

**United Nations Environment Programme  
Global Environment Facility (GEF)**

**National Biosafety Framework of Azerbaijan**

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## Abbreviations

BCH	Biosafety Clearing House
CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biosafety
EU	European Union
FAO	Food and Agriculture Organization
GMO	Genetically Modified Organisms
GEF	Global Environment Facility
NCC	National Coordinating Committee
UNEP	United Nations Environment Programme
UNDP	United Nations Development Programme
<b>WTO</b>	<b>World Trade Organization</b>

## CHAPTER 1. GENERAL OVERVIEW

### 1.1. Overview of the country

The Republic of Azerbaijan enjoys a favorable geographic position and it is located in the southeast of a transit region called Caucasus where Europe meets Asia. The country shares borders with the Russian Federation on the north (390 km), Georgia on the northwest (480 km), Armenia on the west (1007 km), Turkey on the southwest (15 km) and Iran on the south (765 km). Its coastline along the Caspian Sea on the east is 825 km long.

The Republic of Azerbaijan is the most populated country in the Caucasus region. Its population is 8,26 million (by early 2004). Over 90% of its population is represented by Azerbaijanis who belong within the Caspian type of Southern European race and whose language is of the Oguz group of the Turkic language. Labour force (men: 16-59 y.o., women: 16-54 y.o.) constitutes 54,2% and the youth make up 33,5%.

Compared to the globe too a small area of Azerbaijan encompasses 9 climatic zones (of the total 11 available on the planet), 5 geographic, 15 agro-climatic, 17 soil and 16 plant zones. In addition the country's area is composed of 6 landscape and 12 hydro-geological zones, 13 economic and 12 specialized agricultural districts.

According to the Constitution which was adopted on 12<sup>th</sup> November 1995 by nationwide elections Azerbaijan is a democratic, world oriented, unitary Republic. State power in Azerbaijan is divided among legislative, executive and judicial authorities. The Head of State is President with five years tenure.

The legislative power in Azerbaijan belongs to one house National Parliament *Milli Mejlis*. 125 members of Milli Mejlis are selected by general and straight elections for five years tenure.

Executive power is a responsibility of the President of the Republic of Azerbaijan. The President of the Republic of Azerbaijan establishes his/her own supreme executive body Cabinet of Ministers to support the implementation of his/her executive authority. Judicial power comprises Constitution Court, Supreme Court, Court of Appeal and specialized courts. The Republic of Azerbaijan consists of 65 rural administrative regions and Nakhchivan Autonomous Republic with its 7 rural administrative regions. There are 10 settlements in the country with a status of a city (Baku, Ganja, Sumgayit, Ali Bayramli, Mingachevir, Lankaran, Yevlakh, Naftalan, Khankendi, Sheki).

The Republic of Azerbaijan is a party to over 30 international and regional organizations including United Nations (March, 1992), OSCE (February, 1992), Islamic Conference Organization (1992), European Council (January, 2001), Economic Cooperation Organization (1992), Black Sea Economic Cooperation Council (1992), European Bank of Reconstruction and Development (1992), World Bank (1992), Commonwealth of Independent States (September, 1993), ƏYAM, UNESCO, UNICEF, World Tourism Organization, Asian Development Bank.

## **1.2. Economic overview**

The Republic of Azerbaijan regained its independence in 1991 and is a country developing based on market economy. Presently, the country is facing social economic hardships of transition period. Repercussions of military aggression for about 15 years long with 20% of the country's territory invaded by Armenia and with over one million refugees and internally displaced persons as well as other similar factors impede the resolution of the present hardships.

In early 90s the economy of the country and overall social economic situation was characterized by a high rate of inflation. The internal public and political instability hampered the implementation of sound economic reforms. Moreover, an economic slump in the country adversely affected people's living standards.

As from 1995 after the reinstatement of public and political stability, as a crucial prerequisite for economic reforms, strict budgeting, financial credit, taxation and customs policy as well as the liberalization of prices, international trade activities and currency market and implementation of actions on the transformation of property made it possible to achieve a number of positive changes. Notably, the increase in GDP from 1996 through 2004 accounted for 75% reaching the level of 1990. In 2004 GDP accounted for 41,9 trillion manats (8,5 billion US dollars) which made 5,1 million manats per capita (1041 US dollars).

Although the growth in GDP in recent years resulted in the overall increase in living standards there are still certain challenges in this area and relevant actions have been envisioned to overcome them. In this view, new social policy is being implemented which supports major strategic goals on the improvement of social security, providing support to sensitive groups of the population, enhancement of main health and education services, providing aid to refugees and internally displaced persons.

***Climate:*** 9 climatic zones are found in Azerbaijan of the 11 available globally. The variety of climates is affected by the Caspian Sea and a combination of different types of terrain. These factors determine the distribution of climate, air

temperature, atmospheric precipitations and other elements and create a vertical of clearly distinguishable zones. Depending on the height of place and distance from the Caspian Sea several climatic zones are distinguished: dry subtropical, wet subtropical, mild, and cold climates.

**Soil:** The land area of the country is 8,64 million hectares. 4225,2 thousand hectares of them (49,3%) are suitable for agriculture and, subsequently, 1460 thousand hectares of the latter are cultivated land areas. Besides, it is comprised of 2200 thousand ha of grassland, 220 thousand ha of meadows and 340 thousand ha of lands for perennial plants. Azerbaijan is a country of scarce land resources with only 1,05 ha of land per capita including 0,21 ha of cultivated land per capita.

According to the most recent data 42,5% of the country's land, including 33,7% of cultivated land, 68,1% of grassland, 15,2% of meadows, 15,9% of gardens and 26% of forests are subjected to different kinds of erosion.

Over 2 million ha of the country's area is subjected to wind erosion and 1,2 million ha are affected with salination.

#### **1.4. Agrobiodiversity**

**Cultivated crops:** Azerbaijan is an ancient center for growing crops. Having developed throughout million years and being transformed into culture plants by humans species cultivated in a wide area of agriculture along with their wild predecessors are now extensively represented in the country. 454 varieties of cereals are found in Azerbaijan while 25 of them are cultivated ones. 15 varieties of wheat were recorded in Azerbaijan. There are 43 varieties of hard wheat and 87 varieties of soft wheat in the country. Most of their varieties came into being from the ancient times as a result of selection by farming folk. Such varieties are also called in scientific literature as indigenous ones. Some of them were extinct and the remaining is threatened with extinction. Nowadays, more productive varieties were developed based on new and more progressive methods of selection. About ten thousand specimens have been put together in the wheat gene pool of Azerbaijan.

10 varieties of barley are found in Azerbaijan. Two of them (common multicolumn six row barley and two row barley) are cultivated varieties. Some of the indigenous varieties are extinct and threatened with extinction. At present about 500 specimens of barley varieties have been gathered in the gene pool.

5 varieties of rye occur in Azerbaijan. Only one variety is a cultivated one.

Only one variety of corn occurs in Azerbaijan including 90 varieties specimens of which are collected in the gene pool.

Rice is also represented by one variety with 80 varieties in the gene pool.

***Other cultivated plants:*** Dozens of varieties of crops, beans, vegetables, fruits, berries and grapes and their varieties found in the flora of Azerbaijan are widely cultivated. Fruits and berries grown in gardens are varieties that were transformed into a cultivated form as a result of purposeful efforts of humans during a long time. As an example, apple, pear, peach, nut, hazel nut, blackberry, medlar can be mentioned here. In collection gardens more than 6000 specimens of fruits and berries pertaining to 150 varieties are grown. It is very much regretted that nowadays some indigenous fruit and vegetable varieties distinguished for their taste quality and other valuable features have become extinct and some others are still threatened with irreversible extinction.

***Wild predecessors of cultivated plants:*** In Azerbaijan wild varieties of wheat are represented by one-seeded wheat (*T.beotinum*), two-seeded wheat (*T.araraticum*) and others that prevail in plain, foothill and mountainous areas. 8 wild varieties of wheat and 4 wild varieties of rye occur in the country.

Although bean, vegetable and fruit plants and their wild predecessors are widespread most of the cultivated indigenous varieties are threatened with a risk of extinction or reverting to a wild state. Presently, a number of institutes of the Ministry of Agriculture and Genetic Resources Institute of National Academy of Sciences are carrying out actions on gathering wild forms of plants of agricultural significance and their ancient indigenous varieties and doing researches on their storage in a collection, further studying and sustainable use in selection activities. It should regretfully be mentioned that although Azerbaijan possesses the diversity of wild varieties of cereals, bean, vegetable, fruit, berry plants and grape, their ancient local forms and other varieties selected by farming folk most of them have already been irreversibly lost due to a lack of protection and scientifically grounded selection activities in recent and present times.

## **1.7. Impact of GMO to biodiversity**

According to estimations by UN Food and Agriculture Organization (FAO), up to 75% of genetic resources of biodiversity used in agriculture since last century up to now have already been lost. If such a trend is continued and humans do not take solid actions for the conservation of plants' genetic resources mankind will face a shortage of food due to loss of the valuable part of biodiversity. Wildlife of the world including Azerbaijan is very diverse. Nine of the eleven climatic zones known to science are found in Azerbaijan. Each climatic zone has its own typical vegetation cover and biodiversity.

A lack of experts and legal regulation mechanisms to make assessment of tests and propagation of GMO plants and their impact on the environment and human health and eventually on biodiversity facilitates unhindered transfer of such plants into Azerbaijan. Since there are no facilities to test GMO in the country it can only be assumed that certain number of suspect plants having morphological and biological similarities with conventional varieties are already found at farmers' sites and made available in markets evading the state test and registration. For comparison, a review of the agricultural plants distribution register of the Republic of Azerbaijan for 2005 showed that only one variety of water melon was distributed over the regions of the country. However, at least three varieties of water melon are observed in markets. Similar picture is observed in relation to potato, onion, melon, tomato, cucumber and fruit plants.

Azerbaijan ranks first the Caucasus region for the richness of natural resources. 4500 species of higher plants over 9 climatic zones occur in Azerbaijan which constitutes 65% of the Caucasus flora and 24% of the former Soviet Union flora. 7 percent of these plants, i.e. 240 species are endemic and relict incorporated into 108 genera and 36 families. 140 rare and endangered species are listed in the Red Data Book of Azerbaijan. The present fauna of Azerbaijan comprises 97 species of mammals, 357 species of birds, about 100 fish species, 67 species and subspecies of amphibians and reptiles and about 15 thousand species of insects.

Nowadays when agriculture and industry is intensively developing the role of specially protected nature areas in the preservation of natural resources in a complex form is indispensable. The total area of specially protected sites constitutes 8,2% of the country's area (in future this indicator will equate to 10%) which play indispensable role in biodiversity conservation.

On the other hand, organization of research activities by research institutions of the Agroscientific Center of the Ministry of Agriculture based on zoning principles is, in a sense, of particular importance. Biodiversity related selection research activities at the institutes are carried out separately for each region depending on soil and climatic features. Consequently, prevailing adaptive features of a new variety specially developed for a particular region is taken as a driving factor.

Intensive farming in plant husbandry has always resulted in the encroachment of cultivated plants upon wild forms while intensive grazing in animal husbandry has brought in erosion in the wild plant species habitat. Subsequently this has been the cause for their drastic decline and loss. The expansion of cultivated land is also one of the adversely contributing factors in this regard.

The use of poisonous chemicals in cultivation by adversely affecting habitats of a number of animals, birds and fish, sometimes ends up in their complete destruction. Since farmers and other land owners in the country give preference to

more productive and robust varieties and species of cultivated plants the protection of biodiversity in agriculture assumes a limited scale. Therefore, the propagation of only a limited number of plant species and varieties in all regions of the country with such a diverse soil and climatic zones is not appropriate. The cultivation of the same variety of any plant in all regions of the country can be given as an example of this typical case. During epiphytoxicity of a particular plant a relevant variety cultivated throughout the country area is affected by a disease and this results in the loss of most of the harvest. The bitter outcome of this is not so difficult to imagine.

Noting the dependence of food safety of mankind on the application of economically profitable intensive farming technologies in agriculture, increase in productivity without impact on the environmental balance can be achieved through ensuring particular attention to the conservation of genetic resources of biodiversity.

In this regard, one cannot avoid the question as to how GMO based plants, particularly their popular forms might affect biodiversity.

## **CHAPTER 2. DEVELOPMENT OF BIOTECHNOLOGY IN THE COUNTRY, TRANSBOUNDARY TRANSFER, PRODUCTION, PROCESSING, USE OF GENETICALLY MODIFIED ORGANISMS AND ENSURING BIOSAFETY IN THIS AREA**

### **2.1. Present state of biotechnology area in the country**

Starting from 70s of the last century, using the achievements of biotechnology of those times the most advanced countries of the world including the Soviet Union undertook the development of highly qualified human resources on this specialty as well as initial studies in this area. Initial development of biotechnologists and genetic engineers in Azerbaijan took place in 70-80s.

There is a 'Genetic Engineering' laboratory at the Department of Fundamentals of Molecular Processes of Productivity under the Institute of Botany of National Academy of Sciences of the Republic of Azerbaijan. This is a modern and well equipped laboratory with appropriate scientific capacity. One of the achievements of specialists of this laboratory which is the only one in the country is the transfer of virus resistant *Kp* and chimera *K* genes to tobacco. The results of the study of issues of morphogenesis induction and construction of vectors of *Kp* gene transferred to this plant and transfer of alien genes to the same plant to trigger the development of leaves as well as other experiments in this area were published in a number of local and foreign periodicals.

The practical application of the results was confined to the premises of the laboratory.

'Genetic Engineering' laboratory has been equipped to contemporary international standards. The present shortcomings are only linked to a shortage of reagents, even a lack of some of them and, most of all, a lack of relevant vectors for genes transfer.

Studies are also carried out on salt toleration features of cultivated and wild plants at Cells Culture Laboratory of the same Institute. The aim of the studies is by using contemporary methodologies of biotechnology on cells and tissue culture to create a more productive new variety of wheat capable of growing in the regions of the Republic with saline soil.

No studies are carried out at Genetic Resources Institute of National Academy of Sciences of the Republic of Azerbaijan.

Extensive studies are run under the programme entitled 'Development and application of scientific and practical fundamentals of a complex growing technology ensuring creation of new productive, quality and sustainable varieties and hybrids of agricultural plants and gathering in a good harvest of them for

various agroecological regions of the country, reclamation of soil fertility, protection of the surrounding environment and energy saving through elaborating a theory and enhancing the methodologies of a selection process using scientific achievements in physiology, biotechnology and protection of plants'. The basics of this programme were laid at Scientific Research Plants Growing Institute of the Ministry of Agriculture in 70-80s.

Scientific Research Vegetables Growing Institute succeeded in the fast propagation of valuable specimens and obtaining 2-3 and even more generations in one year using the micro-cloning methodology in the research 'On the creation of fast growing, productive, disease and pests tolerant varieties and hybrids of tomato and cucumber for greenhouse farming, development and application of their farming technology and organization of seed growing'.

As a result of the research a new method of selecting fast growing homozygote lines in a high density selection environment during the process of selection of tomato cells and tissues were developed and perfect scientific scheme of in vitro selection were prepared. In addition, the most favorable natural and synthetic hormones for in vitro selection and their impacts as well as optimal density depending on their genotypes were identified. It was detected artificial food environment containing high density exogenous hormones of tissues has an inhibiting impact on the germination. It was also determined that as the number of endogenous hormones increases in genotypes the number of exogenous hormones introduced to the environment falls into decline.

Scientific research is being carried out on 'The study of molecular mechanisms of rapping and aging in plant tissues' at Biochemistry and Biotechnology Department and Biotechnology Laboratory of Baku State University of the Ministry of Education of the Republic of Azerbaijan and the above department closely collaborates with Biochemistry Institute named after A. Bach of the Academy of Sciences of the Russian Federation.

Scientific capacity of the Ministry of Health in the Republic of Azerbaijan is made up of Scientific Research Prophylactic Medicine Institute, divisions and sectors of Azerbaijan Medical University. Since these institutions are not appropriately equipped GMO related research and analyses are not carried out there.

Over 70 scientific articles on biotechnology and genetic engineering written by national specialists were published in local and foreign press and findings of successful studies were published in many foreign magazines and reports of international conferences and symposiums.

It the following Table presented by Azerbaijan National Academy of Sciences provides information about funds earmarked from the State budget in 2003 and

2004 for studies in the area of biology, medicine, health including biotechnology and some official figures reflecting a real state of affairs in this area.

Area	No. of Research Institutes	Subject	Direction	No. of fellows (total)		Budget earmarked for the subject, in thousand manats	
				Doctors	Candidates	By State budget	By non-State budget
Biotechnology	1	1	1	2	7	600.000	0
Biology	9	118	24	67	358	2588800.0	0
Ecology	12	60	18	17	147	1473844.6	3
Agriculture, forestry and fishery	19	164	19	52	542	13476363.0	40
Medicine and health	13	171	86	179	626	10442420.0	10
Total	54	514	148	317	1680	28581428.0	53

As is seen from the Table nowadays there are only 2 PhDs and 7 candidates to PhD in Biotechnology in the country which is unacceptable for Azerbaijan as a country with a good scientific potential.

## **2.2. Research activities in the country in the area of genetic resources**

The implementation of State Programme on Plants Genetic Resources in Azerbaijan started as long ago as in 1996 under which important actions were carried out.

Namely, scientific study groups on plants genetic resources were created at various institutes of Agrarian Scientific Center under the umbrella of the Ministry of Agriculture and these groups have been in charge of gathering, protection, studying of genetic resources and their sustainable use in selection activities. The studying, use and protection of biodiversity genetic resources is included as a subject in research plans of all scientific research institutes and studies are respectively carried out in this area. At Scientific Research Plants Growing Institute mainly seed specimens of wheat, barley, rye, oats, beans, corn, etc. are stored in a small chamber designed for short term storage.

Studies and selection of genetic resources of vegetables, melons, potatoes, onions, greens and other plants are conducted at Scientific Research Vegetables Growing Institute. Seeds specimens are kept in the Gene Pool of the Institute.

Collection of live specimens of plants are kept at various institutes and used in relevant studies, namely: cotton at Scientific Research Cotton Growing Institute, cultivated and wild species of grape at Scientific Research Viticulture Institute, various forage plant species at Scientific Research Forage, Grassland and Pastures Institute, fruit species, tea and subtropical plants at Scientific Research Gardening and Subtropical Plants Institute, silkworm species and mulberry at Scientific Research Sericulture Institute. According to statistics of 2003 studies had been made on more than 55000 varieties, hybrids and clones collected in the gene pool of these institutes of Agrarian Scientific Center.

## **2.3. Overview of GMO production, processing and use in the country**

As stated earlier, other than studies of tobacco at the genetic engineering laboratory no facts are known about the manufacture, processing and use of transgenic products officially registered in the country. However, appropriate climate conditions in the country, development dynamics of the agrarian sector, gaps in GMO regulations increase the probability of unimpeded transfer of transgenic plants, seeds and products into the country.

At the conference devoted to Development Prospects of Experimental Biology (BSU, May 2002) which was held in 2002 poor quality of new genetically modified breeds of cattle and particularly poultry (broiler) imported in the country and their harmfulness to human health were reported A.F. Kocharli, F.O. Mirzayeva). It was indicated in materials of the conference and other scientific

articles (F.O. Mirzayeva) that some companies and business circles retailed meat and meat products the origin of which was unknown and which did not meet standards and sanitary requirements and this brought on infectious diseases among humans.

Articles on this topic are periodically published and relevant information is disseminated by mass media. In article 'Europe steps back' published in Baku News No.063 of 23 March 2004 the author was quite right when remarking that 'At least potato products and particularly potato seeds imported into Azerbaijan from Russia should be taken under strict control. Instead of this, awareness raising and promotion of the cultivation of local potato varieties in Azerbaijan should be pursued'.

Despite a ban on mass production of transgenic plants in Russia which is of great interest to Azerbaijan as a neighboring country, no official prohibition was put on their use in food products.

According to experts' estimates only in 2003 and 2004, 250 to 500 thousand tons of transgenic soy bean protein, 60 to 100 thousand tons of soya and rape oil and corn starch was imported into Russia as part of illicit business. A study ordered by a German company revealed that 30 to 40% of products in retail outlets in Russia are of GMO origin. On the other hand, the problem is aggravated by the fact that only 10-15% of manufacturers in Russia comply with an obligatory requirement to label GMO products as prescribed by the European standards effective from 2004.

Subsequently, taking into account that Russia is one of the major countries in exporting food products and forage into Azerbaijan, the probability of unimpeded and uncontrolled transfer of genetically modified products into Azerbaijan is obvious. Because of a lack of labeling on imported products, unavailability of an appropriate laboratory to identify products subjected to genetic modification as well as a lack of legislative base and regulatory mechanism in this area it is difficult to identify how many varieties and quantity of transgenic seeds and products are imported into Azerbaijan from the neighboring countries and although the availability of transgenic products within the boundaries of the country is assumed it is still impossible either confirm or deny concrete facts in this regard.

#### **2.4. Mechanism of state control over plant protection means, fertilizers, veterinary and health substances imported in the Republic of Azerbaijan**

According to the Ministry of Agriculture 109 varieties of pesticides went through the state registration by 31 December 2004. Annually, 2500 to 3000 tons of various plant protective substances and 50 thousand tons of a variety of mineral fertilizers are imported in Azerbaijan. Within the aforementioned period 353

varieties of veterinary substances and 26 varieties of forage and forage additives went through the state registration.

By the above date, having passed the state registration 4000 varieties of medicines was approved for use by the Ministry of Health. Surveys and studies revealed that documentations of these products imported into the country do not contain any reference as to whether they are of GMO origin and no record about their import and export is kept by the state customs authorities.

Causes of this are as follows:

- a) Encoding system for genetically modified organisms is not envisioned by the goods nomenclature accepted by Newly Independent States in relation to foreign trade. Therefore, statistical written account of transboundary movement of such products cannot be kept;
- b) A lack of certificates on genetic modification of food products imported into Azerbaijan;
- c) A lack of legislative base to regulate import and export certification, manufacture and use of genetically modified organisms;
- d) Unavailability of a modern laboratory and specialists capable of making analyses of genetically modified organisms;
- e) A lack of environmental, technical, sanitary and veterinary standards for GMO based products.

Import into and export from Azerbaijan are governed by 'Regulations of import and export transactions in the Republic of Azerbaijan' approved by the Presidents' Decree No.609 of 24 June 1997. Pursuant to these Regulations medical substances imported into the country are not accepted for customs clearance unless they are supported by a feedback from Ministry of Health.

Pursuant to Regulations on 'Handling import and export of goods under veterinary control in the Republic of Azerbaijan' of 12 May 1998 which is applied by State Veterinary Service of the Republic of Azerbaijan the import of goods of animal origin requires an affirmative feedback from Ministry of Agriculture and unless the goods are supported by veterinary certificates they cannot be cleared through customs.

No customs clearance is allowed in relation to seeds unless approval by Ministry of Agriculture is provided.

However, analyses revealed that neither health nor agricultural and customs authorities do not have information about the import of genetically modified organisms into the country.

## **2.5. Capacity of biolaboratories of the country in GMO analysis**

While laboratories of a number of scientific institutions operating in the country are capable of making high level chemical analyses of food and other products none of them can detect GMO components in products.

Despite the availability of a modern laboratory made in USA with a database of various 400 chemical and organic compounds installed at Independent testing center in Azerbaijan, a laboratory of international company registered in UK named “Intertek Jaleb Brett”, Central Laboratory of State Customs Committee on food products contents and suitability for consumption and other modern laboratories are also incapable of detecting GMO components.

## **2.6. Level of public awareness raising about GMO in the country**

It is today's reality that most of the public are not aware of GMO products. At the same time, the retail of GMO products in Azerbaijan cannot be denied. In view of this it can be unambiguously concluded that this is a direct consequence of poor public awareness raising and education on GMO. Hundreds of newspapers and magazines are published in the country and about 26 TV channels (in the capital city and regions) are broadcast. Although some information concerning this issue is provided findings of a survey among different layers of the public have shown that the level of public knowledge about GMO is very low.

Under the joint initiative of the Ministry of Ecology and Natural Resources of the Republic of Azerbaijan and OSCE Baku Office, in implementation of the Aarhus Convention Public Environmental Information Center was established in Azerbaijan and has been at the public disposal since 22 September 2003.

The Center was established with a view to facilitating public access to environmental information and participation in decision making, ensuring transparency in environmental issues and, subsequently, promoting general democratization and enhancing advanced governance. The Law on Public Environmental Education and Awareness Raising and the Law on Public Access to Environmental Information have been adopted in Azerbaijan. However, the level of NGOs and mass media representatives' abilities to form efficient public activity in this area is low and therefore, the enhancement of public education and awareness raising in the area of biodiversity protection and Biosafety is of important issues.

To this end significant actions were taken in the area of public education and awareness raising, as well as public participation in decision making as part of Development of National Framework Documents on Biosafety. Various mechanisms were used during this period, such as: organization of workshops,

holding press conferences, issuance of press releases, publishing articles in newspapers and magazines, holding round tables in TV studios, giving interviews in mass media from time to time and printing brochures to raise public awareness of biosafety.

In the course of project implementation workshops on the following topics were organized and international experts, farmers, representatives of relevant ministries and committees were involved in the workshops.

**Workshop 1. Conducted in February 2005 on The enactment of Cartagena Protocol and commitments of the Republic of Azerbaijan in the area of biosafety.**

The workshop was designed to familiarize representatives of public institutions, NGOs, press, local experts, members of Milli Majlis and representatives of relevant ministries and committees with Cartagena Protocol and provide information on commitments of the Republic of Azerbaijan in the area of biosafety in connection with the enactment of the Protocol.

**Workshop 2. Conducted in April 2005 on Identification and analysis of biosafety resources under Cartagena Protocol.**

The main objective of the workshop was devoted to the overall situation, challenges, strategic directions and their analysis in the area of biological safety in connection with Milli Majlis' ratification of Cartagena Protocol on Biosafety to the Convention on Biological Diversity with the participation of experts and representatives from Ministry of Ecology and Natural Resources, Ministry of Agriculture, Ministry of Health, State Customs Committee and National Non-Government Organizations. The workshop provided general information on biotechnology and conventional selection, genetic engineering and genetic engineering organisms, the regulation of biological safety in this area of activities and establishment of a state system of biological safety. The workshop benefited from valuable proposals by experts and representatives invited to the workshop in subsequent phases while drafting a national law on biological safety.

**Workshop 3. Conducted in December 2005 on Presenting the results of studies, identification of gaps, needs and priorities.**

The main objectives of the workshop consisted of informing scientists and specialists of National Academy of Sciences and scientific research institutes of different ministries which conduct researches on biotechnology, genetic engineering, selection, genetics and plant genetic resources about research and studies in this area in compliance with the provisions of Cartagena Protocol on Biosafety to the Convention on Biological Diversity, identifying the gaps as well as learning views, thoughts and proposals of scientists and specialists engaged in

this area through verifying strategic directions and priority areas of research and studies.

Although proposals put forward during the workshop were marked by polarity it placed in the forefront the importance of use of biotechnology methodologies in the development of new plant varieties and animal breeds. During deliberations scientists and specialists shared their valuable thoughts on ensuring safe genetic engineering activities and establishment of a national system in this area.

#### **Workshop 4. Workshop devoted to national legislators including public and private sectors within the context of national biosafety.**

The main objective of the workshop was to familiarize members of the National Parliament, specialists on legislation, senior officials of other government institutions and the wide layers of the public with the provisions of Cartagena Protocol on Biosafety, approaches of the Republic of Azerbaijan, as a party to this Protocol, to the fulfillment of its international commitments and, as a whole, how successful these commitments are fulfilled. The workshop participants were also provided the opportunity to get familiar with a compendium of materials on the existing situation and challenges as well as pending tasks in the area of biosafety compiled in the course of project implementation.

#### **Workshop 5. Public awareness raising through the involvement of NGOs, consumer organizations, scientific unions and private sector (farmers including food and chemical industries) within the context of National Biosafety.**

The workshop addressed issues relating to public awareness raising and participation in decision making on biosafety in the context of contemporary needs which is one of the important topics in the biosafety system nowadays. The workshop convened representatives from NGOs, scientific institutions, private entities (farmers, other land owners) and consumers. As expected, the workshop was of great interest to the invitees. Environmental institutions dealing with different areas of environmental problems as well as advocates of a ban on activities in any particular area of genetic engineering shared their views at the workshop.

There are about 20 NGOs in the country dealing with biosafety issues with particular focus on the establishment of a regulation and control system, raising public awareness of possible risks posed by GMO products to human health and the environment in a timely and proper manner and, taking account of the significance of education in this area, they implement certain actions among the public and demonstrate particular activity in this sphere.

The announcement of findings of a survey conducted by Azerbaijan Environmental Standards Monitoring Fund among different layers of the population to determine the level of awareness of GMO raised a great interest among the workshop participants. The survey participants were composed of 38,5% of men and 61,5% of women consumers. Although half of the respondents (44,5%) were aware about transgenic products they were little informed of GMO products. Despite all the above mentioned, irrespective of unawareness of GMO, 78,5% of the surveyed supported the appropriateness of labeling GMO products. Based on the above said it can be concluded that the public is either not aware at all or little aware of the issues related to the use of genetic engineering organisms as food in agriculture as well as in medicine.

The most appropriate means of getting information about biological safety are TV broadcast, radio, newspapers and magazines. Such a source of information as informal conversations among the citizens should not be disregarded. While the above sources of information provide favorable conditions for the dissemination of non-reliable data, this, in the long run, raises interest of the public to this area through distribution of information of concern linked to genetic engineering activities, biological safety and other issues among the public.

#### **Workshop 6. Risk assessment and management on genetically modified organisms.**

The main objective of the workshop was to familiarize scientists and specialists invited at the workshop with necessary information and knowledge about the assessment of risks posed by genetically modified organisms to the environment, environmental balance and human health and about their safe management. It should be noted that the invited specialists can be involved into safety assessment of genetic engineering organisms in the future. In this regard, the knowledge they gained from the workshop concerning major principles and methodologies of biosafety assessment of genetic engineering organisms is of great significance. The workshop was of significant interest to representatives of public and government institutions and other invitees. Information on the molecular genetic methodologies used in researches raised a particular interest.

#### **Workshop 7. Public awareness raising in the area of genetically modified organisms.**

The topic of the workshop was devoted to the implementation of provisions and commitments on ensuring public participation in decision making and access to information on biosafety related issues by authorities in large cities and regions under the Cartagena Protocol to the Convention on Biological Diversity ratified by the Republic of Azerbaijan.

Workshop participants were provided information about major provisions of the Protocol of the Draft Law on National Biosafety which was prepared as part of the project and they shared their feedback and views. Taking into account the fact that a major part of consumers of agricultural products live in rural areas their role in taking part in the development of biosafety system in regions is important.

## **2.7. Attitude of NGOs of Azerbaijan to the GMO issue and their activities in this area**

Biosafety is the issue of concern of over 20 NGOs in Azerbaijan. These NGOs believe that Azerbaijan as a civilized country integrating into the international community cannot brush aside such issues as safety of the population and future generations, protection of biodiversity in the existing ecosystem and sustainable development. They take an active part in promoting activities on the establishment of a system of regulation and control over GMOs and providing timely and proper information to the public about a risk posed by these products to biodiversity and human health.

During a meeting held at Aarhus Public Environmental Information Center at the Ministry of Ecology and Natural Resources representatives of NGOs from Azerbaijan and Georgia put forward the idea of establishing a Union of South Caucasus NGOs and proclaiming this region as a zone free from GMO products and prepared a statement to official government bodies proposing to set up an ad-hoc working group and to ban the import of GMO products.

On 12-13 August 2005 ‘Discussions of Draft Law on Biological Safety in Azerbaijan: Public Participation’ workshop was held in Baku which convened representatives of public institutions and NGOs from Azerbaijan, Bulgaria, Georgia, Russia, Ukraine and Kyrgyzstan.

The workshop participants noted the following:

1. As one of the major spots of biodiversity, the Caucasus region is a central place for plant and animal species as well as microorganisms that came into being as a result of human activities;
2. Pursuant to provisions of the Convention on Biological Diversity and international law the use and distribution of GMOs in this area is strictly prohibited;
3. The topicality of issues related to the protection of diversity of national genetic resources increased with distribution and use of GMOs
4. Unification of the market of contemporary food products and limited choice of products is a threat to our national peculiar features, national and cultural traditions, nutrition culture of each of us in general and our social life as a whole;

The workshop participants proposed:

5. Taking into account that a Draft Law on Biological Diversity of the Republic of Azerbaijan does not fully cover new biological and genetic risks that emerged in recent times and does not meet contemporary needs and
6. Taking into consideration a Draft Law on Biological Diversity of the Republic of Azerbaijan, provisions of Convention of Biological Diversity, Cratahena Protocol, Aarhus Convention and other international legal and regulatory acts to develop a new annex addressing the regulation of GMO use and issues of genetic safety.

The workshop participants adopted Baku Declaration which invited the governments, ministries and relevant institutions of EECCA countries to undertake urgent actions in the area of legislation, standardization of control and monitoring, management and information dissemination.

Although half of the respondents were aware about transgenic products they were little informed of GMO products (Chart A). Namely, with regard to a note about GMO origin on the product 24% of the surveyed responded that it is useful, 37% told that it is harmful, 23,5% stated that it is done by a producer for advertisement purposes to attract consumers' attention or to differentiate the product from others, 13,5% guessed that such a note points to a fraudulent product (Chart B).

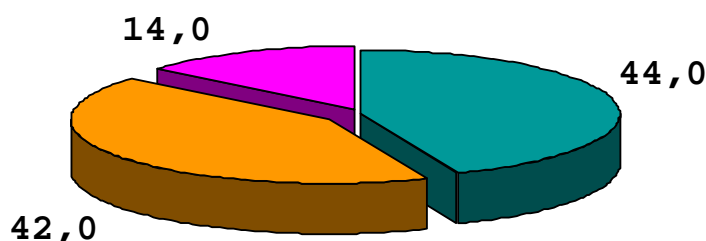
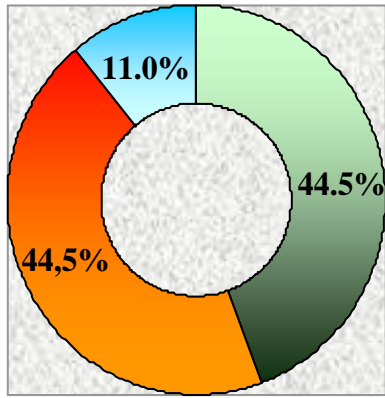


Chart A. Age categories of respondents

■ 18-35 ■ 36-50 ■ 51-70



■ aware ■ unaware ■ abstained

Chart B. Knowledge of respondents about GMO

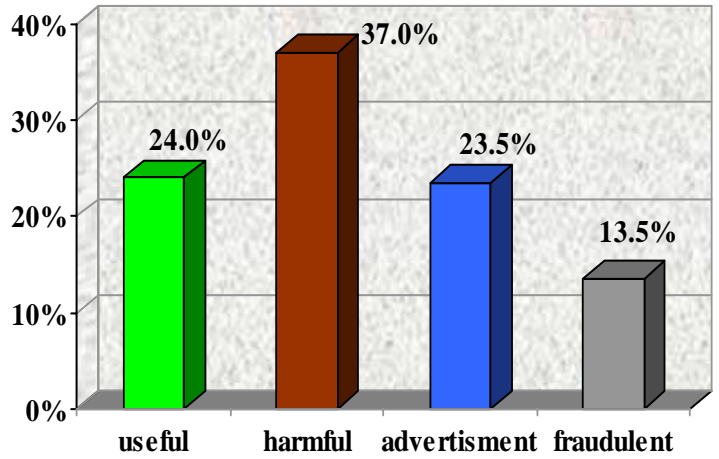
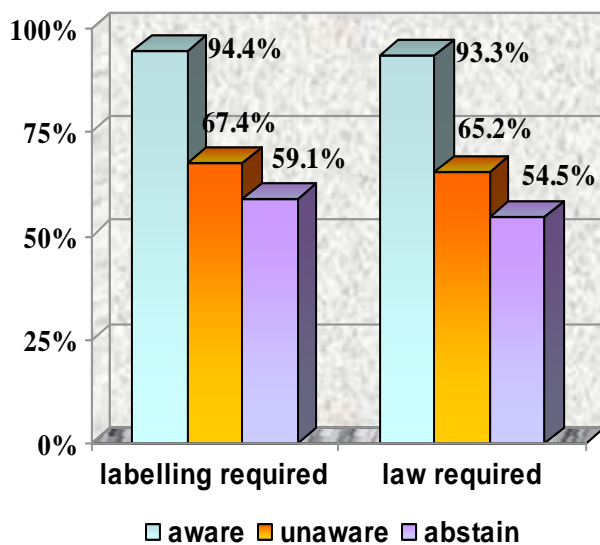


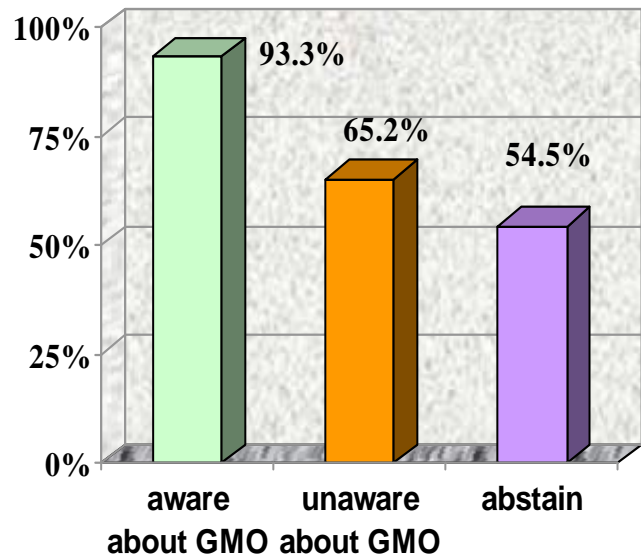
Chart C. How do you explain a GMO note on the product?

In addition, irrespective of unawareness of GMO 78,5% of the surveyed supported the appropriateness of labeling GMO products (Chart D) and also supported the adoption of a relevant regulatory act on the obligation of manufacturers to appropriately label GMO products. (Chart E).



■ aware ■ unaware ■ abstain

Chart D. Is it necessary to require of manufacturers in Azerbaijan to appropriately label GMO



■ aware ■ unaware ■ abstain

Chart E. Is a law on obligatory labeling of GMO products by manufacturers required?

While choosing a food product preference is given by 38,3% of respondents - to quality, by 31,2% - to price and 11,2% - to how well it is advertised (Chart F)

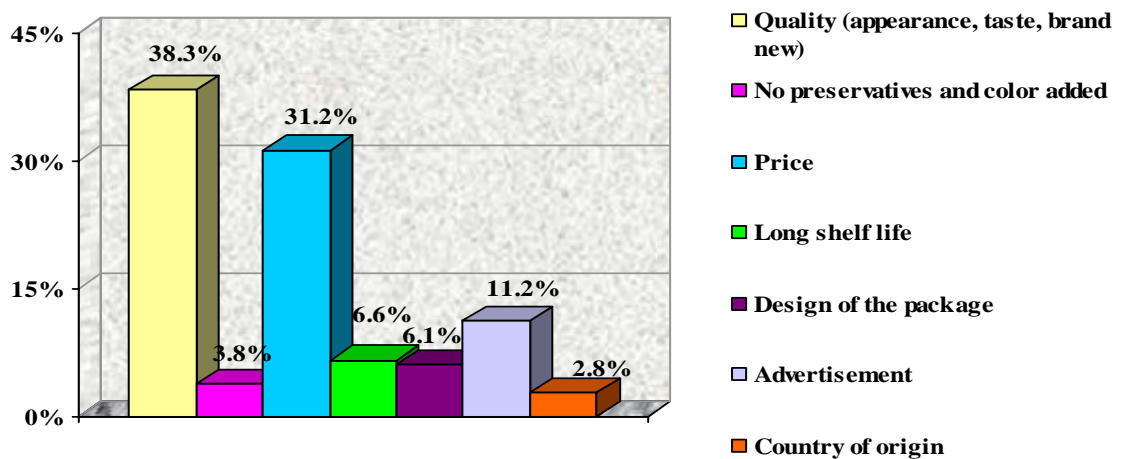


Chart F. Breakdown of consumers' preference criteria when buying food products

## 2.8. Public education and awareness raising and participation in the decision making on issues of safe genetic engineering activities. Current situation.

If the public fully trusts the state's capability to ensure safety of products created by genetic engineering activities, the public can gain a maximum benefit from achievements of the modern biotechnology. A lack of trust in these issues results from public unawareness of the actual state of affairs in this area.

In view of this, public access to information and participation in the decision making are stipulated in the legislation of the Republic of Azerbaijan (Constitution of the Republic of Azerbaijan, articles 39, 47, 50). A provision on access to information on an actual state of the environment is set forth in a number of international agreements ratified by the Republic of Azerbaijan including Cartagena Protocol on Biosafety to Biodiversity Convention (paragraph 23). According to the Protocol:

### 1. Parties:

a) assist and promote public education and awareness raising and its participation in ensuring safe transfer, handling and use of living modified organisms with regard to the conservation and sustainable use of biodiversity taking account of risks to human health;

b) take efforts so that activities on public education and awareness raising cover issues of access to information on the identification of living modified organisms that can be imported in accordance with the Cartagena Protocol;

2. Parties by adhering to their relevant legislation and regulations hold consultations with the public on issues of decision making in relation to living modified organisms and present the outcome of these decisions to the public ensuring confidentiality of the information pursuant to Article 21 of the Protocol;

3. Each party takes efforts for raising public awareness of the instruments of public access to the mechanism of mediation on biosafety.

Article 6.12 of the Aarhus Convention on access to information and public participation in decision making on environmental issues is a separate clause concerned with safety of genetic engineering activities. Pursuant to this Article 'Each party within its national jurisdiction applies to the extent possible and in the required manner provisions of the present Article to decisions relating to the issuance of permits for a deliberate release of genetically modified organisms into the environment'.

Taking account of the aforementioned in the course of project implementation extensive actions have been taken with regard to public education and awareness raising and participation in decisions making on issues of biological safety. Various mechanisms have been used (organization of workshops, press conferences, interviews to media), articles on this issue have been published in official and other newspapers and magazines.

## **2.9. Statistic report**

In order to keep under a strict control compliance with safety rules in the area of genetic engineering in Azerbaijan all legal entities and entrepreneurs engaged in genetic engineering undertake to ensure the implementation of control over production activities, the obedience to sanitary standards, hygienic regulations and nature protection requirements.

Registration of organisms created as a result of genetic engineering activities, state statistic reports in the area of genetic engineering activities and on possible impacts of genetic engineering activities on human health and the environment are carried out by legal entities and entrepreneurs engaged in genetic engineering activities according to the procedure developed by State Statistics Committee based on analyses and observations of relevant executive power bodies.

## **CHAPTER 3. STATE POLICY OF THE REPUBLIC OF AZERBAIJAN IN THE AREA OF BIOSAFETY AND THE EXISTING LEGISLATION**

The policy of the Republic of Azerbaijan in the area of biosafety is part of the state policy on environment protection and health in accordance with the sustainable development concept of the country. The state policy in this area is based on international agreements to which the Republic of Azerbaijan is a party.

The main line of the country's policy in the area of biosafety pursues the protection of human health and biodiversity and ensuring sustainable development through making use of the achievements of contemporary biotechnology in a scientifically grounded manner.

Cartagena Protocol (adopted in 19.01.2000) to the Convention on Biological Diversity was ratified by the Republic of Azerbaijan on 4<sup>th</sup> March 2005 and the establishment of National Coordination Committee is one of the significant steps made by the Republic of Azerbaijan in this area.

The Republic of Azerbaijan joined a number of international conventions to ensure the natural development of wildlife and preserve its species composition and existing stocks. By fulfilling its commitments under the conventions Azerbaijan is demonstrating a strong will in making remarkable progress and reaching tangible results.

In recent years, some work towards the resolution of these problems has been accomplished, State Programme on Plants' Genetic Resources, National Action Plan on Environment Protection, National Programmes on Environmentally Sustainable Social Economic Development and Rehabilitation and Expansion of Forests have been prepared. The implementation of actions envisioned by these programmes will make it possible to overcome the aforementioned environmental challenges including biodiversity protection as well as other challenges the public is concerned about.

Besides, State Programme on Sustainable Use of Summer and Winter Pastures and Meadows and Combating Desertification in the Republic of Azerbaijan was approved in 2004.

The legislative base in Azerbaijan is composed of the following:

- The Constitution of the Republic of Azerbaijan;
- Laws of the Republic of Azerbaijan ensuring State Governance;
- Decrees and Orders of the President of the Republic of Azerbaijan and Orders of the Cabinet of Ministers ensuring the fulfillment of main provisions of Laws of the Republic of Azerbaijan;
- Regulatory documents of central executive power bodies (Ministries and Committees) identifying relevant actions;
- International agreements and conventions to which the Republic of Azerbaijan is a party;

### **3.1. Classification of national and international legislative acts in the area of biosafety**

The availability of the legislation meeting contemporary requirements and standards is a prerequisite for the achievement of necessary results in the area of biosafety. Principles of environment protection, the right of people to live in a healthy environment and protection of their health are reflected in the Constitution

of the Republic of Azerbaijan which was adopted by a nationwide referendum on 12 November 1995 and is a base of the legislative system of the country.

The following provisions such as the state's support to health service development, the right of each individual to safe existence, the right of each individual to live in a healthy environment and have access to information on a real state of the environment, the right of each individual to be indemnified for damage caused to individual's health or property as a result of environmental incompliance, the right of each individual to the protection of health and medical aid, the right of each individual to bring legal proceedings against officials who conceal facts and cases that pose a risk to human life and health are stipulated in Articles 16, 31, 39 and 49 of the Constitution.

Pursuant to the Constitution of the Republic of Azerbaijan international agreements to which the Republic of Azerbaijan is a party are considered to be an integral part of the Republic's legislative system (Article 148, item 2) and in case there are discrepancies between legal and regulatory acts contained in the legislative system of the Republic of Azerbaijan (excluding the Constitution of the Republic of Azerbaijan and acts adopted by a referendum) and international agreements signed by the Republic of Azerbaijan, international agreements in question are applied (Article 151).

Since Azerbaijan regained its independence a number of laws in the area of environment protection and use of natural resources have been adopted and about 35 international conventions and agreements ratified.

**Main legislative acts covering biosafety issues are as follows:**

1. Law on Environmental Safety (08.06.1999)
2. Law on Environment Protection (08.06.1999)
3. Law on Food Products (18.11.1999)
4. Law on Human Health Protection (26.06.1997)
5. Law on Pharmaceutical Activities (05.11.1999)
6. Law on Sanitary Epidemiological Health (10.11.1992)
7. Law on Protection of Consumers' Rights (19.09.1995)
8. Law on Plants Protection (03.12.1996)
9. Law on Plants Quarantine (23.04.1996)
10. Law on Selection Achievements (15.11.1996)
11. Law on Seeds Growing (11.03.1997)
12. Law on Wheat (16.06.2000)
13. Law on Pesticides and Agrochemical Substances (06.05.1997)
14. Law on Veterinary Medicine (17.06.1994)
15. Law on Livestock Breeds Development (26.03.1998)
16. Law on the Animal Kingdom (04.06.1999)

17. Law on Fishery (27.03.1998)
18. Law on Industrial and Municipal Wastes (30.06.1998)

A number of legal and regulatory acts were adopted by the President of the Republic of Azerbaijan, Cabinet of Ministers and relevant central executive power bodies to ensure the implementation of the existing laws. Currently, other regulatory documentation is being drafted. After regaining independence, Azerbaijan as a demonstration of its willingness to integrate into the world community and European domain joined international conventions, bilateral and multilateral agreements dealing with the environment, including environmental safety and human health. This process is presently being carried on.

Acknowledging the importance of the issue on 14 March 2000 the Republic of Azerbaijan joined the UN Convention on Biological Diversity which was signed in 1992 by 156 states. On 4 March 2005 the Parliament of Azerbaijan ratified Cartagena Protocol on Biosafety, an important annex to this convention which was adopted on 19 January 2000. By the Order of the President of the Republic of Azerbaijan of 21 December 2001 State Commission on Biological Diversity Genetic Resources was established under the chairmanship of the First Deputy Prime Minister. Ministry of Ecology and Natural Resources of Azerbaijan was appointed as a focal point to this convention.

### **3.2. Relevant Conventions ratified by the Republic of Azerbaijan**

At present the decline of biodiversity caused by human activities, degradation of natural ecosystems, the threat of extinction of some species are the issues of common concern to humankind.

No country in the world can overcome these challenges on its own and therefore the Government of the Republic of Azerbaijan joined a number of Conventions and agreements to ensure the development of the country's wildlife, its composition and stocks.

1. International Plant Protection Convention (2000)
2. International Convention for the Protection of New Varieties of Plants (2003)
3. UN Convention to Combat Desertification (1998).
4. Convention on Environmental Impact Assessment in a Transboundary Context (1999)
5. Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (1999)
6. UN Convention on Biological Diversity (2000)

7. Cartagena Protocol on Biosafety to Convention on Biological Diversity (04.03.2005)
8. Agreement on Cooperation In the Field Plant Protection and Quarantine (1998)
9. NIS Countries Agreement on Legal Protection of Plant Varieties (2003)
10. Agreement on Cooperation in the Field of Testing and State Protection of Plant Varieties between Ministry of Agrarian Policy of Ukraine and Ministry of Agriculture of Azerbaijan (2005)

Azerbaijan took an active part in the Working Group on Genetically Modified Organisms within the framework of Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters ratified by the Republic of Azerbaijan in 1999 and during the Almaty Meeting on 25-27 May amendments were made to Aarhus Convention concerning genetically modified organisms. According to these amendments Each Party to the Convention shall envision in its national legislation provisions on ‘informing the public at the initial stage about intentional introduction of genetically modified organisms into the environment’.

#### **3.4. Decree of the President of the Republic of Azerbaijan on State Commission for Biodiversity Genetic Resources (2001)**

In fulfillment of commitments by the Republic of Azerbaijan under the UN Convention on Biological Diversity, State Commission on Biological Diversity Genetic Resources was established by the Order of the President of the Republic of Azerbaijan of 21 December which is in charge of ensuring the implementation of complex actions to eliminate threats that may cause the extinction of genetic resources of plants, animals and microorganisms..

The State Commission is responsible for the development of national programmes in the field of protection of genetic resources of plants, animals and microorganisms, conservation and use of valuable and rare genera, species and varieties and breeds of plants and animals, keeping documentation to international standards based on the database of the country’s existing biological diversity gene pool, maximum use of the experience of regional and international organizations and financial sources, the regulation of activities of stakeholders in this area.

The commission is headed by the First Deputy Prime Minister. The Commission is composed of heads of central executive power bodies responsible for the environment, agriculture, economy, education, soil, the President and academicians of the National Academy of Sciences.

There is Research Council on Biological Diversity Genetic Resources. The Executive Secretariat of the Research Council has been established.

### **3.5. Cartagena Protocol on Biosafety to Convention on Biological Diversity**

Cartagena Protocol (19.01.2000) to the Convention on Biological Diversity was ratified by the Parliament of the Republic of Azerbaijan on 4<sup>th</sup> March 2005.

Provisions of this Protocol restrict the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.

### **3.6. Intergovernmental agreements signed/to be signed by the Republic of Azerbaijan**

1. Protocol of the second meeting of Intergovernmental Commission on Economic Development between the Republic of Kazakhstan and the Republic of Azerbaijan:

- exchange in specimens of cereals varieties (wheat, barley, oats, rye, buckwheat).

2. Draft Agreement on Economic and Scientific Technical Cooperation in the area of Agriculture between People Republic of China and the Republic of Azerbaijan:

- conducting joint scientific technical studies and application of findings.

3. Issues of scientific technical cooperation included into the Agreement on Bilateral Cooperation to be signed by Ministry of Agriculture and Forest of Italy and Ministry of Agriculture of the Republic of Azerbaijan:

- scientific cooperation between scientific research institutions in relevant fields;
- exchange of agricultural plants genetic resources.

4. Draft Agreement on Cooperation in the area of State Analysis and Protection of Plant Varieties between Ministry of Agrarian Policy of Ukraine and Ministry of Agriculture of the Republic of Azerbaijan.

5. Draft Agreement on Scientific Cooperation between Hungary and the Republic of Azerbaijan:

- mutual testing of plants genetic resources and new plant varieties.

6. Actions to be implemented under the Memorandum of Joint Intergovernmental Commission on Cooperation in Economic, Trade and Humanitarian areas between Islamic Republic of Iran and the Republic of Azerbaijan:

- mutual testing of new varieties of agricultural plants.

7. Proposals contained in the meeting protocol of the Joint Intergovernmental Commission between the Republic of Belarus and the Republic of Azerbaijan:

- mutual testing of and exchange in varieties and hybrids of white lupine, potato, tomato for indoor and outdoor growing.

8. Document on exchange in the area of plants genetic resources, new varieties, animal breeds, scientific studies and many other areas between Ministries of Agriculture of Turkey and the Republic of Azerbaijan.

9. The Sixth Protocol of the Meeting of the Joint Intergovernmental Commission between the Republic of Uzbekistan and the Republic of Azerbaijan held in Tashkent on 13 June 2003:

- exchange of gene pool materials of cotton, wheat, fruits and vine plants;
- mutual environmental testing of specimens of newly selected varieties of these plants;
- information exchange on new scientific findings.

10. Proposals to the draft Agreement envisioned by the Protocol of the First Meeting of the Joint Commission on Economic, Technical and Scientific Cooperation between Egypt and the Republic of Azerbaijan:

- exchange of specialists in the area of plants growing, cattle breeding, veterinary, plant materials, seeds growing technologies, certified wheat seeds;
- provision of assistance to Azerbaijan in the development of productive breeds of sheep.

### **3.7. National Programmes in the area of biodiversity protection**

- State Programme on Plants Genetic Resources;
- Environment Protection Action Plan;

In addition, under the support of Global Environment Facility, UN Development Programme, Flora and Fauna International Strategy and Action Plan on Biodiversity of Azerbaijan has been developed and adopted.

The objective of the Strategy and Action Plan on Biodiversity of Azerbaijan is to preserve wildlife for future generations through ensuring its rehabilitation, protection and rational use within a context of sustainable development of Azerbaijan and in accordance with major commitments on the implementation of provisions of the Convention on Biological Diversity. The Strategy and Action Plan have set priorities for next five years taking account of the present state and potential of biodiversity and a plan of coordination and relevant actions.

### **3.8. Peculiar features of the establishment of a state biosafety regulation system in the Republic of Azerbaijan**

The establishment of a National biosafety system in the Republic of Azerbaijan does not pursue the idea of setting up an independent government body capable of regulating all the matters in this area. The draft law on national biosafety prepared under the project envisions the implementation of state management on ensuring safety of genetic engineering activities by the President of the Republic of Azerbaijan, the Cabinet of Ministers and authorized state bodies designated for the state management on ensuring safety of genetic engineering activities. The authorized state bodies in this area are Ministries of Ecology and Natural Resources, Health and Agriculture of the Republic of Azerbaijan as well as State Customs Committee and Ministry of Emergency Situations of the Republic of Azerbaijan established on 16 December 2005.

The implementation of rights in the area of regulations of genetic engineering activities and management and ensuring of safety in the manner proposed below can facilitate the establishment of an effective National Biosafety system:

#### **The Cabinet of Ministries of the Republic of Azerbaijan:**

- Adoption of legal acts in the area of safety of genetic engineering activities;
- Adoption of regulations on the organization and implementation of state impact assessment of safety of genetically engineered organisms;
- Approval of regulations on the state register on safety of genetic engineering activities;
- Establishing regulations on state registration of plant varieties, animal breeds and microorganisms culture in the genetic engineering area;
- Implementation of other rights in accordance with the legislation of the Republic of Azerbaijan.

#### **Ministry of Ecology and Natural Resources of the Republic of Azerbaijan:**

- Issuance of a permit for the release of non-pathogenic genetically engineered organisms into the environment for testing purposes in accordance with a specified procedure;
- Subject to prior agreeing with Azerbaijan National Academy of Sciences, Azerbaijan Agrarian Scientific Center and other scientific institutions, Establishing safety requirements for areas specially designated for testing genetically engineered organisms;
- Establishing regulations on the implementation of testing of non-pathogenic GMOs genetically engineered organisms intended for release into the environment;
- Establishing regulations on the assessment of risks that are likely to be posed by genetically engineered organisms to a state of the environment;
- Issuance of a permit for the import of non-pathogenic genetically engineered organisms into the country and for release into the environment for testing purposes in accordance with a specified procedure;
- Establishing safety requirements intended for confined systems in the course of carrying out genetic engineering activities under the first category risk;
- Implementation of state control, within the area of its responsibilities, on safety of genetic engineering activities;
- Implementation of other rights not prohibited by the legislation.

**Ministry of Health of the Republic of Azerbaijan:**

- Adoption of legal and regulatory technical acts on safety of genetic engineering activities under the second, third and fourth categories of risk in confined systems;
- Issuance of a permit for carrying out genetic engineering activities under the second, third and fourth categories of risk in confined systems;
- Issuance of a permit for the import and export of pathogenic or pathogenic genetically engineered organisms into and from the Republic of Azerbaijan and transit through its area;
- Establishing safety requirement for the transportation of conditionally pathogenic and pathogenic genetically engineered organisms;
- Establishing regulations on identifying risk levels in the area of genetic engineering activities as well as regulations on safety requirements for genetic engineering activities under the second, third and fourth categories of risk in confined systems;
- Establishing regulations on the assessment of risks that are likely to be posed by genetically engineered organisms to human health;
- Carrying out the state registration of non-pathogenic genetic engineering cultures of microorganisms;
- Implementation of state control and other rights envisioned by the legislation in the area of genetic engineering safety.

**Ministry of Agriculture of the Republic of Azerbaijan:**

- Adoption of legal and regulatory technical acts on ensuring safety of genetic engineering activities in agriculture;

- Carrying out the state registration of genetically engineered plant varieties, animal breeds and microorganism cultures;
- Implementation of state control and other rights envisioned by the legislation in the area of genetic engineering safety.

### **3.9. Responsibilities of the Republic of Azerbaijan in the area of control over biological safety and its monitoring**

In order to ensure safety of genetic engineering activities, subject to the enactment of a relevant national law, actions should be taken for the establishment of a relevant management body which is the Ministry of Ecology and Natural Resources for preparation of regulatory legal acts, enhancement of knowledge and qualifications of specialists on biosafety and their training.

### **3.10. Proposals on issuing permits and state registration system in the area of genetic engineering activities**

Pursuant to the provisions of the Draft Law of the Republic of Azerbaijan on Biosafety and Protection of Biological Diversity Genetic Resources which was developed during the implementation of Project on Development of National Framework Documents on Biosafety, the issuance of a permit for the use of genetically modified organisms in the national biosafety system which is pending the implementation and ensuring biological safety in the area of their state registration is carried out in the manner given below.

### **3.11. Proposals on issuing permits for the implementation of genetic engineering activities in confined systems**

In accordance with the classification of risks likely to be posed to human health and the environment no permit is required during the implementation of any kind of genetic engineering activities in confined systems provided that these activities fall under the first, i.e. non-pathogenic, category of risk as defined in the draft Law of the Republic of Azerbaijan on biosafety. In general, genetic engineering activities are dealt with in accordance with the procedures envisioned in the legislation of the Republic of Azerbaijan. Genetic engineering activities can be carried out by healthy and professionally qualified individuals and legal entities possessing appropriate premises, equipment, utensils and staff, subject to ensuring safety for human health and the environment in this area.

In accordance with the draft law the implementation of activities falling under the third and fourth categories of risk are not allowed unless they are supported with a permit issued by a relevant executive power body (Ministry of Health, State Customs Committee).

It is assumed that, subject to the enactment of the draft law in accordance with the rules of procedure adopted in the country and a subsequent development of regulatory legal documentation enabling genetic engineering activities, dependent on a potential risk level, separate permits will be issued for activities with microorganisms of each risk category. In that case, permits issued to legal entities will be an official document confirming the provision of the required sanitary hygienic conditions ensuring safety for human health and the environment in the implementation of actions on biosafety.

## **RECOMMENDATIONS**

The national biosafety system of the country should be composed of political, legal, administrative and technical guidelines as well as other norms, requirements and procedures intended for ensuring the conservation and sustainable use of biodiversity taking account of risks that are likely to be posed to human health in the process of manufacturing, processing, transboundary transfer and use of transgenic organisms.

It is obvious, that although the laws discussed above contain a number of provisions that can be applied for governing some issues relating to biotechnology and biosafety they still cannot be considered sufficient.

The analysis of the laws governing the import and export of biodiversity genetic resources and their seeds in the agricultural area makes us assume that gaps in some provisions of this law (Article 26) provided conditions for bringing seeds of new plant varieties into the country including seeds of GMO origin. After making amendments to the law these shortcomings have been eliminated.

With a view to adjusting the Law of the Republic of Azerbaijan on Seeds Growing to international laws at the initiative of Food Safety Programme of European Commission and Ministry of Agriculture of the Republic of Azerbaijan a provision conforming to the requirements of Cartagena Protocol concerning the import of seeds of GMO origin into the country was included into the draft law. The draft law in question was broadly discussed with the participation of representatives of European Commission and Europe House, the special ambassador of European Community to Azerbaijan, representatives of GTZ, IFDC, PCA, a number of accredited representatives of foreign countries, parliament members, authorized representatives of Ministries of Justice, Finance, Economic Development and other ministries and committees. Views and proposals of the participants were taken into account during deliberations. Additional item on the import of seeds of GMO origin was added to the draft law in conformity with the requirements of Cartagena Protocol and other amendments on exceptions on bringing seeds into the country were taken into account. This proved to be the first step in the area of biosafety legislation.

The second step in this area was the initiative on the development of the draft Law on Biosafety in Azerbaijan. Despite the fact that the draft Law reflected, in overall, most of the issues relating to genetically modified plants, food and feed products made of their seeds and components it was considered appropriate to make further amendments to the draft with a view to adjusting it to the requirements of Cartagena Protocol.

**Taking account of the above below is an overview of actions that have been taken towards the establishment of an effective national biosafety system in Azerbaijan in conformity with the requirement of Cartagena Protocol:**

**1. Organizational actions:**

- National Coordination Unit on Biosafety has been established at the Ministry of Ecology and Natural Resources.
- Officials responsible for this area in ministries, committees and other stakeholder organizations have been identified and useful contacts for facilitating information exchange has been established;
- Coordination mechanism on genetic engineering, transboundary transfer, manufacturing, processing and use of GMOs has been set up.

**2. Creation of a national database:**

- Information on scientific studies conducted in Azerbaijan, the existing scientific capacity and prospects in the area of genetic engineering has been gathered;
- The existing situation in the country linked to genetically modified organisms (GMO) and their transboundary transfer, manufacturing, processing and use has been studied;
- Information on cases of introduction of GMOs into the environment in Azerbaijan and their effects on biodiversity and human health has been verified;
- Database on information concerning the public awareness of and attitude to genetically modified organisms has been created.

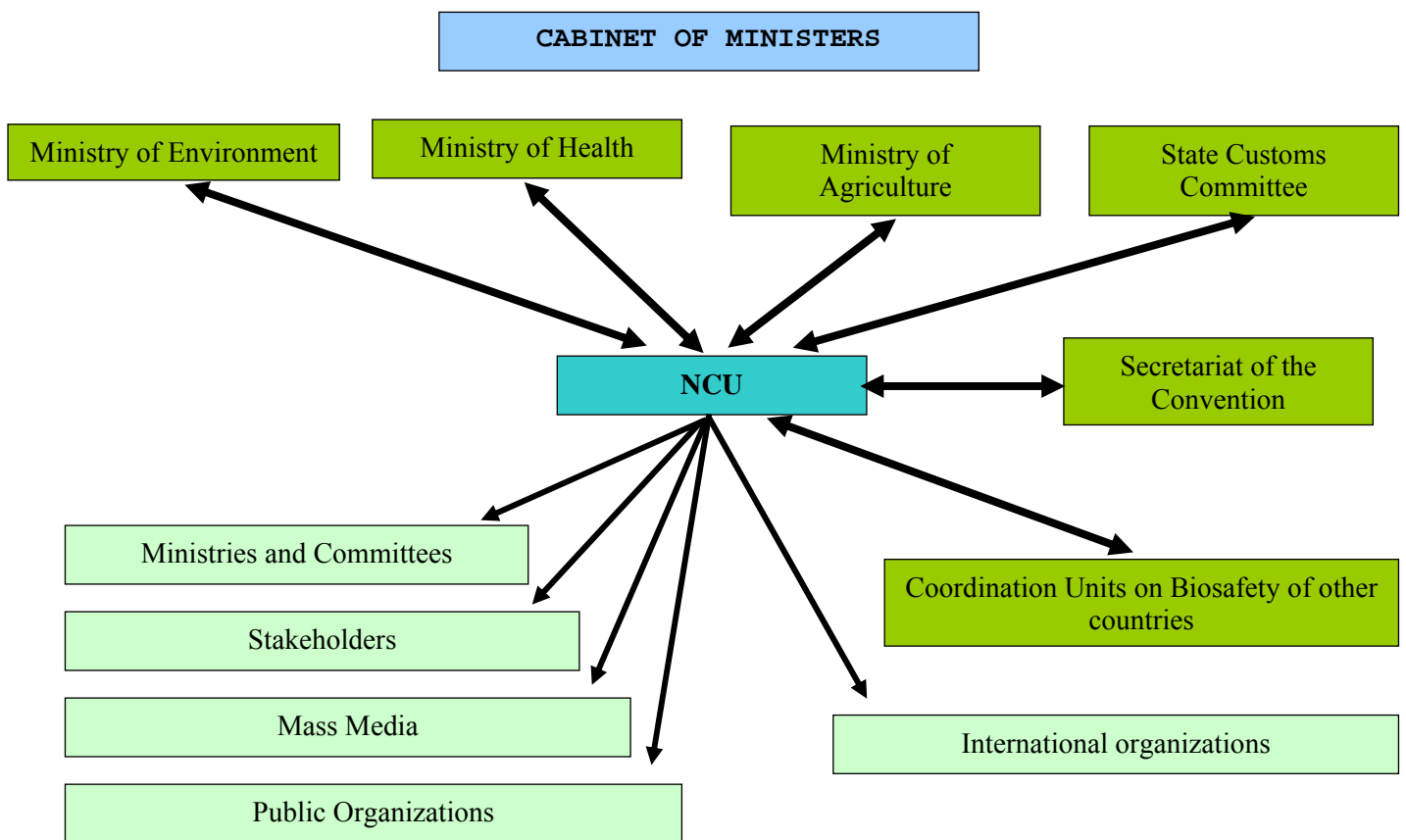
**3. Establishing of a mechanism of national, regional and international cooperation:**

- Links with government and non-government institutions concerned have been established;
- Information exchange with coordination units of neighboring and regional countries is being carried out for enhancing cooperation in the area of biosafety, including participation in workshops and conferences held in these countries and invitations to workshops and conferences in Azerbaijan;
- National coordination system on biosafety involving all stakeholders (Ministries of the Environment, Health, Agriculture, State Customs Committee, National Academy of Sciences, etc.) has been established;
- Actions intended for identifying main directions in the development of National Framework Document on Biosafety and gaps in this area have been implemented based on a thorough analysis of GMOs status in the country

with the involvement of relevant ministries, committees and other stakeholders including NGOs and public representatives.

**4. Public Education and awareness raising:**

7. A booklet in the area of biosafety in a popular format has been published for public awareness raising;
8. By making use of mass media facilities round tables, surveys and workshops have been organized and articles published;
9. Political, cultural and private circles and the public have been involved in the promotion of ideas on the preservation of genetic resources;
10. A web page to facilitate access to information on genetically modified organisms (GMOs) and their products and effects of their transboundary transfer, manufacturing, processing and use on biodiversity and human health has been created.



**Taking account of the above, the implementation of the following actions on the establishment of an effective national biosafety system in accordance with the provisions of the Cartagena Protocol is of importance:**

- Setting up a network of laboratories meeting contemporary needs for testing GMOs;
- Taking account of international practice, building capacity (training of experts and specialists, etc.) on the assessment and regulation of risks posed by GMOs on human health and the environment based on practical observations and scientific findings;
- Organizing trainings and seminars for experts to learn international practice on risks assessment and regulation and establishing a mechanism of risk assessment and regulation;
- Establishing a mechanism and strategy of control, mitigation and management of risks in the country and a monitoring mechanism for an effective management of risks;
- Drafting a national law on biosafety governing the manufacturing, processing, transportation, transfer, import, export, storage of genetically modified organisms and products, the use of seeds of GMO origin in agriculture, safety of releasing into the environment, mechanism of responsibility and control;
- Making appropriate amendments to existing laws (environmental, agricultural, health, etc.) and regulatory legal acts in accordance with the requirements of the Protocol;

- Development of regulations on the application of special labeling of GMO products and their submission for approval;
- Toughening liabilities on illegal transboundary transfer of GMOs in the legislation;
- Development of codes for GMO products in the foreign trade nomenclature;
- Development of regulations on handling GMOs and their submission for approval;
- Development of regulations on the state registration and testing of GMO plant varieties in Azerbaijan;

## **CHAPTER 5. DRAFT LIST OF REGULATORY ACTS TO BE DEVELOPED BY EXECUTIVE POWER BODIES UPON THE IMPLEMENTATION OF THE PROJECT**

*Regulatory legal acts governing safety of activities on non-pathogenic genetically engineered organisms in confined systems under MoE.*

1. Methodological indicators for the assessment of risks arising from genetic engineering activities.
2. Accreditation rules for genetic engineering activities in confined systems.
3. Safety regulations on activities linked to non-pathogenic genetically engineered organisms in confined systems

*Regulatory legal acts governing safety during the release of genetically engineered organisms into the environment for testing purposes under MoH.*

4. Regulations on the issuance of a permit for the release of genetically engineered organisms into the environment for testing purposes
5. Rules of areas accreditation for the controlled release of genetically engineered organisms into the environment for testing purposes
6. Regulations on the organization and implementation of state assessment of safety of genetically engineered organisms

*Regulatory legal acts governing safety and quality of food substances and raw materials under MoH*

7. Rules on the state hygienic registration and regulation of food products and raw materials manufactured with the use of genetically engineered organisms or their derivatives.

*Regulatory legal acts governing the import, export and transit of genetically engineered organisms*

8. Regulations on the issuance of a permit for the import and transit of genetically engineered organisms into and through the country.

## **CONCLUSION**

The main challenges before the national biosafety system in the Republic of Azerbaijan are, on one hand, to promote the development of genetic engineering as one of the priority areas of science by providing appropriate conditions for a maximum rational use of recent biotechnology developments as one of the advanced fields of the contemporary biological science and, on the other hand, while carrying out activities on genetic engineering, applying new biotechnologies and using products derived from them as food and feed to guarantee safety of biotechnological products for the environment and human health including the protection of genetic resources and biodiversity and their sustainable use.

Subject to discussions at various levels in the pursuance of development of a biosafety system, the emergence of relevant problems at different layers and different times is inevitable. Consequently, the process of amending the legislation and administrative management system should be developed and organized based on scientific grounds taking account of reliable information and the existing situation. In this regard, as a basis for the establishment of a national biosafety system the development of the draft Law of the Republic of Azerbaijan on National Biosafety can be acknowledged as an important outcome of the project implementation and subject to its subsequent adoption the law can be used as guidelines in the establishment of a national biosafety system in the field of genetic engineering. The participation of different ministries, committees, agencies and institutions as well as non-government organizations and public representatives as stakeholders produced various thoughts and approaches to the issue which were considered and discussed and taken into account during the development of this document. Thus, as direct participants of this process they fully understand their roles and responsibilities in the national biosafety system. This factor is of importance for capacity building in the field of national biosafety system once the law is adopted.

## **Annex I**

### **Brief overview of relevant parts of biosafety related national legislation and regulatory acts**

**Law on Environmental Safety (1999).** The objective of the law is to identify the legal basis to prevent human life and health; society with its material and spiritual values; the environment, including atmospheric air, cosmic space, water sources, subsoil, soil, natural landscape, the plants and animal kingdom from hazards of natural and human factors (Article 2).

Such principles as ensuring that environmental safety is given priority in the formation and implementation of development strategy; development of international cooperation for securing environmental safety at international, regional and local levels; the elaboration and consistent implementation of measures aimed at the prevention of hazardous and emergency environmental situations, including their repercussions that may impact future generations are the main directions of the state policy on environmental safety as an integral part of the human, public and state security (Article 4).

Causing damage to or putting at risk human life and health as a result of infringement of laws and regulations governing environmental safety is considered as a violation of human rights. Adherence to the requirements of environmental safety is obligatory while exercising rights of property, ownership and use of natural resources (Article 4).

The main rights of the state in the area of environmental safety are identification of the uniform state policy on environmental safety; verifying, in accordance with procedures specified in the legislation including state environmental impact assessment, the conformity of economic and other activities likely to cause environmental risks to environmental safety requirements, organization of and participation, in accordance with the rules of procedure, at international events on environmental safety issues and mutual cooperation with relevant authorities of foreign countries with regard to exchange of experience, specialists and information (Article 5).

The main obligations of the State in ensuring environmental safety are the implementation of state control on the use of natural resources in conformity with the environmental safety rules and verifying the compliance of industrial entities with environmental safety standards, forecasting and detecting cases and events posing a risk of the occurrence and development of hazardous environmental situations, approving state standards and other regulations defining requirements for ensuring environmental safety and promoting public awareness raising and education in the area of environmental safety (Article 5).

The Law defines limits of economic and other activities to ensure environmental safety (Article 9).

The Law shall prohibit:

- Economic and other activities failing to meet requirements ensuring environmental safety;
- Import of substances into the country the use or reuse of which pose a risk to environmental safety;
- Activities causing global changes to the environment and its components including those violating international agreements in the field of environmental safety;
- Import and manufacturing of products the processing, treatment and reuse of which is environmentally hazardous as well as other products that are environmentally hazardous;
- The use of toxic substances which have properties to biodegrade or accumulate in the human organism and the environment as well as the application of toxic substances the treatment of which is environmentally hazardous;
- The application of substances and food products whose harmful level of risk to human health and the environment have been assessed;
- The use, propagation and distribution of artificially developed organisms that are not typical for a certain area subject to providing for appropriate actions on the prevention of their uncontrolled propagation and distribution;
- Taking and implementing those decisions that may provide grounds for activities identified by laws and regulatory acts on environmental safety under the category of environmentally hazardous activities.

As stipulated by the Law, the above rules shall be implemented by relevant executive power bodies and municipalities, by their officials and all legal entities and individuals while carrying out the types of activities indicated above.

The Law sets forth that state bodies concerned ensure state control over the coordination and implementation of actions to eliminate repercussions of hazardous impacts on the environment (Article 11).

In case of impossibility to ascertain an entity responsible for the occurrence of environmental hazards or insolvency of such an entity to indemnify for the damage, consequences of the disaster shall be eliminated at the expense of the State budget and other sources.

The falsification of information on environmental hazards or its delayed presentation or its presentation in an incomplete form as well as failure to fulfill obligations on control over the level and sources of environmental risks are interpreted as violations of the law by officials in this area (Article 13).

In summary, biological safety is an integral part of environmental safety which encompasses a wider scope of the human, public, state and particularly GMO security.

**Law on Environment Protection (1999).** The objective of the Law is to protect environmental balance thus ensuring environmental safety, prevent the hazardous impact of industry and other activities to natural ecological systems, preservation of biological diversity and proper use of natural resources. The Law regulates and establishes correlation between society and nature to provide qualitative improvement of environment, proper use and rehabilitation of natural resources, strengthening conformity with environmental legislative regulations.

The main obligation of the State, as defined by the Law, is the implementation of the state control over the protection, rehabilitation and use of the environment, flora and fauna (Article 4). As outlined in the Law, goods and technologies produced in, or imported to the Republic of Azerbaijan, which may pose risks to the environment, human life and health, rehabilitation and proper use of natural resources, shall be considered as items which are subject to standardization and certification as part of environment protection (Article 19).

The Law shall prohibit handling, manufacturing, supply (sales), storage, transportation, use and repairs of those goods or services which have resulted from a violation of environment protection standards and technical requirements (Article 20).

Environment protection envisions the application of certification to goods, works, services and activities to identify their conformity to standards and technical requirements in accordance with the procedures specified by the Law. The Law shall prohibit the manufacturing of goods unless the goods, which are subject to obligatory certification in terms of ensuring environment protection, have been duly certified (Article 21).

The Law regulates the level of upsetting the environmental balance. This regulation includes the identification of hazards to qualitative indicators of the environment, human health, protection, rehabilitation and sustainable use of natural resources and maximum permissible levels of such hazards to the environment (Article 30).

The Law prescribes that adherence to qualitative environmental standards is obligatory for all legal entities and individuals. These standards shall be published and disseminated by media. The Law defines permissible levels of potentially hazardous chemicals and biological substances contaminating air, water, soil and subsoil with regard to the protection of human health and conservation of flora and fauna and their gene pool (Article 32).

With regard to the protection of human health and conservation of flora and fauna and their gene pool Article 33 of the Law prohibits the overstepping of maximum permissible levels and agrotechnical standards while applying mineral fertilizers in agriculture and forestry and chemicals and stimulators for the protection of plants as well as other agrochemicals.

The Law also identifies certain requirements for the use of natural resources. Special permits shall not be issued for activities which are likely to cause the upset of systems maintaining the environmental balance and pose risks to the human life and health, flora and fauna gene pool (Article 35).

Special permits for production and use of potentially dangerous toxic and biological chemicals are issued after conducting toxico-hygienic, toxico-ecological measurements, identification of hygienic and ecological norms and registration in the relevant State books.

Environmental standards set forth in Article 45 of the Law with regard to the use and manufacturing of biological substances have crucial significance. Introduction of non-indigenous and artificially propagated biological specimens into the environment and their reproduction shall not be allowed without relevant environmental justification and special permits issued by the government bodies.

Pursuant to the Law the state environmental impact assessment shall take the guiding principle the necessity of the maintenance of the environmental balance and conservation of wildlife biodiversity and its gene pool and presumption of potential risks from unregulated use of natural resources to meet the needs of present and future generations. Provisions of the Law stipulate that documentation concerning new equipment and technologies including their import from other countries, contracts envisioning the use of natural resources based on the permission by relevant government bodies and environmental sections of project documents are subject to the state environmental impact assessment. This law also regulates impact of GMO on human health and environment.

**Law on Food Products (1999).** The Law interprets the definition of food products comprising of raw food, food consumed and additives (ingredients) as a group of flavor containing goods. The Law governs the management of safety and quality of agricultural, fishery products and fish used as food products and raw materials, determines the rules of their manufacturing and sales in the market and regulates relationships arising from these activities. The Law states that in case there are discrepancies between the provisions of the present law and regulations set forth in multilateral agreements signed by the state in this area, provisions of the multilateral agreements shall be applied (Article 2).

Pursuant to the provisions of the Law the quality and safety of food products shall be ensured through the establishment and enhancement of requirements for food

products quality and safety, certification of food products, state hygienic registration and ensuring state control over compliance with quality and safety standards (Article 4).

Ensuring quality and safety of food products is implemented through technical, environmental, sanitary, veterinary and phytosanitary standards, limits, rules and regulations determining requirements for food products quality and safety and their manufacturing, delivery, storage, packaging, labeling and sales (Article 5).

In the process of arrangements for the manufacture of new varieties of food products, their contents, quality indicators, shelf life in terms of safety for human organism and compliance with relevant standards and requirements shall be verified, recorded in the specifications of the product and entered into the state register (Article 9).

It is stipulated by the Law that manufacturers of food products shall package and label the products manufactured by them in accordance with relevant regulatory documents and trade regulations of the state legislation. The label shall contain information in the Azeri and/or other language on brand name, type and contents, area and rules of use, date of manufacture and shelf life, storage conditions, name, address of the manufacturer and other details in accordance with the regulations (Article 11).

The Law states that food products meeting state quality and safety standards and requirements and recorded in the state hygiene register and supported by certificates of origin and quality shall be allowed for sales (Article 13).

Special attention is given by the Law to the legal regulation of import and export of food products. Rules and procedures of the existing National certification system shall be applied to the import of food products. Food products recorded in the state hygiene register of foreign countries and supported with a certificate of authenticity issued in accordance with provisionally specified rules shall be allowed for import into the country. Food products lacking relevant certificates issued in accordance with the existing regulations of the country shall not be allowed for clearance through the Azerbaijan customs zone. Such products shall be allowed to cross the borders of the country in accordance with the procedure envisioned by the legislation only for the purposes of demonstration at exhibitions, research and experiment (Article 14).

Quality and safety details of the product shall be contained in the contract on the import of food products signed between the buyer and seller. The authenticity of the food product imported into the country to information on quality and safety contained in the contract and accompanying documents is one of the obligatory conditions of permission for sales in the market.

The Law stipulates main principles of responsibility of the state in ensuring food safety (Article 17).

It prescribes that the state shall ensure food safety of its people and each citizen in accordance with the international law. The main responsibilities of the state in this area include the preparation and implementation of ad-hoc state programmes on public food safety, adoption of legal and regulatory acts in the area of regulation of a food product market and ensuring quality and safety of food products and establishing control over their enforcement (Article 18).

Quality and safety details of the product shall be contained in the contract on the import of food products signed between the buyer and seller. The authenticity of the food product imported into the country to information on quality and safety contained in the contract and accompanying documents is one of the obligatory conditions of permission for sales in the market.

For the purposes of application of the Law of the Republic of Azerbaijan on Food Products the Cabinet of Ministers approved by its Order No.154 of 16 August 2005 Regulations on the Implementation of State Control over Adherence to Standards and Requirements in Ensuring Quality and safety of Food Products.

According to these regulations the objective of state control in the area of ensuring quality and safety of food products is to protect the rights and interests of consumers envisioned by the legislation, prohibit manufacturing, import and sales of food products that are likely to pose a risk to the environment and human life, health and property and facilitate manufacturing and import of good quality products into the country.

Pursuant to the regulations the government bodies responsible for this area shall carry out control on adherence of legal entities and individuals dealing with food products to technical, environmental, sanitary, veterinary and phytosanitary standards, limits, rules and regulations determining requirements for food products quality and safety and their manufacturing, delivery, storage, packaging, labeling and sales.

**Law on Public Health Protection (1997).** The Law states that public health protection and protection of physical and spiritual health of each individual shall be interpreted as a set of political, economic, legal, scientific, medical, sanitary and hygienic measures intended for ensuring active longevity of an individual and provision of medical aid. The Law identifies ensuring environment protection and environmental safety as one of the responsibilities of the state in the area of public health protection (Article 3).

It is set out in a separate article of the Law that citizens shall be entitled to the right of access to regular and true information on factors affecting their health and this

information shall be communicated either by mass media or directly upon request through a relevant government body (Article 11).

Officials concealing facts and events that are likely to pose a risk to human life and health shall be liable to prosecution in accordance with the legislation.

Those liable for the damage caused to citizens' health shall pay indemnity in the amount and manner specified by the legislation. The indemnification for the damage does not exempt medical and pharmacological employees from administrative liability or prosecution as envisioned by the legislation (Article 57).

The indemnity for the damage caused to public health as a result of environment pollution shall be paid, in accordance with the procedures specified by the legislation, by legal entities and individuals responsible for the damage (Article 57).

**Law on Pharmacology (1996).** The Law, in the first instance, identifies main principles of the state policy in the area of pharmacology. These are the provision of medicines to citizens in accordance with international standards, organization of scientific studies for the development of effective and good quality medicines, state control over pharmacology, preservation of natural resources that are used as raw materials in the preparation of medicines and other principles (Article 4).

The Law also identifies responsibilities of state authorities in the area of pharmacology (Article 5):

- State registration of medicines;
- Preparation of state standards and relevant regulatory and technical documentation for the manufacture of medicines;
- Control over the circulation of medicines;
- Identification of a uniform statistical report template for tracking the circulation of medicines;
- Implementation of international cooperation in the area of pharmacology;

The Law defines mineral and plant resources, materials of animal and biotechnological origin, chemicals and other products as a raw material for the preparation of medicines. Pursuant to relevant provisions of the Law in order to determine effectiveness and safety of medicines, experiments and scientific studies can be conducted on animals in compliance with international standards as well as clinical tests can be carried out on humans based on their consent and permission by a relevant state body (Article 9, 12).

The quality of medicines released for circulation in the market shall meet the state standards of the Republic of Azerbaijan. The standardization of medicines is implemented by a relevant government body in accordance with regulations specified by the legislation (Article 20).

The Law prescribes that the citizens of the country shall be entitled to the procurement of good quality and safe medicines, obtaining information from drugs stores, prophylactic treatment and sanitary epidemiological institutions on quality and safety of medicines, applying to state impact assessment bodies for an assessment of quality and safety of medicines (Article 23).

**Law on Sanitary Epidemiological Health (1992).** The Law interprets sanitary epidemiological health as public health and the living environment of humans whose factors do not make harmful or hazardous impact on a human organism and provide favorable conditions for human everyday activities (Article 1).

Procedures on the development, approval, publication, enacting and amendments of countrywide and local sanitary regulations and norms, hygienic requirements as well as procedures on enacting international sanitary regulations and norms, hygienic requirements are established by the state sanitary epidemiological service of the Republic of Azerbaijan which is part of the state health system. The Law stipulates the obligatory publication and free dissemination of sanitary regulations and norms and hygienic requirements (Article 3).

The Law sets forth the right to live in a favorable environment having no adverse effects on health of present and future generations of the country citizens and ensuring their sanitary epidemiological health and the right to have access to complete, true and free information on the scope of a disease, epidemiological state and radiation background, a state of the environment and their impact on human health, and on decisions taken by government bodies and officials concerning human health and the environment and effects of their implementation on human health and the environment (Articles 5,6).

Legal entities and individuals engaged in the manufacture, transportation, storage and distribution of food raw materials and food products shall adhere to medical-biological requirements, sanitary regulations and norms and hygienic standards during their manufacturing, transportation, storage and distribution (sales) and shall apply new additives to food products, specially added biologically active substances, new manufacturing technologies, as well as containers in direct contact with food raw materials and food products, polymeric and other materials only upon obtaining a toxicological hygienic assessment and in accordance with the procedures established by the Ministry of Health (Article 20).

State bodies, all enterprises, institutions and organizations irrespective of the type of property, individuals and non-government organizations shall ensure the authenticity of the quality of water distributed through centralized industrial, municipal and drinking water supply systems to hygienic requirements and state standards and adherence to relevant sanitary regulations and norms during centralized water supply and use of water in impoundments and coastal zone of the

sea and places where water is used for cultural and municipal needs of the public (Article 21).

The Law identifies responsibilities of the state sanitary epidemiological service with a focus on the detection, prevention and elimination of harmful factors of the environment affecting human health with a view to the protection and strengthening of public health, promoting a healthy way of life and ensuring the prophylactic of diseases (Article 27).

One of the responsibilities is the implementation of sanitary protective measures against the introduction and distribution of quarantine infections in the country area and import of food products and goods intended for consumption that are harmful for health. The Law interprets the state sanitary as type of activities which is aimed at ensuring adherence to the sanitary epidemiological legislation and international and national standards on the protection of human health, detection, prevention and elimination of violations of sanitary regulations and norms and hygienic requirements and bringing a prosecution against offenders (Article 28).

Along with the state control the Law also identifies administrative sanitary control and industrial and public control (Article 29, 30, 31).

Administrative sanitary control to regulate sanitary epidemiological health at premises of defense, national security and interior affairs authorities as well as railway, water and air transport services is carried out by special sanitary services of the above authorities.

Adherence to sanitary regulations and norms and hygienic requirements, taking measures intended for the prevention of environment pollution and promotion of a healthy environment, ensuring manufacturing control over hygienic standards of the product during a manufacturing process are the responsibilities of heads and specially assigned officials of enterprises and organizations.

Public unions (NGOs), employees, citizens shall undertake control on adherence to the sanitary legislation and implementation of sanitary hygienic measures. All this control is implemented based on mutual coordination (Article 32).

Pursuant to the provisions of the Law officials and average citizens offending against sanitary rules can be liable to administrative, public and criminal prosecution. Such a liability is also imposed on foreigners and those without citizenship (Article 39).

**Law on the Protection of Consumers' Rights (1995).** The Law was developed based on Governing Principles on the Protection of Consumers' Interests adopted by the UN General Assembly and seeks to meet good international practice in such relations.

The Law identifies the rights of consumers. These rights include the entitlement to access to true and complete information on goods (services) safety, their conformity to accepted standards, amount, varieties and quality of goods (Article 3).

The consumer has the right to demand conformity of the quality of the goods procured to regulatory documentation and contract provisions as well as to the information presented by the seller. Standards of the product meeting safety of consumers' life, health and property as well as safety of the environment are determined by regulatory documents. These standards are defined by the relevant legislation of the state. Goods imported into the country shall be supported by the documentation, specified by the legislation, certifying the required quality (Article 5).

The Law sets forth that in case of adherence by the manufacturer to the regulations on the use, transportation and storage of the goods while the goods pose or likely to pose a risk to the environment or consumers' life, health and property, the manufacturer (seller) shall halt its manufacture (sales) until causes posing the risk have been eliminated or, if necessary, take appropriate actions for its withdrawal from the market and return by consumer to the manufacturer.

The law indicates that in case of impossibility to eliminate causes of the risk, the manufacturer is obliged to withdraw such goods from the production line and the market and take it back from the consumer. A decision on the fulfillment by the manufacturer a requirement on the withdrawal of the goods from the production line and market and its taking back from the consumer shall be taken by relevant state control bodies within the limits of their authority. If food raw materials and food products proved to be unfit for human consumption as a result of the above actions they shall be destroyed or recycled. The manufacturer shall fully indemnify the consumer for the loss arising from the return of the goods.

While making preparations for a new (modernized) product the manufacturer shall submit specifications of this product to a relevant body in order to prove the conformity of the product to safety standards in relation to the environment and public life, health and property and subject it to state impact assessment.

The manufacturer shall be liable for providing information to the consumer on possible risks and safe use rules by means of special signs accepted in international practice (Article 10).

The Law stipulates the rights of consumers to have access to information on the goods. The seller shall provide the consumer, upon his/her request, with necessary true information on the price of the goods, consumption specifics (in the instance of food products: contents, shelf life, calorie, amounts of harmful substances as

compared to those specified by regulatory documents), terms of procurement, guarantees and claims, utilization and storage of the goods and its safe use methods and rules (Article 13).

The seller shall also provide the consumer with complete and true information on retail rules concerning the goods sold by the company and types of services offered. This information is conveyed to the consumer through attached technical documentation, labels and indication of a sales date or by other means accepted in different service areas.

The label of goods manufactured shall contain a production or trade mark or brand name or a geographic indicator. The name, origin, address and signs concerning standards shall be indicated on a production mark. The goods manufactured shall conform to the trade mark. The goods shall have a label (Article 13).

The government bodies responsible for quality and safety of products (Article 19) shall:

- identify obligatory requirements over the safety of products and implement control over adherence to these requirements;
- set standards on human health safety specifications and sanitary hygienic requirements;
- agree regulatory and technical documentation on products posing a risk to human health and implement obligatory hygienic certification during the manufacturing phase;
- subject to results of a test analysis, take decisions concerning a subsequent use of products whose safety indicators failed to meet requirements specified in regulatory and technical documentation;
- agree the manufacture, use and sales of new technological processes, materials, substances and information;
- approve methodologies of hygienic, environmental, seismological, radiological, hormonal, pharmacological and toxicological assessment and studies methodologies of hygienic specifications and indicators of the level of harmful factors.

Individuals offending against the law shall be liable to public, administrative or criminal prosecution in accordance with the country's legislation (Article 21).

**Law on Plants Protection (1996).** The Law interprets plants protection as implementation of scientifically justified complex actions on the protection of plants and products thereof from diseases and pests. Plants protection is supported by the following actions:

- implementation of a set of actions intended for inhibiting the increase in pests and diseases, preventing harvest or productivity loss, securing environmentally clean products of plant origin, protection from harmful effects of pesticides on the environment, human health, flora and fauna,

- implementation of state programmes on application of quarantine and other measures on isolation and extermination of particularly harmful vermin;
- adherence to the plants protection legislation by all entities, individuals as well as officials irrespective of the type of property and level of subordination;
  - training of specialists in the area of plants protection and organization of scientific studies and development of a uniform state policy on manufacturing of plant protective substances and ensuring control on their use (Article 1).

State testing of plants protective substances is carried out in accordance with the country's legislation on the state testing of pesticides and agrochemicals. The government bodies responsible for the implementation of state testing shall develop standards on the application of plants protective substances and permissible levels of their remnants in the environment and agricultural products. Plants protective substances which have undergone state testing shall be registered in a specified manner and, thereafter, included in the list of substances allowed for the use in agriculture and forestry (Article 12).

Subject to their prior state testing, the registration of pesticides, biological and other plants protective substances as well as their prohibition or setting limits on their application shall be carried out by a relevant government body responsible for testing and registration of plants protective substances and agrochemicals in close coordination with the state control sanitary epidemiological, environment and nature protection and veterinary services.

The manufacture, sales, import and application of substances that have not undergone state testing and registration or the use of which has been banned shall be prohibited (Article 12).

**Law on Plants Quarantine (1996).** The Law interprets plants quarantine (phytosanitary quarantine) as a legal regime envisioning a system of measures intended for the protection of plants, products thereof, their seeds, saplings and other products and cargoes of plant origin from quarantine targets (Article 1).

The Law identifies main objectives of plants quarantine. They are composed of the implementation of a state control on taking plants quarantine actions, a timely detection of quarantine targets, taking actions for their isolation and elimination, adherence to quarantine standards and requirements during the manufacture, stocking, transportation, storage, processing, sales and use of products under the quarantine control (Article 3).

One of the important clauses in the provisions of the Law concerning responsibilities of the state plants quarantine service is the preparation of a list of quarantine targets and its submission for approval to appropriate bodies and putting under quarantine and laboratory check-up products imported from other

countries and exported from the country which are subject to quarantine control (Article 6, 7).

**Law on Selection Developments (1996).** The Law states that as a result of accomplishments in the selection area useful plant varieties, animal breeds, their hybrids, cross-breeds and clones have been created (Article 1). Accomplishments in the selection area shall meet the following criteria:

a) be innovative-

a selection development is considered innovative if it has not been sold or given for use during a specified period: seasonal plants (wheat, cotton, etc.) – one year, vine plantations – four years, medicinal and decorative plants, fruit and forest trees, animal breeds – four years, if grown in the country's area, and respectively four to six years if grown in a foreign country.

b) be different-

a presented selection development shall differ from other known selection developments. The known selection developments are, subject to a patent's taking effect from the date of application, those patented selection developments which are included in official catalogues or databases, and/or whose detailed description is given in one of publications. In addition, peculiar and distinguishable traits of a selection development shall make it possible to tell and clearly recognize it.

c) be similar -

traits of selection developments shall be similar in terms of genotype and phenotype subject to exceptions of some differences.

d) be stable-

a selection development shall retain its recognizable traits after it has repeatedly been reproduced. At the same time, selection developments shall not upset the environmental balance and meet requirements of environment protection (Article 3).

The Law defines the objects and subjects of selection developments. The objects of selection developments are plant varieties, animal breeds, their hybrids, cross-breeds, clones, seeds, eggs and other plant materials and productive breeds stocks that are used in selection activities. The subjects of selection developments are all legal entities and individuals that are proprietors of the selection developments and engaged in selection activities (Article 4).

Patent provides the patent owner with an exclusive right to use selection developments and this right is protected by the state. Patent prohibits the use of selection developments without consent of the patent owner (Article 16).

The inventor shall preserve the selection development in such a manner so that the selection development retains its recognisable traits as they were from the date of invention. The inventor shall present, upon request of the authorized body, specimens of a plant material or breed stock for control and test purposes or provide conditions for check-up on the spot (Article 21).

**Law on Seeds Growing (1997).** The objective of seeds growing the legal basis of which is defined by this Law is to grow plant varieties that are distinguished for high productivity, stable heritability, resistance to diseases, pests and different climates and ensure their propagation. The responsibility arising from seeds growing is a mass reproduction of seeds through the implementation of varieties development and enhancement of their purity in order to preserve the purity of varieties and biological productivity qualities of plant varieties included in the state register (Article 3).

The Law defines that plant materials, their hybrids, populations, clones used for seeds growing are the objects of seeds growing (Article 4).

Seeds growing is implemented based on principles outlined in the law. These are the preservation of peculiar and distinguishable features of seeds varieties such as similarity, stability and other ones and imposition of obligatory certification of the seeds used (Article 6).

The status, rights and responsibilities of the state seeds growing service are identified in the Law. The service shall be entitled to such rights as carrying out control over compliance by entities engaged in seeds growing with relevant legislative acts and regulatory documents, withdrawing seeds lacking documents certifying their quality or failing to meet the state standards and technical requirements and prohibiting their sales for seeds growing purposes, defending interests of the Republic of Azerbaijan in the area of seeds growing before international organizations (Article 8).

Seeds of plant varieties included in the state register and meeting the state standards on variety and plantation qualities shall be allowed for circulation in the market.

Pursuant to the Law seeds released for circulation in the market shall be duly packaged and labeled. The label shall contain full information on the quality of seeds. The package of seeds treated by chemical and biological substances shall be marked with relevant warning. Safety instructions on the usage of seeds shall be provided on the label or in accompanying documentation (Article 23).

Seeds of varieties that have been introduced in the regions of the Republic of Azerbaijan and are supported with authenticity and phytosanitary certificates shall be allowed for circulation in the market (Article 24).

The following seeds shall not be allowed for circulation in the market:

- a) varieties that have not been introduced in the regions of the country;
- б) seeds lacking authenticity and phytosanitary certificates;
- в) non-packaged and non-labeled;
- д) seeds whose certificates have expired;
- e) seeds of mixed varieties.

**Law on Wheat (2000).** The Law on Wheat identifies the legal basis for the management of wheat production, stocking, import and export and quality of wheat and products resulting from wheat processing.

The Law interprets quality of wheat and wheat products as their conformity to technical, environmental, sanitary, veterinary and phytosanitary standards, requirements, rules and regulations (Article 1).

Wheat from foreign countries shall be allowed for import into the country provided it has undergone the state registration and is supported by authenticity certificate issued in the specified manner (Article 11).

Wheat products lacking relevant certificates issued in accordance with the existing regulations of the country shall be allowed for import into the country only for the purposes of demonstration at exhibitions, research and experiment in accordance with the procedure envisioned by the legislation. The import of wheat shall be implemented in accordance with the state legislation and requirements of international law (Article 11).

Pursuant to the provisions of the Law contents of wheat produced in the country and imported into the country is tested and assessed based on its chemical, biological, toxicological and radiological indicators. The assessment of quality of wheat products shall be conducted based on a uniform methodology by a specialized laboratory designated by a relevant executive power body in a specified manner.

The Law identifies the state control over the quality of wheat products. The objective of the control is to ensure compliance by legal entities and individuals with standards and requirements governing the manufacture, stocking, storage, transportation, sales, import and export of these products (Article 15).

**Law on Pesticides and Agrochemicals (1997).** This Law identifies the legal basis for of testing, registration, use of pesticides and agrochemicals and the organization of agrochemical service in the Republic of Azerbaijan.

Pursuant to this Law activities linked to pesticides and chemicals within the country's area shall be carried out based on the following principles (Article 3):

- giving preference to the protection of the environment and human health over against economic and biological effectiveness of application of pesticides and agrochemicals;
- necessity of the state control over the manufacture, testing, registration, import, export, storage, treatment, destruction and application of pesticides and agrochemicals;
- bringing to minimum the use of pesticides through the application of environmentally safe, non-chemical methodologies in plants protection measures.

The Law prescribes that pesticides and agrochemicals manufactured in the country and imported from overseas are subject to the state testing and compliance with specified standards and shall not threaten human health and shall ensure safety of the environment, flora and fauna (Article 5).

The state testing of pesticides and agrochemicals manufactured in the country and imported from overseas shall be conducted for the purpose of their biological, hygienic toxicological and environmental assessment and development of their application standards (Article 6).

The objective of the state testing of pesticides and agrochemicals is to identify their biological, hygienic toxicological properties, their effectiveness and impact on pests of agricultural plants and perennials, to enhance harvest productivity and quality, to identify their superiority over analogous substances, to assess their safety to the environment and humans and establish a wide variety of plants protective substances.

Pesticides and agrochemicals tested in an appropriate manner are certified by State Agency on Standardization, Metrology and Patent based on submission by Ministry of Agriculture of the Republic of Azerbaijan.

According to procedures of registration of pesticides and agrochemicals, pesticides and agrochemicals that have undergone the state testing in an appropriate manner are registered by an order of Ministry of Agriculture of the Republic of Azerbaijan. Appropriately registered and certified pesticides and agrochemicals are included in the list of substances allowed for use in agriculture and forestry.

The Law shall prohibit the manufacturing, sales and use of toxic chemicals that do not meet the state standards of the Republic of Azerbaijan or international, regional

or intergovernmental standards accepted by Azerbaijan and may cause damage to human life, health and property as well as the environment (Article 13).

Certain requirements are imposed on the quality of agricultural and food products in the legislative act. The Law sets forth that remnants of pesticides and agrochemicals in agricultural and food products, feeds, raw materials, food substances of plant or animal origin shall not exceed permissible levels determined by the state standards and shall meet sanitary hygienic standards.

In case remnants of toxic chemicals in agricultural and food products exceed permissible levels such products shall be prohibited for sales. Agricultural and food products the use of which is not allowed shall be withdrawn, neutralized or destroyed in an appropriate manner by a relevant executive power body (Article 20).

**Law on Veterinary Medicine (1994).** This Law and its regulatory legal acts govern activities in the area of veterinary medicine in conformity to international practice. The following responsibilities of veterinary medicine are defined in the Law (Article 1, 3):

- Protecting the public from diseases that are common for humans and animals;
- Carrying out control over the veterinary and sanitary quality of products and raw materials of animal origin intended for human consumption and processing;
- Eliminating, jointly with health authorities, sources of infectious diseases posing a risk to humans and animals, implementing other relevant actions, carrying out exchange of information with the health service;
- Carrying out control over the use of biological, chemical and other medicinal substances in cattle breeding and veterinary, making assessment of their impact on animal organisms and quality of products of animal origin, ensuring the implementation of registration of local and overseas veterinary medicines and technical facilities, the issuance of permits for their manufacturing and sales and their standardization;
- Carrying out control on the conformity of exported livestock, other animals, products and raw materials of animal origin to veterinary standards of importing countries.

The Law defines that the application of veterinary medicines, vitamins, feed additives and biologically active substances shall be prohibited unless they have undergone the state veterinary registration and meet requirements of regulatory technical documentation. Overseas medicines imported into the country shall be applied subject to the state veterinary registration and testing by relevant government bodies.

New veterinary medicines as well as biological stimulators and hormones intended for accelerating the reproduction of cattle and increasing the productivity shall be

applied based on permission of the state veterinary authority. The state veterinary service shall take control on the application of the above medicines by individuals and legal entities to cattle and other animals, their storage and destruction of those medicines whose shelf life has expired (Article 20).

While bringing cattle and other animals from overseas into the country permission of the state veterinary authority of the Republic of Azerbaijan shall be obtained and cattle and other animals brought in shall be kept in isolation for a period envisioned by the legislation. While bringing products and raw materials of animal origin, veterinary medicines and biological substances from overseas into the country, regulations established by the state veterinary service of the Republic of Azerbaijan shall be observed (Article 16).

**Law on the Development of Enhanced Breeds (1996).** The Law interprets the development of reproduction breeds as a system of zoo-technical, selection-genetic and organizational measures intended for the enhancement of those features of animals of agricultural use that have economic significance.

Enhanced breeds of animals are cattle, buffalos, sheep and goats, pigs, horses, camels, rabbits, furry animals, poultry, fish, bees, silkworms and other animals that are distinguished for high and repeated productivity and are of known origin. Enhanced breeds resources (materials, products) are interpreted by the Law as animals, their semen, eggs, germs that are supported by a state certificate and are reared for the purposes of breeds enhancement (Article 1).

This legal act defines the objective and responsibilities of enhanced breeds development. The objective of enhanced breeds development is to rear breeds of animals of known origin distinguished for high productivity with stable hereditary characteristics and organize their reproduction on a wide scale. Responsibilities of enhanced breeds development consist of the preservation, improvement, distribution and sustainable use of enhanced breeds resources (Article 3).

The objects of enhanced breeds development are cattle, buffalos, sheep and goats, pigs, horses, camels, rabbits, furry animals, poultry, fish, bees, silkworms and other animals, their semen, eggs and embryos. The subjects of enhanced breeds development are all individuals and legal entities engaged in the development of enhanced breeds in a manner specified by the legislation with a special permit for it. The Law prescribes the registration of individuals and entities engaged in the development of enhanced breeds. These activities shall be carried out in accordance with the legislation. (Article 4,5).

According to the requirement of the Law, the development of enhanced breeds shall be carried out based on principles of protection of enhanced breeds resources and their appropriate use, imposing obligatory use of enhanced breeds resources of

known origin with stable hereditary characteristics, the preservation and enhancement of the gene pool of local animals (Article 4,6).

**Law on Fishery (1998):** This Law identifies the legal basis for the organization and management of fishery and reproduction, use and protection of fish resources.

Fishery is governed by this Law taking account of the regulations on the organization of fishery in water bodies and reproduction, use and protection of fish resources and the legislation of the Republic of Azerbaijan on the state border, intergovernmental contracts and agreements and other international legal documentation. Fish resources are the property of the Republic of Azerbaijan without prejudice to rights and interests of any individual or legal entity. Fish used as food or raw material, other aquatic animals and plants, their eggs, larva and other products are all the objects of fishery.

Regulations on the organization of fishery and reproduction, use and protection of fish resources in the Azerbaijan sector of the Caspian Sea (Lake), determined by this Law, are also governed by Water Code of the Republic of Azerbaijan, contracts, agreements, memorandums signed between the Republic of Azerbaijan and the Caspian littoral States and other international legal documentation.

### **Brief summary**

It can be concluded from brief overview of excerpts from relevant laws that the reviewed topic, despite the fact that it has been briefly addressed in the text of the above laws, has not been exhausted. In this view, the drafting and subsequent adoption of a national law on biological safety and on biological diversity genetic resources is of importance.

In the course of development of the proposed law it would be appropriate if relevant amendments arising from the provisions of Cartagena Protocol on Biosafety are made to a number of laws and regulatory acts, particularly to legislative acts on environmental safety, food products, protection of consumers' rights, plants quarantine, seeds growing, selection, pharmacology, etc. About 10 years has elapsed since the adoption of some laws reviewed herein. They do not meet contemporary needs, European standards and provisions of the conventions to which Azerbaijan is a party. Examples of such laws are Law on sanitary Epidemiological Health (1995), Law on Protection of Consumers' Rights (1995), Law on Veterinary Medicine (1994), Law on Plants Protection (1996) and other laws. The development and adoption of these laws afresh would be appropriate.

Laws and amendments to them to be developed in the future should contain provisions regulating relations concerning genetically modified organisms, namely, activities on their procurement, testing, manufacturing and use.