of the USA | Institute of Genetics and Cytology of the NAS of Belarus |
| 21. Overviews of the existing biosafety structure of Canada | Institute of Genetics and Cytology of the NAS of Belarus |

Overviews of the existing mechanisms of enhancement of risk assessment/ risk management, general recognition and approval of data in the field of biosafety

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| 22. Overviews of the existing mechanisms of enhancement of assessment/ management of risks of potential adverse effects of genetic engineering activities in the Russian Federation, Ukraine and Moldova | Institute of Genetics and Cytology of the NAS of Belarus |
| 23. Overviews of the existing mechanisms of enhancement of assessment/ management of risks of potential adverse effects of genetic engineering activities in the EU Applicant countries from the subregion of Belarus | Institute of Genetics and Cytology of the NAS of Belarus |

Sociological survey findings

- | | |
|---|--|
| 24. Assessment of the biosafety system of the Republic of Belarus in the mass consciousness | Institute of Sociology of the NAS of Belarus |
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8.4. Information web-site of the National Co-ordination Biosafety Centre

For the purpose of providing open access to the information, contained in the national biosafety databank, there permanently functions an information web-site of the National Co-ordination Biosafety Centre, created in 1998 (<http://biosafety.org.by/>). Participation in the UNEP-GEF project made it possible to improve the material and technical base of the Centre (own web and email server has been created and provided speedy Internet access to the National Biosafety web-site), as well as to significantly expand the information base of the site and supplement it with new sections.

The web-site has the following structure:

- “About the Centre”: information on the tasks of the Centre, its staff members, contact addresses and phone numbers;
- “Legislation”: information on the biosafety-related draft laws and other legal acts of the Republic of Belarus, which have been adopted or are currently under review;

- “Risk Assessment”: information on the results of the assessment of the biosafety of the genetically engineered organisms, which have been released into the environment in the Republic of Belarus;
- “GEOs in Belarus”: information on the genetically engineered organisms used in Belarus, as well as on the Belarusian institutions, which create or can use them in their work;
- “Documents”: various national and international documents concerning biosafety;
- “Frequently asked questions”: answers to frequently asked questions concerning biosafety and genetic engineering activities;
- «Reviews»: our reviews of some popular editions on genetic engineering biotechnologies;
- “UNEP-GEF Project”: materials of the joint project of the Government of Belarus and the UNEP “Development of the National Biosafety Framework for the Republic of Belarus”: objective of the project, collaborators, schedule of work, surveys, workshops, etc.
- “Links”: links to national and international web-sites of biosafety organizations and institutions and other references on the issues of biosafety and biotechnology;
- “Forum”: this section of the web-site provides a possibility for feedback: any visitors to the site can ask questions, place information on biosafety, advertisements, etc.

The web-site has two versions: full in Russian and brief in English. It is expected to add more information to it, in particular, a comprehensive description of all transgenic varieties of plants, officially approved for use in economic activities all over the world, is being prepared and is going to be placed at the web-site in the near future (for the first time ever in the countries of the former USSR). Upon the completion of the project, the web-site will keep functioning, since the National Co-ordination Biosafety Centre is funded from the national budget, the funds allocated under the Resolution No. 963 of 19 June 1998 of the Council of Ministers of the Republic of Belarus. Consolidation of the position of the National Co-ordination Biosafety Centre, achieved through the implementation of the UNEP-GEF Project, will contribute to the effective performance of its functions, specified by the Resolution No. 734 of 5 June 2002 of the Council of Ministers – provision of liaison with the Secretariat of the Convention of Biological Diversity on biosafety issues, in particular, with the Biosafety Clearing-House of the Cartagena Protocol on Biosafety.

9. System to handle notifications or requests for authorizations and state registration in the field of safety in genetic engineering activities

With regard to the above information on the design of the national biosafety system of the Republic of Belarus, the system of issuing permits and state registration in the field of safety in genetic engineering activities looks as following.

9.1. Issue of permits for performing genetic engineering activities in contained use

The legislation of the Republic of Belarus does not envisage special permits for implementation of genetic engineering activities of the first level of risk, i.e. for activities with non-pathogenic genetically engineered organisms.

The permits for implementation of genetic engineering activities of the second, third, and fourth levels of risk are issued in accordance with the Regulations on the procedure of issuing permits for conducting work with microorganisms of pathogenicity groups I and II, approved by Resolution No. 25 of the Chief State Sanitary Physician of the Republic of Belarus “On Committee for Control over Compliance with the Requirements of Biological Safety and Anti-Epidemic Conditions (Control Committee) of 25.11.1997.

Pursuant to this document, the Republican Control Committee is a controlling and advisory body of the Ministry of Health of the Republic of Belarus on the issues of compliance with the requirements of biological safety and anti-epidemic conditions in the laboratories of the institutions working with microorganisms of pathogenicity groups I and II. The Control Committee is directly subordinate to the Deputy Minister of Health, who is the Chief State Sanitary Physician.

This regulatory act designates a unified procedure of issuing permits for work with microorganisms of pathogenicity groups I and II in the process of experimental and diagnostic studies and the manufacturing of immunobiological preparations and products of microbial

synthesis. All the above mentioned work may be performed only if the institution holds a permit for such work, issued by a state sanitary control body or institution on the basis of the conclusion of the Control Committee. The permit is issued for every microorganism type, used in the work, and officially confirms that this institution has provided proper sanitary and hygienic conditions, enabling compliance with the biological safety and anti-epidemic requirements, as well as protection of the population and of the environment. The permit for work with microorganisms of pathogenicity groups I and II is issued for 5 years. The permit may be cancelled in case of violation of the biological safety and anti-epidemic requirements and is regarded invalid in case of unauthorized alteration of layout and functions of the premises.

9.2. Issue of permits for releasing genetically engineered organisms into the environment for trials

Any first time release of genetically engineered organisms into the environment is allowed by a permit issued by the Ministry of Natural Resources and Environmental Protection. No permit from the Ministry of Natural Resources and Environmental Protection is needed for release into the environment for trials of genetically engineered organisms, received by traditional breeding methods from the genetically engineered initial materials such as varieties of plants, breeds of animals and strains of microorganisms, which have undergone the procedure of state registration in the Republic of Belarus.

In accordance with the draft of “Procedure of issuing permits for release of genetically engineered organisms into the environment for trials” (<http://biosafety.org.by/rus/legislation.html>) in order to receive a permit for controlled or planned release, the interested legal entity submits an application to the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus. (Fig.2). Enclosed to the application are materials, containing information on the genetically engineered organisms to be released, the potential receiving environment and the goals and modalities of the release.

The Ministry of Natural Resources and Environmental Protection registers the submitted application within a 10-day period, assigns a registration number to it, notifies the applicant thereof, and submits it to expertise. Simultaneously, the application materials go to the National Co-ordination Biosafety Centre.

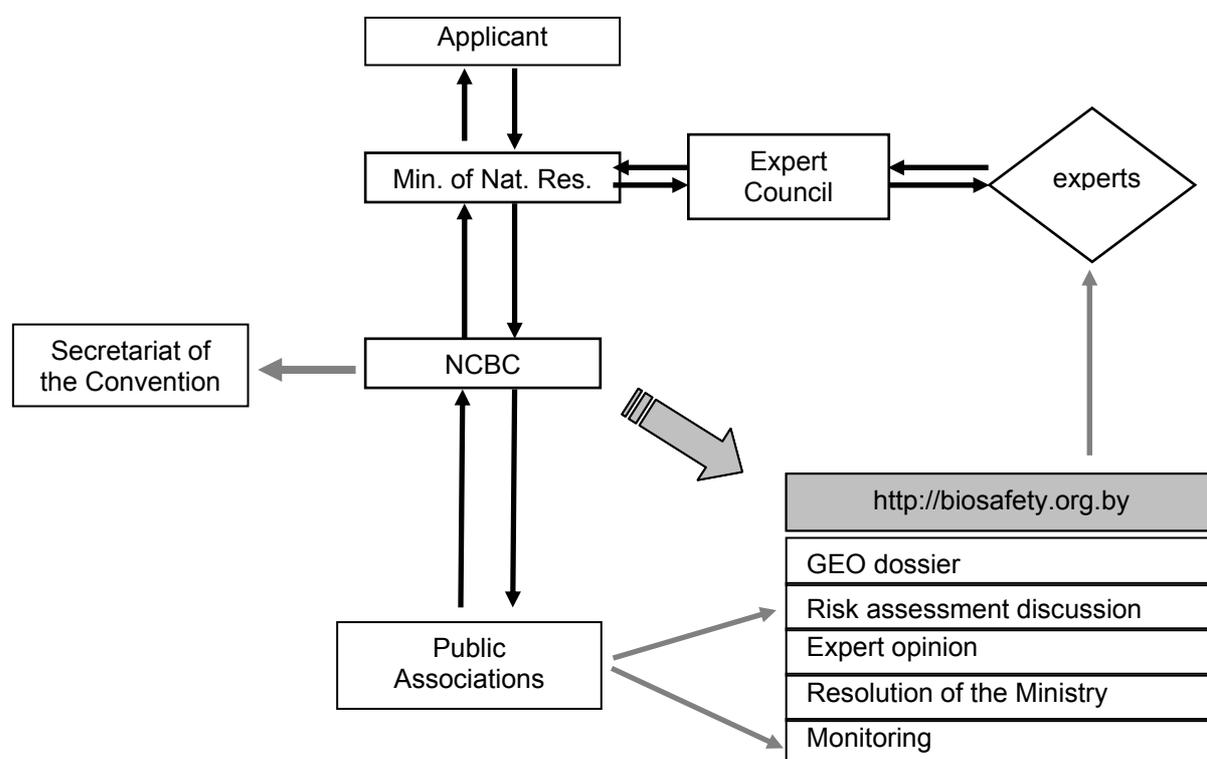


Figure 2. Scheme of expertise for release of genetically engineered organisms into the environment for testing purposes

The state expertise of the safety of genetically engineered organisms is carried out pursuant to “Regulations on Procedure of Organization and Performing State Expertise of the Safety of Genetically Engineered Organisms” (draft). The State expertise shall be organized by expert councils on safety in genetic engineering activity (hereinafter called expert councils) which shall be set by specially authorized national state governing bodies in the field of safety of genetic engineering activities. The expert council for the assessment of the biosafety of genetically engineered organisms at the time of their first-time release into the environment is formed by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus.

For performing expertise, relevant special national state governing authorities in the field of safety in genetic engineering activities shall appoint state experts, on recommendation of expert councils. The state experts may be relevant leading research organizations of the Republic of Belarus, scientists and specialists which are nationals of the Republic of Belarus and are included into the register of state experts.

On the basis of the expert opinion of the safety of genetically engineered organisms, the Ministry of Natural Resources and Environmental Protection issues a permit for release of genetically engineered organisms. The permit is valid for all subsequent release of concrete genetically engineered organisms (genotypes) if there has been no change in the release modalities (receiving environment, safeguards, etc.). It may be specified in a permit for controlled release of genetically engineered organisms into the environment may specify that it is also valid for planned releases, if it is indicated in the expert opinion that release of these genetically engineered organisms is safe in the context of both controlled and planned releases.

The draft of “Procedure of Issuing Permits for Release of Genetically Engineered Organisms into the Environment for Trials” envisages that the National Co-ordination Biosafety Centre within 10 days from the arrival of the application materials for release of genetically engineered organisms into the environment shall place the information (excluding confidential one), contained in the application, at the information web-site of the National Co-ordination Biosafety Centre for familiarization of the community. Comments and proposals from the community, related to the release of genetically engineered organisms into the environment, are accepted by the Centre within 60 days from the release of the application materials. The experts, performing the expertise of the application, are obliged to review and, where appropriate, take into account the comments and proposals submitted by the community. In case it is impossible to take into account particular comments and proposals of the community, the experts are obliged to provide written reasonable objections to the Centre. The comments and proposals submitted by the community and results of their review by the Expert Committee should be reflected in the expert opinion.

The results of the review of the application for release of genetically engineered organisms into the environment (the resolution of the Ministry of Natural Resources and the expert opinion) within 10 days after adoption of the resolution shall be placed at the information web-site of the National Co-ordination Biosafety Centre for familiarization of the community.

9.3. Procedure of state registration of genetically engineered varieties of plants, breeds of animals and strains of microorganisms

The following additional documents are required for the registration of genetically engineered varieties of plants, breeds of animals, and strains of microorganisms, the use of which in economic activities implies their release into the environment, compared to the traditionally bred varieties, breeds and strains.

First, it is a permit from the Ministry of Natural Resources and Environmental Protection for release of concrete genotypes of genetically engineered organisms into the environment for trials, which is issued on the basis of positive results of the state expertise of their biosafety.

Second, it is a report on the results of the testing of these genotypes of genetically engineered organisms for biosafety, which indicates that no significant adverse effects on the environment have been detected in the process of testing the genetically engineered organisms.

Third, it is a positive expert opinion of the safety of these genetically engineered organisms to human health.

The sequence of obtaining these documents and the procedure of the state registration, for instance, of locally bred genetically engineered varieties of plants, is presented in Table 9.

At the first stage, the Applicant submits an application for a permit for release of genetically engineered organisms into the environment for trials with the Ministry of Natural Resources and Environmental Protection. The procedure of issue of such a permit is described above in section 9.2. The permit for release specifies concrete conditions which must be complied with in the process of the release, in particular, measures for preventing proliferation of the genetically engineered organisms in the environment, and a list of additional studies to be conducted in the process of the release. Inspectors of the Ministry of Natural Resources and Environmental Protection exercise control over the compliance with the above named requirements pursuant to the legislation on monitoring. Upon the completion of the testing, a report is prepared, to be approved by the Ministry of Natural Resources and Environmental Protection.

Further on, the forms selected according to a set of positive traits are transferred for the state crop variety trials. The state crop variety trials are carried out by the Inspectorate for State Trials and Protection of Varieties of Plants under the Ministry of Agriculture and Food at the state variety test plots in various regions of the Republic for the period of 2-3 years. In the process, the varieties are assessed against a whole range of traits (yield capacity, resistance to diseases, quality traits, etc.) The genetically engineered varieties, which intend for use in economic activities for food production, should undergo, prior to the state registration, the state expertise for safety to human health (in particular, toxicity and allergenicity tests, etc.).

Table 9. Procedure of the state registration of genetically engineered varieties of plants

| Stage | Performer |
|--|--|
| 1. Release of genetically engineered organisms into the environment for trials | |
| 1. The state expertise of the safety of genetically engineered organisms to human and environmental health. | Experts, the Expert Council under the Ministry of Natural Resources and Environmental Protection |
| 2. Issue of a permit for release of genetically engineered organisms into the environment for trials | The Ministry of Natural Resources and Environmental Protection |
| 3. Testing of genetically engineered organisms in the controlled release conditions (i.e. with application of measures, restricting proliferation of the genetically engineered organisms in the environment). Testing of genetically engineered organisms for biosafety and preparation of a report on biosafety testing. | The applicant under control by the Ministry of Natural Resources and Environmental Protection (its territorial bodies) |
| 4. The state crop variety trials of the forms selected according to a set of positive traits | The Inspectorate for State Trials and Protection of Varieties of Plants under the Ministry of Agriculture and Food |
| 2. The state registration of genetically engineered varieties of plants | |
| 1. Inclusion of the forms, which have been selected upon the results of the crop variety trials, into the lists of varieties to be entered into the State Register of Varieties of Plants and Woods and Shrub Species | The Inspectorate for State Trials and Protection of Varieties of Plants under the Ministry of Agriculture and Food |
| 2. The state expertise for safety to human health of the genetically engineered varieties, which can be used in economic activities for production of crude food products (tests for toxicity, allergenicity, and essential equivalence). Drafting an expert opinion. | Experts, accredited laboratories, the Expert Council under the Ministry of Health (or a unified Expert Council under the Ministry of Natural Resources and Environmental Protection) |
| 3. Adoption of the resolution on inclusion of the genetically engineered variety into the State Register of Varieties of Plants and Woods and Shrub Species | The Inspectorate for State Trials and Protection of Varieties of Plants under the Ministry of Agriculture and Food |

Upon the results of the state crop variety trials the Inspectorate for State Trials and Protection of Varieties of Plants takes a decision whether to include or not to include a variety into the State Register of Varieties of Plants and Woods and Shrub Species of the Republic of Belarus. Only

following that, the genetically engineered variety is permitted for use in economic activities for production of agricultural and other goods.

A similar procedure is used for foreign bred genetically engineered varieties of plants. The difference is in that their first release in the Republic of Belarus can be, upon the conclusion of the state expertise, performed not at the sites intended for controlled release but immediately in the planned release conditions – at the sites belonging to the system of the state crop variety trials.

9.4. Issue of permits for import and release of non-pathogenic genetically engineered organisms into the environment for trials

Pursuant to the Draft Law of the Republic of Belarus “On Safety in Genetic Engineering Activities”, import into the Republic of Belarus of non-pathogenic genetically engineered organisms designed for release into the environment for trials, including the state crop variety trials, which is an integral stage of the procedure of the state registration of new varieties, shall be allowed if there is a permit for import and release of genetically engineered organisms into the environment for trials, issued by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus.

The procedure of obtaining such a permit is described in Section 9.2. of the Report. Thus, the issued permit gives the right to:

- import genetically engineered organisms of a particular genotype;
- release genetically engineered organisms into the environment on the conditions and in accordance with the requirements specified in the permit.

9.5. Issue of permits for import and transit of pathogenic and opportunistic pathogenic genetically engineered organisms

Import into the Republic of Belarus and transit through its territory of opportunistic pathogenic and pathogenic genetically engineered organisms shall be allowed exclusively for scientific research in the conditions of accredited contained use if there is a permit for import, issued by the Ministry of Health of the Republic of Belarus according to the procedure specified by the Council of Ministers of the Republic of Belarus.

9.6. Procedure of import of genetically engineered organisms intended for direct use as food, feed or for processing

The procedure of import of the above named genetically engineered organisms is exercised in compliance with the requirements of the Cartagena Protocol on Biosafety, i.e. in compliance with the labeling and packaging requirements to transportation of genetically engineered organisms. The legislation of the Republic of Belarus does not envisage any special conditions for import of genetically engineered organisms which are not intended for release into the environment, compared to the existing procedure of import of living organisms into the territory of the country.

9.7. Procedure of state hygienic registration of edible raw materials and foodstuffs derived from or with the use of genetically engineered sources

The state hygienic registration of edible raw materials and foodstuffs, derived from or with the use of genetically modified sources, in the Republic of Belarus is performed by the Centre for Expertise and Testing in Health Care under the Ministry of Health of the Republic of Belarus. Pursuant to the current legislation, hygienic requirements to the aforementioned food products do not differ from those applied to regular products. In any case, they must meet the requirements, laid down in the Sanitary Rules SanPiN 11-63 RB 98 “Hygienic Requirements to Quality and Safety of Edible Raw Materials and Foodstuffs”, Minsk, 1999.

The state hygienic registration of edible raw materials and foodstuffs, derived from or with the use of genetically modified sources, envisages performance of molecular genetic analyses with the purpose of identifying fragments of transgenic DNA in the edible raw materials and foods. The results of the analyses are used for labeling the forenamed raw and food products with a view to indicate if they contain components from genetically modified sources.

Conclusion

The national biosafety framework has to create an enabling environment for deriving maximum benefit from the achievements of modern biotechnology, to foster development of genetic engineering as one of the priority research areas of focus and, on the other hand, to ensure human and environmental health when carrying out genetic engineering activities, implementing new biotechnologies and consuming their products. Its implementation raises different types of issues which should be addressed at the appropriate time and level. Strengthening and/or developing adequate regulatory mechanisms and authorities should base on sound scientific data and clear correct facts. The most important output of the project is that now we have ‘Draft National Biosafety Framework for the Republic of Belarus’, which can serve as a basic guide to the implementation of the biosafety system in our country. The involvement of different ministries and several stakeholders in the preparation of this document ensures that different views were taken into account, that stakeholders in NBF now recognize their roles much better. It is very important for future capacity building when the Law of the Republic of Belarus “On Safety in Genetic Engineering Activity” will come into force.

Acknowledgements

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Annex

unofficial translation

Draft
Submitted by the Council of Ministers
Republic of Belarus

L A W R E P U B L I C O F B E L A R U S On Safety in Genetic Engineering Activities

Adopted by the House of Representatives
Approved by the Council of the Republic

This Law establishes legal and organisational principles for ensuring safety in genetic engineering activities and is aimed at protection of the environment and human health and fulfilment by the Republic of Belarus of its international commitments in this field.

CHAPTER 1 GENERAL PROVISIONS

Article 1. Basic notions and their definitions

The following notions and their definitions are used in this Law:

Safety in genetic engineering activities: means the state of protection achieved through implementation of the system of measures aimed at prevention or reduction to the safe level of genetically engineered organisms' harmful effects for the environment and human health, during performance of genetic engineering activities;

Genetic engineering activities: means activities related to the production of genetically engineered organisms , their release into the environment for trials, their use in economic (business) activities, 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;

A genetically engineered organism (a genetically modified, transgenic organism): means a living organism containing a new combination of genetic materials produced by means of genetic engineering;

Genetic engineering: means a technology for production of new combinations of genetic material by means of extra-cell manipulations with molecules of nucleic acids and transfer of new gene constructions into a living organism resultant in their inclusion into, and their activity in this organism and in its progeny;

Living organism: means any biological entity capable of transfer and replication (reproduction) of genetic material, including sterile organisms, viruses and viroids;

Pathogenic genetically engineered organisms: means organisms capable of inducing human diseases;

Non-pathogenic genetically engineered organisms: means organisms not capable of inducing human diseases;

Opportunistic pathogenic genetically engineered organisms: means organisms capable of inducing human diseases in specific conditions;

Contained use system: physical structure (plant, installation, etc.) for making operations related to genetically engineered organisms, equipped with required special equipment and devices, excluding contact of genetically engineered organisms with the environment and environmental impact;

Release of genetically engineered organisms into the environment: means authorised introduction of genetically engineered organisms into the environment;

Use of genetically engineered organisms in economic activities: means breeding and/or growing (cultivation) of genetically engineered varieties of plants, breeds of animals and strains of micro-organisms for production of agricultural and microbiological products, as well as for other economic purposes.

Article 2. Scope of this Law

This Law regulates relations in the field of safety in genetic engineering activities.

This Law 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.

Article 3. Legislation on safety in genetic engineering activities

Legislation on safety in genetic engineering activities is based on the Constitution of the Republic of Belarus and includes this Law and other regulatory and legal acts that regulate relations in this field.

Relations connected with genetic engineering activities in a contained use system are regulated by legislation on safety in genetic engineering activities and on health protection.

Relations connected with release of genetically engineered organisms into the environment for trials are regulated by legislation on safety in genetic engineering activities and on environmental protection.

Relations connected with import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of genetically engineered organisms are regulated by customs legislation, legislation on safety in genetic engineering activities, on health and environmental protection.

Relations connected with deactivation of genetically engineered organisms are regulated by legislation on safety in genetic engineering activities and legislation on waste.

Article 4. Basic principles of ensuring safety in genetic engineering activities

The basic principles of ensuring safety in genetic engineering activities are:

- precautionary principle during genetic engineering activities;
- conservation of biological diversity and natural ecological systems;
- scientifically-grounded, integrated and case-by-case approach to risk assessment of potential adverse impacts of genetic engineering activities on human health and environmental conditions;
- liability for violation of legislation in the field of safety in genetic engineering activities;
- access of individual persons and civil associations to information in the field of safety in genetic engineering activities;
- international cooperation in the field of safety in genetic engineering activities.

Article 5. Objects and subjections of relations in the field of safety in genetic engineering activities

Objects of relations in the field of safety in genetic engineering activities shall be genetically engineered organisms and the right to perform genetic engineering activities.

Subjects of relations in the field of safety in genetic engineering activities shall be state authorities engaged in state governing in this field, and legal entities and natural persons engaged in genetic engineering activities.

Requirements established by this Law shall cover relations in the field of safety in genetic engineering activities involving foreign and international legal entities, as well as foreign nationals and stateless persons, unless international agreements of the Republic of Belarus establish otherwise.

Article 6. System for ensuring safety in genetic engineering activities

Safety in genetic engineering activities shall be achieved through:

- adoption of regulatory legal acts and technical regulatory acts in the field of safety in genetic engineering activities;
- issue by specially authorized state authorities of permits for genetic engineering activities and state registration of genetically engineered organisms;
- establishment and observance of requirements on safety in genetic engineering activities;
- planning and implementation of measures on ensuring safety in the field of genetic engineering activities;
- performance of state expertise of safety of genetically engineered organisms;

making of control in the field of safety in genetic engineering activities;
account in the field of safety in genetic engineering activities;
establishment of legality measures for violation of legislation requirements to safety in genetic engineering activities;
other measures on safety in genetic engineering activities according to legislation.

Article 7. International cooperation in the field of safety in genetic engineering activities

The Republic of Belarus shall exercise international cooperation in the field of safety in genetic engineering activities in compliance with widely recognised principles and norms of international law and international agreements of the Republic of Belarus in the field of safety in genetic engineering activities.

**CHAPTER 2
STATE GOVERNING IN THE FIELD OF SAFETY
IN GENETIC ENGINEERING ACTIVITIES**

Article 8. Authorities exercising state governing in the field of safety in genetic engineering activities

State governing in the field of safety in genetic engineering activities shall be exercised by the President of the Republic of Belarus, the Council of Ministers of the Republic of Belarus, as well as special national state governing authorities in the field of safety in genetic engineering activities: Ministry of Natural Resources and Environmental Protection of the Republic of Belarus, Ministry of Health of the Republic of Belarus, Ministry of Agriculture and Food of the Republic of Belarus and their territorial bodies.

Article 9. Authorities of the Council of Ministers of the Republic of Belarus in the field of safety in genetic engineering activities

The Council of Ministers of the Republic of Belarus shall:
adopt regulatory and legal acts in the field of safety in genetic engineering activities;
determine the procedure of issue of permits for genetic engineering activities;
approve regulations on the procedure of organization and performance of state expertise on safety of genetically engineered organisms;
determine legal status and procedure of activity of the National Co-ordination Biosafety Centre;
determine the procedure of state registration of genetically engineered varieties of plants, breeds of animals and strains of micro-organisms;
determine the procedure of issue of permits for import into the Republic of Belarus or transit through its territory of genetically engineered organisms;
determine the procedure of state control in the field of safety in genetic engineering activities;
exercise other powers in conformity with legislation.

Article 10. Authorities of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus in the field of safety in genetic engineering activities

The Ministry of Natural Resources and Environmental Protection of the Republic of Belarus shall:

adopt regulatory and legal acts and technical regulatory acts in the field of safety in genetic engineering activities related to release of genetically engineered organisms into the environment for trials;
issue, according to the specified procedure, permits for release of non-pathogenic genetically engineered organisms into the environment for trials;
establish safety requirements to sites for testing of genetically engineered organisms;
determine the procedure of testing of genetically engineered organisms released into the environment;

establish the procedure for assessment of risks of potential harmful impacts of genetically engineered organisms on the environment;

issue, according to the specified procedure, of permits for import into the Republic of Belarus and release into the environment for trials of non-pathogenic genetically engineered organisms ;

exercise state control in the field of safety in genetic engineering activities within its competence; and

exercise other powers according to the legislation.

Article 11. Authorities of the Ministry of Health of the Republic of Belarus in the field of safety in genetic engineering activities

The Ministry of Health of the Republic of Belarus shall:

adopt regulatory and legal acts and technical regulatory acts in the field of safety in genetic engineering activities of the second, third and fourth risk levels, exercised for contained use;

issue, according to the specified procedure, permits for performing genetic engineering activities in contained use systems of the second, third and fourth risk levels;

issue, according to the specified procedure, permits for import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of opportunistic pathogenic and pathogenic genetically engineered organisms;

establish safety requirements to transportation of opportunistic pathogenic and pathogenic genetically engineered organisms;

establish procedure on assessment of risk of potential harmful impacts of genetically engineered organisms on human health;

exercise state registration of genetically engineered micro-organism strains within its competence;

exercise state control in the field of safety in genetic engineering activities within its competence; and

exercise other powers according to the legislation.

Article 12. Authorities of the Ministry of Agriculture and Food of the Republic of Belarus in the field of safety in genetic engineering activities

The Ministry of Agriculture and Food of the Republic of Belarus shall:

adopt regulatory and legal acts and technical regulatory acts in the field of safety in genetic engineering activities when genetically engineered organisms are used in economic activities;

exercise state registration of genetically engineered varieties of plants, breeds of animals and strains of micro-organisms within its competence;

exercise state control in the field of safety in genetic engineering activities within its competence; and

exercise other powers according to the legislation.

**CHAPTER 3
RIGHTS AND DUTIES OF PERSONS EXERCISING GENETIC ENGINEERING
ACTIVITIES. REQUIREMENTS IN THE FIELD OF SAFETY
IN GENETIC ENGINEERING ACTIVITIES**

Article 13. Rights and duties of persons exercising genetic engineering activities

Legal entities and individual entrepreneurs exercising genetic engineering activities shall have the right to:

exercise genetic engineering activities on the basis of permits issued according to the established procedure;

submit, according to the established procedure, proposals to state authorities on improvement of legislation on safety in genetic engineering activities;

appeal against illegal actions (omissions) of state authorities and officials exercising state control in the field of safety in genetic engineering activities in superior state authorities or court of justice;

exercise other rights in the field of safety in genetic engineering activities according to the legislation.

Legal entities and individual entrepreneurs exercising genetic engineering activities shall be obliged to:

observe requirements to safety in genetic engineering activities;

plan and implement actions on ensuring safety in their genetic engineering activities;

have a permit for exercise of genetic engineering activities, issued according to the established procedure;

fulfil the conditions of exercise of genetic engineering activities, indicated in the permit for such activities;

use in economic activities only those genetically engineered organisms for which there is a certificate on state registration of genetically engineered organisms and information about their safety (in transportation documents and on packages);

submit, for state expertise of safety of genetically engineered organisms and state registration of genetically engineered organisms, documents containing full and true information on safety of genetically engineered organisms;

submit, on request of concerned individuals and civil associations, information on issues of safety in their genetic engineering activities;

make, according to the established procedure, account and reporting in the field of genetic engineering activities;

organize and make production control in the field of safety in genetic engineering activities;

fulfil instructions of special national state governing authorities, their territorial bodies and officials exercising state control in the field of safety in genetic engineering activities on elimination of identified violations of legislation on safety in genetic engineering activities.

Article 14. Levels of risk of genetic engineering activities

Four levels of risk related to genetic engineering activities in working with genetically engineered organisms shall be established:

the first level of risk includes working with non-pathogenic genetically engineered organisms;

the second level of risk includes working with opportunistic pathogenic genetically engineered organisms ;

the third level of risk includes working with genetically engineered organisms capable of inducing dangerous infectious diseases and spreading infection for which effective prevention and treatment measures are available;

the fourth level of risk includes working with genetically engineered organisms inducing especially dangerous infectious diseases which can be rapidly spread and for which no effective prevention and treatment measures are known.

Genetic engineering activities of the second, third and fourth levels of risk shall be exercised exclusively state authorities for contained use.

Article 15. General safety requirements to genetic engineering activities

Persons exercising genetic engineering activities shall plan and make actions to ensure safety in genetic engineering activities coordinated with territorial bodies of special national state governing authorities in the field of safety in genetic engineering activities.

Persons exercising genetic engineering activities must ensure biological and physical protection of humans and the environment according to the requirements of technical regulatory and legal acts.

Work related to exercise of genetic engineering activities for contained use and release of genetically engineered organisms into the environment for trials can be performed by personnel whose professional training ensures safety in genetic engineering activities.

Permits giving the right to exercise genetic engineering activities, indicated in Articles 16, 17 and 20 of this Law, may specify requirements to safety in genetic engineering activities, as well as restrictions for exercise of genetic engineering activities according to legislation.

In case of transportation of genetically engineered organisms, the transportation documents and packages, and in case of storage of genetically engineered organisms, their package must have data indicating that these products are genetically engineered organisms.

Persons exercising genetic engineering activities, when they use genetically engineered organisms in their economic activities, transport or store genetically engineered organisms, must

be obliged to ensure separate keeping (storage) of genetically engineered organisms from other organisms.

Article 16. Requirements to safety in genetic engineering activities exercised for contained use

Exercise of genetic engineering activities of the second, third and fourth levels of risk for contained use is allowed only if there is a permit for exercise of genetic engineering activities issued by the Ministry of Health of the Republic of Belarus.

The procedure for determination of the levels of risk of genetic engineering activities, as well as the requirements to contained use systems when performing work of the second, third and fourth levels of risk shall be determined by the Ministry of Health of the Republic of Belarus.

Contained use system in which genetic engineering activities are exercised shall be subject to mandatory accreditation. Accreditation of contained use systems for exercise of genetic engineering activities of the second, third and fourth levels of risk shall be made by the Ministry of Health of the Republic of Belarus according to procedures specified by this ministry. Accreditation for contained use systems for exercise of genetic engineering activities of the first level of risk shall be made by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus according to procedures specified by this ministry.

Article 17. Requirements to safety of genetic engineering activities related to release of genetically engineered organisms into the environment for trials

It may be allowed to release non-pathogenic genetically engineered organisms into the environment for trials.

Release non-pathogenic genetically engineered organisms into the environment for trials shall be allowed by a permit for release of genetically engineered organisms into the environment, issued by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus.

The procedure of issue of permits for release of genetically engineered organisms into the environment for trials shall be specified by the Council of Ministers of the Republic of Belarus.

Trials of genetically engineered organisms during their first release into the environment must be made on specially equipped testing sites designed for trials of genetically engineered organisms

Safety requirements to sites for testing of genetically engineered organisms shall be determined by regulatory and legal as well as technical legal acts, adopted by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus on coordination with the National Academy of Sciences of Belarus.

The procedure of testing of genetically engineered organisms, when they are released into the environment, shall be defined by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus on coordination with the National Academy of Sciences of Belarus.

Article 18. Requirements to safety of genetic engineering activities when genetically engineered organisms are used in economic activities

The use of opportunistic pathogenic and pathogenic genetically engineered organisms for economic activities shall not be allowed.

Genetically engineered varieties of plants, breeds of animals and micro-organism strains, including those imported into the Republic of Belarus, can be used for economic activities only after their state registration by the Ministry of Agriculture and Food of the Republic of Belarus or the Ministry of Health of the Republic of Belarus in conformity with their competence according to the procedure established by the Council of Ministers of the Republic of Belarus. State registration shall be made after performance of state expertise of safety of genetically engineered organisms and provided positive results of testing of genetically engineered organisms released into the environment are obtained.

Article 19. Requirements to safety in genetic engineering activities during transportation of genetically engineered organisms

Transport facilities used to transport non-pathogenic genetically engineered organisms must be equipped with devices excluding potential unauthorised release of genetically engineered organisms into the environment.

Transportation of opportunistic pathogenic and pathogenic genetically engineered organisms must be made in conformity with legislation on transportation of dangerous cargo and safety requirements to transportation of such organisms, as specified by the Ministry of Health of the Republic of Belarus.

Article 20. Requirements to safety in genetic engineering activities when importing into the Republic of Belarus, exporting from the Republic of Belarus and transit through its territory of genetically engineered organisms

Import into the Republic of Belarus of non-pathogenic genetically engineered organisms designed for release into the environment for trials shall be allowed provided there is a permit for import and release of genetically engineered organisms into the environment for trials, issued according to Article 17 of this Law.

Import into the Republic of Belarus of non-pathogenic genetically engineered organisms designed for economic (business) activities shall be made provided there is a certificate on state registration of genetically engineered varieties of plants, breeds of animals and strains of micro-organism, issued according to Article 18 of this Law.

Transit through the territory of the Republic of Belarus of non-pathogenic genetically engineered organisms shall be allowed after the carrier informs the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus.

Import into the Republic of Belarus and transit through its territory of opportunistic pathogenic and pathogenic genetically engineered organisms shall be allowed exclusively for scientific research provided there is a permit for import, issued by the Ministry of Health of the Republic of Belarus according to the procedure specified by the Council of Ministers of the Republic of Belarus.

In case of unauthorized import of genetically engineered organisms, the person who imports them shall remove them from the territory of the Republic of Belarus according to the customs legislation.

Export from the Republic of Belarus of genetically engineered organisms shall be made provided there is a permit for export issued by a special body of the country of destination according to international agreements of the Republic of Belarus. Export from the Republic of Belarus of opportunistic pathogenic and pathogenic genetically engineered organisms shall be allowed provided there is a permit for import issued by a special body of the country of destination according to international agreements of the Republic of Belarus and provided there is a permit for export issued according to the procedure specified by the Ministry of Health of the Republic of Belarus.

Article 21. Requirements to safety for deactivation of genetically engineered organisms

Deactivation of genetically engineered organisms shall be made according to the legislation on waste and this Article.

Deactivation shall be performed in relation to genetically engineered organisms classified by the legislation as waste, as well as genetically engineered organisms:

which are produced as a result of genetic engineering activities exercised without a permit issued according to the established procedure;

which were released to the environment for trials without a permit issued according to the established procedure;

which are used for economic activities without a certificate on state registration of genetically engineered varieties of plants, breeds of animals and strains of micro-organisms.

Deactivation of opportunistic pathogenic and pathogenic genetically engineered organisms shall be made according to the requirements of regulatory legal as well as regulatory technical acts adopted by the Ministry of Health of the Republic of Belarus.

CHAPTER 4

STATE EXPERTISE OF SAFETY OF GENETICALLY ENGINEERED ORGANISMS

Article 22. State expertise of safety of genetically engineered organisms

State expertise of safety of genetically engineered organisms (hereinafter called expertise) shall be made for the purpose of their identification, determination of probability of potential harmful impact of genetically engineered organisms on human health and the environment, as well as determination of admissibility of their release into the environment or their use in economic activities.

Expertise shall be mandatory in case of:

the first release of genetically engineered organisms into the environment for trials;
state registration of genetically engineered varieties of plants, breeds of animals and strains of micro-organisms designed for use in economic activities.

Objects of expertise shall be:

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 risk of potential adverse impacts related to genetic engineering activities.

Article 23. Performance of state expertise of safety of genetically engineered organisms

State expertise shall be organized by expert councils on safety in genetic engineering activity (hereinafter called expert councils) which shall be set by special national state governing authorities in the field of safety in genetic engineering activities. The composition of expert councils shall be approved by the relevant national state governing authorities.

Expertise shall be performed at the expense of the applicant.

For performing expertise, relevant special national state governing authorities in the field of safety in genetic engineering activities shall appoint state experts, on recommendation of expert councils. State experts could be the relevant leading scientific organisation of the Republic of Belarus, scientists and specialists who are nationals of the Republic of Belarus and are included into the register of state experts. Experts could not be persons who have some interest, including personnel of the legal entity which applied to the special national state governing authority in the field of safety in genetic engineering activities, submitting an application for performance of expertise. The state expert shall bear responsibility for timely, objective and skilled performance of expertise according to legislation.

Results of state expertise shall be used by state experts to prepare a statement containing unambiguous conclusions on admissibility of release of genetically engineered organisms into the environment for trials or their use in economic activities. Positive conclusion of state experts shall be the ground for issue of a permit for release of genetically engineered organisms into the environment for trials, as well as for issue of a certificate on state registration of genetically engineered varieties of plants, breeds of animals and strains of micro-organisms. The conclusion of state experts shall be reviewed at the session of the expert council. The results of the review of the conclusion shall be used by the expert council to give recommendations to the relevant state governing authority to issue (not to issue) a permit for release of genetically engineered organisms into the environment for trials, or to issue (not to issue) a certificate on state registration of genetically engineered varieties of plants, breeds of animals and strains of micro-organisms or on performance of a new expertise.

The procedure of organisation and performance of expertise shall be determined by the Council of Ministers of the Republic of Belarus.

CHAPTER 5
INFORMATION, ACCOUNT AND REPORTING IN THE FIELD OF GENETIC
ENGINEERING ACTIVITIES.
THE NATIONAL CO-ORDINATION BIOSAFETY CENTRE

Article 24. The right of population and civil associations to receive information in the field of safety in genetic engineering activities

Citizens and civil associations shall be guaranteed the right to receive full, timely and true information in the field of safety in genetic engineering activities.

Special national state governing authorities in the field of safety in genetic engineering activities, as well as legal entities and individual entrepreneurs exercising genetic engineering activities shall, on request of concerned citizens and civil association, submit information on issues of genetic engineering activities according to legislation.

Article 25. Requirements to information on safety of genetically engineered organisms during their transportation and storage

Information on safety of genetically engineered organisms during their transportation must be included in to transportation documents and placed on packages or made known otherwise, and must include:

the name of the genetically engineered organism;

the number and the date of issue of the certificate on state registration of the genetically engineered varieties of plants, breeds of animals and strains of micro-organisms (for genetically engineered organisms designed for use in economic activities);

data concerning methods of deactivation, storage, transportation and use of genetically engineered organisms ;

the name and the location of the legal person or the individual entrepreneur who ship the genetically engineered organisms ;

the name and the location of the legal person or the individual entrepreneur who receive the genetically engineered organisms ;

other data specified by legislation.

Information on safety of genetically engineered organisms during their storage must be placed on the packages or made known otherwise, and must include:

the name of the genetically engineered organism;

the number and the date of issue of the certificate on state registration of the genetically engineered varieties of plants, breeds of animals and strains of micro-organisms (for genetically engineered organisms designed for use in economic activities);

data concerning methods of deactivation, storage, transportation and use of genetically engineered organisms ;

other data specified by legislation.

Article 26. Account of genetically engineered organisms and state statistical reports in the field of genetic engineering activities

Account of genetically engineered organisms and state statistical reports in the field of genetic engineering activities, as well as determination of potential impact of genetic engineering activities on human health and the environment shall be made by legal entities and individual entrepreneurs who exercise genetic engineering activities, according to the procedure established by the Ministry of Statistics and Analysis of the Republic of Belarus on coordination with the Ministry of Health of the Republic of Belarus, the Ministry of Agriculture and Food of the Republic of Belarus, the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus and the national Academy of Science of Belarus.

Article 27. National Co-ordination Biosafety Centre

The National Co-ordination Biosafety Centre shall:

collect, analyze and systematize information in the field of safety in genetic engineering activities;

form the databank on genetically engineered organisms;

submit information on issues of safety of genetic engineering activities to concerned national state governing authorities, mass media, citizens and civil associations;

exchange information with the co-ordination centres on biosafety of other state and international organizations;

keep the state register of experts on safety in the field of genetic engineering activities;

perform other functions according to legislation.

The National Co-ordination Biosafety Centre shall carry its activities according to the regulations approved by the Council of Ministers of the Republic of Belarus.

Special national state governing authorities in the field of safety in genetic engineering activities shall, within ten days from the day of issue of a permit for exercise of genetic engineering activities for contained use, issue a permit for release of genetically engineered organisms into the environment for trials, certificates on state registration of genetically engineered varieties of plants, breeds of animals and strains of micro-organisms, and the State Customs Committee shall, within ten days after persons who exercise import, export or transit of genetically engineered organisms cross the customs border of the Republic of Belarus, submit relevant information to the National Co-ordination Biosafety Centre using forms prescribed by these authorities on coordination with the National Co-ordination Biosafety Centre.

CHAPTER 6

CONTROL IN THE FIELD OF SAFETY IN GENETIC ENGINEERING ACTIVITIES

Article 28. State control in the field of safety in genetic engineering activities

State control in the field of safety in genetic engineering activities shall be made for verification of observance of legislation on safety of genetic engineering activities, fulfilment of safety requirements in the field of genetic engineering activities, as well as over measures on ensuring safety of such activities and prescriptions of special national state governing authorities in the field of safety in genetic engineering activities and of their territorial bodies and officials.

State control in the field of safety in genetic engineering activities shall be made by special national state governing authorities in the field of safety in genetic engineering activities within their competence, specified by Articles 10, 11 and 12 of this Law, their territorial bodies and officials according to the procedure specified by the Council of Ministers of the Republic of Belarus.

National state governing authorities, their territorial bodies and officials who are authorised to make state control in the field of safety in genetic engineering activities shall have the right, within their competence, to:

issue mandatory instructions on correction of violations of legislation in the field of safety in genetic engineering activities, causes of such violations and contributory conditions;

lodge lawsuits on indemnification for damage caused as a result of genetic engineering activities;

take, according to the procedure established by legislation, decisions on restriction, suspension of genetic engineering activities exercised with violations of their safety requirements;

exercise other rights according to the legislation.

Article 29. Departmental, production and community control in the field of safety in genetic engineering activities

Departmental control in the field of safety in genetic engineering activities shall be exercised by state authorities or organisations for ensuring the fulfilment by subordinated organisation of the requirements of legislation in the field of safety in genetic engineering activities and environmental protection.

The procedure of exercise of departmental control in the field of safety in genetic engineering activities shall be specified by state governing authorities or organisations exercising such control in their subordinated organisations on coordination with the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus (when first risk level genetic engineering activities are exercised), and the Ministry of Health of the Republic of Belarus (when second, third and fourth risk level genetic engineering activities are exercised).

Legal entities and individual entrepreneurs exercising genetic engineering activities shall organise and exercise production control for verification of observance of requirements to safety in

genetic engineering activities, as well as observance of sanitary norms, rules, hygienic principles and environmental protection requirements.

The procedure of exercise of production control in the field of safety in genetic engineering activities shall be specified by legal entities and individual entrepreneurs exercising genetic engineering activities, on coordination with the respective territorial bodies of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus (when first risk level genetic engineering activities are exercised), and of the Ministry of Health of the Republic of Belarus (when second, third and fourth risk level genetic engineering activities are exercised).

Community control in the field of safety of genetic engineering activities shall be exercised by citizens and civil associations according to legislation.

CHAPTER 7

LIABILITY FOR VIOLATION OF LEGISLATION IN THE FIELD OF SAFETY IN GENETIC ENGINEERING ACTIVITIES

Article 30. Offences in the field of safety in genetic engineering activities

Offences in the field of safety in genetic engineering activities shall include:

violation of requirements to safety in genetic engineering activities;

exercise of genetic engineering activities without the relevant permit;

failure to fulfil conditions for exercise of genetic engineering activities specified in the permit for such activities;

use, in economic activities, of genetically engineered organisms that do not have certificates of state registration of genetically engineered varieties of plants, breeds of animals and strains of micro-organisms;

submission for state expertise of safety of genetically engineered organisms and for state registration of genetically engineered organisms, of documents containing knowingly false information about safety of genetically engineered organisms ;

failure to fulfil instructions of special national state governing authorities in the field of safety in genetic engineering activities, and of their territorial bodies and officials, for correction of identified violations of legislation on safety in genetic engineering activities;

issue by officials of special national state governing authorities of permits for exercise of genetic engineering activities, permits for release of genetically engineered organisms into the environment for trials, as well as of a certificate on state registration of genetically engineered varieties of plants, breeds of animals and strains of micro-organisms, with violation of the established procedures.

Legislative acts may also stipulate other offences in the field of safety in genetic engineering activities.

Article 31. Liability for violation of legislation in the field of safety in genetic engineering activities

Violation of legislation on safety in genetic engineering activities shall entail administrative or criminal liability according to the legislation.

Bringing of persons to liability for violation of legislation on safety in genetic engineering activities shall not relieve them from indemnification for the damage caused as a result of exercise of genetic engineering activities.

Article 32. Indemnification for damage caused as a result of violation of legislation in the field of safety in genetic engineering activities

The amount and the procedure of indemnification for damage caused as a result of violation of legislation on safety in genetic engineering activities shall be determined according to legislation.

Article 33. Settling of disputes in the field of safety in genetic engineering activities

Disputes in the field of safety in genetic engineering activities shall be settled in the court of justice.

CHAPTER 8
FINAL PROVISIONS

Article 34. Coming of this Law into force

This Law shall come into force as from the day of its official publication.

Article 35. Bringing legislative acts of the Republic of Belarus in compliance with this Law

The Council of Ministers of the Republic of Belarus, within one year after this Law comes into force, shall:

ensure bringing of solutions of the Government of the Republic of Belarus in harmony with this Law;

ensure bringing by the national state governing authorities of their regulatory and legal acts in harmony with this Law;

ensure adoption of regulatory and legal acts required for implementation of this Law;

take other measures required for implementation of the provisions of this Law.

President of the Republic of Belarus