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LEGAL REGULATION OF GENETICALLY ENGINEERED ACTIVITIES

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Abstract

The idea that science has no boundaries comes from recent discoveries in the field of genetics. This is the science that deals with the study of genes, genetic variation and heredity in organisms. Over the past 25 years, the most revolutionary in the field has been the study of double helix DNA genes and genomes; this research has led to new discoveries, including the ability of humans to alter genetic sequences, the discovery of gene modification mechanisms such as the CRISPR-Cas (cluster regular short palindromic repeats) and Cas (CRISPR-related) system. Improvements in genetic engineering have opened up access to new opportunities to save lives and create new treatment options for diseases that cannot be cured by known classical methods. However, despite the current possession of such knowledge, two very important questions arise: First, can we make changes to a system that is not fully understood? Second, who controls the limits of genetic science? Unfortunately, there are no answers to fully answer these questions, because legal systems have not kept pace with the genetic engineering revolution and lawyers and scientists often do not understand the rules. In such a situation, the only true answer would be for the public authorities to intervene with adequate legal regulations and to apply the concept of bioethics to genetic engineering. This article presents the legal regulation of genetic engineering activities

Keywords: Bioethics, divorce, genome editing, regulatory practices

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1. Introduction

Modern science has achieved very significant results in various areas of activity. For the common man, it is encouraging that such advances help to treat complex diseases, and the technology itself is now making the treatment procedure cheaper, unlike most other factors affecting medicine. One such area of scientific knowledge is genetic engineering, which can alter only individual parts of the human body or affect the transformation of the human body as a whole (Global.., 2016). This raises ethical issues that generate a great deal of controversy in society. To overcome them there is necessary a clear conceptual understanding of problems associated with diagnostics and editing of human genome, on the basis of which there should be developed the effective normative legal regulation, which will satisfy the interests of all participants of the indicated legal relationship (Gonzalez-Avila et al., 2021). Advances in genetic engineering have led to the creation of modern medicines, food, supplements, and other products that can be used in human economic activities (Okada & Watanabe, 2016). The socio-economic benefits and prospects of genetically engineered research are already highly appreciated by mankind, having obtained drugs such as insulin, erythropoietin, alpha-interferon, food additives that help increase the shelf life of food products.

It is worth noting that the rapid development of genetically engineered technologies, in addition to their positive effect, may in the foreseeable future have a negative impact on human life, health and the environment (Baghbani-Arani et al., 2021). Therefore, there is a need for the legal regulation of genetically engineered activities.

According to the data of the Federal Service for Supervision of Consumer Rights Protection and Welfare, the amount of food products containing genetically modified components is only 0.7 percent of the total food market share. And the share of samples with genetically modified organisms detected in imported products is 7.7 percent of the total share of food products imported into the RF.

It would seem that the share of food products containing genetically modified components in the Russian food market is not large (Golubkov, 2015). However, data from the Federal Service for Supervision of Consumer Rights Protection and Welfare take into account only those food products where the share of genetically modified components is 0.9 percent of the weight of the food product. The actual number of such food products on the Russian Federation food market is much higher than the official number (Lebedeva & Standson, 2019).

There is an imperative approach in the modern regulation of relations in the sphere of genetically engineered activities (Shilyuk, 2019). But this is not true, because the scope of use of genetically engineered products is expanding accordingly and methods of regulation should be many, and they should be different depending on the sphere of application, of course, the most attractive are civil law methods, which on the one hand provide autonomy of will of participants of genetically engineered legal relations, and on the other control over their activities from the state (Mokhov, 2020).

2. Problem Statement

Genetic engineering is a set of methods and techniques and technologies for isolating genes from an organism, manipulating organisms and genes, and introducing them into other organisms.

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Genetic engineering is the use of various methods and manipulations of genetic engineering techniques to experimental research and production activities. It is carried out in the laboratory.

The result of such work is genetically modified organisms whose genetic material has been altered using genetic engineering techniques. Work with genetically modified organisms should be carried out in closed specific systems that do not affect the environment (for example, when conducting an experiment as part of a complex study).

Currently, genetically modified organisms as part of a specific system are used in the production of various food products as additives for animal feed (Nguyen et al., 2021), in some medicines, in veterinary medicine, etc., so a separate object of regulation is products obtained using genetically modified organisms or containing genetically modified organisms.

Potentially dangerous is the impact of genetically modified organisms on the environment when they enter open systems, as well as the impact on the human body of food products obtained from genetically modified organisms. That is why today it is necessary to pay special attention to the regulation of genetically engineered activity (Voyushin et al., 2016). On the one hand, the Russian Federation has certain normative-legal acts for the regulation of genetically engineered activity. However, the study of the basic laws states the presence of legal gaps in the regulation of the turnover of food products, medicines obtained by genetic engineering methods. One of the directions to improve the legislation in the field of genetic engineering and further effective regulation is to establish its basic principles as guiding ideas in the implementation of their powers in the field in question. This will allow to the creation of normative and legal acts, which can prevent the risky nature of the genetic modification process and reduce the negative consequences of genetic engineering. It should be noted that scientists distinguish various general legal principles (Romanovsky & Romanovskaya, 2016). These principles are legality, justice, legal equality, social freedom, social, civil duty, objective truth, responsibility for guilt. Social justice, equality of citizens, the unity of rights and duties, humanism, the combination of persuasion and coercion in law. Principles that are reflected in the administrative-legal regulation in the field of genetic engineering activities include the principles of separation of powers, federalism, legality, respect for human and civil rights, publicity, responsibility. It is these principles that act as the guiding ideas that characterize the content and essence of the legal regulation of genetically engineered activities (Romano et al., 2019). Realization of these principles is closely connected with a whole spectrum of rights and freedoms: to health protection; to information about factors of influence of genetically modified organisms on human health, environment, ecology; to information about the content of genetically modified organisms in food; to a favourable environment, etc. As in other cases, when we speak about ensuring the rights and freedoms in the field of genetically engineered activities, we primarily mean the rights and freedoms of citizens, leaving out the rights of producers of genetically modified products.

The law on state regulation in the field of genetically engineered activity does not specify the rights and obligations of any of the participants of public relations, nor does it establish corresponding guarantees for them, including in case of violation of such rights or harm caused by one of the parties. At the same time, such provisions can be found in foreign laws that establish the basics of state regulation in the field of genetic engineering (Levushkin, 2019). Under such conditions, there is a need to change the

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current legislation on state regulation in the field of genetic engineering activities, which should find expression in the expansion of the list of guidelines laid down on the basis of state regulation in the field of genetic engineering activities. In addition, it seems necessary to establish the obligation to provide citizens with full, reliable information not only about measures taken to ensure safety but also about the results of genetically engineered activities, harms and benefits of genetically modified products; to delimit the competence of federal authorities and authorities of the subjects of the Russian Federation on the regulation in the field of genetic engineering; to establish the rights of citizens and developers of genetically modified organisms, as well as guarantees when they carry out their activities.

3. Research Questions

The legal regulation of genetic engineering activity in the Russian Federation is at the stage of formation, in connection with this there are problems of legal regulation. And that is why the norms of the law on genetic-engineering activity cannot properly ensure the safety of people, future generations and the environment from the negative impact of the genetic-engineering activity.

A variety of issues of legal regulation of genetically engineered activity can be conditionally divided into two groups: issues arising directly during the implementation of genetically engineered activity and issues arising during the application of results of the genetically engineered activity. Let's take into account that the Federal Law "On state regulation in the field of genetic engineering activity" of 05.07.1996 № 86-FZ, does not regulate the civil-law obligations and does not contain provisions on concluding an agreement on carrying out genetic-engineering works. Therefore, there is a need for special regulation of the contract for genetic-engineering works (Rossinsky, 2019a).

The problem of licensing of genetic-engineering activity can also be mentioned, according to article 6 of the Federal Law "On state regulation in the field of genetic-engineering activity" of July 05, 1996, No 86-FZ (Federalnyy zakon.., 1996) the genetic-engineering activity of III and IV risk levels which are carried out in closed systems is subject to licensing. In turn, genetically engineered activities carried out in closed systems of risk levels I and II are not licensed (Leskova, 2018). This provision is inconsistent with one of the basic principles - the principle of safety. Since genetically engineered activities are found to be potentially dangerous, this is why all genetically engineered activities must be licensed to prevent the possible negative consequences of their use.

Currently, there is no established procedure for licensing certain types of genetic engineering activities: gene diagnostics and gene therapy; all types of testing of genetically engineered and modified organisms, including laboratory, clinical, field and pilot testing.

Therefore, in order to solve the problem in question, we propose to introduce mandatory licensing of all genetically engineered activities (Bogatyreva, 2017).

It is necessary to supplement the provisions on licensing, according to which the applicant for a license must submit to the licensing body in order to obtain a license:

a) Documents indicating the purpose, quantity, volume and place of release into the environment, use of the genetically modified organism;

b) documents containing identification data of the genetically modified organism;

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c) a statement describing the genetic modification, the method applied and the obtained characteristics of the genetically modified organism;

d) documents describing the methods to be used when controlling the safety of a genetically modified organism;

e) documents containing methods for safe handling of genetically modified organisms and products containing such organisms, as well as documents specifying the rules of their storage, transportation and use, including packaging and labelling, if applicable.

Another problem of legal regulation of genetically engineered activities is the problem of insurance of liability to third parties of entities engaged in such activities (Rossinsky, 2019b). Such insurance as an element of the legal mechanism for regulating access to the exploitation of natural capital, based on contractual relations. This all can have a positive effect on the implementation of various tasks in the field of environmental protection in the implementation of genetically engineered works and will allow achieving the currently important balance between the economic needs of the economic entity and society interested in ensuring a favourable environment and at the same time the development of new technologies. The existing legislation on environmental protection in the Russian Federation refers to environmental insurance to the methods of economic regulation in the sphere of environmental protection, which is carried out in order to protect the property rights of individuals and legal entities in case of environmental risks. Ecological insurance of genetically engineered activity is currently voluntary, we think that this activity should be subject to obligatory insurance, we should refer genetically engineered activity of III and IV risk levels carried out in closed systems to obligatory insurance.

4. Purpose of the Study

At the present stage of genetic engineering development in the Russian Federation, special attention deserves the question about the possibility of using genes, genomes and genomic technologies, their constructions in circulation and especially in the civil legal turnover, therefore a relevant legal regulation of all the above mentioned is required. Today a sufficient number of scientific and practical studies and many practical experiments and tests of both medical and legal importance are being carried out (Sokolov & Bogatyreva, 2018). All these experiments and trials addressed to use of genes and genetic constructions in civil legal relations as objects of civil rights. Accordingly, there is a very important question about the legal regulation of genetic engineering activity and accordingly the question about the defensibility of genes.

In most countries of the world, a scientific school has already been formed both from the medical point of view and from the legal one (Petushkova, 2013). The practice of implementation of genetic engineering has been established and the main path followed by the Western countries is the realization of genetic improvement of human beings, their life and health. And most importantly, society has been in the era of genetic engineering for quite a long time, and, therefore, it is impossible to do without legal regulation of genetic engineering activity. It is necessary to determine that a gene can directly affect the presence of any trait of an organism or take part in the formation of several traits, forming a specific genetic construction, which is involved in the legal turnover. According to part 1 of article 8 of the Constitution of the Russian Federation the unity of economic space, free movement of goods, services

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and financial means, support of competition, freedom of economic activity are guaranteed in the Russian Federation. It is worth noting that the rapid development of genetically engineered technologies, in addition to their positive effect, may in the foreseeable future have a negative impact on human life, health and the environment. In this regard, there is a need for the legal regulation of genetically engineered activities.

5. Research Methods

The research methods of the work are:

- historical;
- method of complex analysis;
- comparative legal method.

The empirical basis was the current legislation of the Russian Federation on genetic engineering activities, judicial practice of courts of general jurisdiction

6. Findings

At the present stage of legal regulation in the sphere of genetically engineered activities, there remains a set of unresolved issues related to the improvement of the regulatory framework and the need to study the long-term impact of genetically modified organisms on human health and the environment and requiring theoretical, methodological and normative approval (Anisimov & Popova, 2017). In addition, to date, there is no current legislation on genetic engineering to ensure the safety of human activities, as well as future generations and the environment from the adverse effects of genetically modified organisms. The absolute safety of genetically modified products for human health has not been proven, and the use of such products poses a huge risk to humans. In addition, to date, there is no current legislation on genetic engineering to ensure the safety of human activities, as well as the safety of future generations and the environment from the adverse effects of genetically modified organisms. The absolute safety of genetically modified products for human health has not been proven, and the use of such products poses enormous risks to humans (Gonzalez-Avila et al., 2021). In addition, to date, there is no current legislation on genetic engineering to ensure the safety of human activities as well as future generations and the environment from the adverse effects of genetically modified organisms. The absolute safety of genetically modified products for human health has not been proven, and the use of such products poses a huge risk to humans. This requires a special approach to the legal regulation of genetically engineered activities.

7. Conclusion

It should be noted that, unfortunately, the awareness of the need for adequate and consistent with the current realities of life regulation of genetically engineered activities in relation to the human body has been used in the Russian legislation only recently. Technical regulation in the field of genetic engineering activities (Romano, et al., 2019), ensuring the safety of citizens and the environment in the process of genetic engineering activities and the use of its results (Voeikova, et al., 2020) are recognized

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as promising areas of development that require qualitative normative legal enshrinement. Therefore, the most important thing to pay the most attention to is the recognition that the object of genetic engineering consideration is recognized as the method of constructing a genetically modified microorganism, rather than a specific microorganism. That is what allows us to understand that the important and very responsible tasks which should be successfully realized by means of genetic technologies are obtaining the positive and important for the development of this direction, namely the transition to individual medicine, high-tech health care and health saving technologies, highly productive and environmentally friendly agriculture and aquaculture, rational use of chemical and biological protection of agricultural plants and animals, creating safe and high quality At present the Russian Federation is not always able to compete with the leading countries in this field in the field of genetically engineered technologies. The Organization for Economic Cooperation and Development pointed out back in 2016 that the share of biotechnology companies performing research and development in total research and development spending in the Russian Federation was only 0.53%, compared to 12.31% in the United States of America and 8.95% in France (Aygarinova et al., 2017)

Genetic engineering in the Russian Federation has not received sufficiently serious attention from the authorities and the law as a whole only a few normative documents define the basic provisions of the legal regulation of these relations arising primarily in the field of genetic engineering activities proper; legal mechanisms that ensure the constitutional rights of citizens to environmental safety in the process of both the implementation of the above activities and their results; the legal basis for cooperation of the Russian Federation (Bogatyreva, 2017). In 2018, a roadmap for the development of biotechnology and genetic engineering was approved (Mokhov & Yavorsky, 2019), which included measures such as the creation of bioresource centres, preclinical translational research centres, a national centre for strategic biomedical technologies, the creation of professional standards in biotechnology and genetic engineering, the opening of a national depository of biomaterials and GCP-certified cell laboratories, and measures to harmonize standards in force in Russia. Under such conditions, it is very important to understand the potential danger of genetically engineered activities based on a number of principles, which are enshrined in the legislation of the Russian Federation. These principles include the following: safety of citizens (individuals) and the environment; safety of clinical trials; public availability of information about the safety of genetically engineered activities; mandatory confirmation of compliance of products containing the results of genetically engineered activities; state registration of genetically engineered and modified organisms.

Genetically engineered activities are based on technical and legal norms, which are contained in Federal laws, state standards, regulations and national standards. Technical-legal norms also regulate the labelling of products containing genetically modified organisms. Thus, in accordance with the legislation, the manufacturer is obliged to indicate information about the presence of genetically modified organisms in such products if the content of such genetically modified organisms in the product exceeds 0.9%.

A significant role in the development of genetic engineering is played in the Russian Federation by the contract on implementation of genetic engineering activity according to which the contractor undertakes to carry out the genetic engineering activity according to the customer's assignment and the customer undertakes to accept the results of such activity and to pay for them. Special norms regulating

this civil-law institute do not currently exist, which is a certain problem. Therefore, when regulating this type of obligation, it is necessary to apply both the provisions of the General Part of the Civil Code of the Russian Federation and the provisions of the law of obligations for research, development and technological works.

To summarize all of the above, it should be noted that genes and genomes are special objects that require special legal regulation, of course, these conclusions are not indisputable. The most important thing is to understand that the legal regulation at the present time is not possible and will not exist in isolation from interstate interaction. However, the dynamics of the legal regulation of the objects of genetic technologies in Russia allows us to speak about new trends in the development and implementation of a new concept of biomedical legislation, in particular not only changes in traditional sectoral institutions but also the appearance of new institutions and sub-branches - biomedical law. We consider it justified, based on the current level of development of science, practice and technology, to consider genes as specific objects, and this, in turn, will allow regulating genetic engineering activities from a legal point of view in more detail.

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