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Biotechnology Update 2015

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Report Highlights:
Little has happened in Kazakhstan over the last year with regard to of genetically engineered (GE) products. The Kazakhstan's draft law on "On State Regulation of Genetic Engineering Activities" still has not moved out of the Kazakh Parliament. However, substantial progress has been made in the negotiations for Kazakhstan's accession to the World Trade Organization (WTO). Some sources have maintained that progress on the GE legislation was unlikely until after Kazakhstan's WTO accession.

Section I. Executive Summary:

Kazakhstan's draft law on "On State Regulation of Genetic Engineering Activities" remains in the Kazakh Parliament, where it has been since early 2011. Since 2011 it has been under review by the Parliamentary Committee and in not expected to come up for discussion again until February, 2016. Some sources believe that it is unlikely this law will be passed until after Kazakhstan's WTO accession. Without this law in place, development of agricultural biotechnology is unlikely to occur in Kazakhstan.

Kazakhstan's crop production is dominated by wheat, which makes up nearly two-thirds of all planted area. The Ministry of Agriculture, however, has a strategy of diversifying crop production away from wheat and into more feed grains and oilseeds. Currently, agricultural biotechnology is not part of the Ministry's 7-year Agricultural Plan to 2020.

Customs Union (CU) regulations (covering not just Kazakhstan but also Russia, Belarus and Armenia) have recently come into force regulating labeling and imports of GE products. As Kazakhstan continues to integrate into the Customs Union, it is expected that policies and views of the other members states (especially Russia) will play a greater role in regulating biotechnology in Kazakhstan.

Section II. Author Defined:
PLANT AND ANIMAL BIOTECHNOLOGY

Chapter 1: Plant Biotechnology
Part A: Trade and Production:

a. Product Development: Currently, one GE crop development project has been finished in Kazakhstan. The new GE crop development project is for a drought resistant wheat variety, conducted jointly with Australian researchers. This research project was completed in 2014 and developed 21 polyploid wheat lines. Field trials are currently under way.
b. Commercial Production: Kazakhstan does not produce any GE crops, and without the passage of the law "On State Regulation of Genetic Engineering Activities" it is unlikely that substantial development will occur. In the new 7-year agricultural program designed by the Ministry of Agriculture for 2013-2020, there is no mention of GE crops or GE technologies. Area in Kazakhstan planted with genetically engineered (GE) varieties for commercial use is extremely small. The only instance where this occurs is if farmer decides to plant GE crops for his own use.

Kazakhstan crop production is dominated by wheat, which accounts for 64 percent of all field crop area, and 83 percent of all grain area. Crops for which GE varieties exist globally for commercial use are not significant in Kazakhstan, with corn (for grain) area at only 0.5 percent and soybean area at only 0.4 percent of total crop planted area. Rapeseed area has been growing, but remains at only one percent of total planted area. Cotton area is only 0.6 percent of the total, and sugar beet production area is almost non-existent. The Kazakh Government does have a plan to diversify production away from wheat, and this could lead to increases in area to oilseeds and other feed grains.

a. Exports: There is no commercial production of GE crops in Kazakhstan and Kazakhstan does not export any GE crops to the United States or any other countries.

b. Imports: Imports of GE crops or products are allowed into Kazakhstan, but must abide by Customs Union regulations (see Appendix 1) which cover the entire Customs Union of Belarus, Russia, Armenia and Kazakhstan. For instance, the Customs Union Technical Regulation on Grain stipulates that grain/oilseeds (both for food and for feed use) may contain only registered GE lines (registered in accordance with the legislation of the states, members of the CU), and that the GE grain presence of non-registered lines shall not exceed 0.9 percent. (Please see the FAS GAIN Annual Report for the Russian Federation for Agricultural Biotechnology for a list of lines registered in Russia/CU for importation).

Kazakhstan imports only small amounts of corn or soybeans. However, Kazakhstan does import an average of 10,000 tons of soybean meal each year, mainly from Argentina. In 2014, in addition to 5,189 tons of soybean meal imported from Argentina, Kazakhstan imported 4,034 tons of soybean meal from Ukraine for the first time.

The Kazakh law "On Seeds Farming" specifies that GE seeds for planting can only be imported for testing and research, not for cultivation.

a. Food Aid Recipient Countries: Kazakhstan is not a food aid recipient.

Part B: Policy:

Regulatory Framework: In early 2011, the Kazakh Government drafted a law, "On State Regulation of Genetic Engineering Activities," in order to regulate biotechnology in Kazakhstan (please see un-official translation of the entire law in Appendix 2). This law remains stalled in the Kazakh Parliament. It was presented by the Ministry of Education and Science to the Socio-Cultural Committee of the Parliament in February, 2011. Since 2011 it has been under review by the Parliamentary Committee and in not expected to come up for discussion again until February, 2016. Some sources believe that it is unlikely this law will be passed until after Kazakhstan's WTO accession. Without this law in place, development of agricultural biotechnology is unlikely to occur in Kazakhstan.

In January 2014, Kazakh President Nursultan Nazarbayev instructed the government to adjust the plan for the development of the agro-industrial complex, to permit genetically modified crops. However, implementation of this provision is likely to take an extended period.

This draft law on State regulation of genetic engineering activity specifies separate roles for different government bodies on the regulation of agricultural biotechnology. However, these authorized bodies have not yet been identified. The draft law specifically states:

(Note: All Kazakh legislative and regulatory documents use the term GMO (genetically modified organisms) or GMM (genetically modified microorganisms) instead of genetically engineered (GE) organisms/microorganisms.)

1. The authorized body on health:
1) implements the state policy on genetic engineering activities within its jurisdiction;
2) develops, approves, within its competence, the normative legal acts on genetic engineering;
3) makes within its competence, risk assessment of first-time produced and first-time imported genetically modified organisms (GMOs);
4) runs State Registry of GMOs;
5) makes state registration and re-registration of GMO;
6) approves the form of registration certificate of GMOs;
7) performs other functions stipulated in this Law, other laws, acts of the President of the Republic of Kazakhstan and the Government of the Republic of Kazakhstan.
2. The authorized body on agriculture:
1) implements the state policy on genetic engineering activities within its jurisdiction;
2) develops, approves, within its competence the normative legal acts on genetic engineering;
3) makes risk assessment within its competence;
4) performs other functions stipulated in this Law, other laws, acts of the President of the Republic of Kazakhstan and the Government of the Republic of Kazakhstan.
3. The authorized body on environmental protection:
1) implements the state policy on genetic engineering activities within its jurisdiction;
2) develops, approves, within its competence the normative legal acts on genetic engineering;
3) performs other functions stipulated in this Law, other laws, acts of the President of the Republic of Kazakhstan and the Government of the Republic of Kazakhstan.

According to the draft law the authorized body on genetic engineering issues permits to the following genetic engineering activities:
1) LMOs/GMOs creation and/or testing;
2) LMOs/GMOs use in closed systems;
3) LMOs/GMOs release into environment and use in open system.
With regard to approval timelines, the draft law states that the authorized body on genetic engineering is required to issue decisions and permits to applicants within the following timelines of receiving the necessary documents from the applicant.
1) LMOs/GMOs creation and/or testing – 120 calendar days;
2) LMOs/GMOs use in closed systems – 90 calendar days;
3) LMOs/GMOs release into environment and use in open system – 130 calendar days
If any documentation is missing or incorrect, the applicant must submit it within 45 calendar days.

a. Approvals: The registration of GE lines for the entire Customs Union (Belarus, Russia, and Kazakhstan) for use in food is done by the Russian Federal Service for Surveillance in the Sphere of Human Rights Protection and Human Well-Being (Rospotrebnadzor). (For the list of approved lines by Rospotrebnadzor please see FAS GAIN Annual Report for the Russian

Federation for Agricultural Biotechnology).

b. Field Testing: The Kazakh law "On Seeds Farming" theoretically allows GE crops field-testing although the draft law "On State Regulation of Genetic Engineering Activities" sets out the approval process and until it is enacted, it is unlikely any field trials would occur. Currently there are no field trials.

c. Stacked Event Approvals: The draft law on biotechnology does not include any information on stacked events.

d. Additional Requirements: Not applicable

e. Coexistence: The draft law does not specify coexistence rules. However, they can be developed after law is passed.

f. Labeling: Labeling rules are now covered by a Customs Union Technical Regulation on Labeling (please see Appendix 1) which came into force on July 1, 2013. This regulation states that all products containing more than 0.9 percent GE-ingredients must be labeled as such. If it contains less than 0.9 percent GE-ingredients then it does not have to be labeled. Also, the regulation states that labeling of food products as non-GE is voluntary.

g. Trade Barriers: All imported GE grains and oilseeds must have their lines registered in the Customs Union prior to importing into Kazakhstan, and the presence of non-registered lines cannot exceed 0.9 percent. Currently, Kazakhstan's imports of U.S. corn and soybeans (and soybean products) are largely non-existent because the GE lines are not yet registered.

In October 2012, Kazakhstan banned the importation of GE-corn NK603, mirroring a temporary restriction imposed in September 2013 by Russia as a result of a published study by a French scientist questioning the safety of that type of GE-corn. The European Food Safety Authority (EFSA) responded to this published study by stating that it was "of insufficient scientific quality to be considered as valid for risk assessment" and that "such shortcomings mean that EFSA is presently unable to regard the author's conclusions as scientifically sound." Russia removed the ban without any public acknowledgement and Kazakhstan has also not made public if the ban is removed.

a. Intellectual Property Rights (IPR): The Kazakh Law "On Selection Achievements Copyright" allows for patents for plant and crop improvements.

b. Cartagena Protocol Ratification: Kazakhstan ratified the Cartagena Protocol in 2008.

c. International Treaties/Fora: After nineteen years, Kazakhstan's negotiations on accession to the World Trade Organization (WTO) have concluded at a final Working Party Meeting on June 22.2015. The Working Party will now forward the Accession Package to the General Council for formal adoption by all 161 WTO members. It is expected, that Kazakhstan will be complete WTO membership by the end of 2015.

d. Related Issues: The Ministry of Agriculture has welcomed training and discussions on Agricultural Biotechnology Legislation. However, the development of GE products is not a priority of the Ministry. Some producers, farmer groups, and Ministry officials advocate that Kazakhstan could have a competitive advantage in producing and marketing "ecologically clean" agricultural products for exports, and as a result the country should not develop domestic GE crops.

e. Monitoring and Testing: In 2012, the Ministry of Health reported conducting a series of tests on imported and domestically-produced products for the presence of GMOs. The Ministry of Health reported that 1,939 food samples were studied from 27 countries, including 41 percent of samples from domestic production. Of these tests, six samples tested positive for the presence of GE products. Two samples, of sweet corn from Russia and Hungary, contained a GE presence above 0.9 percent and thus, according to Kazakh regulations, should have been labeled. In four other samples, (sweet corn from Russia, a corn dessert from China, a cake product from Iran, and a sausage product from Russia), detections of GE presence were found within permissible limits of 0.9 percent. No other GE testing has been reported since that time.

f. Low Level Presence Policy: According to Customs Union Regulations, up to 0.9 percent of unapproved GE events are allowed.

Part C: Marketing:

a. Market Acceptance: In Kazakhstan, the general public is apprehensive about purchasing GE

products. However, there seems to be an understanding that due to global trade, it is difficult to be completely isolated from these products. There is some marketing of products as non-GE (especially for items like baby-food) but for the most part, non-GE labeling is not an important marketing strategy.

b. Public/Private Opinion: There is limited active campaigning for or against GE products or production. Since Kazakhstan production of crops for which GE varieties exist is very minor, this issue is not of great importance to farmers groups, the Grain Union, or the Ministry of Agriculture in general.

c. Marketing Studies: No known marketing studies exist on the acceptance of GE plants or products in Kazakhstan.

Part D: Capacity Building:

a. Activities: The United States Department of Agriculture, (USDA) has helped to recruit candidates for two International Visitor Leadership Programs in the United States on Agricultural Biotechnology. The first took place in 2009, and the second took place in 2013.

In November 2012, FAS helped organize a workshop in Astana with Ministry of Agriculture officials on agricultural biotechnology legislation.

Strategies and Needs: Misinformation on GE products is widespread in Kazakhstan. Providing scientific information on the safety of GE products, and the increasing use of GE products throughout the world would better inform the general public.

Chapter 2: Animal Biotechnology

Cloning is an animal biotechnology that developers frequently utilize in conjunction with other animal biotechnologies such as genetic engineering and therefore included in this report.

Part E: Production and Trade

a. Biotechnology Product Development: There are no GE animals or livestock cloning known to be under development in Kazakhstan.
b. Commercial Production: Although the Government has made increased cattle production the top agricultural priority (including turning Kazakhstan into a beef exporter), this strategy includes importing pedigree breeding animals, semen and embryos but does not include any research on GE animals or clones.
c. Biotechnology Exports: Kazakhstan does not export any GE animals or livestock clones.

d. Biotechnology Imports: Kazakhstan does not import any GE animals or livestock clones and there are no restrictions in place.

Part F: Policy

a. Animal biotechnology would be governed by the draft law "On State Regulation of Genetic Engineering Activities", which remains in draft before the Kazakh parliament. The approval process and governing bodies responsible for regulating animal biotechnology are expected to be the same as proposed in the draft law, as it does not differentiate between plant and animal biotechnology. In the draft law it classifies GE as "products of plant and (or) animal and (or) microbial origin, produced using genetic engineering techniques." As a result, when the draft law refers to the process for registering, regulations, and approvals of GMOs, this is understood to include both plant and animals.
b. Labeling and Traceability: Not applicable
c. Trade Barriers: Although Kazakhstan imports U.S. livestock, including U.S. cattle, in substantial quantities, there have never been any GE-related trade barriers.
d. Intellectual Property Rights: Not applicable
e. International Treaties/Fora: Not applicable

Part G: Marketing

a. Market Acceptance: Not applicable
b. Public/Private Opinions: Not applicable
c. Market Studies: There are no known market studies on the marketing of GE animals in Kazakhstan.

Part H: Capacity Building

a. Activities: In March 2014 USDA organized training under Cochran Fellowship program for Kazakhstani group on Livestock Genetics, which included lecture on cloning and genetic illnesses treatment.

Strategies and Needs: Not applicable

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Appendix 1 – Decisions of the Customs Union Regarding Biotechnology

Since July 2010, the Customs Union adopted several technical regulations that will influence agricultural and food biotechnology. These technical regulations come to force on July 1, 2013, and require marking the presence of GE, and informing consumers in cases when food products are processed from or with the use of GE even if there are no DNA's or proteins of GE components in the marketed food products:

1. CU Technical Regulation (TR) No 021/2011 on Safety of Food Products (adopted in December 2011, comes to force on July 1, 2013). The definition of GMO in this TR is "genetically modified (genetically engineered, transgenic) organisms (hereinafter - GMO) – an organism or several organisms, any noncellular, unicellular or multicellular formations able for reproduction or transfer of genetic material differing from natural organisms obtained with the use of genetic engineering methods and (or) containing genetically engineered material including genes, their fragments or gene combinations". In the chapter about the General Food Safety Requirements (Chapter 2) the TR states the following: (paragraph 9): "During production (manufacturing) of food products from food raw materials obtained from GMO of plant, animal, and microbial origin, GMO lines that underwent state registration shall be used. If the manufacturer did not use GMO during production of food products, presence in food products of 0.9 percent or less of GMO is considered an adventitious or technically intractable impurity, and such products do not belong to food products containing GMO". In the safety requirements for Specialized Food Products (Article 8) paragraph 1 states the following: "During production (manufacturing) of food products for baby food, food products for pregnant and nursing women, use of food raw materials containing GMO is not allowed". The GOST R 52173-2003 (Food Raw Material and Food Products. Methods for detection of genetically modified organisms (GMO) of plant origin" and GOST R 52174-2003 "Biological Safety. Raw materials and food products. Methods for detection of genetically modified organisms (GMO) of plant origin by using biological microchips" shall be used. MUK (methodological guidelines) 4.2.2304-007 "On surveillance over circulation of food containing GMO". This TR 021/2011 stipulates that food products can be processed only from GMO/GMM registered in the CU. If the producer did not use GMO at processing of food products, the presence of 0.9 percent and less of GMO is considered an adventitious, unavoidable presence, and products is not GE. The TR also bans use of GMO in baby food and in food for pregnant and nursing women;

2. CU TR No 022/2011 on Food Labeling (adopted in December 2011 and comes to force on July 1, 2013). This TR requires that food products with GMO shall be labeled, and determines the format of this labeling. Presence of 0.9 percent and less GMO shall not be labeled, and the product is not considered GM products. Labeling of food products as non-GMO is voluntary and absence of GMO shall be proved and documented. In Article 4, paragraph 4.1 "Requirements for labeling of packaged food products": 10) Information on the presence of food product ingredients obtained with the use of genetically modified organisms (hereinafter referred to as GMO). In paragraph 4.4 "General Requirements for Indication of Ingredients in Food Products Labeling": 2. If the food product contains a compound ingredient (with two or more components), all the components which are part of such compound ingredient shall be listed, according to the requirements of Clause 1 of Part 4.4 of this Article, or the name of the compound ingredient shall be indicated with addition of components thereof, in brackets, depending on the mass fraction thereof, highest to lowest. If the mass fraction of the compound ingredient equals 2% or less, it is allowed not to specify the components thereof, except in cases of food additives, flavoring agents and food additives which are part thereof, biologically active substances and medical plants, ingredients derived using GMOs and ingredients specified in Clause 14 of Part 4.4 of this Article. In paragraph 4.10. General Requirements for Specification of Information on

Specific Characteristics of Food Products in Food Products Labeling: 2. The information on specific characteristics of food products, including that on the absence of components obtained from GMO (or) with the use of GMO, shall be confirmed by proofs, submitted by a person, making this statement in the food product labeling independently or received by this person with participation of other persons. Organizations or individual entrepreneurs releasing such food products in circulation in the unified customs area of the Customs Union shall keep the proofs of presence of specific characteristics of food products; the latter shall be presented in the cases stipulated in the legislation of the Customs Union. There is a special paragraph 4.11. "Requirements for Specification of Information on Presence of Ingredients Obtained with the Use of Genetically Modified Organisms in Food Products in Food Products Labeling":

1. For food products obtained with the help of GMO, including those not containing deoxyribonucleic acid (DNA) and proteins, the following information shall be specified: "Genetically modified products" or "Products obtained from genetically modified organisms", or "The product contains components of genetically modified organisms".

If the manufacturer did not use genetically modified organisms in the process of manufacturing food products, the content of GMO of 0.9% or less is an accidental or technically irremovable impurity, and such food products shall not be referred to as food products containing GMO. When labeling such food products, the fact of the GMO presence shall not be stated.

2. The indication of the following information is obligatory for food products obtained from genetically modified microorganisms or with the use thereof (bacteria, yeast and filamentous fungi, the genetic material of which was modified with the help of genetic engineering methods) (hereinafter referred to as the genetically modified material, GMM):

- For products containing living GMM - "The product contains living genetically modified microorganisms"
- For products containing unviable GMM - "The product was obtained with the help of genetically modified microorganisms";
- For products freed from engineered GMM or for products produced with the help of components freed from engineered GMM - "The product contains components obtained with the help of genetically modified microorganisms".

3. Labeling of food products shall not contain information on GMO presence with respect to the used processing aids, produced from or with the help of GMO.

3. CU TR No 015/2011 on the Safety of Grain (adopted in December 2011, comes to force on July 1, 2013). The TR determines requirements to information on grain /oilseeds during transportation either in bulk of in consumer packs (for feed purposes). In Article 4 (Safety Requirements, paragraph 16 stipulates that grain transported unpacked should be accompanied by shipping documents that ensure its traceability and provide information on GMO if presence of GMO is higher than 0.9 percent. …For the grain obtained with the use of GMOs the information should be given: "Genetically modified grain" or "grain obtained from the use of genetically modified organisms" or "grain contains components of genetically modified organisms", indicating the unique identifier of the transformation event. Besides, in the sanitary requirements for grain/oilseeds (MRLs of toxic elements, micotoxins, pesticides, radionuclide and pests) the TR stipulates that grain/oilseeds (both for food and for feed use) may contain only registered GMO lines (registered in accordance with the legislation of the states, members of the CU), and in the GM grain presence of non-registered lines shall not exceed 0.9 percent "Grain may contain only those GMO lines that are registered in accordance with the legislation of states – members of the Customs Union. In grain that contains GMO presence of not more than 0.9 percent of

non registered GMO lines is allowed". The same GOSTs as in TR 021/2011 shall be applied (GOST R 52173-2003 and GOST R 52174-2003)

Appendix 2 – Non-Official Translation of Draft Law of the Republic of Kazakhstan "On state regulation of genetic engineering activity."

This Law regulates public relations arising from the creation, testing, use in closed systems and (or) open systems, release into the environment, transboundary movement, disposal and destruction of living modified organisms and genetically modified objects.

Chapter 1. General Provisions

Article 1. Basic concepts used in this Act

In this Act, the following definitions:

1) The accident - the incident giving rise to an unintended release into the environment of living modified organisms, their use in closed systems, which has or may have adverse effects on human health and the environment;

2) an open system - a system which assumes the contact of living modified organisms and genetically modified objects to the public and the environment in their deliberate release into the environment;

3) genetic engineering - a combination of methods and technologies to produce new combinations of genetic material outside the cell through the ongoing manipulation of the nucleic acid molecules and structures created by the transfer of genes in a living organism, which resulted in the inclusion is achieved and their activity in this organism and its progeny;

4) gene therapy - a set of genetic engineering and medical techniques aimed at making changes in the genetic apparatus of human somatic cells to treat disease;

5) gene diagnostics - a set of methods for detection of changes in genome structure;

6) genetic engineering activities - with the creation, testing of living modified organisms and genetically modified objects, using them in the closed and (or) open systems, the release into the environment, transboundary movement, transit, import, export;

7) The risks of genetic engineering (hereinafter - the risk) - the probability of the adverse effects of living modified organisms and genetically modified facilities on human health and the consequences of this effect, leading to the emergence of risks to life and human health and the environment;

8) the safety of genetic engineering - state of security of people, animals, plants and the environment, based on a system of measures aimed at preventing the possibility of adverse effects and ensure the effective use of advances in genetic engineering;

9) genetically modified objects (hereinafter - GMOs) - products of plant and (or) animal and (or) microbial origin, produced using genetic engineering techniques;

10) the authorized body in the field of genetic engineering - the state body implementing the state policy and leadership in the field of genetic engineering;

11) the subject of genetic engineering (hereinafter - the subject) - entity that carries out activities related to building, testing of living modified organisms and genetically modified objects, their use in closed and (or) open systems, the release into the environment, trans- movement, transit, import and export and is responsible for such activities;

12) genome - a set of genes of an organism;

13) identification data - data that provide an unambiguous recognition of certain living modified organisms and genetically modified objects to the distinctive features;

14) Risk assessment - evaluation of direct and indirect effects on ¬ use of living modified organisms and (or) genetically modified facilities;

15) release into the environment - intentional or unintentional introduction into the environment of living modified organisms and genetically modified facilities;

16) State Register - the accounting system of living modified organisms and genetically modified

objects that have passed a risk assessment on the impact on human health and the environment, the definition of household goods and measures to support the biosafety regime;
17) pathogens - microorganisms that can cause diseases of plants, animals and humans;
18) non-pathogenic micro-organisms - organisms that are unable to cause disease on plants, animals and humans;
19) the transboundary movement of living modified organisms and genetically modified objects - any movement of living modified organisms and genetically modified objects from the territory of one state into another of ¬ States;
20) living modified organisms (hereinafter - the LMOs) - any living organisms / microorganisms possessing a novel combination of genetic material obtained through the use of genetic engineering techniques, capable of reproduction or transmission of the hereditary genetic material;
21) use in closed systems - any operation (in which LMOs / GMOs are cultured, propagated, stored, transported, destroyed, neutralized, or otherwise used), carried out in closed systems;
22) a closed system - the system is equipped with the necessary special equipment and devices that prevent contact of LMOs / GMOs to the environment and their impact on the implementation of genetic engineering;
23), conditional pathogens - microorganisms that can cause diseases of plants, animals and humans under certain conditions.

Article 2. Legislation of the Republic of Kazakhstan on genetically engineering

Legislation of the Republic of Kazakhstan on genetic engineering is based on the Constitution of the Republic of Kazakhstan and consists of this Law and other regulations of the Republic of Kazakhstan. If an international treaty ratified by the Republic of Kazakhstan stipulates other rules than those stipulated in this Law, the rules of international treaty.

Article 3. Objectives, principles and objectives of state regulation of genetic engineering
1. The objectives of state regulation of genetic engineering include:
1) protection of public health in the implementation of genetic engineering;
2) protection and restoration of the environment by using LMOs / GMOs;
3) the development of genetic engineering;
4) The security of the country in carrying out genetic engineering work.

2. Principles of state regulation of genetic engineering are:
1) prioritize the safety of genetic engineering for human life and health and the environment;
2) prevent the possible harmful effects on human health and the environment;
3) The scientific basis of risk assessment;
4) transparency, accessibility, reliability of information about genetic engineering;
5) transparency of activities undertaken by government in the field of genetic engineering.

3. The main tasks of state regulation of genetic engineering are:
1) The establishment of state control over the circulation of LMOs / GMOs;
2) conservation of biological diversity at genetic engineering;
3) creating an enabling environment for the advancement of the priorities of genetic engineering;
4) establishing a system of risk assessment.

Article 4. The scope of the legislation of the Republic of Kazakhstan

genetic engineering

The provisions of this Law shall apply to the following types of genetic engineering:
1) to establish and (or) testing of LMOs / GMOs;
2) the use of LMOs / GMOs in closed systems;
3) release into the environment, the use of LMOs / GMOs in open systems;
4) The transboundary movement, transit, import and export of LMOs / GMOs.

Article 5. Confidential information

Confidential information provided by the genetic engineering of the authorized bodies in the field of genetic engineering, and health cannot be disclosed to officials, and may not be transferred to third parties, except as provided by laws of the Republic of Kazakhstan.
Confidential information is not recognized by the information need for which is provided by the laws of the Republic of Kazakhstan.

Chapter 2. Basics of genetic engineering

Article 6. Forms of regulation of genetic engineering

State regulation of genetic engineering is carried out through:
1) Risk assessment
2) the introduction of public registers of LMOs / GMOs;
3) licensure types of genetic engineering;
4) the state control over genetic engineering activities.

Article 7. Competence of the Government of the Republic of Kazakhstan

The Government of the Republic of Kazakhstan:
1) develop the main directions of state policy in the field of genetic engineering;
2) directs the activities of authorized agencies on genetic engineering;
3) approve the technical regulations in the field of genetic engineering;
4) approve the rules for issuance of authorization to engage in types of genetic engineering;
5) approve the qualifications for the subjects;
6) carry out international cooperation in the field of genetic engineering;
7) exercise other powers stipulated by the Constitution and laws of the Republic of Kazakhstan and the acts of the President of the Republic of Kazakhstan.

Article 8. The competence of the authorized body in the field of genetic engineering

The authorized body in the field of genetic engineering:
1) implements the state policy in the field of genetic engineering activities within its jurisdiction;
2) develop, approve, within its competence the normative legal acts in the field of genetic engineering;
3) coordinating the activities of the Coordinating Center;
4) ensure implementation within their competence, risk assessment was first produced in the country and first imported to the country of LMOs;
5) carries out the state registration and re-LMO;
6) maintains the state registry of LMOs;
7) approve the form of registration certificate of the LMO;
8) grants permission to engage in types of genetic engineering;
9) exercise state control over the genetic engineering activity;

10) prepare technical regulations in the field of genetic engineering;
11) develop and submit for approval to the Government of the Republic of Kazakhstan to the subjects of the qualification requirements;
12) carries out international cooperation in the field of genetic engineering;
13) perform other functions stipulated in this Law, other laws, acts of the President of the Republic of Kazakhstan and the Government of the Republic of Kazakhstan.

Article 9. Competence other authorized bodies
1. The authorized body in health care:
1) implements the state policy in the field of genetic engineering activities within its jurisdiction;
2) develop, approve, within its competence the normative legal acts in the field of genetic engineering;
3) provide for implementation within its competence, risk assessment was first produced in the country and first imported into the territory of GMOs;
4) conduct public register of GMOs;
5) carries out the state registration and re-GMO;
6) approve the form of registration certificate of GMOs;
7) perform other functions stipulated in this Law, other laws, acts of the President of the Republic of Kazakhstan and the Government of the Republic of Kazakhstan.
2. The authorized body in the field of agro-industrial complex:
1) implements the state policy in the field of genetic engineering activities within its jurisdiction;
2) develop, approve, within its competence the normative legal acts in the field of genetic engineering;
3) provides an assessment of risks within their competence;
4) perform other functions stipulated in this Law, other laws, acts of the President of the Republic of Kazakhstan and the Government of the Republic of Kazakhstan.
3. The authorized body in the field of environmental protection:
1) implements the state policy in the field of genetic engineering activities within its jurisdiction;
2) develop, approve, within its competence the normative legal acts in the field of genetic engineering;
3) perform other functions stipulated in this Law, other laws, acts of the President of the Republic of Kazakhstan and the Government of the Republic of Kazakhstan.

Article 10. Coordination Center
1. Coordination Center - an organization created by the authorized body in the field of genetic engineering.
2. Coordinating Center performs a risk assessment expert opinion which is advisory in nature.
3. Risk assessment carried out by the Coordination Centre, made by the applicant, who is the initiator of the event.

Article 11. Levels of risk
1. Depending on the degree of potential risk to human health and the environment arising from the implementation of the activities regulated by this Law, establishes the following risk levels:
Level I - corresponds to the activity poses no danger to human health and is comparable to the risk when working with non-pathogenic microorganisms;
Level II - corresponds to a low risk activity, comparable to the risk of opportunistic organisms;
Level III - corresponds to the activity with a moderate risk, comparable to the risk of pathogens that could potentially transmit infection, for which known effective treatment and control;

Level IV - corresponds to the activity with an increased risk, comparable to the risk of pathogenic micro-organisms able to disseminate the particularly dangerous infections, and crop pests, weeds and parasitic plants, for which known effective treatment and control.
2. Activities carried out by micro-organisms contained in the volumes that go beyond the laboratory, refer to III and IV levels of risk.

Chapter 3. The procedure for issuing permits to engage in types of genetically engineering

Article 12. General rules for granting authorization to engage in types of genetic engineering

1. The authorized body in the field of genetic engineering issues permits to engage in these kinds of genetic engineering:
1) to establish and (or) testing of LMOs / GMOs;
2) the use of LMOs / GMOs in closed systems;
3) release into the environment, the use of LMOs / GMOs in open systems.
2. The types of activities covered by this Act, allowed the applicants meet the qualifications established by the Government of the Republic of Kazakhstan.
3. For permission to engage in types of genetic engineering applicant submits an application, a sample of LMOs / GMOs and the documents specified in Article 14 of this Law, the authorized body in the field of genetic engineering.
4. To obtain an expert opinion authorized body in the field of genetic engineering activity shall send the documents and samples of LMOs / GMOs, the applicant in the Coordinating Center.
5. Based on the submitted documents and a sample of LMOs / GMOs Coordination Center conducts a risk assessment.
6. Taking into account expert advice of the Coordination Centre, the authority in the field of genetic engineering takes a positive or negative decision on a permit to engage in types of genetic engineering.
7. After receiving authorization to engage in types of genetic engineering, the subject is the authorized body in the field of genetic engineering reports on the results of genetic engineering with an indication of any identified risk to human health and the environment. Deadline for submission of reports specified in a permit, the frequency of which ranges from 6 months to 3 years depending on the type carried out by genetic engineering.

Article 13. The decision to refuse a permit for the genetic engineering activity

Authority's decision in the field of genetic engineering to refuse to grant authorization to engage in types of genetic engineering made in the case:
1) The applicant providing an incomplete and (or) inadequate information;
2) use of substances and materials which are not approved for use in the Republic of Kazakhstan;
3) failure of the applicant to conduct additional tests that may be required to determine the safety of LMOs / GMOs;
4) unsatisfactory results of tests that characterize the safety of LMOs / GMOs.

Article 14. Documents submitted by the applicant to engage genetic engineering activity

1. For permission to engage genetic engineering activity, the applicant provides the following

documents:
1) to engage in activities related to the creation and (or) testing of LMOs / GMOs:
statement indicating the names, addresses and contact information of the applicant;
certificate indicating the purpose and place of incorporation, and (or) testing of LMOs / GMOs;
certificate indicating the level of risk to which the work on the creation and (or) testing of LMOs / GMOs;
help with the strategy and monitoring plan, as well as measures that can be taken in case of accident;
preliminary conclusion that results from the study of risk assessment for human health and the environment held by the applicant;
confirming the applicant meets the established qualification requirements;
2) to engage in activities associated with the use of LMOs / GMOs in closed systems:
statement indicating the names, addresses and contact information of the applicant;
certificate indicating the target location and use of LMOs / GMOs in closed systems;
certificate indicating the level of risk to which the work on the use of LMOs / GMOs in closed systems;
certificate indicating the methods used in monitoring safety of LMOs / GMOs;
help with the strategy and monitoring plan, as well as measures that can be taken in case of accident;
certificate indicating the information received by the applicant in the State and (or) outside it, the results of use of an identical LMOs / GMOs in closed systems;
confirming the applicant meets the established qualification requirements;
Finally, the resulting study assessing risks to human health and the environment held by the applicant;
3) to engage in activities related to the release into the environment, the use of LMOs / GMOs in open systems:
statement indicating the names, addresses and contact information of the applicant;
certificate indicating the purpose and place of their release into the environment, use of LMOs / GMOs in open systems;
certificate indicating the identity of the LMO / GMO;
certificate indicating the amount or volume of LMOs / GMOs introduced into the environment;
certificate indicating the description of gene modification, the method and the resulting characteristics of the LMO / GMO;
certificate indicating the level of risk to which the activity on release in the environment, the use of LMOs / GMOs in open systems;
certificate indicating the method used in monitoring safety of LMOs / GMOs;
certificate indicating the information received by the applicant in the State and (or) outside it, the results of an identical release of LMOs / GMOs into the environment;
certificate indicating the proposed method for the safe handling, storage, transport and use, including packaging, labeling;
help with the strategy and monitoring plan, as well as measures that can be taken in case of accident;
confirming the applicant meets the established qualification requirements;
Finally, the resulting study assessing risks to human health and the environment held by the applicant.
2. The documents referred to in subparagraphs 2) and 3) of paragraph 1 of this Article, the applicant shall submit a sample of LMOs / GMOs to risk assessment.
3. Documents on the types of work in genetic engineering activities referred to in paragraph 1 of this Article shall be submitted under the signature of the head of the applicant.
4. After receiving authorization to engage in activites related to the creation and (or) test of LMOs/GMOs, the subject ctonract for mandatory environmental insurance in accordance with the laws of the Republic of Kazakhstan about environmental insurance.

Article 15. Terms of the authorized body in the field of genetic engineering to issue permit on genetic engineering activity
1. The authorized body in the field of genetic engineering makes decisions about issuing permits to engage in types of genetic engineering for the following periods from the filing of documents by the applicant:
1) to establish and (or) testing of LMOs / GMOs - 120 calendar days;
2) the use of LMOs / GMOs in closed systems - 90 calendar days;
3) release into the environment, the use of LMOs / GMOs in open systems - 130 days.
2. While providing no complete set of documents referred to in Article 14 of this Act to obtain authorization to engage in types of genetic engineering activities, the authority in the field of genetic engineering, in writing, notify the applicant of that fact, then the applicant must submit the missing documents within 45 calendar days. The period of the applicant to provide the information requested is not included within the period specified in paragraph 1 of this article.
Chapter 4. State control over the genetic engineering activity, general requirements for the implementation of genetic engineering and the requirements for the activities carried out during an accident

Article 16. State control over the genetic engineering activity
1. State control over the genetic engineering work is carried out in order to detect violations of the laws of the Republic of Kazakhstan on genetic engineering on the basis of reporting entities in accordance with the Law of the Republic of Kazakhstan "On private entrepreneurship." State control over the genetic engineering activity shall be subject to genetic engineering activities to develop and (or) testing of LMOs / GMOs, the use of LMOs / GMOs in contained use, release into the environment, the use of LMOs / GMOs in open systems, transboundary movement, transit, import and export of LMOs / GMOs.
2. If, after issuing a permit to engage in types of genetic engineering activities authorized body in the field of genetic engineering and (or) Coordination Center will find the facts that the genetic engineering work on the creation and (or) testing of LMOs / GMOs, the use of LMOs / GMOs in closed systems, release into the environment, the use of LMOs / GMOs in open systems will have adverse effects on human health and (or) the environment, the subject is obliged to change the terms of genetic engineering.

Article 17. General requirements for the implementation of genetic engineering
1. Requirements for LMOs / GMOs and the processes of their life cycle (including design, manufacturing, maintenance, storage, transportation, disposal and recycling) shall be established by technical regulations.
2. Transit of LMOs through the territory of Kazakhstan is carried out in accordance with the laws of the Republic of Kazakhstan and international law.
Article 18. Requirements to emergency respond activities
1. In case of emergency managers shall, within twelve hours to inform the authorized body in the field of genetic engineering and to provide it:
1) information about the circumstances of the accident;
2) information about the type and quantity used of LMOs;
3) information on measures taken, as well as any information necessary to evaluate the effects of the accident on human health and the environment.

2. In case of emergency authorized body in the field of genetic engineering:
1) in one day inform the public of the media, assessing and specifying the extent arising threats to human health and the environment;
2) produces a more complete assessment of the accident and, if necessary, make recommendations to prevent similar accidents in the future, as well as the exclusion of the possible consequences of such accidents;
3) ensure that the necessary measures to address the causes and consequences of the accident.
Article 19. Restrictions on genetic engineering
In the Republic of Kazakhstan shall be prohibited:
1) The manufacture, production, circulation, import and export special-purpose products, baby food and food ingredients intended for the production of baby food containing LMOs / GMOs;
2) human cloning;
3) the implementation of genetic engineering without the permission of an authorized body in the field of genetic engineering activities to engage in such activities;
4) the transit and import of LMOs / GMOs are not registered in public registries of LMOs / GMOs.

Chapter 5. The state registration, re-registration and review decision on state registration of LMOs / GMOs

Article 20. The state registration of LMOs / GMOs
1. The state registration of LMOs / GMOs include:
1) examination scientific evidence provided by the applicant as proof of safety of LMOs / GMOs;
2) risk assessment of LMOs / GMOs;
3) introduction of LMOs / GMOs in the State Register of LMOs / GMOs approved for use in the Republic of Kazakhstan and the issuance of the Certificate of Incorporation.
2. Risk assessment at the state registration of LMOs / GMOs by the Coordinating Centre.
3. For the state registration of LMOs / GMOs applicant shall submit to the authority in the field of genetic engineering and to the authority in the field of health, respectively, the following documents:
1) a statement indicating the names, addresses and contact information of the subject;
2) evidence that LMOs / GMOs are approved for their intended use in the exporting country, with a description of the scope, identity of LMOs / GMOs as such or in the products and its unique identifier (if any);
3) The list of countries where the LMO / GMO registered or authorized for use, including the period of such registration, the permissible scope of LMOs / GMOs and special conditions that must be done in such countries for the implementation of the LMO / GMO (if any);
4) results of risk assessment conducted by the applicant, including information necessary to evaluate the safety of LMOs / GMOs:
description of the recombinant DNA of the organism;
description of the organism (s) of the donor (s);
description of the genetic modification (s) including vector and construct;
characterization of the genetic modification (s);
methods of monitoring the safety of LMOs / GMOs;
the results of scientific risk assessment and medico-biological examination conducted by the manufacturer of LMOs / GMOs, including laboratory studies and clinical tests and evaluation of security:

compositional analysis of key components;
evaluation of metabolites;
changes in nutritional quality;
methods of detection, sampling and identification of transformation events (including references to existing official and standardized sampling methods);
5) in addition to LMOs / GMOs, which are derived from recombinant DNA microorganisms (bacteria, yeast and filamentous fungi), safety assessment:
potential toxicity and other characteristics associated with known pathogens isolated substances;
immunological allergic or similar actions;
survival and growth of microorganisms in the gastrointestinal tract of man;
resistance to antibiotics and the ability to transfer genes.
4. For risk assessment the applicant must submit a sample of LMOs / GMOs.
5. To the original document of the importing country must be accompanied by a notarized translation into Kazakh or Russian languages. Documents submitted for state registration (re), the applicant will not be returned.
6. Risk assessment authorized body in the field of genetic engineering and the authorized body in health care, respectively, sent the documents referred to in paragraph 3 of this Article in the Coordination Center.
7. The authorized body in the field of genetic engineering and the authorized body in health care make decisions about state registration of LMOs / GMOs, respectively, within 180 calendar days from the date of application by the applicant.
8. While providing no complete set of documents referred to in paragraph 3 of this article, for registration of LMOs / GMOs, the authority in the field of genetic engineering and the authorized body in health care, respectively, in writing, notify the applicant of this fact, then the applicant must submit missing documents within 45 calendar days. The period of the applicant to provide the information requested is not included within the period specified in paragraph 7 of this article.
9. Name and description of registered LMOs / GMOs placed on the official websites of the authorized body in the field of genetic engineering and the authorized body in the field of health, respectively.
10. Validity of registration certificate is 10 years.
11. With the refusal of state registration of LMOs / GMOs, the authority in the field of genetic engineering and the authorized body in health care, respectively, within 10 working days, in writing, notify the applicant of the refusal of state registration of LMOs / GMOs and shall justify this decision .
12. The decisions of the authorized body in the field of genetic engineering and the authorized body in health care, respectively, on the refusal of state registration of LMOs / GMOs are taken in the cases provided for in Article 13 of this Law.
Article 21. State re-registration of LMOs / GMOs
1. State re-registration LMOs / GMOs conducted in the following cases:
1) the expiration of the previously issued registration certificate;
2) changing the name, composition, and combinations of DNA or RNA;
3) change the brand of the manufacturer, place of production or manufacturing company of LMOs / GMOs.
2. Application for state re-registration of LMOs / GMOs in the cases referred to in paragraph 1 of this Article shall be filed subject to the authority in the field of genetic engineering and to the authority in the field of health, respectively.
Application for state re-registration of LMOs / GMOs fed for 60 days before the onset of the cases referred to in paragraph 1 of this article.

3. For state re-registration LMOs / GMOs, the applicant provides to the authority in the field of genetic engineering and to the authority in the field of health, respectively, the following documents:
1) a statement indicating the names, addresses and contact information of the subject;
2) a copy of the original registration certificate;
3) a report on the results of genetic engineering, if so specified in the permit;
4) any other available information for evaluating the safety of food products and the risk of food products for the consumer or the environment;
5) if necessary, a proposal to amend or supplement the original permit conditions, in particular, the conditions for monitoring.
4. The authorized body in the field of genetic engineering and the authorized body in health re-direct the application of LMOs / GMOs and related documents to the Coordinating Center. Coordination Center checks the completeness and accuracy of the information and within 35 working days shall issue an expert opinion, based on which an authorized body in the field of genetic engineering and the authorized body in health care, respectively, takes a positive or negative decision on state re-registration of LMOs / GMOs.
5. The authorized body in the field of genetic engineering and the authorized body in health care make decisions about the state re-registration of LMOs / GMOs within 60 calendar days from the date of application by the subject.

Article 22. Recalling Registration Certificate of LMOs / GMOs
1. Registration certificate of LMOs / GMOs is subject to revocation if the authorized body in the field of genetic engineering and (or) the authorized body in health care after the registration of LMOs / GMOs, respectively, in the use of LMOs / GMOs detect (at) adverse effects on human health and environment.
2. Decision to revoke the registration certificate of LMOs / GMOs adopted by the authorized body in the field of genetic engineering and the authorized body in health and may be appealed in the manner prescribed by the laws of the Republic of Kazakhstan.
3. After the expiration of the registration certificate of LMOs / GMOs, the use of LMOs / GMOs imported during the period of the document to the Republic of Kazakhstan, will be permitted before the expiry date of LMOs / GMOs.

Chapter 6. Import and export of LMOs / GMOs

Article 23. Import of LMOs / GMOs
1. Activities on the import of LMOs / GMOs must meet the following conditions:
1) prevention of illegal traffic, unintentional transboundary movements and ensuring that adequate measures in case of emergencies;
2) provide for the exchange of information;
3) protection of confidential information and intellectual property rights;
4) compliance with the requirements for packaging, labeling, transport and use.
2. The importer must ensure that the documents attached to the LMO / GMO requirements of the laws of the Republic of Kazakhstan and international law regarding transboundary movement of LMOs / GMOs.
3. In cases of illegal transportation of LMOs / GMOs authorized body in the field of genetic engineering activity shall request from the subject of their repatriation (re) or destruction at its own expense, in accordance with international law.

4. Go to the import of LMOs are allowed / GMO, registered in public registries of LMOs / GMOs.
5. Import batches of seeds of varieties derived from genetic engineering is allowed by agreement with the competent authority in the field of agriculture.

Article 24. Export of LMOs / GMOs
1. To export LMOs are allowed / GMO registered in public registries.
2. Quantitative and qualitative characteristics of the LMO / GMO documents and conditions for export must comply with the regulations applicable in the exporting country.

Chapter 7. Final Provisions

Article 25. Responsibility for violation of the law
Republic of Kazakhstan on genetic engineering
Violations of legislation of the Republic of Kazakhstan on genetic engineering activities shall entail liability established by the laws of the Republic of Kazakhstan.

Article 26. The order of entry into force of this Act
This Law shall come into force at the expiration of ten calendar days from the date of its first publication.

President of the Republic of Kazakhstan
End non-official translation