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### **Legal regulation of GMO introduction: problems and ways of their solution**

This article is devoted to the problems of legal regulation of GMOs introduction. The study lies in comprehensive research of modern ecological and legal problems on the basis of analyzing international, foreign and national legislation in the field of legal regulation of GMOs and use of chemicals in agricultural production. In this regard, proposals to improve and fill gaps in the current legislation of the Republic of Kazakhstan are worked out.

**Key words:** GMO, legal regulation, modern ecological and legal problems.

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#### **ГТА айналымын құқықтық реттеу: проблемалар және шешу жолдары**

Нақты мақала гендік түрлендіріліген ағзалардың айналымын құқықтық реттеу мәселелеріне арналған. Зерттеу ГТА айналымы және ауылшаруашылығында химиялық заттарды пайдалануды құқықтық реттеу саласында халықаралық, шетелдік және ұлттық заңнамалардың негізінде заманауи экологиялық проблемаларды зерттеуге бағытталған.

**Түйін сөздер:** ГЕА, құқықтық реттеу, заманауи экологиялық проблемалар.

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#### **Правовое регулирование оборота ГМО: проблемы и пути решения**

Статья посвящена проблемам правового регулирования внедрения ГМО. Исследование заключается в комплексных исследованиях современных экологических и правовых проблем на основе анализа международного, иностранного и национального законодательства в области правового регулирования ГМО и использования химических веществ в сельскохозяйственной продукции. В связи с этим разрабатываются предложения по улучшению действующего законодательства Республики Казахстан.

**Ключевые слова:** ГМО, правовое регулирование, современные экологические и правовые проблемы.

#### **Introduction**

Today, worldwide environmental problem is considered one of the most important. This is because, according to scientists, irresponsible consumer's attitude to nature brought the world to the brink of ecological disaster. But the state of nature and its troubles are reflected on human organism. Sick children are born, human life expectancy is reduced. With development of scientific and technical progress negative impacts on environment also

increase: air, waters and lands are polluted, woods and animals die. Opening of the genetically modified organisms (GMOs) will worsen the quality of human life even more. In this regard, the informing question about GMOs and consequences of their use is vital for as large number of people as possible.

#### **Literature Review**

The problems of legal support of safety of the food, made with use of genetically engineering

methods, and obligatory marking, responsibility for violation of the legislation in the field of genetically engineered activity, social and ethical problems of human cloning and his organs, environmental pollution by transgene plants and animals are researched in the works of L.K. Erkinbayeva, M.M. Brinchuk, O.L. Dubovik, N.G. Zhavoronkova, O.A. Krassovskiy, M.S. Pashova.

Certain questions of legal regulation of genetically engineered activities were researched in the thesis of O.A. Krassovskiy «Legal problems of genetic engineering».

### **Methodology**

Methodological basis of the research. Methodological basis of the research is the application of dialectical and system and functional approach to the analysis and assessment of legal regulation of GMO introduction and use of chemicals in agriculture. Following methods were used: general scientific, particular and special methods, including historical, systemic, structural, classification, comparative, analysis and formal and legal method and others. Normative basis of the work is: Environmental legislation of the Republic of Kazakhstan, legislation in the field of genetic engineering activity; international legal acts, directly or indirectly regulating the relationships in this field, as well as normative acts of the European Union in the sphere of production and turnover of genetically modified products.

### **Problems of legal regulation of handling with chemicals in agrarian production**

Fast development of biotechnologies and expansion of a circle of spheres, where they are used, leads to that the legislative base is not in time behind this progress. Those actions which our state launch such as coming into force in March accepts of the Criteria of Risk Assessment of Potential Influence of Genetically Modified Organisms on surrounding environment, though is a positive moment, but nevertheless, do not solve all the problems.

The term «genetically modified organism» is legislatively defined by the Directive of the EU 2001/18/EU dated December 16, 2002, dealing with intentional release of genetically modified organisms in the environment. According to the part 2 of the Art. 2 of the present Directive genetically modified organisms are any organisms, except a person in whom the genetic material

was changed, which is impossible under natural conditions in the course of pairing and/or natural recombination. The directive accurately defines that people are not considered to be organisms, and lists the technologies, use of which allows to receive genetically modified organisms. The biosafety to the Convention of biological variety the term «living modified organism» is used (LMO). In the Article 3 of the protocol to this Convention LMOs are defined as any living organisms, possessing a new combination of a genetic material, received thanks to modern biotechnology, and a «living organism» is any biological entity, capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.

It should be noted that today in Kazakhstan there is no single state body that would deal with the issues of GMOs. Respectively, in the Law on Biosafety the authorities to control and regulations are dispersed between five executive authorities: RK government, Ministry of Education and Science, Ministry of Environment and Water resources, Ministry of Health and Ministry of Agriculture. Besides the fact that there is no single body, it is worth noting a certain awkwardness, which is reflected in the fact that if GMOs are contained in the product, which can be both a source of food and feed, registration is required both in the Ministry of Health and Ministry of Agriculture. Consequently, the primary measure is the creation of a single body which focuses on GMOs.

It is well known that Kazakhstan uses genetic engineering to produce food and feed, otherwise, our country does not raise the issue of GMOs; however, on the other hand, we have registered no GMOs, which clearly shows that no effective mechanisms of registration and control of GMOs are created, resulting in the need to strengthen the state control over this field and increase the responsibility of the owners for the unauthorized use of a product.

The Article 15 of the Law of the Republic of Kazakhstan «On protection of consumers' rights» provides the consumers' right to receive full and reliable information about the product, including the content of GM components. However, it is difficult to put it into practice. First reason is that those laboratories which were created for researches accept the statement about production checks on GMO existence only from legal entities. Natural persons in given cases can address to the sanitary and epidemiologic station, which at the present stage is not equipped properly for carrying out such researches. And secondly, all the procedures of

GMO identification is rather expensive because of what not all citizens are able to afford this as it is possible to judge from the service price, «luxury» to exercise the right for information and the right on safe for life and health environment, which, by the way, are constitutional laws, so they have the highest validity, and also have to be state priorities; however, as we see, not everything is so iridescent as we wanted.

For a long time scientists have been discussing the project of Product List, the content of GMOs in which is permissible, but for different reasons, this document is not accepted; although, the introduction into force of it would help us to arrange the borders of GMO use.

Important change, which we offer, is reducing the term of permission of GMO production from 5 to 2 years with the quarterly report on the activity to the specialized body, establishment of which we have offered earlier. And to establish limit quantity of the products, containing GMO, which will be put on the market. It will be expedient to establish price differences between the products, containing GMO, and products, made without intervention of genetic engineering, as it is made in the majority of European countries.

Given above solutions of the problem of legal regulation will help to stabilize these relations and concretize them. They will promote not only reduction of confusing this rather dynamic sphere of the relationships, but also give a chance of public control that, certainly, can be important for a democratic state.

Agriculture is one of the spheres of active applying chemical and other dangerous substances, which, on the one hand, stimulate growth of agricultural production, and, on the other, excess of their use can lead to pollution of surrounding environments and make negative impact on human life and health.

«In the European community the first field in the ecological plan was the adoption of a number of measures to control the use of chemicals in agriculture. There are two main directions – limited use of pesticides with a list of banned ones, and measures to prevent water and soil nitrification. The latter was connected with already reached very high norms of nitrogen fertilizer application. Therefore, it was necessary mechanism to limit further increasing doses of fertilizers».

Currently, there are more than 250 of pesticides (insecticides) in the Republic of Kazakhstan. Annually the list of registered pesticides is

replenished with 15-20 new products, thus, expanding the list of pesticides (insecticides), which are produced (formulated) in the Republic.

Pesticides production refers to environmentally hazardous activities. RK EC gives the following definition of environmentally dangerous economic and other activity is the activity of physical and legal entities, which leads or may lead to emergency of environmental pollution. It should be understood as sudden unintended environmental pollution, caused by the accident that occurred in the implementation of environmentally dangerous types of economic and other activities by physical and legal persons, and which is the emission and (or) discharge of harmful substances into water or dispersal of solid, liquid or gaseous pollutants on the part of the earth surface, in the bowels or forming odors, noise, vibration, radiation, or electromagnetic, thermal, light or other physical, chemical, biological harmful effects of excess of permissible level for this time.

Any natural and legal entities, having the license agreement with firm-registrant of pesticide (toxic chemical) on the right of its production (formulation) and approved technical conditions, can freely be engaged in pesticides. There are no other restrictions for this kind of activity.

In the Republic of Kazakhstan from 8 to 10 thousand tons of pesticides (insecticides) of various phytosanitary purposes are annually imported and used, only 20-30% of which are specimen, purchased by the national budget.

Import of pesticides (toxic chemicals) to the territory of the Republic of Kazakhstan is carried out by about 20 major companies, which enables their realization through the network within regions. Along with them a huge number of individuals and legal entities, private entrepreneurs are engaged in realization of pesticides, total number of which cannot be counted because their activity does not require license registrations. Random people without skills, special education, adapted warehouse space, not enough understanding potential hazards of pesticides to human health and surrounding environment are often engaged in realization of pesticides.

The RK law dated July 3, 2002, No. 331-II «On protection of plants» gives the following definition of pesticides. These are chemical, biological and other substances, used against harmful and especially dangerous harmful organisms, and also for pre-harvesting drying, removal of leaves and regulation of growth of plants. Pesticides pass the state registration, following the registration results

and production tests in the order, established by authorized body, in coordination with bodies of state environmental and sanitary and epidemiologic control, after which it is allowed to apply them. Production (formulation), import, storage, transportation, realization and use of pesticides, which have not passed the state registration, and also initial components for production of unregistered pesticides (toxic chemicals) are forbidden, except the prototypes, imported for registration, production tests and scientific researches. The amount of pesticides (toxic chemicals), imported for registration, production tests and scientific researches, is defined by the authorized body (Art. 14 of the law). In addition, Art. 19-7 of the considered law regulates safety requirements at use of pesticides (toxic chemicals), in particular their use is carried out with observance of effective and safe application technologies, technical regulations. Leaving of unused pesticides (toxic chemicals) on a work place, except places specially intended for temporary storage, is forbidden.

In the Article 239 of RK EC foresees environmental requirements during transportation, storage and application of plant protection means, mineral fertilizers and other preparations, used in business and other activities, developing new products.

During transportation, storage and application of plant protection means, mineral fertilizers and other preparations, used in business and other activities, development of new products for physical and legal persons are obliged to observe the rules of transportation, storage and usage of these drugs and implement measures to ensure the prevention from disease and death. When creating new drugs regulations on their application in the environment should be developed.

It is allowed to apply pesticides (toxic chemicals), which are included in the list of pesticides (toxic chemicals), approved by authorized government body in the field of protection and quarantine of plants in coordination with authorized body in the field of environmental protection and government body in the field of sanitary and epidemiologic wellbeing of the population. It is forbidden to leave the pickled seeds in agricultural and other grounds on the surface, which have not been closed up in the soil and available to eating by wild animals.

Considering that pesticides (toxic chemicals) are potentially dangerous substances, which can make negative impact on human health and pollute environment, and their production (formulation) belongs to ecologically dangerous kinds of activity,

the Law of the Republic of Kazakhstan «On licensing» contains the provisions, which deals with licensing of activity on production (formulation) and realization of pesticides (toxic chemicals).

Introduction of the specified norm allowed to strengthen control over production (formulation) and realization of pesticides (toxic chemicals), which, in turn, will reduce risks of possible negative influence of preparations on human health and surrounding environment, and also will create an additional barrier to penetration of forbidden and other especially dangerous toxic preparations, including those, relating to resistant organic pollutants, on the Kazakhstan market.

EC RK contains general environmental requirements for production and use of potentially hazardous chemicals. It states that in the course of operations on production and use of potentially hazardous chemicals implementation of standards of maximum permissible impact on the environment during production, storage, transport and use; implementation of measures on prevention of harmful consequences of their application to human health and the environment should be ensured as well.

The study of the current legislation showed that the procedure and conditions of chemicals require detailed regulation, which contains only a fragmented list of requirements to certain types of activity with them.

In this regard, we would like to pay attention that in March, 2007, Kazakhstan ratified the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, legal mechanisms of which are not created yet.

In our opinion, it is necessary to inventory available rules of law in the field of handling chemicals, which processing can create a basis of the special act «On handling chemicals». Why do we focus attention on handling chemicals? The current legislation regulates activity with chemicals, regarding their production, import and application, and such life cycles as neutralization, utilization, burial of dangerous chemicals did not receive the corresponding specification that it is possible to carry out within the offered normative document.

In the production of agricultural products other dangerous substances can be applied, including potentially dangerous biological substances and genetically modified organisms and products.

This perspective is rather new, difficult and undeveloped in domestic jurisprudence. Such

situation takes place in the current legislation, which contains a fragmentary regulation of genetically engineered activity.

For example, the Article 282 of RK EC prodies that when using genetically modified organisms and products, certain duties are assigned to users of nature:

- implementation of the established standards of maximum permissible impact on environment in the course of production, storages, transportations and uses;

- performance of measures for prevention from harmful consequences of their application for human health and environment;

- to use of genetically modified products only within the list, allowed for use by the authorized body in the field of environmental protection and government body in the field of sanitary and epidemiologic wellbeing of the population.

During operations on production and use of genetically modified products and organisms it is required to possess systems and definition procedures, from where and where genetically modified products arrive. This information in a detailed form is to be transferred to authorized body in the field of environmental protection and government body of sanitary and epidemiologic services.

For genetically modified organisms in food, forage or processing, users of nature have to give the declaration to authorized body in the field of environmental protection that a product has to be used only as food, forage or for processing with the description of features of genetically modified organisms, which a product may contain.

Concerning foodstuff and forages, made of genetically modified organisms, users of nature have to inform buyers that the product is received from genetically modified organisms.

Users of nature have to keep information about the production and use of genetically modified products and organisms within five years and to provide it in authorized body in the field of environmental protection and government body in the field of sanitary and epidemiologic wellbeing of the population according to their requirements.

Agricultural users of nature have to inform a buyer of their crop by means of marking that s/he purchases a genetically modified product, and to keep the register of buyers, to whom they deliver the production.

Government bodies distribute existing regulations on marking to all genetically modified

foodstuff and forages. All foodstuff and forages, containing or consisting or made of genetically modified organisms, are subject to marking. The purpose of marking is informing consumers about the actual properties of a product or forage.

The marking system of genetically modified products is founded on opportunity to find genetically modified desoxyribonucleids or proteins in final foodstuff.

At the present time the twenty seventh plenary session of Inter-parliamentary Assembly of the states – CIS participants (Resolution No. 27-9, dated November 16, 2006) adopted the Model law on safety of activities, related to genetically modified organisms [2].

In our opinion, adoption of the similar law in Kazakhstan, is important in view of the fact that it is a question of life and human health.

Studying of legal problems of environmental protection and use of natural resources allowed to make a number of the following theoretical conclusions and formulate the practical results, directed on improvement of ecological, land, water and other branches of the current legislation of RK.

The production of ecologically clean products are not enough regulated in the legislation, which requires strengthening of legislation and ecological requirements for production of agricultural products, their primary processing, storage, industrial processing. Moreover, laws should enshrine economic incentives to produce organic agricultural products.

The problem of food supplies is one of those, which have plagued mankind since the moment of its origin. Attempts of solving this problem have been made repeatedly, however, and now, in the XXI century, the problem of providing the population with food is acute. Almost a billion of people in Africa and Asia consume on average 2040 kcal per day, which is below the physiological minimum (international classification of UN Food and Agriculture Organization (FAO), food for the level 2150 kilocalories is regarded as a condition of constant malnutrition.

Thus, among 6 billion inhabitants of the Earth the sixth part exists in the conditions of hunger. Production of food in underdeveloped countries lags behind the increase of population. One of panaceas in solving the problem to provide mankind with food was universal introduction in the process of agricultural production of agrochemicals, i.e. a wide range of mineral fertilizers and pesticides. Use of these chemical industry means, actually, solved a

problem of providing the population with own food for many developed states.

For many years the USA were leading exporters of grain, and Germany overcame a problem of half-starved existence of the population with success, which was characteristic for all the XIX century, despite the subsequent wars and ruin.

Widespread application of chemicalization means led to that by the end of the XX century every third inhabitant of the planet ate the products, received by of means of chemical industry.

This fact would not be anything that is disturbing, if modern data of biomedical researches did not clearly prove the harmful effects of chemicals on human health.

This provision clearly shows the necessity of adopting national measures, including legal, which can and must change the current situation, related to the health of our population, especially as the nation's health is a necessary condition for successful development of any state.

It is necessary to notice that the given above facts and others of negative impact of agrochemicals on human health are taken into consideration within legal relationships in our country.

Unreasoned use of chemicals in agriculture is only one of the problems of food production. Next problem, in our opinion, is the usage without considering the possible effects of genetically modified organisms.

For a long time achievements in genetic engineering were regarded as a revolutionary step in the course of providing mankind with food. There is no doubt that gene-modified cultures, as a rule, more fruitful, steady against a frost and other climatic conditions, can be toxic for natural wreckers, and also possess other set properties. These circumstances formed the basis for their broad cultivation in a number of the countries. These circumstances formed the basis for their broad cultivation in a number of the countries. For last 11 years the areas, sowed with transgene cultures, increased by 60 times. Now more than 120 species of transgene plants, including 86 – in Europe, are allowed to use in the different countries. Currently, considering progress of modern genetics, a circle of the products, , containing gene-modified organisms, which are consumed by our fellow citizens, became even wider. If we take into account scientists' data of rather possible harmful effects of GMO on a human body, which can be shown in the form of pathological changes in the subsequent generations, a problem of use of the foodstuff, containing GMO,

can be not only a problem of separately taken region, but also universal.

For the safety of population health the systems of national and international control are created, for example, in the Russian Federation the legislative and standard-methodical base, regulating production, import and turn of the food products, made of GMO, functions. Sanitary and epidemiologic examination of the products, including medicobiological, medical and genetic and technological assessment, as a result of which quality and safety indicators, possibility of allergenic, mutagen properties of foodstuff are studied, is obligatory.

Sanitary epidemiological conclusions and certificates of state registration are valid for 12 types of food products of plant origin, obtained with the use of transgenic technologies: 6 varieties of maize, 4 varieties of potatoes, 1 variety of rice and 1 variety of sugar beet. However, in laboratory testing of food products, received from GMOs, facts of falsification are being identified, when for food products, containing genetically modified components, the documents, which were declared their absence, were presented. If we analyze a regional situation, for example, according to laboratory researches in the 1<sup>st</sup> quarter of 2014 foodstuff with more than 0,9% GMO are found in 0,5% of tests – in the 1<sup>st</sup> of the 201<sup>st</sup> investigated

However, when carrying out laboratory researches of the foodstuff received from GMO, the facts of falsification of this production when on the foodstuff containing genetically modified components, documents in which their absence was declared were submitted continue to be elicited. If to analyze a regional situation, for example, according to laboratory researches in 1 quarter 2014 foodstuff with the maintenance of GMO more than 0,9% are found in 0,5% of tests – in 1 of the 201<sup>st</sup> investigated.

It should be noted that the labels of these products have no information about the use of GMO components in the production. Thus, consumer's right to choose products was violated [4, p. 1].

It seems that toughening producers' responsibility for the failure to provide information about GMO presence in the products on the product labels, accompanying documentation, would facilitate the realization of constitutional citizens' rights to protect health and be a factor, contributing to the preservation of nation's health.

The next possible health risks are associated with the use of nanotechnologies.

At the present time researches are widely conducted, and elaborations on wide nomenclature

of nanoindustry promoting are developed in the world. Practical use of nanotechnologies, which are technologies, targeted at obtaining and using material elements of nanometer size – up to 100 nm in one dimension with specified structures and properties, is perspective and is planned in many sectors of economic activity such as industry, agriculture, medicine, etc. Along with the fact that the use of nanotechnology is undoubtedly one of the most promising areas of science and technology, it is important to study the potential dangers of using nanomaterials and nanotechnologies, as well as the development of criteria for their safety for human health.

In a number of the European Union countries and the USA works on development of regulatory and methodical base, directed on assessing the safety of production and use of nanotechnological products are already begun. Intensive introduction of nanotechnologies in different branches of economic activity inevitably puts also a problem of nanomaterial influence on habitat of a person. The most important object of attention at risk assessment for health, connected with nanomaterials, is the use of nanotechnologies in producing foodstuff, perfumery and cosmetic products, as at their direct use or consumption and at impact of nanoparticles and nanomaterials on environment in the course of their production. In the world certain experimental materials of nanomaterial characteristics, assessment methods of inhalation and peroral loading, methods of toxicological testing and risk assessment are already compiled. Adverse effects of inhalation receipt of nanomaterials in a human body thus are the most studied. At the same time possible biological effects of nanomaterials on an organism through a gastrointestinal path are studied insufficiently; however, there are the data, testifying that various substances and materials at their transfer to a form of nanoparticles can change the physical and chemical properties considerably, which can be reflected in their physiological effects in the course of absorption in a digestive tract and assimilation in an organism [4, p.1].

We think the law should fix producers' obligations to specify the information for consumers about the use of nanotechnologies or nanomaterials in the products.

Analysing the situation, dealing with the use of chemicals in agriculture, genetically modified organisms and nanomaterials in food production, you can come to the conclusion that domestic regulatory framework in the field of control over the quality and

safety of food products requires significant changes. A truly effective system of quality assurance of food products in Kazakhstan is missing. The use of modern science latest achievements in the production can result both in good and negative consequences. Under these conditions the detailed legal regulation of production process and sale of food products for the purpose of citizens' rights realization to protect their health is vital.

### Summary and Conclusions

The exacerbation of global food challenge requires from the international community to develop new international and legal solutions, aimed at the progressive development of international law by speeding up the process of forming the principles and standards in this area. In this regard, acceptance of the framework convention in the sphere of supporting international food security – Conventions on cooperation in the field of supporting international food security – is offered. It should reflect the definition of international food security and legal bases of cooperation between states in the research sphere – respect of the human right to nutrition, food safety for human health, food aid. The draft of convention can serve as a basis for developing international legal instruments, devoted to the problem of ensuring international food security.

In order to increase the efficiency of solving food problem at the international level it is required to review a number of 1999 UN Convention regulations on the provision of food aid. We offer to expand the list of principles of food aid (integrate the principles of equality and non-discrimination, special protection for the most vulnerable populations, efficiency, timeliness, participation, food aid quality), and change the mechanism of its provisions, obliging to send food aid solely through international organizations. The offer is connected with the possibility of food distribution, proceeding not from needs of the countries, lacking it most, but from foreign policy considerations of leading donor countries, which is a direct violation of the basic principle of international law – principle of non-interference to internal affairs of a state.

For implementing the precautionary principle, establishment of a Commission for independent research of long-term influence of food products, containing genetically modified organisms (GMOs), on human health and its future generations,

and for monitoring the health of people who consume corresponding products is proposed. The Commission could be established by the Conference of the Parties as a subsidiary body under the Cartagena Protocol on Biosafety 2000. The offer

is due to the absence of objective research data on the safety of food products, containing GMOs, and the lack of international legal norms, obliging to conduct independent researches of long-term impact of products, containing GMOs on human health.

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