



United
Nations
Environment
Programme



Ministry of
Environmental
Protection of
RK

**NATIONAL BIOSAFETY FRAMEWORK DOCUMENT
OF THE REPUBLIC OF KAZAKHSTAN**



Astana, 2004

Disclaimer

Information contained in this document is provided by Committee of Forestry and Hunting, Ministry of Agriculture of the Republic of Kazakhstan and the views presented in the document are those of Committee of Forestry and Hunting, Ministry of Agriculture of the Republic of Kazakhstan. The United Nations Environment Programme (UNEP) is not responsible for the information provided in this document. UNEP does not make any warranty of any kind, either express or implied, including, but not limited to, warranties of the accuracy, reliability, completeness or content of such information in this document. Under no circumstances shall UNEP be liable for any loss, damage, liability or expense incurred or suffered which is claimed to have resulted from the use of or reliance upon the information contained in this document, including, but not limited to, any fault, error, mistake, omission or defect. Under no circumstances shall UNEP be liable for any direct, indirect, incidental, special, punitive or consequential damages.

**The Document has been developed in the frames of implementation UNEP project
“Development of National Biosafety Frameworks for the Republic of Kazakhstan”
with the financial support of the Global Environmental Facility.**

The document has been prepared according to the objective and the provisions of the international legal document – the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

The Document is aimed at the necessity of improving the normative and legal basis, the structure of governmental management as well as appropriate control on use of living modified organisms in the country.

The Document is issued with the support of:

UNEP- GEF	United Nations Environment Program – Global Environmental Facility;
MEP RK	Ministry of Environmental Protection of the Republic of Kazakhstan;
FHC MA RK	Forestry and Hunting Committee of the Ministry of Agriculture of the Republic of Kazakhstan

Copyright:

Ministry of Environmental Protection of RK,
Forestry and Hunting Committee of the Ministry of Agriculture of RK

Editors:

Yerlan Zhumabayev; Gulnara Nurpeisova

Participants: Inyutina V.P., Isayev N.T., Kalamkarova L.I., Lysenko V.V., Sinyavskiy Y.A., Tulemisova K.A., Yolkin K.F., Bogza L.V., Dissembayev R.N.

The Ministry of Environmental Protection of the Republic of Kazakhstan, Forestry and Hunting Committee of the Ministry of Agriculture of the Republic of Kazakhstan and the personnel of the Project “Development of National Biosafety Framework for the Republic of Kazakhstan” express their gratitude to UNEP for the support in the project management and also to the Global Environmental Facility for financial support of the project.

INTRODUCTION	7
1. POLICY ON BIOSAFETY	8
2. REGULATION SYSTEM	9
<i>2.1. Current situation</i>	9
<i>2.2. Plans for the fututre and needs in updating of legislation</i>	11
3. ADMINISTRATIVE SYSTEM	12
<i>3.1. Existing governmental bodies</i>	12
<i>3.2. Existing closed systems</i>	13
<i>3.3. Plans for the future and needs</i>	13
4. SYSTEM OF DECISION MAKING INCLUDING RISK ASSESSMENT AND MANAGEMENT	15
<i>4.1. Current situation</i>	15
<i>4.2. Plans for the future and needs Планы на будущее и потребности</i>	15
5. MECHANISM OF PUBLIC PARTICICPATION AND AWRENESS RAISNG INCLUDING CONSULTING THE PUBLIC ON THE PROCESS OF DECISION MAKING ON GMO	18
<i>5.1. Current situation</i>	18
<i>5.2. Plans for the future</i>	19
<i>5.3. Needs</i>	<i>Error! Bookmark not defined.</i>
6. INFORMATION ON THE PROJECT ACTIVITY	<i>Error! Bookmark not defined.</i>
7. CONCLUSION	27
8. GRATITUDE	28
<i>Appendix I</i>	29

INTRODUCTION

Colossal success of genetic engineering opens perspective opportunities for solution of the most important national-economic issues. However, along with this, there is arising an anxiety on possible potential risks for biodiversity and human health caused by use of GMO and GM products.

The existing potential threats, unpredictability of GMO virtue in ecological systems, lack of their use control by the governmental bodies are the reasons for urgent solution of the problem on biosafety in the country. In this connection developed under the UNEP – GEF Project national biosafety frameworks structure for the Republic of Kazakhstan is evaluated positively and it takes into account positive experience of foreign and CIS countries, where the basic elements of biosafety provision already exists. It is necessary to mention that the project was in due time and extremely useful for Kazakhstan.

The activities implemented by the project contributed to public awareness on the problem - this is a significant factor in the light of ratification of the Aarhus Convention on Access to Information, Public Participation in Decision- making and Access to Justice on Environmental Matters.

Beginning consistently the development of the system on biosafety at the national level and paying a great attention to the problem at the international level, the Ministry of Environmental Protection initiated the process of joining the Republic of Kazakhstan to the Cartagena Protocol on Biosafety.

An important step to involve Kazakhstan into the processes of developing national Biosafety frameworks and joining to the Cartagena Protocol on Biosafety was implementation of UNEP-GEF project on biosafety.

The main objective of the project was conducting multilateral analysis, informing the Government of the RK and the public on the problem in the country and also defining the key components of the system on biosafety and developing necessary activities for their application and sustainable functioning.

The Document is the final result of the Project Implementation Group activity in the frames of the first phase. It contains the information on the current state of the problem in the country, clearly stated main components of the system and corresponding them needs.

Many participants of the workshops, work meetings, round tables and representatives of the Ministry of Environmental Protection, the Ministry of Agriculture, the Ministry for Foreign Affairs, the Ministry of Healthcare, the Ministry of Education and Science, the Agency of Custom Control, the Ministry of Industry and Trade, the national Academy of Sciences of RK as well as non-governmental organizations provided a great support in NBF development.

The Document will serve as a main guide on implementation of the Biosafety system

A. B. Samakova
Minister on Environmental Protection
of the RK

I. A. Koval
The First Deputy of the Forestry and
Hunting Committee of MA RK

ABBREVIATION

GMO	Genetically modified organism
GEF	Global Environmental Facility
DNA	Desoxyribose nucleic acid
FHC	Forestry and Hunting Committee
MFA	Ministry for Foreign Affairs
MH	Ministry of Healthcare of RK
MES	Ministry of Education and Science of RK
MEP	Ministry of Environmental Protection of RK
MA	Ministry of Agriculture of RK
NCC	National Coordination Committee
NGO	Non-governmental organizations
NBFD	National Biosafety Frameworks Document
NGE	National Governmental Enterprise
MM	Mass Media
CIS	Commonwealth of Independent States
UNEP	UN Environmental Program

INTRODUCTION

Modern biotechnology gives great opportunity to raise the well being of mankind, if it is developed and used following appropriate measures of environmental and human health safety.

GMO is any organism, excluding human one, the genetic material of which was changed by the way different from interbreeding and/or natural recombination. GMO is a result of intended impact on genic level (changing of the structure of its own genes or introduction into it alien natural or artificial genic constructions) and construction of new genomes, which didn't exist in nature before that. Biological danger is in the fact that these organisms can make destabilizing impact on fragile natural balance by interbreeding with wild family species and produce new modifications, which often have dangerous features.

For Kazakhstan with its vast territory and specific landscapes the issues of biosafety are quite important. In the country, where biotechnological products are produced and used there are potential risks of GMO impact on biodiversity.

The importance of the problem is stipulated due to number of existed in Kazakhstan social-economic, environmental and geopolitical factors.

Taking into account the importance of the problem and urgent necessity to solve it, the Ministry of Environmental Protection jointly with UNEP-GEF made a decision on implementation of the project "Development of the National Framework Document on Biosafety for the Republic of Kazakhstan".

The objective of the project is analyzing the situation on the problem, making inventory of the national legislation in the sphere of biosafety and defining the components of the national framework system on biosafety.

The system on biosafety should cover the interests of different structures – governmental, public and scientific ones.

The national framework system on biosafety is directed to provision of proper control over GMO and GM products, which could cause negative impact on biological diversity and human health, and also provide the basis for the public to be sure in safety use of them.

The present Document has been developed as a guide on implementation of the national framework system on biosafety. All the necessary activities on functioning the system will be included the Government of RK Activity Plan.

The guide presents the main steps on development of the structure in the sphere of biosafety and has only recommendation character.

While preparing the document views of all concerned ministries, nongovernmental and scientific organizations were taken into account.

1. POLICY ON BIOSAFETY

Kazakhstan considers biosafety as one of the most important components of the Convention on Biodiversity. In this connection the Cartagena Protocol on Biosafety has positive evaluation. On the 3rd of December 2003 according to the Resolution of the President of RK the Concept on Environmental Safety for 2004-2015 was approved, where one of the important points is joining of the Republic of Kazakhstan to the Cartagena Protocol on Biosafety. The Government of RK acknowledges adherence to solution of the problem and has started the procedure on agreeing of the present Protocol.

Understanding that biotechnology development allows to solve a number of industrial-technological, environmental and social-economic problems in the nearest future and in strategic aspect as well, the Government adopted a number of state programmes on biosafety, which are being implemented.

For agriculture of Kazakhstan with its various contrast environmental zones (risk land cultivation) biotechnological approaches will play more important role in the selection process. Along with this it should be mentioned, that notwithstanding the growing level of modern biotechnology development, and the benefits from them, the basis of the policy on biosafety in the Republic of Kazakhstan is taking a complex of measures, directed to creation of adequate environmental population health protection from possible negative effects and also the guarantee of safety of modern biotechnology use.

The effectiveness of the policy on biosafety should be mainly defined according to consistent activity of the governmental bodies and also co-operation with the concerned parties. Currently the following concerned ministries are involved into the developing system on biosafety:

- Ministry of Environmental Protection
- Ministry of Agriculture
- Ministry of Healthcare
- Ministry of Industry and Trade
- Ministry of Economics
- Agency of Custom Control

Understanding, that it is necessary to create the basis for effective biosafety system, the Ministry of Environment approved the implementation of the project “Development of National Biosafety Framework Document for RK”.

The National system on biosafety in the country currently is at the beginning of its development, and to make the system quite effective in the view of environmental and human health protection and at the same time meet all the requirements of the international character, Kazakhstan will introduce into action such elements of the national frames as:

- Regulation system
- Administrative system
- Decision-making system, which includes assessment and risk management
- Public Participation and awareness mechanism, including consulting the public on the process of decision-making on GMO.

2. REGULATION SYSTEM

2.1. The current state

Currently Kazakhstan adopted a number of normative acts, comprising the issues of product use, produced by modern technology. So, the Resolution of the Government, 29 November 2000 adopted “Instruction on quality and safety of foodstuffs”. It defines the requirements on quality and safety of foodstuffs and regulates relationships between the producer and consumer during production, purchase, delivery, storage, transportation and realisation of the foodstuffs.

Also the Ministry of Healthcare adopted “Hygienic requirements to safety and food valuation of food stuffs” Sanitary Rules and Norms. A section on foodstuffs produced from GMO sources is introduced there. Activities on labelling of foodstuffs containing GMO components are included into the Government Action Plan for 2003-2006. Besides that the Law of the Republic of Kazakhstan № 543-II, 8 April 2004, «About Quality and Safety of Foodstuffs», comprises the issue of registration and labelling of foodstuffs, received from GMO sources. However, the Law, does not subdivides the foodstuffs and food material into a special product group, which demands a separate approach to assessment of quality and population safety.

In the national legislation of the Republic of Kazakhstan currently there is no a separate branch on legal regulation of public relations, related to biosafety, though some legal norms have been already included in the current laws.

Some of the laws should be mentioned:

- The Law of the Republic of Kazakhstan «**on Environmental Protection**», 15 July 1997, N160, regulates separate issues of biosafety when biological objects are used taking into account environmental norms and environmental requirements. The authorised body is the Ministry of Environmental Protection of the Republic of Kazakhstan;
- The Law of the Republic of Kazakhstan «**on Plant Protection**», 3 July 2002, N 331-II – defines legal, economic and organisational basis of activity implementation in the sphere of plant protection from pests and plant diseases. It is directed on conservation of the crop, its quality and prevention of hazardous impact on human health and environment while conducting phytosanitary activities on the territory of the Republic of Kazakhstan. The authorised governmental body is the Ministry of Agriculture of the Republic of Kazakhstan.;
- The Law of the Republic of Kazakhstan «**on Protection, Reproduction and Use of Animal Species**», 21 October, 1993, N 2463-XII, «**on Especially Protected Natural Territories**», 15 July 1997, N 162-1, regulated separate issues on biological safety of animal and plant species. The authorised governmental body is the Ministry of Agriculture of the Republic of Kazakhstan.
- The Law of the Republic of Kazakhstan «**on Plant Quarantine**», 11 February 1999, N 344-1 – directed on country territory protection from delivery or self penetration of quarantine objects from foreign countries or quarantine zones. The authorised governmental body is the Ministry of Agriculture of the Republic of Kazakhstan;
- The Law of the Republic of Kazakhstan «**on Veterinary**», 10 July 2002, N 339-II – directed on provision of veterinary-sanitary safety and products and material of animal origin, veterinary preparations, forage and forage additives safety and also protection of population from common animal and human diseases. The authorised governmental body is the Ministry of Agriculture of the Republic of Kazakhstan;
- The Law of the Republic of Kazakhstan «**on Citizen Health Protection in the Republic of Kazakhstan**», 19 May 1997, N 111-1 and «**on Sanitary-Epidemiological Safety of the Population of the Republic of Kazakhstan**», 4 December 2002, N 361-II, regulates separate issues of biosafety in the sphere of health protection and medicine. The authorised governmental body is the Ministry of Healthcare of the Republic of Kazakhstan;

- The Law of the Republic of Kazakhstan «**on Standardisation**», 16 July 1999, N 433-1. The present law regulates public relations in the sphere of standardisation, defines legal basis of governmental system on standardisation and measures on state and consumer interests protection on the issues of product quality, processes (works) and services through development and application of normative documents on standardisation;
- The Law of the Republic of Kazakhstan «**on Certification**», 16 July 1999, N 434-1. Regulates observation of standards and norms at production and delivery of products.
- The Law of the Republic of Kazakhstan «**on Consumer Rights Protection**», 5 June 1991, strengthens legal, economic and social basis and also guarantees consumer rights protection;
- The Law of the Republic of Kazakhstan «**on Foodstuff Quality and Safety *качестве***», 8 April 2004, N 543. The law establishes relations in the sphere of provision of foodstuff quality and their safety for health and regulates relations between the producer, salesperson and consumer during production, purchase, delivery, transportation and realisation of the food products. The authorised governmental body is the Ministry of Healthcare of the Republic of Kazakhstan;
- The Law of the Republic of Kazakhstan «**on Selection Achievements Protection**», 13 July 1999, N 422-1. The present law defines legal, economic and organisational basis of the activity in the sphere of selection achievements protection, regulates property and also non property relations related to them, which appear due to creation, definition, development, legal protection and use of selection achievements;
- **The Forest Code** of the Republic of Kazakhstan, 23 January 1993. The objectives of the Forest Code are regulation of relations on ownership, use, management of forests for the aims of provision of conditions for increase of environmental and resource forest potential, rational and non exhausting use of forest resources, their protection and reproduction, strengthening of legality in the sphere of forest relations.
- Some legal norms on biosafety are in the custom and trade legislation of the country. Responsibility measures for established rules and norms of violation are defined in the **Criminal Code** of the Republic of Kazakhstan (16 July 1997, N 167-1) and the Code of the Republic of Kazakhstan «**on Administrative Violations**» (30 January 2001, N 155-II).
- A part of regulatory and prohibition norms on biosafety is presented in some tens of sub law acts, adopted according to their competence, by the Government, the ministries and other central executive bodies.

The existing normative and legal acts just in a little degree are related to biosafety and do not refer to the majority of aspects. Some efforts on biological diversity conservation were made and action plans were developed in the country but they didn't acquire legal force, because they were not adopted at the governmental level.

Currently a number of programme are being realised in the country, such as: «Use of biotechnology methods and genetic engineering in medicine, agriculture and industry», «Scientific-technical provision and organisation of biotechnological products in the Republic of Kazakhstan for 2001-2005», the state programme on development of pharmaceutical and medicine industry in the Republic of Kazakhstan and the Programme on Establishment and Development of Biotechnology Production for 2003-2005. However it should be mentioned, that these programmes are of technical character and do not consider the aspects of the Cartagena Protocol, related to biosafety.

Preliminary research showed, that the main drawbacks in the regulatory system are:

- Lack of profile Law, which would regulate public relation in this sphere;
- Insufficient policy on biosafety;
- Management of the problem by different governmental structures.

2.2. Plans for the future and needs in updating the legislation

For Kazakhstan with its minimal legislative base on biosafety it is necessary to take into account the main directions of governmental GMO regulation, just at the stage of development legal basis. Together with existed Law «on Food Products Quality and Safety» and Draft Law «on Biosafety in Gene-engineering Activity» it will be necessary to develop the Provision on GMO Forage Registration.

The Ministry of Environmental Protection jointly with other concerned ministries will develop draft normative-methodical documents and present them for the Government for approval. There are **the necessary normative-legal documents:**

The National Commission on Biosafety

- Provisions on establishment and functioning the National Commission on Biosafety.

Use of GMO in a closed system

- Application form for use of GMO in closed systems;
- The Provision defining the elements and amount of risk assessment for closed systems and also the methodology for their production and the Provision defining criteria for GMO classification according to definite levels of protection measures, restraint of dissemination and other measures on biosafety, management rules and other conditions for individual classes will be defined in separate provisions;
- The Rule on GMO storage, disposal, transportation and liquidation, utilisation of wastes, which are the results of genic engineering methods application;
- The Rule defining conditions of GMO use in a closed system;
- The instruction on preparation of information on operative plans;
- The provision defining detailed content and a plan in case of emergency according to a work class, a methodology of its preparation, testing and supply, and also the format and amount of informing and warning of competent bodies, services and population in case of emergency.

Delivery of GMO products at the market

- The Provision defining elements and amount of risk assessment on delivery GMO products at the market and methodology of its making;
- The Provision defining the amount of data on a label or in GM product declaration and also requirements for product labelling.

GMO deliberate release into the environment

- The Provision defining full content of awareness on GMO deliberate release into the environment;
- The Rules of GMO release into the environment;
- The Provision defining methodology on deliberate GMO release into the environment;
- The Provision defining the amount and content of the report on the results of deliberate GMO release into the environment.
- The rules on the order of GMO testing in field conditions.

Composite state GMO register

- The Form of Composite State Register of Registered GMO.

GMO transportation, packaging and identification

While developing the provisions on GMO transportation, packaging and identification, Kazakhstan will keep on the norms and rules of national and international character as well (the Cartagena Protocol on Biosafety).

Custom affairs

Provisions:

- On interaction of custom bodies in the system of biosafety;
- On GMO transfer through the custom boarder of RK;

- On the order of GMO transit through the territory of the country;
- On the order of GMO custom control;
- On the order of definition, confirmation of GMO country of origin for taking measures on non tariff regulation.

3. ADMINISTRATIVE SYSTEM

3.1. The existing governmental bodies

It is necessary to mention, that in Kazakhstan there is no quite developed administrative system, which regulates GMO production, testing, delivery in and out of the country. Functioning of such system is extremely important for the country. However it should be mentioned, that just now some governmental bodies, partially accept some functions, such as:

1. The issues of **environmental protection** are regulated by the Ministry of Environmental Protection. The activity of which is implemented according to the Rules of organisation and introduction of the General State System of Environmental and Natural Resources Monitoring (N 885, the Resolution of the Government of RK, 27 June 2001). The General State System of Environmental and Natural Resources Monitoring is a multi aim informational system including environmental and natural resources conditions control and also analysis of the data on factual environmental and natural resources conditions with the purpose of environmental safety of the country; Biological diversity basically is presented by forest ecosystems. Forest monitoring is a system of regularly complex supervision, assessment, control and prognosis concerning their condition. It is conducted in order to receive constantly updated information on the forest fund and on the basis of which could be made decisions on multi aim forest resources use as well as prognosis of changing forest ecosystem conditions due to natural and anthropogenic factors.

2. Governmental supervision and control in the sphere of provision of **food products and agricultural raw material quality** is implemented within their competence by:

- Bodies and institutions on standardisation, metrology and certification – over correspondence of food products and agricultural raw material to the requirements of state standards and other normative documents and also identification of food products delivered to the country and planned to be produced;
- Bodies and institutions of state sanitary-epidemiological service – over observation sanitary rules and norms on import, production, processing, storage, transportation of food products, materials and stuffs, implementation of sanitary-hygienic, conducting preventive and preventive-epidemiological activities by physical and judicial persons;
- Bodies of state veterinary supervision – over correspondence of animal origin raw material to veterinary – sanitary rules and norms, observation of the requirements at production, processing, storage and transportation of the products mentioned above, delivery of them to the territory of the country, implementation of veterinary-sanitary activities, rules of realisation of food material and food products at the markets by physical and judicial persons;
- Bodies of state phytosanitary control – over correspondence of plant origin raw material to phytosanitary rules and norms.

3. **New agricultural crop sort testing** with the aim of defining their safety use in agricultural production and expertise of them is made by the State Commission on Sort Testing of Agricultural Crops under the Ministry of Agriculture. The State Commission Госкомиссия формирует Государственный реестр охраняемых сортов растений, разрешённых к использованию в стране.

4. All the governmental bodies, mentioned above co-operate with each other. When food products of plant and animal origin are delivered to Kazakhstan, at the check-admission points of the custom boarder of the Republic of Kazakhstan they make sanitary-epidemiological, veterinary and phytosanitary control, inspection of the delivered food products, food material, checking of commodity-covering documents for **further decision-making on possibility of legalisation** of such food products and food material delivery to the territory of the country. In case food products and material are considered to be hazardous, delivery is prohibited and a mark is made in the commodity-covering documents, that such food products and material is hazardous for human health and realisation of the is prohibited.

3.2. The existing closed systems

Currently in the country there is a number of scientific institutions (closed systems), where research on GMO is made.

- **Governmental institution «the National Sanitary–epidemiological Station».** It conducts testing of food material and food products, food additives, corresponding technologies and production and also sanitary-chemical research of environmental objects defining and making quantitative analysis of toxic and other elements and also makes microbiological researches and laboratory control over environmental objects, tests new methods of microbiological researches on disease diagnosis.;
- **The Institute of Molecular Biology and Biochemistry named after M.A. Aithozhin.** It uses the following research methods: DNA separation, restriction analysis, PTSP-technologies, different methods of molecular hybridisation and electrophoresis, creation of genic constructions on the basis of vectors, genetic transformation, defining expression of alien parts, creation of initial lines and GMO transgenic plants;
- **«The Kazakh Academy of Nourishment» ZAO.** It makes testing of food products, biologically active additives to food, whether they correspond to the requirements of sanitary norms according to the established quantitative and qualitative criteria of safety (organoleptic, physic-chemical, microbiological, radiological and also toxicity). Currently the laboratory is planning test researches of genetically modified products using the method of polymerise chain reaction, which allow to detect the traces of modified DNA (approximately 0,1%).

3.3. The plans for the future and needs

Concerned ministries

In the frames of the proposed National Framework Structure on Biosafety the administrative structure on biosafety will be developing on the basis of governmental bodies:

1. The Ministry of Environmental Protection – a governmental body responsible for conservation and proper use of the environment, will provide GMO environmental impact assessment and also observation the norms of impact on natural environment.

Additional responsibility of the ministry will be organisation of monitoring and control over the use in GMO closed systems. Also it will provide access to informational resources of clearing house mechanism on biosafety.

2. The Ministry of Agriculture – through territorial bodied will provide control on agricultural crop safety, veterinary and phytosanitary safety and also on sort testing.

3. The Ministry of Healthcare – having general leadership in the sphere of citizen health protection, it will provide the assessment of GMO impact on human health, sanitary – epidemiological control and food and pharmacological products safety.

4. The Ministry of Industry and Trade – as a responsible governmental body in the sphere of standardisation, metrology and certification will provide human health and environmental safety through product certification.

The National Commission on Biosafety

The National Commission will consist of 16 members. It will consist of representatives of the concerned ministries: environmental protection, economics, agriculture, healthcare, science and education, custom control. Also representatives of social, environmental, medical, veterinary science institutions, environmental NGOs, the Union of Kazakhstan Farmers and association of consumer rights protection will be included into the Commission. The National Commission on Biosafety will function as intersectoral body responsible for co-ordination of all the activities of the concerned ministries and units on biosafety and will be organised by the Ministry of Environmental Protection. The Commission will take political decisions.

Commission's responsibilities:

- ensuring of creation and updating the infrastructure on monitoring and control system on gene-engineering activity safety;
- co-ordination of executive bodies, scientific, industrial organisations and educational institutions activity in the sphere of development of the order and genetically modified organisms and their fragments transfer safety;
- provision of development of proposals on gene-engineering priority directions activity development in the Republic of Kazakhstan;
- control over harmonisation of biosafety mechanism in the Republic of Kazakhstan the existing international analogies;
- informing and consideration of public points of views on genetically modified organisms and products made of them;
- delivery an annual report on biosafety provision in the country to the Government of the Republic of Kazakhstan.

Risk assessment, including field testing

Risk assessment will be made by the scientific laboratories of the profile ministries. It will be necessary to define on what kinds of GMO and by what competent bodies or scientific institutions the risk assessment will be made.

Other available infrastructure

In spite of the fact, that there are different scientific laboratories in the country able to identify GMO, additional infrastructure support will be needed.

In the country there are 3 main laboratories on the basis of which GMO and GM product expertise could be made. Such kinds of laboratories should be:

1. the laboratory on food quality and safety control of the Kazakh Academy of Nourishment (GM food product expertise);
2. the laboratory of the Institute of Molecular Biology and Biochemistry (GMO expertise).
3. the laboratory of “the National Sanitary-epidemiological Station” Governmental institution.

To provide research on risk assessment in field conditions, it will be necessary to make additional technical supply of test sites.

4. THE SYSTEM ON DECISION-MAKING INCLUDING RISK ASSESSMENT AND MANAGEMENT

4.1. The current situation

Currently it is possible to say, that in the country there is no system on decision-making on GMO. In the existing draft law «on Safety in genetic-engineering activity» such systems defined in general, however for its efficiency, it is necessary to develop a number of positions.

Among the interested state bodies, which take part in decision-making, the bodies mentioned below are the main and have corresponding spheres of actions:

The Ministry of Environmental Protection deals with licensing of ecologically dangerous kinds of economic activities, dumps and emissions of hazardous substances into the environment, sets limits and quotas;

The Ministry of Agriculture – agricultural crops and forages, veterinary preparations, protection and quarantine of plants, introduction of new sorts of plants and animal breeds;

The Ministry of Healthcare – pharmacology, food cadastres, expertise product quality;

The Committee on Standardization, Metrology and Certification at the Ministry of Industry and Trade of PK – control conformity of food products and food material to the requirements of state standards and other normative documents, and also identification of imported food products and the ones, which are planned to be produced.

Risk assessment of GMO use is connected with many objective difficulties. There is lack of knowledge, especially concerning functioning ecosystems and biodiversity issues. Moreover, a number of short-term effects are to some extent unpredictable due to stochastic behavior in the climatic or biological conditions, to the specific conditions in area and time of GM plants.

In Kazakhstan the risk assessment is one of stages of allowing campaign (licensing of various kinds of activities) that is necessary for making justified decision on the issues related to environmental and human health safety. Risk assessment is carried out within the framework of the existing state control system including sanitary-and-epidemiological service, the state system of product works and services certification, and the state supervision of certification rules observance, quality of certificated products, veterinary inspection, phytosanitary inspection, the state ecological expertise, the customs control which have potential in the given area.

4.2. Plans for the future and needs

Any activity connected with GMO (Art.4 Draft Law on Biosafety) should be carried out when there is a corresponding sanction from the Authorized Body on Biosafety based on the decision of Commission on Biosafety.

In decision-making process and consideration of applications **MEP will provide:**

- Receipt and registration of applications and notices;

- Technical consideration of applications and notices on completeness of the information, and also on correctness of submitting and registration the documentation, according to the requirements of the Cartagena Protocol;
- Inform the notifier about reception of the notice within 90 days after its reception;
- Preparation of the review for presentation the documentation to the National Commission on Biosafety, carrying out document circulation, organization and meetings of the Commission;
- Organization and provision to the interested persons the information on normative legal acts in the sphere of biosafety and organization of consultations on the issues of specified organisms and products use for the population.

The National Commission on Biosafety provides:

- consideration of the application and estimation of the presented materials;
- consideration of scientific substantiation according to the results of risk assessment and adoption of risk management;
- preparation of full substantiation for decision-making according to the received application;
- decision-making within 270 days after reception of the application;
- informing and consideration of public point of views on genetically modified organisms and products made of them.

At decision-making the requirements of the Cartagena Protocol on Biosafety will be taken into account and carried out on the basis of the procedures defined in the articles 9,10,11,12 and 13.

As it has been told before, Kazakhstan plans to use the Law on Biosafety, where one of the important items will be decision-making on gene-engineering activity, and also risk assessment and management.

Below there is a system on making assessment and risk management which will be obligatory from the moment when the Law on Biosafety comes into force:

GMO use closed systems

Risk assessment and classification

According to the draft law, mentioned above, before beginning of GMO use in a closed system it is necessary to make risk assessment, in order to define what level of the listed protection measures is required for the planned activity:

- 1 level – it is not dangerous for human health and is comparable with the risk at work with not pathogenic microorganisms;
- 2 level - represents insignificant danger for human health, and is comparable with danger at works with conditional - pathogenic microorganisms;
- 3 level - represents moderate danger for human health and is comparable with danger at works with the microorganisms potentially capable to transfer infections;
- 4 level - represents danger for human health and is comparable with danger at works with activators of especially dangerous infections.

The National Commission on Biosafety.

Notice and sanction

Before the first use of GMO in the closed system the applicant should submit the application to the National Commission on Biosafety.

For each level of danger there are required measures on restraint of distribution, and also other safety measures and necessary provisions. The activity of the 1st level can be started without a notice to the National Commission on Biosafety. Before the beginning of GMO activity of the 2nd level, the user should present the application on the prospective activity to the National Commission on Biosafety. The activity may be started, only if the National Commission on Biosafety will not make other decision during 60 days from the moment of reception of the notice, and only according to the obligations of the Draft Law, mentioned above. For realization of gene-engineering activity of the 3rd and the 4th risk levels sanction of the National Commission on Biosafety is necessary.

Emergency plan

Before the beginning of GMO use in the closed systems the National Commission on Biosafety will check:

1. Whether the emergency plan for use in the closed systems is developed, if inefficiency of measures on isolation can have the serious immediate or subsequent consequences concerning health of people and/or an environment outside of the installation location;
2. Whether the information on such emergency plans is provided properly; it should include obligatory safety measures to be carried out by the bodies interested in prevention of emergency. The information should be actual and public.

Emergencies

In case of emergency the user should inform immediately the National Commission on Biosafety and present the corresponding information. The National Commission in this case informs the public about it, estimates and specifies a degree of the existing danger for human health and the environment. Along with this the National Commission makes full assessment of the emergency and if it is necessary gives recommendation on prevention of similar emergency in the future and also on possible consequences of such emergencies to the user.

GMO deliberate release into the environment

Notice

Any applicant before the first deliberate release into the environment of GMO or combinations of them with a purpose of research, testing, production, realization and/or in other purposes, except production for release into the market, should present a notice to the National Commission on Biosafety.

Risk Assessment

Risk assessment should be carried out on the principles of scientific character and transparency, in view of MEP Provision requirements and with use of corresponding methods of risk assessment. The purpose of risk assessment will be identification and definition of negative GMO impact on human health and environment. Also, the National Commission on Biosafety will decide, what competent bodies or scientific institutes will make risk assessment.

Permit

The applicant can begin its activity only after receipt of permit from the National Commission on Biosafety, and meet the conditions established by it, including definition of genetic safety zone of.

Delivery GM products to the market

The issues of GM product delivery are regulated by the existing law «on Food Product Quality and Safety». Though in the given Law the issues of risk assessment and GM product labeling are not defined, it is necessary to supplement the Law in a more extended way by the following items:

Registration

According to the Law, mentioned above, new kinds of foodstuff, materials and products, products of children feed, food and biologically active additives produced in the Republic of Kazakhstan, and also foodstuff, materials and products import of which is carried out on territory of the Republic of Kazakhstan for the first time, are subject to state registration. In this connection, imported GM products should be registered even before their import on territory of the country. The state registration should be carried out by the organizations and institutes of the State Sanitary-and-epidemiological Service.

The state registration of GM products should include:

- 1) expertise of documents which are presented by the manufacturer (supplier) of GM products and confirm their compliance to the requirements of the normative documents, to the conditions of manufacturing or deliveries of them, and also the results in case of their test need;
- 2) registration of GM products and their manufacturers/suppliers into the State Register of foodstuff, materials of products, products of children feed, food and biologically active additives permitted for manufacturing on the territory of the country or importing for their realization on the territory of the country;
- 3) issue certificates on the state registration of GM products for the applicants; this will allow producers to produce them on the territory of the country or import them to the country.

Packaging, packing and labeling

Private and legal persons, who make packaging and packing of GM products, will be obliged to comply with the requirements of the normative documents on packaging and packing of foodstuff, their marks, and also on materials used for packing and labeling of foodstuff. The applicant could import GM products only after its obligatory labeling. The information on GM components in structure of a product should occupy not less than 10 percent of the label place and/or covering documents.

5. THE MECHANISM OF PUBLIC PARTICIPATION AND INFORMING, INCLUDING CONSULTATION OF THE PUBLIC ON DECISION-MAKING PROCESS ON GMO

5.1. The current situation

An important component in development of the frameworks on biosafety is the mechanism of public participation and informing. It could be explained, - first of all, the activity related to gene-engineering causes anxiety among the population. In this case openness and transparency from the stage of receiving application up to issuing permit are important. In this connection Kazakhstan adheres to the principles of the international agreements – Art. 23 of the Cartagena Protocol, and Art. 13 of the Convention on Biodiversity, and also the Aarhus Convention.

At the present moment the country has sufficient experience in carrying out of open public hearings on a wide spectrum of issues on environmental protection as well as dialogues between NGO, citizens, consumers, mass media, competent bodies and the scientific organizations.

In Kazakhstan NGOs are becoming more and more active. Their representatives participate in national and international workshops on the problem of biosafety, carry out campaigns on informing the public on the risks connected with GMO.

Since ratification of the Aarhus Convention by Kazakhstan, non-governmental organizations have received the right on access to environmental information, and also the right on participation in decision-making process on GMO use.

At the moment the mechanism of participation, awareness and education of the public, is stipulated in a number of existing legal acts. However, mechanisms of public participation and informing, including consultation of the public on decision-making process on GMO has not been defined yet.

For evaluation of public awareness in 2003 «Fund of Environmental Culture integration» NGO made sociological research on a level of public awareness on the problem of GMO use for the first time in Kazakhstan. Thus, the following data have been received:

- 50 % of the respondents know, what GMO is;
- respondents in the age of from 20 to 40 years are informed best of all;
- 61 % of respondents consider that GMO is dangerous to health;
- 91 % would like to have the information;
- 92 % support obligatory labeling of GM products.

5.2. Plans for the future

The national legislation, which is being developed should provide mechanisms of involving the public in decision-making process and the account of such an opinion, as the important component of democratization of the society and citizen right on information.

Issues of informing and consultation with the public are presented in a separate chapter in the Draft Law on Biosafety « Informing and Consultation of the Public ».

Also, the public principle is introduced in the Draft Law in different provisions:

The National Commission on Biosafety

According to the Draft Law the Government will approve the Regulations on Establishment and Functioning of the National Commission on Biosafety, where representatives of the public should be included. The National Commission on Biosafety informs and considers public points of views on GMO and products made of them.

The authorized body in the sphere of biosafety

Organization and provision of information on normative legal acts in the field of biosafety to the interested persons and the organization of consultation of the population on the issue of specified organisms and products use.

Consideration of applications

When considering the applications, the necessary preconditions for providing access to the public at a stage application consideration of will be created in the country. During consideration of the application exchange of points of views through accessible resources of informing will be provided, and according to the comments of the public, public hearings and explanatory work can be organized. Environmental NGOs can play significant role.

Decision-making

According to the draft Law the procedure of permitting of deliberate release GMO into the environment is available for the public. The transparency of activity on GMO use in closed systems is provided by the Authorized Body on Biosafety. In the period of 10 days since receipt of the notice the Authorized Body on biosafety should inform on it the public with indication of the way the information was received.

The comments of the public would be accepting within 30 days since the date of informing and are taken into account by the Authorized Body on Biosafety at decision-making. According to the comments public discussions of any aspects of the considered problem can be organized. In addition to this, the Authorized Body on Biosafety informs public, if required consult on decision-making on permitting of activities regulated under the Draft Law (Art. 4).

5.3. Needs

Further, during realization of the National Frameworks on Biosafety a number of activities with the purpose of awareness rising of the public will be needed:

- Development new and making changes and amendments (legal aspects) to the current legislation for providing the public access to information on GMO according to the provisions of the Cartagena Protocol Biosafety,
- Set frames of cooperation between NGOs and the state bodies on the issues of biosafety and forming and functioning of the state structure of gene-engineering activity regulation;
- Organizing and carrying out public hearings with the purpose of involving the public with the right of recommendatory voice in the process of decision-making on the issue of GMO deliberate release into the environment.
- Preparing and demonstrating several broadcasts on this problem over the central TV;
- Organizing and carrying out of workshops with participation of NGOs, commercial structures, representatives of scientific institutions;
- Publication of informational materials;

During realization of the I Phase of the Project on Biosafety the website of the project has been developed and placed: www.biosafety.kz, with the purpose of public awareness rising. There is a hope that Kazakhstan with the support of UNEP-GEF will develop the mechanism of collection, classification and dissemination of the information on biosafety.

6. INFORMATION ON THE PROJECT ACTIVITY

Taking into account importance of the biosafety problem, and urgent necessity for its solution, the Ministry of Environmental Protection of RK jointly with UNEP-GEF signed the agreement on implementation of the project “Development of National Biosafety Frameworks for the Republic of Kazakhstan” in the Republic of Kazakhstan.

According to the order of the Deputy the Prime Minister – the Minister of Agriculture of RK approved the National Executive Agency of the project is Forest and Hunting Committee of the Ministry of Agriculture. The agency was established with the purpose of administrative support to the project.

So, the project was started for the period of 18 months (beginning of the project: January 2003; completion: June 2004), with a total sum of GEF financing of 162700 US dollars and with co-financing on the part of Government of RK in the amount of 85000 US dollars.

Later within the frames of the project, the National Co-ordinating Committee which the functions of coordination and monitoring of the project implementation was established. The structure of representatives of the state authority institutes, the scientific organizations and NGOs were included into the Committee.

The basic activities on the project were subdivided into the following stages:

Stage 1: Research making

The purpose of the first stage was to carry out research on the current situation on biosafety in the country and to define the key issues. So, during the first stage the following researches have been prepared:

System of risk assessment and regulation, use and transboundary movement of GMO in RK;
Review of national frame structures on biosafety in the countries of commonwealth of the independent states (CIS);

National legislation of the Republic of Kazakhstan in sphere of biological safety;
Scales and consequences of GMO and commercial products release;
Current condition of scientific and technical programs in the field of biotechnology and biosafety in the Republic of Kazakhstan.

Stage 2: Analysis and consultations

During realization of the Second stage of the project a number of seminars and working meetings with the purpose was discussion the problem in the country and development of the required measures were held.

Stage 3: NFDB project preparation

At the closing stage of the project NFDB was prepared, which was agreed with all interested parties.

Along with these tasks it was planned, that the project will carry out activities on informing the public, creation of a database on biosafety with establishment in the Internet, and the most important was expert support to the Ministry Environmental protection in acceding RK to the Cartagena Protocol on Biosafety. Also, the Project Implementation Group developed the Draft Law « on Safety in Gene-engineering Activity », and also recommendations and proposals on the following state documents were made:

- Environmental Action Plan for 2005-2007;
- Concept on Environmental Safety of RK;
- Draft Law of RK « on Foodstuff Quality and Safety».

It should be mentioned, that all of the project tasks, mentioned above, were implemented by joint efforts of all the parties interested in the problem. The main result of the project was identification of components of the National Biosafety Framework Structure and development of the required activities on its introduction and functioning taking into account the peculiarities of the state system of the Republic of Kazakhstan.

During realization of the project one of the important actions there was an inventory of the national legislation. The information on the project activity is available on the site www.biosafety.kz

The following workshops were held:

- *The workshop on informing the public on the national frame document (Almaty, Jun, 27, 2003).*

The objective of the workshop was presentation of the project and general information on the problem. Representatives of the state authorities and scientific institutions, NGOs were invited to the meeting.

The materials are available in hard copies and/or electronic format (for further use of the files it is necessary to have the authors confirmation):

The agenda;

The list of participants;

Presentations and other materials used by the lecturers;

Photos;

The minutes of the meeting.

- *The workshop «Implementation of the provisions of the Cartagena Protocol on Biosafety » (Almaty, August 15-16, 2003).*

Representatives of the Ministry of Agriculture of RK, the Ministry for Foreign Affairs of RK, the Ministry of Environmental Protection of PK, scientific and branch institutions, joint-stock organizations, NGOs, representatives of mass media, national experts of the project took part in the workshop.

The objectives of national workshops were improvement of understanding necessity of ratification of the Cartagena Protocol on Biosafety_by Kazakhstan, discussion of the ways of creation potential on biosafety at the national level, definition of priority directions of activity on development of normative-legal base and management system.

In the first day of workshop the participants presented reports. In the second half of workshop work of the Working groups on the issues of implementation the provisions of the Cartagena Protocol on Biosafety– administrative and legal obligations and procedural requirements was organized.

According to the results of the discussion of the issues, which also were mentioned in reports, the participants of the workshop noted, that there are no normative-legal and administrative

resources in the country, capable adequately react on the problems of GNO and GM products use, and accordingly, there is a low level of biosafety priority as a whole as it was considered before.

The participants developed and proposed a model on the system of biosafety regulation in RK and priority directions of the national legislation development.

The agenda;

The list of participants;

Presentations and other materials used by the lecturers;

Photos;

The minutes of the meeting.

■ *The working meeting of experts (Almaty, November 7, 2003).*

The meeting of experts on the project was caused by the necessity of discussion of the content of analytical reviews, discussions the issues and problems connected with their preparation. Also within the framework of this meeting the issues of the Concept on Environmental Safety preparation and «Environmental Protection for 2005-2007» the Ministry of Environmental Protection branch program project, namely, reflection of the problem on biosafety in the state program documents were discussed.

The agenda;

The list of participants;

Presentations and other materials used by the lecturers;

Photos;

The minutes of the meeting.

The round table on the issues of acceding to the Cartagena Protocol on Biosafety (Astana, on March 2, 2004).

The participants of the Round table expressed their points of view on the necessity of creation the national legislative base on biosafety, monitoring systems on import ГМО, the system of control on GMO import, environmental monitoring on GMO and ecosystems, into which they will be introduced in the future, and also provide beforehand the sum of membership dues to the Secretariat through inclusion of the budgetary application when the national budget for 2005 is formed or to provide payments from the budget of the second phase of the project, to continue carrying out of similar working meetings and workshops with the purpose of improvement of understanding on the issues of use and transboundary movement of living modified organisms, the provisions of the Cartagena Protocol, and also increase of informing the public on the problem.

The agenda;

The list of participants;

Presentations and other materials used by the lecturers;

Photos;

The press release;

The minutes of the meeting.

■ *The first session of Working group on NRFB project consideration (Astana, on March 29, 2004).*

The session was organized with the purpose of consideration of NFDB project and making amendments and remarks. The representatives of the Ministry of Agriculture, Economy and Budgetary Planning, Environmental protection, Healthcare, Industry and Trade of RK, agencies of customs control PK, scientific and nongovernmental organizations, representatives of press and national experts of the project took part in the session.

■ *The national workshop on biosafety and the Second meeting of the Working Group on NFDB project consideration (Astana, August 17, 2004).*

Representatives of the Ministry of Agriculture of RK, the Ministry of Industry and Trade of RK, the Ministries of preservation of the environment PK, the Ministry of Economics and Budgetary Planning of RK, the Ministry of Healthcare of RK, UNDP, NGOs, representatives of the press, national experts of the project took part in the workshop and the working group.

The objective of the workshop was consideration of submitted NFDB project, and also finalizing the results of the project activity. The participants of the meeting gave recommendations on development of the key components of the system on biosafety, in case of acceding of Kazakhstan to the Cartagena Protocol. And also possible actions for further cooperation.

The following scientific lectures were organized:

■ «Genetically modified food stuffs are potential risk », «Biosafety and the Cartagena Protocol » were organized at such Higher educational institutions, as:

1. Almaty Technological University
 2. The Kazakh Agrarian University
 3. Almaty State University
- Presentations.

■ at Almaty Technological University - « The principles of the control over GM food stuffs », Almaty

■ at the Kazakh Agrarian University - « Organization of GMO and GM food stuffs monitoring», Almaty

■ at the Eurasian National University - « Genetically modified organisms and GM products: pros and cons », Astana

■ at the Kazakh National University named after Al-Faraby - « Genetically modified products and biosafety », Almaty

■ at the Almaty State University named after Abai - « the Attitude of the population to GMO and GM products use in Kazakhstan, Almaty

Also, actions on informing on the problems of biosafety in mass media were carried out):

■ Interview to KTK, HABAR, ORT telechannels - Eurasia, Rahat on June, 27, 2004 on informing the public on the problem of biosafety;

■ Interview to NTK, KTK telechannels, 31 channel, Rahat, Kazakhstan on August, 15, 2004 about the necessity of acceding to the Cartagena Protocol on Biosafety;

■ Interview to " NS " national radio on March, 16, 2004 about the problem of biosafety in Kazakhstan;

■ Interview to " NS " national radio on April, 1, 2004 about the First working meeting on NFDB project discussion;

■ Interview to " NS " national radio on April, 7, 2004 about the problem of GMO use;

■ Interview to "Caspionet" telechannel on November, 7, 2003 about the problems of genetically modified food stuffs concerning labeling;

■ Interview to « the ERA TV » telechannel on March, 2, 2004 about acceding of Kazakhstan to the Cartagena Protocol on Biosafety;

■ An article in « Food and a processing industry of Kazakhstan » magazine ,№ 5, 2003, genetically modified sources: problems and prospects;

■ An article in "Panorama" national newspaper, June 25, 2004, the Problem of genetically modified food stuffs in Kazakhstan.

During project implementation a number of printed editions was prepared:

- The booklet on project implementation in Kazakhstan - 1000 copies.

In a proper way the general information on the problem of biosafety and UNDP-GEF project implementation in Kazakhstan is provided there.

Circulation of 1000 copies.

- Posters, calendars on the problem of biosafety.

The materials were disseminated at the workshops and high schools of the country.

All the publications listed below were disseminated at all the ministries, higher educational institutions, libraries, for local authorities, and also at the Parliament.

- The collection of analytical reviews and articles - « Solution of the problem on GMO use as one of aspects of biosafety problem solution in the Republic of Kazakhstan »

In the collection the analysis for GMO research choice strategy and practical application of them in the country is presented, that will allow to develop mechanisms of observance and control transboundary movement and decrease of GMO use in risks in Kazakhstan.

The collection is recommended for edition by the Scientific Council of « the Kazakh Academy of Nourishment ».

150 copies ISBN 9965-646-22-8

- The collection of analytical reviews and articles - « Prospects of living modified organisms development and possible risks for the environment and human health in the Republic of Kazakhstan »

In the collection the analysis of the situation on biosafety in the countries of commonwealth of the independent states, definition of the existing problems and needs for the countries of the subregion is presented. The issues of assessment and regulation of risks on GMO use and transboundary movement in the Republic of Kazakhstan, and also current methods of identification of genetically modified sources in foodstuff.

150 copies ISBN 9965-646-24-4

- The analytical review - «Biosafety problems solution in the Republic of Kazakhstan »

In the review there is analysis of the current situation on biosafety, development of recommendations and definition of the components of the national framework structure on biosafety.

150 copies. UDC 574

Heading 34.35.25.

34.35.51.

- The analytical review « Problems and prospects of living modified organisms development in the Republic of Kazakhstan »

The objective of the review was gathering the knowledge, which has been accumulated on traditional not modified sorts of plants and breeds of animals, and also acquisition of knowledge and formulation of potential risks which can be brought into the environment by transgenic organisms, for development the necessary recommendations on biosafety provision in Kazakhstan.

500 copies. UDC 574

Heading 34.35.25.

- The analytical review - « The state and prospects of development of the national legislation on biotechnologies and biosafety in the Republic of Kazakhstan»

In the present review information there are issues of the legislation on biodiversity, biotechnologies and biosafety in Kazakhstan.

500 copies. UDC 57*001.25*342.52

Heading 87.05.33

■ *The analytical review - «Assessment and regulation of risks on living modified organisms use in Kazakhstan »*

In the analytical review there is an inventory of mechanisms on safety assessment in the existing management system and recommendation on creation the system of risk assessment in view food material and food stuffs transfer, organization of the state control of food stuffs and food material import on territory PK.

500 copies. UDC 574

Heading 34.35.25

■ *The analytical review « The current state of the scientific and technical program on biotechnology and biosafety in the Republic of Kazakhstan »*

In the analytical review existing scientific and practical results are presented and the prospects of further development of biotechnological researches in Kazakhstan are defined, which are currently urgent due to the problems of biological safety.

500 copies. UDC 57.047

Heading 87.05.33

International and regional activities.

■ The chairperson of the National Co-ordinating Committee (N.A.Aithozhina), NKK members (K.A.Tulemisova, L.Astanina), and also the Coordinator of the project participated in “ Risk assessment and management ” CEECCA Subregional Workshop and “ Public awareness and participation ”, (Vilnius, Lithuania , May 27-30, 2003).

■ For participation in « Implementation of the provisions of the Cartagena Protocol on Biosafety » workshop (Almaty, August 15-16, 2003) an expert from the Republic of Tajikistan, d.b.s. Mrs. F.Nasyrova was invited with the presentation - « Implementation of UNEP-GEF project on biosafety in Tajikistan ».

■ The expert of the project (D.Pjankov) took part in « the workshop on biosafety: the results of the I Phase of the project and potential evaluation » in Dushanbe, Republic Tajikistan, August 18-19, 2003.

■ NKK members (J.A.Sinjavsky, E.Aitkenov) and the Coordinator of the project participated in CEECCA Subregional Workshop on Development of Regulation Mode and Management System for the National Structure on Biosafety, (Antalya, Turkey, December 9-12, 2003).

■ The National Coordinator of the project (E.Zhumabaev) took part in the work of the National Workshop on Biosafety, (Dushanbe, Tajikistan, June 25-26, 2004)

7. CONCLUSION

Implementation of the UNEP-GEF project “Development of National Biosafety Frameworks for the Republic of Kazakhstan” for the first time allowed to increase the interest in the problem on biosafety in the country and to involve the state bodies, scientific and non-governmental organizations in active participation in solution of it.

The activities implemented within the framework of the project, in particular, the national workshops, working meetings, publications and other contributed very much to the content and the general understanding of the problem of biosafety.

The National Framework Document on Biosafety is the basic result of the first phase activity on UNEP-GEF project on biosafety in Kazakhstan and is developed as a guide on implementation of the national framework structure on biosafety in Kazakhstan.

We hope, that the analysis, which was carried out within the frames of the activities and the produced recommendations, which were given, will be a starting point in the establishment of the National Framework System on Biosafety in the Republic of Kazakhstan.

8. EXPRESSION OF GRATITUDE

The Project Implementation Group expresses gratitude to all the participants of the development of the framework structure on biosafety and all those who promoted it, first of all, to the United Nations Environment Program and Global Environmental Facility.

We would like to express gratitude to all our partners who participated in preparation of the present document:

The Department on Customs Control Organization under the of Agency of Customs Control of RK;

The State Commission on Sort-testing of Agricultural Crops;

The Department of a science and Department of Protection and Quarantine of Plants under the Ministry of Agriculture of RK;

The Department of Multilateral Cooperation under the Ministry for Foreign Affairs;

Department of Foreign Trade activities of « Food Contract corporation » Joint-Stock Company;

The Committee of the State Sanitary-and-epidemiologic Supervision of Ministry of Healthcare of RK;

The Ministry of Environmental Protection of RK;

The Institute of Molecular Biology and Biochemistry;

The Institute of Physiology, Genetics and Bioengineering of Plants;

« Kazakh Academy of Nourishment » Joint-Stock Company;

The Research-and-production Center of Processing and food Industry;

"Greenwomen" Agency on Ecological News" NGO;

«Ecological Culture Integration Fund» NGO.

In the conclusion, we would like to express our great gratitude to Dr. Nizar Mohammed for his valuable advices and support during all the period of activity on the project.

Also, we would like to thank Dr. Christopher Briggs for his efforts in project development in Kazakhstan, and also general management.

Since the very begining of project development and till its completion in the form of Nbfd, the process was accompanied by a constant exchange of useful and rather valuable information with our regional colleagues from NIS countries. We would like to thank all of them.

The LAW of Republic Kazakhstan On Safety in gene-engineering activity

The present Law defines legal and organizational bases of safety in genic engineering activity and is directed on protection of the environment and health of the population against adverse impact of genetically modified organisms.

Chapter 1. GENERAL PROVISIONS

Article 1. The basic notions used in the present Law

In the present Law the following basic notions are used:

- 1) **emergency** – an incident attracting inadvertent release of genetically modified organisms into the environment during their use in closed systems, able to have the immediate or subsequent consequences for human health and the environment;
 - 2) **safety in genic-engineering activity (further – biosafety)** – the system of the actions directed on prevention or reduction to a safe level of adverse influences of living modified organisms on human health and the environment at realization of **genic** -engineering activity;
 - 3) **genic engineering** – set of methods and technologies, including technologies of reception of recombinant ribonucleic and desoxyribose nucleic acids, on allocation of genes from an organism, to realization of manipulations with genes and to their introduction in other organisms;
 - 4) **genic -engineering activity** – the activity related to creation, test, use, import and export of genetically modified organisms;
 - 5) **genetically modified organism** – the living organism containing a new combination of a genetic material, received with the help of genic engineering methods;
 - 6) **the state register of selection achievements** - The state register of the Republic of Kazakhstan of protected sorts of plants and the State register of the Republic of Kazakhstan of protected breeds of animals which include sorts and breeds on which patents are given;
 - 7) **the living organism** – means any biological formation capable to transfer or replicate genetic material, including viruses, cells of animals and plants in the crop;
 - 8) **the applicant** – the person who submits the notice;
- zone of genetic safety – territory within the limits of which any activity connected to use of genetically modified organisms is not supposed.
- 9) **import** – deliberate import from the territory of one state to the territory of other state of genetically modified organisms and combinations of such organisms;
 - 10) **the importer** – physical or legal person who has state jurisdiction on carrying out import who organizes and has responsibility for import of genetically modified organisms, combinations of such organisms;
 - 11) **use in the closed system** – means any operation which is carried out within the limits of installation, a construction or other physical structure, connected with genetically modified organisms which are regulated by special measures effectively limiting their contact to the environment and impact on it;
 - 12) **undeliberate transboundary movement**– any movement through border of genetically modified organisms or their combinations which consequences should be assessed from the point of view of biological safety and safety for human health with corresponding measures;
 - 13) **risk assessment** – assessment of the direct or indirect immediate or subsequent consequences of release into the environment of genetically modified organisms or their components for human health and the environment;

- 14) **field testing** – an experiment on studying genetically modified organisms in field conditions, taking place under the control, with the confidence, that these organisms will not be kept in the environment after completion of the experiment;
- 15) **the user** – a physical or legal person who carries out and has responsibility for the activity connected to reception, testing, production and realization of genetically modified organisms in the closed or open systems, and also with reception, testing, production and realization of the products made of these organisms;
- 16) **deliberate release into the environment** – deliberate release into the environment genetically modified organisms or their combinations which do not require specific measures of isolation and have a high level of safety for people and the environment;
- 17) **deliberate transboundary movement** – any export-import transaction with genetically modified organisms or their combinations, carried out according to the sanction of the competent national bodies and national and international rules;
- 18) **transboundary movement of genetically modified organisms** – any movement of genetically modified organisms or combinations of such organisms, and also products made of them from territory of one state to the territory of another state;
- 19) **the notice** – the document by means of which the person notifies the National Commission on Biosafety on activity which is carried out according to the sanction;
- 20) **the authorized body** – the governmental structure formed for activities at the national level on duties, international contracts following from requirements concerning realization of the measures on biosafety at use of genetically modified organisms;
- 21) **export** – deliberate export of genetically modified organisms, combinations of such organisms from the territory of one state to the territory of another state;
- 22) **the exporter** – a physical or legal person who has state jurisdiction to export products who organizes and has responsibility for export of genetically modified organisms and combinations of such organisms;

Article 2. The legislation of the Republic of Kazakhstan on safety in genic-engineering activity

1. The legislation of the Republic of Kazakhstan on safety in genic-engineering activity is based on the Constitution of the Republic of Kazakhstan and will consist of the present Law and other normative legal acts of the Republic of Kazakhstan.

2. If the international agreements ratified by the Republic of Kazakhstan, establishes other rules, than that of defined in the present Law, rules of the international agreement are applied.

Clause 3. The tasks of state regulation in the field of biosafety

The primary objectives of the state regulation in the field of biosafety are:

- 1) definition of the basic directions of activity of the state controls and legal persons on biosafety;
- 2) establishment of substantive provisions of legal regulation of relations in the field of biosafety;
- 3) protection of territory of the republic from release of genetically modified organisms or independent release from foreign countries;
- 4) revealing, localization and liquidation of illegally imported genetically modified organisms, and also prevention of their release into the regions of the republic without them;
- 5) carrying out the state control over observance of the legislation in the field of biosafety on the territory of the republic.

Article 4. The sphere of activity

The provisions of the present Law are applied to all kinds of activity, related to:

- 1) reception, duplication, test and use of genetically modified organisms in the closed systems in the various purposes, with genic engineering methods application;
- 2) deliberate release of genetically modified organisms, including any living structures, capable to reproduce organisms what seeds, tubers, cuttings, pollen, spores, etc. into the environment.;
- 3) indeliberate release of genetically modified organisms into the environment;
- 4) any kinds of researches of genetically modified organisms, including laboratory, clinical, field, trial industrial tests;
- 5) indeliberate or illegal transboundary movement of genetically modified organisms;
- 6) storage, disposal place and destruction of genetically modified organisms, recycling of waste products which are resulted from genic engineering methods application;

Chapter 2. GOVERNMENT MANAGEMENT IN THE FIELD OF BIOSAFETY

Article 5. The competence of the Government of the Republic of Kazakhstan in the field of biosafety

To competence of the Government of the Republic of Kazakhstan in the field of biosafety concerns:

- 1) development of the basic directions of the state policy in the field of biosafety;
- 2) approval according to presentation the authorized body in the field of biosafety of the national programs;
- 3) acceptance or approval according to presentation of the authorized body on biosafety of normative legal acts on biosafety;
- 4) approval of the Regulations on Establishment and Functioning of the National Commission on biosafety;
- 5) acceptance or approval according to presentation of the authorized body on biosafety of the list of the registered genetically modified organisms;
- 6) cooperation with foreign states and international organizations in the field of biosafety;
- 7) realization of other functions in the field of biosafety according to the present Law and other acts of the Republic of Kazakhstan.

Article 6. The competence of the National Commission on Biosafety

The National Commission on Biosafety is established and functions as an interdepartmental body responsible for coordination of all the activities of the interested ministries and departments on biosafety. The competence of the National Commission on Biosafety includes:

- 1) creation and perfection of an infrastructure of the system of monitoring and control over safety in genic-engineering activity;
- 2) coordination of activity of the enforcement authorities, scientific, industrial organizations and educational institutions in the field of development of the order and safe transfer of genetically modified organisms and their fragments;
- 3) provision of development of offers on development of priority directions of genic-engineering activity in the Republic of Kazakhstan;
- 4) control over harmonization of the mechanism on biosafety in the Republic of Kazakhstan with the existing international analogues;
- 5) informing and consideration of public points of vies on genetically modified organisms and products made of them;
- 6) presentation of annual report on biosafety in the country to the Government of the Republic of Kazakhstan.

Article 7. The competence of the Authorized Body on Biosafety

The authorized body in the field of biosafety organizes works on realization of the legislation of the Republic of Kazakhstan in the field of biosafety.

The competence of the Authorized body in the field of biosafety includes:

- 1) formation and representation to the Government of the Republic of Kazakhstan of personal structure of the National Commission on Biosafety;
- 2) organization and carrying out of meetings of the National Commission on Biosafety;
- 3) implementation of the decisions of the meetings of the National Commission on Biosafety;
- 4) development and presentation of the list of the registered genetically modified organisms to the Government of the Republic of Kazakhstan;
- 5) development and representation of the programs in the field of biosafety to the Government of the Republic of Kazakhstan;
- 6) organization and carrying out of examination of the data on biosafety of genetically modified organisms represented by the applicant;
- 7) delivery of sanctions for the kinds of activity regulated by the present Law, on the basis of the decision of the National Commission on Biosafety;
- 8) organization of monitoring and control over use of genetically modified organisms in the closed systems;
- 9) organization of industrial tests of genetically modified organisms;
- 10) development and approval of the rules of storage, disposal place, transportation and dissemination of genetically modified organisms, recycling of waste products which are resulted from application of genic engineering methods;
- 11) development and approval of the corrected realization of genic -engineering activity in the closed system;
- 12) development and approval of the rules of carrying out industrial tests and the state registration of genetically modified organisms;
- 13) organization and provision of the information on normative legal acts in the field of biosafety to the interested persons and organization of consultation of the population on the issues of specified organisms and products use;
- 14) realization of cooperation with the international organizations and the state bodies and participation in realization of the international programs in the field of biosafety;
- 15) other functions stipulated by the legislation of the Republic of Kazakhstan.

Chapter 3. USE OF GENETICALLY MODIFIED ORGANISMS IN THE CLOSED SYSTEMS

Article 8. Implementation of genic -engineering activity in the closed system

1. The user, before use of genetically modified organisms in the closed systems is obliged to carry out risk assessment, defining protective measures listed below and the level required for the planned activity

I level - does not represent health hazard of the person, and is comparable with risk at work with not pathogenic microorganisms;

II level - represents insignificant health hazard of the person, and is comparable with danger at works with conditional - pathogenic microorganisms;

III level - represents moderate health hazard of the person, and is comparable with danger at works with the microorganisms potentially capable to transfer of an infection;

IV level represents health hazard of the person, and is comparable with danger at works with activators of especially dangerous infections.

2. Before the beginning of activity with genetically modified organisms of II level, the user should notify the National Commission on Biosafety on the prospective activity. Activity can begin, only if the National Commission on Biosafety will not make other decision during 60

days since the moment the notice was received, and only according to the obligations stipulated by the present Law;

3. For realization of genic -engineering activity in the closed system III and IV risk levels it is necessary to have the sanction from the Authorized Body on Biosafety on the basis of the decision of the National Commission on Biosafety;

4. Assessment and used measures on protection, should be reconsidered periodically and also in case there are proofs that the estimation is made incorrectly; thus the new data on scientific or technical researches is considered.

Article 9. An operating plan

Before the beginning of genetically modified organisms use in the closed systems the National Commission on Biosafety checks:

1) whether the operating plan for use in the closed systems in a case when the inefficiency of measures on isolation can have serious immediate or subsequent consequences concerning health of people and/or the environment outside of the location of installation is developed;

2) whether the information on such operating plans, including obligatory security measures for application is submitted properly, to the bodies interested in prevention of emergency. The information should be actual and public.

Article 10. Emergencies

1. In case of emergency the user should inform immediately the Authorized Body on Biosafety about it and present the corresponding information;

2. In case of emergency the Authorized Body on Biosafety informs the public on it, having estimated and having specified a degree of danger for human health and the environment;

3. The Authorized Body on Biosafety makes more detailed assessment of the emergency and in case of need gives recommendation on prevention of similar emergencies in the future to the user, and also on possible consequences of such an emergency.

Chapter 4. DELIBERATE RELEASE OF GENETICALLY MODIFIED ORGANISMS INTO THE ENVIRONMENT

Article 11. The order of release of genetically modified organisms into an environment

1. Any applicant before the first release of genetically modified organisms or combinations of them into the environment with the purpose of research, test, manufacture, realization and/or other purposes, except for production for delivery to the market, should present a notice to the National Commission on Biosafety.

The notice should contain:

1) a technical file with the information stipulated in the Provision and necessary for assessment of expected risks, immediate or subsequent ones, which genetically modified organism or a combination of such organisms can make for human health and/or the environment;

2) assessment of impact and risks for human health and/or the environment, caused by release of genetically modified organisms or combinations of such organisms into the environment; or

3) the information received by the applicant on the territory of the Republic of Kazakhstan and/or behind its boundaries, on the results of the release of the same genetically modified organisms or the same combinations of these organisms, the notice about which was presented earlier or delivered at the same time.

2. The National Commission on Biosafety can permit, that release into the environment into the certain place of a combination of genetically modified organisms or the same genetically

modified organism in different places with the same purpose and during the limited period of time may be made by one notice.

3. At the subsequent release of the same genetically modified organism or the same combination of the specified organisms about which already it was notified earlier as on a part of the same research program, the applicant should present a new notice, having included in it the data of the previous notices and/or the data of the registered previous results.

4. In case of change of the conditions of deliberate release, according to that the applicant can have consequences for human health and/or environment, or in case of new information on risks the applicant is obliged:

- 1) to reconsider the measures stipulated in the notice;
- 2) to inform the National Commission on Biosafety on it;
- 3) to take necessary measures for human health and environment protection.

5. In the time, stipulated for consideration of the application, the time necessary for it is not included:

- 1) presentations of the additional information required from the applicant;
- 2) presentations of the conclusions;
- 3) realization of consultation with the public and the organizations by the Authorized Body on Biosafety.

6. If the information on possible significant consequences of release of genetically modified organism into the environment becomes known after reception by the user of the corresponding sanction, the Authorized Body on Biosafety should demand change of conditions of release from him. In case of insubordination the Authorized Body on Biosafety demands to stop or prohibit further activity.

Article 12. Procedure on consent justification made beforehand

This procedure is applied only to the first deliberate release of genetically modified organisms into the environment. Procedure on consent justification made beforehand is not applied to genetically modified organisms:

- 1) in case of their transboundary transit;
- 2) intended for use in the closed systems;
- 3) intended as foodstuff, forage for animals and for processing.

1. Any exporter before the first export delivery of genetically modified organisms intended for release into the environment or a combination of them with a view of research, test, production, realization and/or in other purposes should present to the Authorized Body on Biosafety the detailed written information on genetically modified organisms just before shipment.

2. The Authorized Body on Biosafety should confirm reception of the given written information during 90 days since the date of reception and makes one of the following decisions:

- 1) to permit realization of import, with conditions or without them, with specification as they are applied to the further import of the same genetically modified organism;
- 2) to forbid import;
- 3) to demand presentation of the additional information according to the Provisions of the Authorized Body;
- 4) to make risk assessment of genetically modified organism according to article 13.

Article 13. Risks assessment

Risk assessment should be carried out on the principles of scientific character and transparency, in view of the requirements of the Provision of the Authorized Body and with use of corresponding methods of risk assessment. The purpose of the assessment is revealing and definition of negative impact of genetically modified organisms on human health and the environment. Risk assessment is made during 270 days. The National Commission on Biosafety:

- 1) decides, what competent bodies or scientific institutes make risk assessment;

- 2) it is obliged to make sure, that risk assessment on the basis of which the decision can be taken;
- 3) the National Commission has responsibility for Risk assessment of genetically modified organisms in the closed systems;
- 1) financial expenses related to risk assessment are made by the exporter .

Article 14. Procedures

1. The applicant can begin activity only after reception of sanction of the National Commission on Biosafety, and following the requirements established by it, including definition of a genetic safety zone. The width of the zone for the state natural protected territories should be not less than 3 kms.;

2. If the Authorized Body on Biosafety considers, that the Applicant has sufficient experience of release of the certain genetically modified organisms into the environment in view of conformity to the criteria established in the Provision of the Authorized Body, it can make decision to simplify procedure on release;

3. The sanction to deliberate release of genetically modified plants into the environment, given out by the Authorized Body on Biosafety on the basis of the decision the National Commission on Biosafety, is obligatory at registration of sorts for test for the agronomical and technological value, carried out by the State Commission on Sort Testing of Agricultural Crops, with the purpose of production of them in the Republic of Kazakhstan;

4. All sorts of the plants which were produced from genetically modified organisms, s corresponding to the requirements for agronomical and technological value, are registered in the State Register of Selection Achievements received from genetically modified organisms of the Republic of Kazakhstan.

Article 15. Abeyance or prohibition of genic -engineering activity

If the information on possible significant consequences of release of genetically modified organism into the environment becomes known after reception of the corresponding sanction by the user, the Authorized Body on Biosafety should demand change of conditions of release from him. In case of insubordination the Authorized Body on Biosafety demands to stop or forbid further activity.

Article 16. Provision of genetically modified organisms movement

1. The importer before realization of import should make sure that the exporter provides corresponding:

- 1) packing, identification, labeling and transportation of genetically modified organisms at the level corresponding to realization of these operations on the part of export;

- 2) Observance of other conditions stipulated by the present law.

2. The importer is obliged to provide conformity of accompanying documents to the requirements of the national legislation and to the provisions of the international legal acts concerning transboundary movement of genetically modified organisms.

Article 17. Activities in case of illegal transportation of genetically modified organisms

1. In case of illegal transportation of genetically modified organisms the Authorized Body on Biosafety has the right to demand from the country of export their repatriation or destruction at his own expense according to the norms of the international law;

2. Competent international bodies are informed on the cases of illegal transportation of genetically modified organisms according to the procedures established by the international legal acts in this field.

Article 18. Activities in case of inadvertent transboundary movement of genetically modified organisms

1. In case of inadvertent transboundary movement of genetically modified organisms the Authorized Body on Biosafety undertakes measures under the notice, stipulated by the

international legal acts and also measures on prevention of any risks concerning human health and the environment;

2. The National Commission on Biosafety informs the public on the measures on prevention the situations which can be caused by inadvertent transboundary movement of genetically modified organisms.

Chapter 5. INFORMING AND CONSULTATION WITH THE PUBLIC

Article 19. Procedure of informing and consultatiNG the public

1. Procedure of the sanction of deliberate release of genetically modified organisms into the environment is open. Transparency activity on use of genetically modified organisms in the closed systems concerning for which the sanction is requested, it is provided by the Authorized Body on Biosafety;

2. In a period of 10 days since the notice is received, the Authorized Body on Biosafety should inform the public on it indicating the way the information was received;

3. The comments of the public are accepted within 30 days since the date of its informing and are taken into account by the Authorized Body on Biosafety at decision-making on the sanction for the requested kind of activity. According to the comments public discussions of any aspects of the considered problem can be organized;

4. The Authorized Body on Biosafety provides participation of the public in decision-making on the sanction of kinds of the activity regulated by the present Law, according to the provisions of the national legislation and the international legal acts, one of the parties of which is the Republic of Kazakhstan.

Chapter 6. RESPONSIBILITY IN THE AREA OF GENIC-ENGINEERING ACTIVITY

Article 20. Actions in case of illegal genic-engineering activity

1. Illegal activity on reception, testing, production, use, realizations, import / export of genetically modified organisms implies responsibility according to the legislation of the Republic of Kazakhstan;

2. If owing to the activity on reception, testing, production, use, realizations and import of genetically modified organisms there is a risk or damage to human health and the environment, the user and/or the importer, according to the circumstances, has the responsibility according to the legislation of the Republic of Kazakhstan;

3. The degree of risk, character and the size of the damage caused by the activity, stipulated regarding part (2), and is defined by a commission of experts appointed by the National Commission on Biosafety from representatives of the central bodies of environmental protection, agriculture and public health services;

4. Measures on compensation of the damage, suggested by a commission of experts, are established by judicial instance;

5. If the damage is caused by means of import and use on the territory of the country of genetically modified organism, the provisions of the international legal acts are applied.

Chapter 7. FINAL PROVISIONS

Article 21. Confidential information

1. The Authorized Body and the National Commission on Biosafety has no right to open to the third party, any information recognized confidential, and is obliged to protect the rights of the intellectual property connected to the received information;

2. In the notice delivered to the Authorized Body on Biosafety, the applicant can specify, having presented a necessary substantiation, what information should be considered as confidential.

Article 22. Solution of disputes in the field of biosafety

Disputes in the field of biosafety are solved by courts or in the order established by the legislation of the Republic of Kazakhstan.

**Chapter 8. INTERNATIONAL COOPERATION
IN THE FIELD OF BIOSAFETY**

Article 23. The international cooperation in the field of biosafety

The Republic of Kazakhstan carries out the international cooperation in the field of biosafety, being guided by the principles of observance of general environmental safety priority.

Article 24. Activity of foreign organizations and citizens in the field of biosafety on the territory of the Republic of Kazakhstan

On territory of the Republic of Kazakhstan activity of foreign organizations and citizens is allowed, if it does not contradict the legislation of the Republic of Kazakhstan or is regulated by the international agreements ratified by the Republic of Kazakhstan.

Article 25. The international agreements of the Republic of Kazakhstan in the field of biosafety

If the international agreements are ratified by the Republic of Kazakhstan, establish other norms, than that ones, defined in the legislation of the Republic of Kazakhstan the rules of the international agreements are applied.

The President
The Republic of Kazakhstan