

The Status of Agricultural Biotechnology and Biosafety in Belarus

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LIST OF ACRONYMS

BCH	Biosafety Clearing House
DAS	Department of Agricultural Sciences of the NAS
FAO	Food and Agriculture Organization of the United Nations
GEF	Global Environment Facility
GM	Genetically Modified
GMO	Genetically Modified Organism
LMO	Living Modified Organism
NAS	National Academy of Sciences
NRLA	National Roster of Legal Acts
PLRV	Potato Leaf Roll Virus
PVY	Potato Virus Y
RPC	Research and Production Centre
SCPR	State Complex Programme of Research
SP	State Programme
SPAR	State Programme on Applied Research
SPOBR	State Programme on Oriented Basic Research
UNEP	United Nations Environment Programme

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SUMMARY

As part of the former Soviet Union, Belarus was a major food producer, particularly of meat and dairy products. However, since gaining independence in 1991, it hardly instituted any structural reforms in the agricultural sector, largely retaining the former system of subsidised collective and state farms. Agricultural production generally declined following independence, but over the last six years, yields have stabilised and even increased in some instances. Private smallholdings contribute significantly to agricultural production. Following the nuclear accident at Chernobyl in 1986, a sizeable area of the productive agricultural land and forest remains contaminated with radioactive fallout. Belarus is a signatory to several international agreements on issues of biosafety and while it has introduced substantial national legislation in this regard, there are, as yet, no transgenic crop varieties grown in the country. Research on genetic engineering of plants, animals and microorganisms is relatively undeveloped and there is room for considerable capacity building. Facilities for field testing and monitoring release of GMOs in the environment are in need of upgrading.

1. Profile of national agriculture

The Republic of Belarus is located in east-central Europe, borders the Russian Federation, Ukraine, Poland, Lithuania and Latvia, and represents a strategic corridor linking Russia and Europe. Belarus covers an area of about 207 600 km² and is mostly hilly lowland with many lakes and gently sloping ridges. The highest point is 346 masl and altitude averages 160 masl. The main rivers are the Dnieper, the West Dvina, the Pripyat and the Neman. One third of Belarus is covered by mixed forests and 13 percent of the territory is low-lying swamp. The climate is temperate continental, with average annual precipitation of 550 to 700 mm. The economy is highly industrialized and relies heavily on imported raw materials from the Russian Federation. The population of Belarus is nearly ten million, with a potential workforce of 6 066 million, 460 000 of whom work in agriculture.

An area of about 93 390 km² (45 percent of land area) is used for agriculture, of which arable land occupies 30 percent. The soils are mainly podsolis and peats and large areas remain constantly water-logged. The soils, with the exception of those in the southern marshy region, are generally fertile, especially in the river valleys. In 1993 agriculture and forestry accounted for almost a quarter of gross domestic production and almost 6 percent of the total agricultural production of the former Soviet Union, when agriculture consisted mainly of state and collective farms. Since independence in 1991 the agriculture sector has been largely unreformed and Belarus retains many features of a planned economy.

Agriculture suffered a setback in 1994, when there was a severe drought that resulted in an overall decline of 19 percent in crop production: wheat yield declined by 35 percent, sugar beet by 31 percent and potato by 29 percent. Animal products declined by 11 percent and cattle and sheep numbers by two and thirty percent respectively. In 2006 agriculture contributed about 20 percent to the gross domestic product. The main agricultural products are meat, dairy stock, grain, potato, flax, sugar beet, fruits and vegetables. In general, agricultural production is concentrated in large farms, but about 37 percent derives from the domestic farms of the rural population. A disproportionate volume of agricultural products derive from such smallholdings – 85 percent of vegetables, 90 percent of potatoes and >30 percent of milk. Although there has been an increase in the number of private farms since independence, they have remained relatively small in size in comparison with the state and collective farms.

Agricultural production declined steadily throughout the 1990s. Gross yield of grains - wheat, rye, barley and oat - have remained at about 6 million tonnes pa over the last six years, but sugar beet gross yields have more than doubled, to reach about 4 million tonnes. Potato yields have increased slightly to about 8 million tonnes, but maize yields have gone from about 25 000 to 153 000 tonnes. Over the same period vegetable production has risen from 1,5 million tonnes to >2 million tonnes. Productivity per unit area of the major crops has remained similar over the last fifteen years, and meat, milk and egg production has risen slightly since 2000. Forest covers nearly one third of Belarus and supplies wood for furniture and paper production, but forests have been logged faster than they have been replanted.

The greatest problem facing agriculture and forestry in Belarus stems from the nuclear accident at Chernobyl in 1986. Most of the radioactive fallout was on Belarus and long-term radiation affects 18 percent of the most productive farmland and 20 percent of the forests. The marshy areas also retain high levels of radiation. Additional environmental problems derive

from widespread overuse of agricultural chemicals and industrial pollution, although agricultural products are still exported to former Soviet republics after testing for radioactive contamination.

2. National agricultural policy

During the Soviet era, agriculture in Belarus was based mainly on state and collective farms, although allotments were allowed for home production of fruit and vegetables. At that time Belarus specialized in meat and dairy production based on subsidised imported fodder (mainly grain). Government policies in the early 1990s were based on the Soviet model and large-scale farming was retained to supply food for domestic consumption and export. In 1993 the Law on the Right to Land Ownership was passed, which represented an addition to the Land Lease Law of 1990. This allowed farmers to lease, on a long term basis, up to fifty hectares for house construction and fruit and vegetable production. This meant that agriculture would effectively remain the responsibility of the government. Although the number of private farms increased from 84 in 1990 to nearly 3 000 in 1993, average private farm size was only about twenty hectares, in comparison with over three thousand hectares for state and collective farms. The agricultural sector has not yet been effectively restructured.

In the early 1990s there was a large decrease in the area of land under cultivation and a shift from livestock to crop production, as sale prices for the latter increased, while livestock inputs, including imported fodder, increased in price. Private farms suffered as the guaranteed producer prices were eaten away by inflation. In 1993 the government introduced minimum guaranteed prices that could be adjusted according to changes in input prices and direct subsidies to agriculture were discontinued, although food price subsidies were maintained to keep domestic food prices low. In 1995, following a severe drought that substantially reduced agricultural output, state and collective farms were awarded credits and producer prices were increased to encourage agricultural production.

There is currently an attempt to revitalise agriculture through specialized production, improved management and increased investment. The state is subsidising modernization of the agricultural sector and is providing grants for purchase and lease of modern agricultural equipment. The aim is to revitalize the rural areas through raised incomes and improved living conditions and social services.

3. Status of agricultural research

Agricultural research in Belarus is mainly conducted in institutions of the Department of Agricultural Sciences of the National Academy of Sciences (DAS NAS). DAS NAS was established in 2002 based on the former Academy of Agricultural Sciences of the Republic of Belarus. DAS NAS coordinates research and applies the results to practical farming, including crop production, stock-breeding, veterinary medicine, mechanization, food production, agricultural economics and planning and organization of agricultural production.

The main research themes of the institutions included in DAS NAS are:

- Strategy development for agro-industry, including economic and organizational mechanisms for improving national food safety.
- Breeding productive, high quality, stress resistant agricultural and horticultural crop varieties based on scientific advances that make it possible to realize genetic potential, decrease resource inputs, encourage sustainable use of natural resources and protect the environment.
- Development of a strategy for rational use of soil resources, effective methods of protecting soil from degradation, methods for improving soil fertility based on resource saving and environmentally friendly technologies, improving technologies for exploiting, repairing and reconstructing land reclamation systems.
- Development of sound principles of pest and weed regulation, and reducing the harmful effects of plant diseases, based on modern methods of plant protection.
- Breeding improved, highly productive livestock, including poultry and fish, based on modern methods of breeding and biotechnology.
- Development and improvement of environmentally friendly, resource-saving technologies for livestock production and veterinary medicine, including methods and facilities for improved diagnostics, prophylaxis and therapy.
- Development of new and improved technologies for production, stocking, storage and rational use of feeds, aimed at ensuring optimal health of agricultural animals, making it possible to realize their genetic potential to produce high quality products.
- Development of novel technologies based on modern technical means of crop production, stockbreeding and food industry management.

DAS NAS includes five Research and Production Centres (RPC) (for farming, stockbreeding, potato growing, vegetables and horticulture, and agricultural mechanisation and the food industry), the Institute of Genetics and Cytology, Grodno Zonal Institute for Plant Production, Poleski Agriculture and Ecology Institute, five regional agricultural research stations and Poleskaja Research Station for Land Reclamation and Grass Farming. In total, as of 2006, the centres employed 3 540 staff, including 1 560 researchers (81 D.Sc. and 447 Ph.D.).

4. National biotechnology policy

The biotechnology policy of Belarus is included in health care and environmental protection policies and is based on the concept of sustainable development. Biosafety policy is guided by a number of international agreements that Belarus is a party to, as well as by various national legislative acts. The main objective is, on the one hand, to create an enabling environment for deriving maximum benefits from the achievements of modern biotechnology, particularly through development of genetic engineering as a priority research area, and on the other hand, to ensure optimal human and environmental health regarding genetic engineering, implementation of new biotechnologies and consumption of biotech products (National Strategy for Sustainable Development: Continuity and Renovation: Analytical Report. – Minsk: Unipak, 2003. p. 103–109).

Biotechnology and genetic engineering are on the list of priority research areas and technologies of Belarus (Resolutions No. 139 of February 27, 1997 and No. 111 of 29 January 2002 of the Council of Ministers of the Republic of Belarus) (the complete Russian texts of the legislative acts referred to in this project are available on the web site of the National Co-ordination Biosafety Centre at <http://biosafety.org.by/rus/legislation.html>).

Three main directions in modern biotechnology have been followed in Belarus:

- (1) Creation of new effective strains of microorganisms for microbial synthesis of biologically active compounds and their use in industry and agriculture, and for environmental protection.
- (2) Breeding transgenic varieties of agricultural and ornamental plants.
- (3) Application of genetic engineering biotechnologies in medicine for diagnostics, treatment of diseases and creation of fundamentally new pharmaceuticals.

In accordance with this, there is a set of state-supported scientific and research programmes, the main one of which is that on 'Development of biological science, biological education and biological industry for 2007-2011 and for the period until 2015 (SP "Biotechnology")'. In addition to research themes, this programme includes a set of organisational and human resource activities intended to expedite development of promising lines of research. Other research programmes that include projects in the field of agricultural biotechnology are:

- (1) The state programme on oriented basic research 'Genetic, physiological, biochemical and immunological basis of adaptive plant breeding, directed towards producing plants with high performance, stress resistance and high quality products' [(Breeding, Seed Farming and Genetics)] (2006-2010).
- (2) The state programme on applied research, 'Physiological, biochemical and genetic basis of using microorganisms, plant and animal cells in biotechnologies' [(Novel Biotechnologies)] (2006-2010).
- (3) The state complex programme of research on 'Molecular cell mechanisms of vital plant and animal systems as the basis for developing new agricultural and medical technologies' [(Biological Engineering and Biosafety)] (2006-2010).

Within the framework of the Belarus-Russia union, a research programme is underway on, 'Creation of Highly Effective and Biologically Safe New Generation Medicinal Preparations Based on Human Proteins Produced in Milk of Transgenic Animals (BelRosTransGen)'. Belarus has also undertaken some important steps in the field of safe use of biotechnologies. Among these is establishment of the National Biosafety Co-ordination Centre, whose functions include full-scale monitoring of developments in biotechnology (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 January 2006 parliament passed the law on 'Safety in Genetic Engineering Activities'. Work is ongoing on improving the current legislation and developing new regulatory legislation in biosafety.

Belarus is a party to several international conventions related to safe use of modern biotechnology, the most important being:

- (1) The 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 on 10 June 1993 and entered into force on 29 December 1993.

- (2) The Cartagena Protocol on Biosafety to the Convention on Biological Diversity, adopted 29 January 2000 in the city of Montreal at the extraordinary meeting of the Conference of the Parties to the Convention on Biological Diversity. It entered into force on 11 September 2003. Belarus ratified the Cartagena Protocol on 5 May 2002, passing the law on 'Belarusian Accession to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity'. In accordance with 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, performing the functions of the National Co-ordination Biosafety Centre, was designated the national focal point, responsible for liaison with the Secretariat of the Protocol. The Ministry of Natural Resources and Environmental Protection (as part of the functions related to release of LMOs into the environment) and the Ministries of Health Protection and Agriculture and Food (for the issues related to commercial use of LMOs) were designated as the competent authorities.
- (3) The International Convention for the Protection of New Varieties of Plants, adopted 2 December 1961, was 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 on 24 June 2002, 'On Accession of the Republic of Belarus to the International Convention for the Protection of New Varieties of Plants'.
- (4) The 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', was approved by the Decree No. 726 of 14 December 1999 of the President of the Republic of Belarus.

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 parliament, were made part of the national legislation of Belarus in accordance with the Law of the Republic of Belarus 'On Regulatory Legal Acts'. However, in order to meet the international commitments contained in these international agreements, it was necessary to pass domestic legislation. Compliance with the commitments of Belarus, contained in the international agreements, is one of the most important biosafety legislative requirements.

5. Status of biotechnology research and applications of biotechnology

Biotechnologies based on research of *in vitro* plant tissue and cell culture, micropropagation, DNA-markers etc. have gained some ground in Belarus. Most institutions of the NAS conducting research in plant biotechnology have biotechnology and micropropagation laboratories (Table 1). Genetic engineering research and production of GMOs is done in three laboratories only: the Laboratory of Molecular Genetics of the Institute of Genetics and Cytology, the Department of Plant Biochemistry and Biotechnology of the Central Botanical Garden and the Laboratory of Molecular Biology of the Cell of the Institute of Biophysics and Cell Engineering (Table 1).

Table 1. Biotechnology research in Belarus

Institution	Contact	Programme details, strengths and weaknesses
NAS Institute of Genetics and Cytology	Prof. Alexander Kilchevsky, Director 27, Academicheskaja St., Minsk 200072 office@igc.bas-net.by tel.: (375) 172949183 fax.: (375) 172841917	State research organization founded in 1965. 159 scientific staff, 16 M.Sc., 39 Ph.D.; 1 M.Sc., 2 Ph.D. and 3 non-graduates involved in biotechnology. 1 M.Sc., 2 Ph.D. and 1 non-graduate involved in biosafety. Main areas of activity in production of transgenic plants (potato, rape, model species) and work of the National Co-ordination Biosafety Centre. <ul style="list-style-type: none"> - physical infrastructure satisfactory; - equipment good; - manpower could be expanded; - financial resources good; - funding through public projects; - Internet available.
NAS Institute of Biophysics and Cell Engineering	Prof. Igor Volotovski, Director 27, Academicheskaja St., Minsk 200072 ipb@biobel.bas-net.by tel.: (375) 172841568 fax.: (375) 172842356	State research organization founded in 1973. 66 scientific staff, 6 M.Sc. and 34 Ph.D.; 1 M.Sc., 2 Ph.D. and 7 non-graduates involved in biotechnology. Main areas of activity in production of transgenic plants (potato, model species). <ul style="list-style-type: none"> - physical infrastructure satisfactory; - equipment good; - manpower: could be expanded; - financial resources good; - funding through public projects; - Internet available.
NAS Central Botanical Garden	Prof. Vladimir Reshetnikov, Director 2B, Surganov St., Minsk 200012 cbg@it.org.by tel.: (375) 172841484 fax.: (375) 172841484	State research organization founded in 1932. 29 scientific staff of the Department of Plant Biochemistry and Biotechnology (2 M.Sc. and 11 Ph.D.); 1 M.Sc., 2 Ph.D. and 3 non-graduates involved in biotechnology. Main areas of activity in production of transgenic plants (cranberries, cowberries, clover, model species). <ul style="list-style-type: none"> - physical infrastructure satisfactory; - equipment good; - manpower could be expanded; - financial resources good; - funding through public projects; - Internet available.

<p>NAS Research and Production Centre for Farming</p>	<p>Dr. Fedor Privalov, Director General. 1 Timirjazev St., Zhodino, Minsk region 222160 izis@tut.by tel.: (375) 177597033 fax.: (375) 177537066</p>	<p>State research organisation founded in 2006. 366 scientific staff (9 M.Sc. and 53 Ph.D.); Laboratory of genetics and biotechnology conducts works on hybridization between distantly related species, production of haploids and micropropagation (grain crops, rape, legumes).</p> <ul style="list-style-type: none"> - physical infrastructure satisfactory; - equipment good; - manpower could be expanded; - financial resources good; - funding through public projects; - Internet available.
<p>NAS Research and Production Centre for Potato Growing, Vegetables and Horticulture</p>	<p>Dr. Sergey Turko, Director General. 2a Kovaljov St, Samokhvalovichi, Minsk region 223013 bripotat@it.org.by tel.: (375) 175066145 fax.: (375) 175067001</p>	<p>State research organization founded in 2006. Laboratory of genetics and biotechnology conducts works on somatic hybridization between distantly related species of potato and micropropagation of potato.</p> <ul style="list-style-type: none"> - physical infrastructure satisfactory; - equipment good; - manpower could be expanded; - financial resources good; - funding through public projects; - Internet available.
<p>NAS Institute of Forestry</p>	<p>Dr. Alexander Kovalevich, Director 71 Proletarskaja St, Gomel 246001 forinst@server.by tel.: (375) 232741423 fax.: (375) 232747373</p>	<p>State research organization founded in 1930. 140 scientific staff, 4 M.Sc. and 22 Ph.D. Laboratory for genetics and biotechnology conducts works on PCR-markers in forestry, on micropropagation (birch, wild berries).</p> <ul style="list-style-type: none"> - physical infrastructure satisfactory; - equipment good; - manpower could be expanded; - financial resources good; - funding through public projects; - Internet available.
<p>NAS Institute of Microbiology</p>	<p>Prof. Emilia Kolomiets, Director 2 Kuprevich St. Minsk 220141</p>	<p>State research organization founded in 1975. 84 scientific staff, 8 M.Sc. and 25 Ph.D. Laboratory for biological control agents develops bioinsecticides and biofertilizers.</p>

	microbio@mbio.bas-net.by tel.: (375) 172674766 fax.: (375) 172674766	<ul style="list-style-type: none"> - physical infrastructure satisfactory; - equipment good; - manpower could be expanded; - financial resources good; - funding through public projects; - Internet available.
NAS Research and Production Centre for Livestock Breeding	Dr. Nikolay Popkov, Director General 11 Frunze St., Zhodino, Minsk region 222160 belniig@tut.by tel.: (375) 177533426 fax.: (375) 177535283	State research organization founded in2006. Laboratory of biotechnology conducts work on cattle cloning, transplantation and production of transgenic goats. <ul style="list-style-type: none"> - physical infrastructure satisfactory; - equipment good; - manpower could be expanded; - financial resources good; - funding through public projects; - Internet available.

The following projects associated with genetic transformation of plants are carried in the programmes outlined in Table 1:

SP, Biotechnology:

- (1) To develop effective technology for *Agrobacterium* transformation of hop-clover for the production of new genotypes in breeding (implementing institutions: Central Botanical Garden, Institute of Experimental Botany, Research and Production Centre for Farming; Project leader – Academician V. Reshetnikov).
- (2) To clarify the role of expression of *taumatin II* in antifungal activity and changing the taste of cranberries. To develop the technology for indoor and outdoor trials of transgenic cranberries for the selection of genotypes with resistance to pathogens and modified fruit taste (implementing institutions: Central Botanical Garden; Project leader – Academician V. Reshetnikov).
- (3) To develop transgenic antimicrobial peptides in cells of potato plants (implementing institutions: Institute of Biophysics and Cell Engineering; Project leader – Academician I. Volotovski).
- (4) To develop the technology for trials and use of transgenic potato plants resistant to PVY. To select initial material resistant to PVY, which can be considered a new potato variety (implementing institutions: Research and Production Centre for Potato Growing, Vegetables and Horticulture; Project leader - Dr. G. Yakovleva).
- (5) To develop effective technology for and to breed genetically modified lines of potato, characterized by enhanced insect resistance (implementing institutions: Institute of Genetics and Cytology; Project leader – Academician N. Kartel).

SPOBR, Breeding, Seed Farming and Genetics:

- (1) Development of effective technologies for transformation of rape with *aroA* and *P450_{sc}CYP11A1* genes and to study their expression (implementing institutions: Research and Production Centre for Farming, Institute of Genetics and Cytology; Project leader – Dr. M. Shishlov).
- (2) Production of transgenic potato and study of expression of the endochitinase gene and its contribution to improved resistance to phytopathogens (implementing institutions: Institute of Genetics and Cytology, Research and Production Centre for Potato Growing, Vegetables and Horticulture; Project leader – Academician N. Kartel).
- (3) Production of transgenic potato plants with higher resistance to phytopathogenic microorganisms using cationic peptides (implementing institutions: Institute of Biophysics and Cell Engineering, Research and Production Centre for Potato Growing, Vegetables and Horticulture; Project leader – Academician I. Volotovski).

SPAR, Novel Biotechnologies:

Genetic transformation of cowberry varieties introduced into Belarus (implementing institutions: Central Botanical Garden, Institute of Experimental Botany; Project leader – Academician V. Reshetnikov).

SCPR, Biological Engineering and Biosafety:

Expression of the *CYP11A1* gene for cytochrome P450_{sc} from bovine adrenal cortex in plants to alter stearin metabolism (implementing institutions: Institute of Genetics and Cytology; Project leader – Academician N. Kartel).

Belarusian researchers cooperate closely with some institutions of the Russian Federation. In particular, there is substantial collaboration in research concerning plant genetic engineering with the Institute of General Genetics of the Russian Academy of Sciences, the Institute of Bioorganic Chemistry, and the Centre for Bioengineering of the Russian Academy of Agricultural Sciences.

Table 2. Key contact persons in biotechnology research and biosafety

Institution	Address	Name
NAS Institute of Genetics and Cytology	27 Akademicheskaja St., Minsk 200072	Prof. Nicolay Kartel, Academician NAS, Head of the Laboratory of Molecular Genetics N.Kartel@igc.bas-net.by tel.: (375) 172841848 fax.: (375) 172841917
NAS Institute of Genetics and Cytology	27 Akademicheskaja St., Minsk 200072	Dr. Alexander Yermishin, Head of the National Biosafety Co-ordination Centre biosafety@biosafety.org.by tel.: (375) 172840297 fax.: (375) 172841917
NAS Institute of Biophysics and Cell Engineering	27 Akademicheskaja St., Minsk 200072	Prof. Igor Volotovski, Academician, Director of the institute, Head of the Lab. of Molecular Biology of the Cell ipb@biobel.bas-net.by tel.: (375) 172841568 fax.: (375) 172842356
NAS Central Botanical Garden	2B Surganov St., Minsk 200012	Prof. Vladimir Reshetnikov, Academician, Director of the institute, Head of the Department of Plant Biochemistry and Biotechnology cbg@it.org.by tel.: (375) 172841484 fax.: (375) 172841484

Most research results on GMOs have yet to be applied in agricultural production and there are as yet no varieties of transgenic crops (national or international) registered in Belarus. The first official trials of transgenic organisms, involving their release into the environment, took place in 1999. At the request of AgrEvo (German company, now Bayer Crop Science) the Institute of Genetics and Cytology of the NAS investigated the safety of a transgenic variety of sugar beet resistant to the glufosinate (Liberty, Basta, Finale). The risk assessment methodology was that used in the EU countries. On the basis of their investigations into the safety of this transgenic variety, the Ministry of Natural Resources issued a permit for its import and testing. There have been no applications for release of GMOs into the environment since that time.

6. Regulatory frameworks

Selecting an appropriate biosafety model for Belarus

In order to select an appropriate model for Belarus to ensure safety in genetic engineering, it is necessary to balance the benefits of the application of applied molecular biology against possible adverse consequences. Genetic engineering is a science-based and well proven technology that can assist in plant and animal breeding and allows for significant expansion of the possibilities beyond traditional breeding methods, through increased access to a range of valuable genes in near and distant relatives. Using genetic engineering techniques it is possible to add genes to the genome of a crop variety, an animal breed or a microorganism without altering their basic genetic characteristics. The risks to human health and the environment related to genetic engineering activities do not fundamentally differ from those of using traditional breeding technologies (UNEP International Technical Guidelines for Safety in Biotechnology, point 6 of Introduction. UNEP. 1995. p. 2). The GMOs can be identified and assessed during early phases of the breeding process and it is possible to avoid or minimize possible adverse effects.

When developing the national biosafety model, the following requirements were borne in mind:

- (1) Protection of human health and the environment are paramount in genetic engineering research and application of the results.
- (2) When designing the biosafety system, the state should minimize amendments to current legislation and avoid establishment of new state bodies that are likely to represent an additional burden on the national budget and tax payers. It is necessary to use currently available bodies, granting them, if need be, extended authority.
- (3) It is important that new legislation in the field of biosafety includes regulations and procedures that can be implemented using minimum resources. The procedures themselves should be simple and clear.
- (4) Society has the right to be made aware of information on the results of genetic engineering activities and should be able to exercise community control. Therefore, the evolving biosafety framework should include a mechanism for promoting public awareness and participation in decision-making processes.

The concept of the state governing biosafety activities in Belarus is based on the expertise of several leading nations, current legislation in Belarus, the existing national system of state governance and commitments under international agreements.

Biosafety legislation in Belarus

Current biosafety legislation in Belarus includes, *inter alia*, legislation in the area of human health, environmental protection, agriculture, human rights, intellectual property rights and specific biosafety legislation in the law ‘On Safety in Genetic Engineering Activity’ (in the following text referred to as the ‘Biosafety Law’) adopted 9 January 2006, which came into force on 10 July 2006. Some amendments to the current legislation have been made in accordance with this ‘Biosafety Law’.

Legislation in Belarus in the field of safety in genetic engineering for contained use includes:

- (1) A law on health, which determines the state policy on health protection for Belarusian citizens and constitutes the legal, socio-economic and organizational basis of the health care system.
- (2) A law on well-being of the population regarding sanitation and epidemics, which regulates public relations in the field of provision of health and well-being of the citizens of Belarus, preserving and improving public health, physical and spiritual growth and life expectancy and quality. The law designates competent national and local enterprises, institutions, organizations and other entities, regardless of their form of ownership, public associations, officials and citizens in complying with sanitary regulations and norms of hygiene. These bodies monitor sanitation and hygiene, and engage in preventive, anti-epidemic and anti-radiation activities. There is state control and monitoring; and penalties for violation of sanitary legislation are given.

In order to ensure observance of the requirements on biological safety and handling of hazardous microorganisms, including transgenic microorganisms, the laboratories in the institutions of the Ministry of Health adhere to 15 national regulatory and legal acts and methodological guidelines. This list includes a number of regulatory documents, developed in the former Soviet Union, which do not conflict with the legislation of Belarus. They will remain effective until national regulatory and legal acts are developed and adopted.

The Biosafety Law includes a number of important provisions regarding safety in genetic engineering activities for contained use. Firstly, it establishes four levels of risk related to genetic engineering activities:

- (1) Working with non-pathogenic, transgenic organisms.
- (2) Working with opportunistic pathogenic transgenic organisms.
- (3) Working with transgenic organisms capable of inducing dangerous infectious diseases and spreading infection for which effective prevention and treatment measures are available.
- (4) Working with transgenic organisms inducing especially dangerous infectious diseases that can be rapidly spread and for which no effective prevention and treatment measures are known.

Genetic engineering for contained use only at the second, third and fourth levels of risk is carried out exclusively by state-owned organisations. Implementation of these activities is allowed only if a permit is issued by the Ministry of Health. The procedure for determination of the risk level, as well as the requirements for carrying out work at the second, third and fourth levels of risk are also determined by the Ministry of Health. A contained use system for genetic engineering activities at the second, third and fourth level of risk is subject to mandatory accreditation given by the Ministry of Health according to procedures specified by it. Thus, Belarus has established an effective system of ensuring biosafety when working with microorganisms, including transgenic microorganisms, of various pathogenicity groups. This biosafety system can also be applied to non-pathogenic transgenic organisms in contained use when such work does not pose a significant threat to human health. Concerning risk to the environment, there are measures for preventing inadvertent release of transgenic organisms into the environment that are described in Resolution No. 50 of 17 August 2006 of the Ministry of Natural Resources and Environmental Protection 'On Safety Requirements for Contained Use Systems for Work at the First Risk Level of Genetic Engineering Activities and for Subjects Carrying out the Development of Transgenic Organisms' (NRLA, 2006, 144, 8/14952).

Legislation on biosafety for genetic engineering involving release of transgenic organisms into the environment for trials

The law 'On Environmental Protection' (17 July 2002) includes Article 49, 'Requirements in the field of environmental conservation for 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 those created by artificial means, without developing measures for preventing their harmful impact on the natural ecosystems, obtaining expert advice and (or) permits in accordance with the legislation of the Republic of Belarus, are prohibited, etc.'. This provision is fully applicable to transgenic organisms, but contains a reference to the special legislative act regarding release of transgenic organisms into the environment, for which the described requirements should be detailed.

A comprehensive list of national legislation, regulating safety in the processes of release of transgenic organisms into the environment for trials is given below. It also includes acts associated with implementation of international legislation.

- 6 May 2002, 'On Accession of the Republic of Belarus to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity'.
- 17 July 2002, revised version of the law 'On Environmental Protection'.
- 9 January 2006, the law 'On Safety in Genetic Engineering Activities' ('Biosafety Law').
- 5 June 2002, Resolution No. 734 of the Council of Ministers of the Republic of Belarus 'On Measures for Implementing Provisions of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity'.
- 19 June 1998, Resolution No. 963 of the Council of Ministers of the Republic of Belarus 'On Establishment of the National Co-ordination Biosafety Centre'.
- 17 August 2006, 'Regulations regarding the advisory committee on biosafety of transgenic organisms of the Ministry of Natural Resources and Environmental Protection' (approved in Resolution No. 52 of the Ministry of Natural Resources and Environmental Protection//NRLA, 2006, No. 145, 8/14954).
- 22 August 2006, 'Directions on carrying out risk assessment for possible adverse effects of transgenic organisms on the environment' (approved in Resolution No. 55 of the Ministry of Natural Resources and Environmental Protection//NRLA, 2006, No. 150, 8/15002).
- 25 August 2006, 'Directions on carrying out risk assessment for possible adverse effects of transgenic organisms on human health' (approved in Resolution of the Chief State Sanitary Physician, No. 076-086).
- 29 August, 2006, Resolution No. 56 of the Ministry of Natural Resources and Environmental Protection 'On safety requirements for the trial fields and other sites designed for trials of transgenic organisms during their first-time release into the environment', (approved by the Ministry of Natural Resources and Environmental Protection//NRLA, 2006, No. 151, 8/14993).
- August 29, 2006, 'Directions for carrying out trials of transgenic organisms during their release into the environment' (approved in Resolution No. 57 of the Ministry of Natural Resources and Environmental Protection//NRLA, 2006, No. 151, 8/14994).
- 8 September 2006, 'Regulations on state expertise for conducting biosafety procedures for transgenic organisms and developing model agreements for its implementation'

(approved in Resolution No. 1160 of the Council of Ministers of the Republic of Belarus//NRLA, 2006, No. 151, 5/22922).

- 8 September 2006, 'Regulations on issuing the permits for the release of transgenic organisms into the environment for trials' (approved in Resolution No. 1160 of the Council of Ministers of the Republic of Belarus//NRLA, 2006, No. 151, 5/22922).

According to Article 15 of the Biosafety Law, only non-pathogenic GMOs are allowed for release into the environment for trial purposes. Any first time release of GMOs into the environment is only allowed by 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 field trials of plant varieties that are produced by traditional breeding methods from transgenic materials, such as varieties of plant that have undergone the procedure of state registration in Belarus. The procedure of issuing permits is described in the 'Regulations on issuing permits for the release of transgenic organisms into the environment for trials'.

The Ministry of Natural Resources and Environmental Protection issues permits for release of GMOs into the environment on the basis of expert recommendations according to the Biosafety Law, Art. 20, 21; 'Regulations on state expertise for conducting biosafety procedures for transgenic organisms and developing model agreements for its implementation' and 'Regulations regarding the advisory committee on biosafety of transgenic organisms of the Ministry of Natural Resources and Environmental Protection'. Regulations on risk assessment for experts and applicants are: 'Directions on carrying out risk assessment for possible adverse effects of transgenic organisms on human health' and 'Directions for carrying out trials of transgenic organisms during their release into the environment'.

The permit is valid for all subsequent releases of GMOs if there has been no change in release details (recipient environment, safeguards, etc.). A permit for release of GMOs into the environment can be cancelled or suspended in cases of violation of the legislation, as well as in the case of receiving additional reliable information on the adverse effect of the GMOs on human and environmental health.

Article 15 of the Biosafety Law states that trials of GMOs, during their initial release into the environment, must be performed in specially equipped trial fields and at other sites specially monitored to prevent possible adverse effects on the environment and to meet the requirements prescribed by the Ministry of Natural Resources and Environmental Protection. The first release of GMOs is regulated by Resolution No. 56 of 29 August 2006 of the Ministry of Natural Resources and Environmental Protection, 'On safety requirements for the trial fields and other sites designed for trials of transgenic organisms during their first-time release into the environment' and 'Directions for carrying out trials of transgenic organisms during their release into the environment'.

State legislation on the use of transgenic plant varieties for crop production

Current legislation in Belarus only permits the use of crop varieties that have undergone state registration following favourable results in national crop variety trials. Transgenic plants, in accordance with the law 'On Patents for Varieties of Plants' 13 April 1995 (amended and supplemented 14 July 2004), belong to the category of varieties that to a significant degree

inherit traits from another variety (Article 7). Consequently, any transgenic variety of interest for breeding must undergo registration pursuant with this law in order to be entered on the State Register of Protected Varieties of Plants of the Republic of Belarus and, thus, be legally protected.

According to the law 'On Seeds' of 14 February 1997, seeds of varieties of plant, including trees and shrubs, can be cultivated only after having been entered on the State Register of Varieties of Plants and Woody and Shrubby Species, or after having been recognized as having potential. In order to determine economic value and other traits for the purpose of recommending them for use in production, state variety trials are carried out. The results of these trials are taken into account for patent application and constitute the basis for inclusion on the state register. Amendments to the law on GMO seeds have been made by adding provisions concerning such seeds. The latest version of the 'Regulations on crop variety trials' (approved in Resolution No. 1135 of the Council of Ministers of the Republic of Belarus on 5 September 2006//NRLA, 2006, No. 149, 5/22894) includes provisions for GM plants.

According to the Biosafety Law, Article 16 states that registration of transgenic plant varieties is to be carried out by the Ministry of Agriculture and Food by entering the corresponding data in the State Register of Transgenic Plant Varieties, Animal Stocks and Strains of Non-pathogenic Microorganisms. State registration is carried out after a positive decision is made by state experts in GMO safety on the basis of results of field trials. The procedures for state registration are described in the 'Regulations on state registration of transgenic plant varieties, animal stocks and strains of non-pathogenic microorganisms' (approved in Resolution No. 1195 of the Council of Ministers of the Republic of Belarus on 12 September 2006//NRLA, 2006, No. 149, 5/22920). The current legislation of Belarus, in contrast with that of the EU, does not envisage a special registration procedure for transgenic plant varieties intended for food, feed and processing. The import of seeds of such varieties is regulated by Art.11 of the Cartagena Protocol and national legislation on food safety and veterinary rules on import of feeds.

Export and import of seeds of transgenic plant varieties

Export and import of seeds is regulated by the Law 'On Seeds' of 14 February 1997 (with amendments concerning GMOs); the Customs Code of the Republic of Belarus of 6 January 1998 and additional legislation.

According to the Biosafety Law (Art. 18) and regulations on import of GMOs into Belarus for release into the environment for trials, a permit is issued by the Ministry of Natural Resources and Environmental Protection. Import of GMOs for commercial purposes, including crop production, is allowed with an appropriate state registration certificate. Transit of non-pathogenic GMOs is allowed if the carrier notifies the Ministry of Natural Resources and Environmental Protection.

According to the 'Regulations on issuing permits for import into and export from the Republic of Belarus of seeds' (approved in the Resolution of the Ministry of Agriculture and Food of 19 September 2006, No. 61//NRLA, 2006, No. 164, 8/15089), the Main State Inspection on Seed Farming, Plant Quarantine and Plant Protection and its regional offices are responsible for examination of applications for import or export of GM seeds and issuing permits. Permits are issued according to 'Directions on carrying out state phytosanitary

control in points of admission through the state borders of the Republic of Belarus and (or) the places of destination' (approved by the decision of the Council of Ministers of the Republic of Belarus on 14 June 2006, No. 881//NRLA. 2006, No. 123, 5/22635). No transgenic seeds have been imported into Belarus since adoption of national biosafety legislation.

The biosafety legislation of Belarus, in this regard, is in full compliance with the requirements of the Cartagena Protocol and, in general, with the biosafety legislation of the European Union (Regulations 90/219/EC and 2001/18 EC).

Food and Feed Safety

The relevant legislation includes:

- (1) The law 'On Health' of 18 June 1993, which determines state policy in the field of health care.
- (2) The law 'On Sanitary and Epidemic Well-Being of the Population' of 23 November 1993, which establishes legal and organisational requirements for prevention and elimination of adverse effects of foodstuffs, among other items, on people and regulates activities of state bodies and legal entities to ensure good health and well-being of the population.
- (3) The law 'On Quality and Safety of Edible Raw Materials and Foodstuffs for Human Life and Health' of 29 June 2003 (referred to as the law 'On Quality of Foodstuffs'), which details provisions and requirements for ensuring safe nutrition.

The main state bodies that exercise control over food safety include the Ministry of Health, the Ministry of Agriculture and Food, the Committee for Standardisation, 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 law 'On Sanitary and Epidemic Well-Being of the Population' guarantees citizens the right of access to information on foodstuffs. The law 'On Quality of Foodstuffs' specifies requirements in line with the law 'On Protection of Consumers' Rights' of 9 January 2002, which states that the consumer has rights to purchase safe food products and to receive comprehensive information on them. In particular, according to Paragraph 2.4 of Article 5 of the law on protection of consumers' rights, information on commodities must indicate if the food product is genetically modified or contains genetically modified ingredients.

Compliance of food products with regulatory acts and standards is assessed in accordance with the law 'On Assessment of Compliance with Requirements of Technical Regulatory Legal Acts in the Field of Norm Setting and Standardisation', which requires mandatory certification of products. It is illegal to market and import products subject to mandatory certification without a certificate of conformity.

In order to control food quality and ensure biosafety, the State System of Hygienic Regulation and Registration of Chemical and Biological Substances, Materials and Products was established by the Council of Ministers in 1993. All substances, materials and products, manufactured and used in Belarus, including imports, are subject to registration and regulation. Registration is based on the results of directed research and existing data, which

quantify permissible concentrations of harmful substances in all food products. Coordination of the work, expert assessment of the results of toxicological and hygiene studies, responsibility for the quality, 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.

Resolution No. 1807 of the Council of Ministers of the Republic of Belarus of 14 December 2001, 'On Improving the State System of Hygiene 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 procedures for registration and regulation and for carrying out laboratory trials and sampling of products for laboratory trials. International agreements are also adhered to.

Among other important documents that aim at ensuring quality and safety of food products are the sanitary rules 'Hygiene Requirements for Quality and Safety of Edible Raw Materials and Foodstuffs' (SanPiN 11 63 RB 98), which prescribes hygiene norms for quality and safety of edible raw materials and food products, as well as requirements for compliance with the prescribed norms for handling food, which are the same for all products and raw materials, irrespective of whether genetic modification is involved. There are, in addition, 41 supplementary documents concerning the food processing industry (technological processes and raw materials) and 11 documents on compliance with the sanitary conditions at enterprises that sell food products. The general methods of inspection and analysis of food products, technical specifications for their manufacture and quality requirements are contained in over 200 Standards of Belarus, 1,000 National Standards (GOSTs) and Technical Specifications.

On 2 September 2003 the Chief State Sanitary Physician adopted Resolution No. 116, 'On the State Hygiene Regulation and Registration of Edible Raw Materials and Foodstuffs, Derived from or Using Genetically Modified Sources'. Starting from 1 January 2004, edible raw materials and foodstuffs and components used for their manufacture, derived from or using genetically modified sources, if they contain 2 percent or more of the latter, must undergo mandatory state hygiene regulation and registration. This resolution is no longer applicable to edible raw materials and food products that do not contain DNA or proteins. The results of analyses appear on food labels that indicate the levels of GM components. This was approved in Resolution No. 434 of the Council of Ministers of the Republic of Belarus of 28 April 2005, 'On Some Aspects of Consumer Information on Edible Raw Materials and Food Products', which supersedes Resolution No. 116. Use of GM products is not allowed in production of children's food. The list of foods that are subject to mandatory laboratory tests for presence of genetically modified components was restricted to soybean and corn products marketed in Belarus. A network of twelve GM testing laboratories was established and accredited (Table 3).

Table 3. List of laboratories accredited for GMO testing of edible raw materials and foodstuffs in Belarus

Institution	Address
Republican Centre of Hygiene, Epidemiology and Public Health	50 Kazintsa St, 220099 Minsk mail@rcheph.by tel.: (375) 172780549 fax.: (375) 172784207
Minsk Municipal Centre of Hygiene and Epidemiology	13 P.Brouki St., 220013 Minsk tel.: (375)1720861
Brest Regional Centre of Hygiene, Epidemiology and Public Health	11 Svobody Sq., Build. "B", 224030 Brest ocgi@brest.by tel.: (375) 162215429 fax.: (375) 162216769
Mogilev Regional Centre of Hygiene, Epidemiology and Public Health	82 Grishin St, 212011 Mogilev tel.: (375) 222468723
Gomel Regional Centre of Hygiene, Epidemiology and Public Health	49 Moiseenko St, 246001 Gomel clerk@gmlocge.by tel./fax.: (375) 232745326
Belarusian State Institute of Metrology	93 Starovilensky trakt, 220053 Minsk belgim@belgim.belpak.minsk.by tel.: (375) 172336217 fax.: (375) 172880938
Brest Centre of Standardisation and Metrology	10/1 Kizhevatova St., 220041 Brest csm@brest.by tel.: (375) 162285780 fax.: (375) 162285608
Grodno Centre of Standardisation and Metrology	56 Kosmonavtov St., 230003 Grodno csms grodno@tut.by tel./fax.: (375) 152723817
Gomel Centre of Standardisation and Metrology	17a Poleskaja St., 246003 Gomel gomelcsms@beinfo.by tel./fax.: (375) 232717285
Mogilev Centre of Standardisation and Metrology	33 Belinskogo St., 212011 Mogilev csms mogilev@tut.by tel./fax.: (375) 222240578
NAS Institute of Genetics and Cytology	27 Akademicheskaja St., 220072 Minsk NCBC@biosafety.org.by tel.: (375) 172841691 fax.: (375) 172841917
Belarusian State Veterinary Centre	19a Krasnaja St., 220005 Minsk bgvcentr@open.by tel.: (375) 172904259 fax.: (375) 172904275

Labelling of GMOs

There are some principal differences in GMO labelling legislation in Belarus and the EU (as well as in the Russian Federation). Current Belarusian legislation, in contrast with that of the EU, does not require special registration procedures for transgenic plant varieties intended for food, feed and processing purposes. If the food was produced from a transgenic crop variety registered, for example, in the USA, and grown in the USA in accordance with national biosafety legislation, there is no reason to consider such food as hazardous to health. For labelling purposes, the national laboratories are able to identify characteristic DNA sequences such as the 35S promoter of cauliflower mosaic virus. In contrast with EU and Russian legislation, in Belarus there is no threshold content of GM-components in foods that determines whether a food should be labelled or not. This makes it possible to use simple and not too expensive methods for GMO detection.

GMO labelling legislation for feed is different from that for food in Belarus. For a long period it was not necessary to label GM feed, but new veterinary norms on 'Feed Safety Indices' have been approved (Resolution No 48 of the Ministry of Agriculture of 28 April 2008, amended on 21 May 2008 Resolution No 54 and 23 December 2008 Resolution No. 94). According to the new norms, the maximum permissible level of GMO content in feed and feed raw materials is 0.9 percent, except for GTS 40-3-2, A 2704-12 (GM-soybean) and MON810, Bt 11, T25, GA21, NK603, MON863 (GM-maize), for which their content is not limited .

Administrative system for biosafety

The Ministry of Natural Resources and Environmental Protection (for functions related to release of GMOs into the environment) and the Ministries of Health, and Agriculture and Food (for the issues of commercial use of GMOs) were designated as the competent authorities for complying with international obligations under the Cartagena Protocol. The Institute of Genetics and Cytology of the NAS, which earlier performed the functions of the National Coordination Biosafety Centre, was designated the national focal point, responsible for liaison with the Secretariat of the Cartagena Protocol.

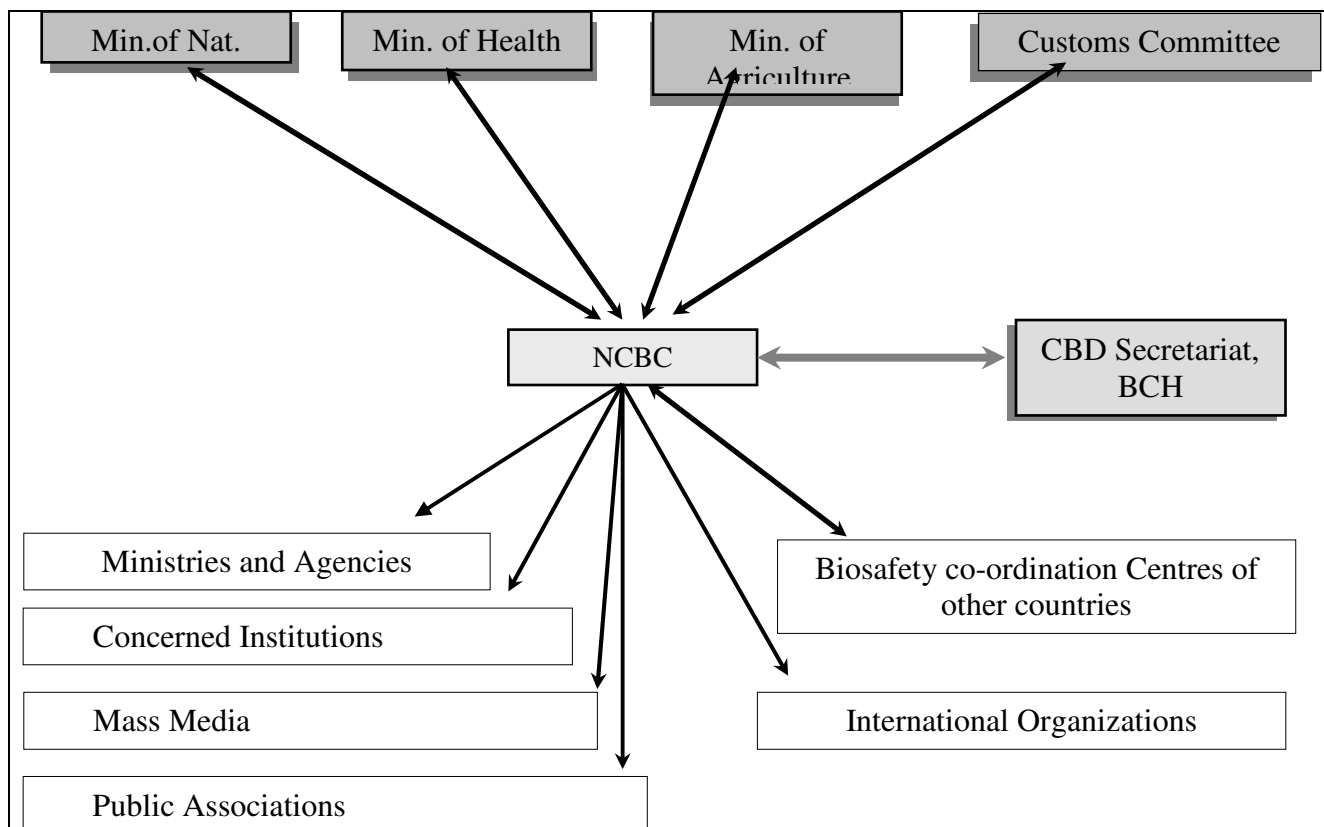


Figure 1. Structure of the administrative biosafety system of the Republic of Belarus.

Min. of Nat. – 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

The National Co-ordination Biosafety Centre was 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 on 5 June 1992 and regarding the issues for the safe use of the results of modern biotechnology’. Its main tasks have been:

- To collect, analyse and systematize information on legislation and research in the field of biosafety, field trials of transgenic organisms, import, export and commercial use in Belarus of transgenic organisms and products made on their basis, as well as the above mentioned information on biosafety from international databases and to create a national biosafety database.
- To provide information on biosafety issues to the concerned ministries and other national bodies and mass media.
- To share information with biosafety focal points of other countries and international organizations.
- To organize scientific expertise on the safety of transgenic organisms and products of transgenic origin intended for use in Belarus.

- To provide advisory support to the ministries and other national bodies in drafting legislative acts, dealing with imports, exports and safe use of transgenic organisms and products of transgenic 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 bodies in the preparation of proposals on conclusions of bilateral and regional agreements and in the development of international agreements on biosafety issues.

Design of the national biosafety system does not envisage establishment of new state governance. According to the law 'On Safety in Genetic Engineering Activities', state governance 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 authorised national state governing bodies, including 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.

In the field of regulating genetic engineering activities, the government will:

- Adopt regulatory and legal acts in the field of safety of genetic engineering activities.
- Determine the procedures for issuing permits for import into Belarus, export out of Belarus or transit through its territory of transgenic organisms, as well as permits for release of transgenic organisms into the environment for trials.
- Approve regulations on the procedures for organisation and performance of state expertise on safety of transgenic organisms.
- Determine the procedure for state registration of varieties of transgenic plants, breeds of transgenic animals and strains of transgenic microorganism.
- Determine the procedure for state control in the field of safety of genetic engineering activities.
- Determine the procedure for providing information from databases on transgenic organisms.
- Exercise other powers according to the legislation.

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

- Adopt regulatory and legal acts and technical regulatory acts in the field of safety of genetic engineering activities.
- Issue, according to the specified procedures, permits for release of non-pathogenic transgenic organisms into the environment for trials.
- Establish safety requirements for contained use for genetic engineering activities of the first risk level.
- Establish safety requirements for sites for trials of non-pathogenic transgenic organisms in coordination with the National Academy of Sciences of Belarus.
- Determine the procedures for the trials of non-pathogenic transgenic organisms released into the environment in coordination with the National Academy of Sciences of Belarus.

- Establish the procedures for risk assessment for potential adverse impacts of transgenic organisms on the environment.
- Issue, according to the specified procedures, permits for import into the Republic of Belarus and release into the environment for trials of non-pathogenic transgenic organisms.
- Exercise state control in the field of safety of genetic engineering activities within its competence.
- 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.
- Establish safety requirements for contained use systems for genetic engineering activities of the second, third and fourth risk levels.
- Issue, according to the specified procedures, permits for import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of opportunistic pathogenic and transgenic pathogenic organisms.
- Establish safety requirements for transportation of opportunistic pathogenic and transgenic pathogenic organisms.
- Establish procedures and exercise accreditation for contained use systems for genetic engineering activities of the second, third and fourth risk levels.
- Establish procedures for risk assessment of potential adverse effects of transgenic organisms on human health.
- 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:

- Adopt regulatory and legal acts and technical regulatory acts in the field of safety of genetic engineering activities.
- Exercise state registration of transgenic varieties of plants, animal breeds and strains of microorganisms.
- Exercise state control in the field of safety of genetic engineering activities and exercising other powers according to the legislation.

System of state expertise on the safety of genetic engineering activities

State expertise for safety of transgenic organisms is performed in the case of:

- The initial release of transgenic organisms into the environment for trials.
- State registration of transgenic varieties of plants, animal breeds and strains of microorganisms intended for commercial use.

First-time release of transgenic organisms into the environment, which requires a permit from the Ministry of Natural Resources and Environmental Protection, may include the following:

- Individual breeding samples (primary transformants or their progeny), which are released into the environment at the testing site (controlled release) for assessing breeding value and biosafety, and selecting the best genotypes.
- Transgenic varieties from foreign breeders, which are released into the environment in state variety trials (planned release) for state registration and commercial use.

During the initial trial stages particular attention is paid to environmental safety of released organisms and affects on human health. An initial strict screening reduces the numbers of individual genotypes, in the case of plants, to a core group that can be investigated in detail. The screening is done by independent experts appointed by the state, with reference to national laws, published manuals, scientific literature etc. The experts prepare a statement based on their findings containing unambiguous conclusions on the possible consequences of release of the organisms into the environment or for their commercial use. This statement is reviewed by a state appointed expert council that makes recommendations to the appropriate state authority for issuance or not of the relevant permit and registration certificate.

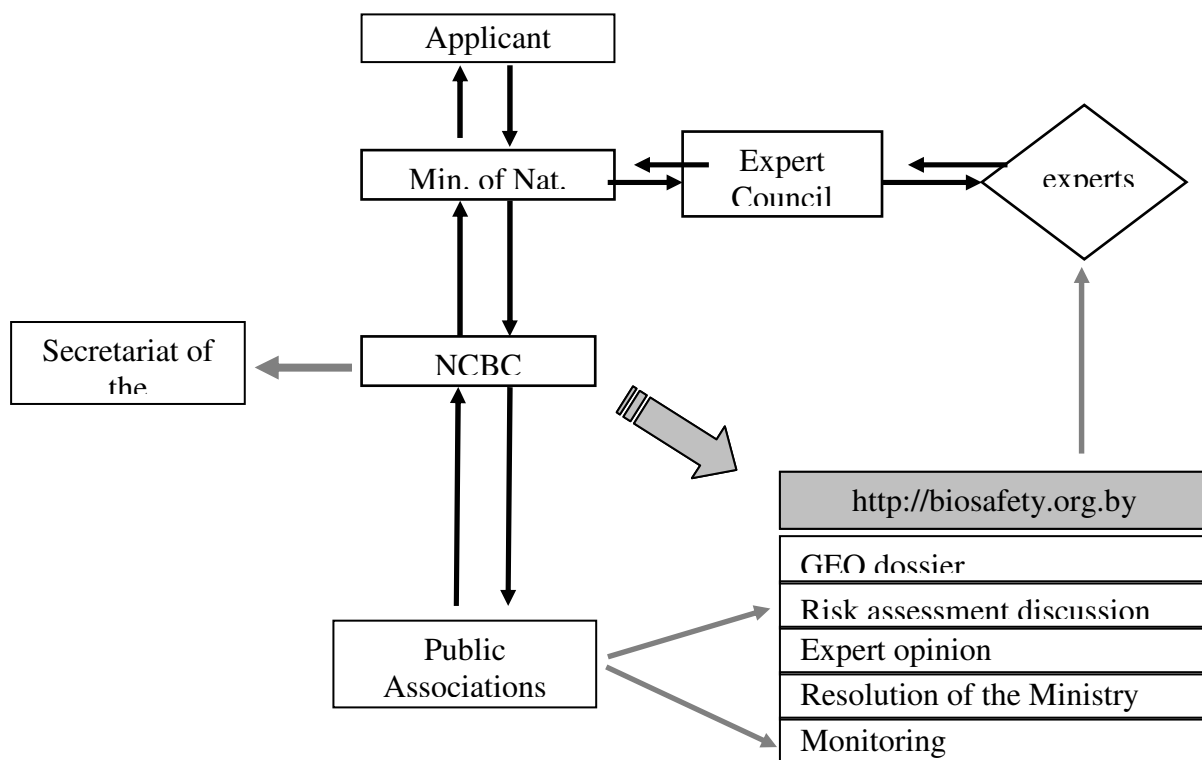


Figure 2. Scheme for release of genetically engineered organisms into the environment for testing purposes

Promoting public awareness and public participation in biosafety decision-making

Belarusian legislation secures citizens' rights to receive information and participate in decision-making processes in accordance with 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) Endeavour 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 endeavour to inform its public about the means of public access to the Biosafety Clearing-House’.

The Aarhus Convention concerns informing the public and public participation in decision-making processes on issues of environmental importance, which regarding genetic engineering, contains a clause (Article 6, par. 11) stating that ‘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’. The national law ‘On Protection of Consumers’ Rights’, of 9 January 2002, and various additional laws and resolutions echo this.

The National Co-ordination Biosafety Centre provides information on issues of the safety in genetic engineering to state government bodies, mass media, citizens and public associations. A number of workshops dedicated to developments in biosafety have been held and reports on topical issues in biosafety have been presented at numerous national and international conferences and symposia. Staff members of the Centre have given interviews to the mass media and have prepared and published materials on biosafety in newspapers and journals. The public can express their opinion in petitions and through an interactive web site, which is currently being redesigned. There are no special information programmes exclusively dealing with biotechnology, but TV and radio frequently deal with these issues. There are some special programmes for the rural population.

The law ‘On Safety in Genetic Engineering Activities’ contains a number of provisions maintaining people’s rights of access to environment-related information and participation in decision-making in issues of environmental importance. The law obliges specially authorised government bodies to submit relevant information to the National Co-ordination Biosafety Centre, in particular that regarding permits and state registration certificates for transgenic varieties of plants, animal breeds and strains of microorganisms. The web site of the National Co-ordination Biosafety Centre (<http://biosafety.org.by/forum/>) ensures public participation and transparency in decision-making.

In 2003-2005 the National Co-ordination Biosafety Centre completed the UNEP-GEF project ‘Development of the National Biosafety Framework for the Republic of Belarus’. The most important output of the project was the ‘Draft National Biosafety Framework for the Republic of Belarus’, which can serve as a basic guide to implementation of the national biosafety system. The Report on the project, (Ed. A.Yermishin, Minsk, 2004, 126 pp.) is available in Russian and in English on the website of the National Co-ordination Biosafety Centre.

Intellectual Property Rights

Following independence, Belarus ratified important international agreements in the area of protection of intellectual property. Corresponding national legislation was adopted and administrative structures were established. The State Patent Committee was made the agency responsible for protection of intellectual property rights. The main legislative acts include the laws, 'On Patents for Inventions and Useful Models', 'On Patents for Industrial Standards', 'On Patents for Varieties of Plants' (of 13 April 1995, amended and supplemented 14 July 2004), 'On Accession of the Republic of Belarus to the International Convention on Protection of New Varieties of Plants' (of 24 June 2002) and some resolutions of the Council of Ministers. A database of inventions, industrial standards, patents and breeding achievements was established.

7. State of information and communication needs

Use of the Internet is growing in Belarus, although the telecommunications sector lags behind that of neighbouring countries. All NAS institutions, ministries and other major agencies have open access to the Internet and have their own websites. Relevant information is available on the web site of the National Co-ordination Biosafety Centre, <http://biosafety.org.by>. The National Co-ordination Biosafety Centre has good contacts with biosafety coordination centres of most countries of former the Soviet Union, in particular, with Russian and Ukrainian colleagues. The centre also has good contacts with international organizations, including the BCH of the Cartagena Protocol, UNEP and FAO. The officers of the centre take part in international workshops and conferences on biosafety organised by UNEP, FAO and other international organisations.

8. Areas requiring support

Capacity in modern biotechnology research in Belarus is limited. Only three laboratories carry out research on development of GMOs and no GM crop variety is registered in Belarus. In this regard, capacity building in the area of plant biotechnology is important. Strengthening biotechnology research capacity would be possible through collaboration with leading institutions and biotechnology firms. Use of transgenics in breeding improved Belarusian crop varieties could assist in combating Colorado potato beetle (CPB) and PVY and PLRV. It would also be useful for the production of F1 hybrid oil seed rape and maize and to develop herbicide tolerance in soybean, sugar beet, barley, wheat and flax. Belarus has a rational biosafety framework and assured government support. Comprehensive biosafety legislation came into force in 2006, and covers all aspects of GMOs, but special legislation may be developed to regulate GM crop management and co-existence of traditional, organic and GM crop production. There are currently no special regulations in Belarus that distinguish among the various types of crop production.

Implementation of the biosafety legislation would benefit from some assistance in technical and capacity building issues. For example, there are no test sites designed for trials of

transgenic crops for release into the environment and no specialized laboratories equipped for monitoring transgenic organisms released into the environment. The existing laboratories require substantial upgrading in order to test and monitor the release.

9. Participation in networks and international cooperation

Belarus is a member of the Commonwealth of Independent States that was formed after the dissolution of the Soviet Union, but does not belong to other organisations. In 2003 Russia, Belarus, Kazakhstan and Ukraine negotiated the setting up of a Single Economic Space to facilitate trade among the members, but this is unlikely to function as it goes against the principles of the World Trade Organization, which Russia, Kazakhstan and Ukraine hope to join. The main trading partner of Belarus remains Russia, but there is also trade with Ukraine, Poland and Germany. There are no special networks and programmes with neighbouring countries regarding biotechnology. There are some agreements on general research cooperation between the National Academy of Sciences of Belarus and academies in Russia, Ukraine, Moldova and France, among others, that include joint projects on biotechnology.

10. Recommendations

Belarus has a near comprehensive biosafety framework, but lacks up-to-date technical facilities and sufficient scientific expertise in the area of applied molecular biology. Consequently recommendations fall into five broad categories:

- (1) Strengthening biotechnology research capacity through collaboration with leading international institutions and biotechnology firms.
- (2) Use transgenics in breeding improved Belarusian crop varieties.
- (3) Development and approval of legislation on co-existence among traditional, organic and GM crop production methods.
- (4) Establishment of fully equipped testing areas for trials of transgenic organisms for release into the environment.
- (5) Establishment of specialised laboratories for monitoring transgenic organisms during their release into the environment.

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