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Ecological and Legal Regulation of Genomic Research: Statement of the Problem

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Abstract

Based on the analysis of the work of Russian and foreign lawyers, geneticists, biochemists, biotechnologists, bioecologists, molecular biologists, and microbiologists, the article studies the environmental and legal regulation of genomic research in the Russian Federation. It has been shown that a large number of works deal with the environmental and legal problems of genomic research abroad, however, with regard to Russian legislation, relevant studies are extremely few. It was revealed that in Russia in the field of environmental protection, ensuring human environmental safety and rational nature management, the legal regulation of genomic research is limited only by the legal regime of biotechnologies in general and the legal provision of genetic engineering in particular. At the legislative level, social relations are recommended to be recognized as homogeneous according to the genetic and genomic versions of genetics and genomics. A broad understanding of genomic research is defined, consisting of two groups of social relations: (1) directly genomic research - structural genomics, genomic analysis, functional genomics (proteomes and transcripts), genomic polymorphism, mapping and sequencing of genomes, etc.; (2) activities related to genomic research - genetic research, biotechnology, genetic engineering, experimental mutagenesis, genomic selection, etc.). The question is raised about the need to develop differentiated environmental and legal regulation of heterogeneous social relations in genomic research, depending on targeted or non-targeted changes in the genome. The proposed classification is important in terms of applying various environmental and legal means of environmental protection for the selected groups of public relations on genomic research.

Keywords: Environmental regulation, Genomic research, Genomics, Environmental safety, Food safety, Environmental risks

1 Introduction

Presidential decree No. 899 of July 7, 2011 "On the approval of priority areas for the development of science, technology and technology in the Russian Federation and the list of critical technologies of the Russian Federation", classified genomic, proteomic and postgenomic technologies as technologies necessary for the modernization and technological development of the Russian economy and for an increase in its competitiveness. It has been recognized by domestic political and legal documents that genomic research can help resolve a number of major challenges of the Russian state. For example, the Forecast of Scientific and Technological Development of the Russian Federation approved by the Government of the Russian Federation for the period until 2030 focuses on the intensity of development of genomic, proteomic, and postgenomic technologies, which are caused by the need to preserve the resource potential, including the biological resources of the World Ocean; counteract the spread of various types of diseases of humans and animals; obtain biomaterials from renewable raw materials to replace traditional industries; as well as improve other areas of activity.

The normal functioning and further development of any sphere of relations, including genomic research, requires their effective legal regulation. There is almost no legal regulation of genomic research affecting environmental protection, human environmental safety, and environmental management. Practically no environmental and legal studies have been carried out in the field of the genomic, proteomic, and postgenomic technologies. Without clear legal support for genomic research, relevant tasks and national priorities cannot be implemented at the proper level. The objective of this research was to identify a circle of social relations that potentially fall under the environmental and legal regulation of genomic research in Russia.

2 Materials and Methods

The assessment of the possible environmental and legal regulation of genomic research was carried out on the basis of an analysis of Russian political and legal documents and the works by lawyers specializing in the legal regime of biotechnologies and legal support for genetic engineering

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(*N.A. Abdallah, E.V. Luneva, V.J. Meretsky, F. Francioni, Z.F. Safin, T. Sovová, J.D. Wolt* and others). In addition, the findings were based on the work by geneticists, biochemists, biotechnologists, bioecologists, molecular biologists, and microbiologists (*J.M. Alonso, J.R. Ecker, S.T. Cole, I. Saintgirons, Е.Я. Тетушкин,* and others).

The methodological basis of the study was the dialectical method, which made it possible to learn in indissoluble unity and in a general connection the specifics of social relations by genomic research. The achievement of the objective was also promoted by logical methods in the form of analysis and synthesis, induction and deduction, comparison and generalization, analogy and typology. The system-structural method revealed a broad understanding of genomic research, consisting of two groups of social relations.

3 Results

Going beyond the limits of legal science allows us to understand the features of public relations and to develop optimal legal regulation. The appeal of lawyers to the scientific developments of geneticists, biochemists, biotechnologists, bioecologists, molecular biologists, and microbiologists is associated with the need to clarify the scope and essence of social relations in the field of genomic research affecting environmental protection, human ecological safety, and sustainable nature management (1-4).

The problems of legal regulation of genomic research require considerable attention in terms of its complexity since it is already clear that the results of applying genomic technologies will affect many aspects of human activity (5). The legal support of genomic research, to some extent, begins to be studied and affected by representatives of almost all branches of law and legislation. The complexity of the description of the current state of legal research in the claimed field is due to the vague understanding of the category of "genomic research" by lawyers. Genetics, biochemists, biotechnologists, bioecologists, molecular biologists, and microbiologists cannot fully determine the area of social relations that form genomic research.

As a result of a review of existing scientific developments in this field of jurisprudence, the broadest understanding of genomic research is proposed, which includes two blocks of social relations: 1) directly genomic research - structural genomics, genomic analysis, functional genomics (proteomes and transcripts), genomic polymorphism, mapping and sequencing of genomes, etc.; 2) activities related to genomic research - genetic research, biotechnology, genetic engineering, experimental mutagenesis, genomic selection, etc.). The formulated scientific position is confirmed by the reasoning of specialists in genomic research, who recognize the interdisciplinary relations between the genetic and genomic versions of genetics and genomics as essentially the same (6-8). Consequently, in order to build effective environmental and legal regulation, it is advisable at the legislative level to recognize homogeneous public relations by genetic and genomic "variations", as well as to consolidate a broad understanding of genomic research.

4 Discussion

Abroad, a large number of works has been devoted to the problems of legal regulation of genomic research, considering the peculiarities of natural resource (9, 10), agrarian (11-13), and environmental law (14, 15), but with regard to Russian legislation, the relevant studies are extremely few. Basically, the national environmental and legal science is developing only in two areas of genomic research: biotechnology and genetic engineering. The above circumstance is connected with the Federal Law No. 86-FZ of July 5, 1996 (as of July 3, 2016) "On State Regulation in the Field of Genetic Engineering" and many by-laws and regulations on biotechnology that have been adopted long ago.

The legal regulation of relations in the field of biotechnology aimed at solving relevant socio-economic, energy, environmental, and other problems were described by Z.M. Fatkudinov and R.N. Salieva. They proposed to consider biotechnology as a technological process rather than a set of objects so that it would be possible to establish mandatory safety requirements not only for biotechnological products but also for the process of their creation. They substantiated the importance of identifying the legal features of each biotechnological product or process separately, consolidating the legislative classification of such objects and establishing appropriate differentiated legal regimes for them. Lawyers have come to the important conclusion that the specifics of the legal regulation of biotechnologies should be related to environmental and food safety and other factors that affect the health of citizens (16).

A.V. Sheverdin analyzed the legal regulation of the creation and use of biotechnology in Russian and foreign legislation. He showed that in domestic legislation the legal acts regulating the development and use of biomedical technologies and biotechnologies in the field of agricultural activity are more represented (17).

The science of environmental law has recognized that biotechnology allows intervening in the genetic apparatus and exposing living organisms to targeted modifications, selecting the best among artificially created genotypes. Biotechnologies have discovered and shown the special value of genetic resources, which, in the legal sense, are a public treasure. Therefore, the state is obliged to ensure the preservation of national genetic resources, including in the field of cultivated biological resources (18).

S.Iu. Miroliubova insists on the need to develop and adopt a State program of national cultured biological resources that would ensure the collection, processing, storage, and use, including the dissemination among scientists, of information about the genetic resources of living organisms important for the food industry and agricultural production. She proposes to improve the regulatory framework in the following areas: 1) protection of human and civil rights and freedoms in the application of genetic resources and biotechnologies in the food industry and agriculture; 2) preparation of standards for cultivated biological resources and biotechnologies; and 3) the legal regulation of biosafety, including genetic safety (18).

The latest agrobiotechnologies, in particular, include 1) the creation of new highly productive, resistant to

pathogens and adverse environmental conditions varieties of hybrids of agricultural plants based on biotechnologies; 2) the improvement of breeding by using genetic selection methods for farm animals; 3) the creation of databases containing information on the genome of breeds of farm animals for the introduction of cloning and genetic certification methods in breeding. For Russia, there are a number of threats in this area such as 1) low agricultural productivity; 2) a critical lag in the research and production and technological base in the field of biotechnology; 3) low demand for practical applications; 4) insufficient business investment in the development of biotechnological industries; 5) high barriers to entry into the global market for biotechnological products; and 6) the risk of turning the country into a raw material base for world leaders in the biotechnology market (19).

A.V. Sheverdin investigated the mechanism of legal regulation of genetic engineering activity. In the structure of this legal mechanism, he included licensing, certification, registration of genetically modified organisms, and control (17, 26).

Most scientific legal developments in the field of genetic engineering concern the safety of introducing genetically modified organisms into the environment and using them as food. This situation has been a result of food problems.

A.O. Malofeev writes about the consolidation of a number of legal constructions that ensure the consideration of moral ideas of society regarding the use of genetically modified organisms in the economy. He proposes 1) the legal construction of the state registration procedure of genetically modified organisms themselves and their producers; 2) the legal design of the licensing of the production of genetically modified organisms; 3) the legal design of the state environmental review, mandatory for all producers of genetically modified organisms, carried out to determine the level of negative impact of the corresponding production on the environment **(**20, 25**)**. The indicated legal constructions should ensure the balance of private and public interests in legal regulation, and express the socio-humanistic content of the law.

The benefits of using genomic technologies are obvious today, however, the side effects of the progress of genomics, humanity can only evaluate in practice after several decades **(**21,27**)**. Researchers are faced with the task of predicting possible environmental risks of introducing genomic technologies into human economic activity **(**22, 23, 24**)**.

Thus, in Russia in the field of environmental protection, ensuring human environmental safety and rational nature management, the legal regulation of genomic research is limited only by the legal regime of biotechnologies in general and the legal provision of genetic engineering in particular. The current situation is explained by more or less formed national legislation exclusively in these areas. The Russian regulatory framework should be expanded to cover the relationship that has arisen for all genomic research, which is increasingly penetrating into various spheres of human activity.

5 Summary

The environmental and legal regulation of genomic research in Russian legislation is poorly developed. Therefore, it is of primary need to formulate and introduce into the conceptual and categorical apparatus of environmental law basic terms adapted from jurisprudence from the field of genomic research such as “genome”, “genetic manipulation”, “waste resulting from genomic research”, and others. In order to increase the effectiveness of the relevant legal impact, it is advisable to enforce the legal principles and specific measures to ensure the environmental safety of genomic research in environmental legislation.

Differential legal regulation of heterogeneous social relations on genomic research is required depending on the targeted (genetic research, biotechnology, genetic engineering, experimental mutagenesis, genomic selection, etc.) or non-targeted (under the influence of the consequences of negative impact on the natural environment) changes in the genome. The specified delimitation is important in terms of applying various environmental and legal means of environmental protection for the selected groups of public relations on genomic research.

6 Conclusion

The field of genomic research for a long time will be one of the most promising and attractive areas not only for the legal but also for other sciences, both natural and humanitarian. The plans include a separate legal assessment and legal analysis of DNA manipulations of various organisms, cloning, the impact of genetically modified products on humans and the environment in general, and ensuring of biosafety.

Conflicts Of Interest

The author declares that the provided information has no conflicts of interest.

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References

[1] Luneva E.V., Safin Z.F. Legal Issues Supporting Production and Distribution of Biotech Products, International Journal of Advanced Biotechnology and Research. 2016;7(4):1260-1264.

[2] Guerrini CJ, McGuire AL, Majumder MA, Bollinger JM, Rowan PJ. Constraints on gene patent protection fuel secrecy concerns: a qualitative study. Journal of Law and the Biosciences. 2017 Nov 16;4(3):542-64.

[3] Bubela T, Vishnubhakat S, Cook-Deegan R. The mouse that trolled: the long and tortuous history of a gene mutation patent that became an expensive impediment to Alzheimer's research. Journal of Law and the Biosciences. 2015 Apr 23;2(2):213-62.

[4] Kariyawasam K, Takakura S, Ottomo N. Legal implications and patentability of human stem cells: Australia and Japan compared. Journal of Intellectual Property Law & Practice. 2015 Feb 12;10(3):198-209.

[5] Tennant R.W. Genomics and Environmental Regulation: Science, Ethics and Law. Environmental Health Perspectives. 2009;117(9):414.
[6] Cole S.T. and Saintgirons I. BACTERIAL GENOMICS, Fems Microbiology Reviews. 1994;14 (2):139-160.
[7] Alonso JM, Ecker JR. Moving forward in reverse: genetic technologies to enable genome-wide phenomic screens in Arabidopsis. Nature Reviews Genetics. 2006 Jul;7(7):524.
[8] Tetushkin E.Ia. Landscape and environmental genomics // Genetics. 2013;49(10):1133-1148.
[9] Francioni F. and Scovazzi T. Biotechnology and International Law. Journal of Environmental Law. 2007;19(3):419-421.
[10] Meretsky V.J., Atwell J.W., Hyman J.B. Migration and conservation: frameworks, gaps and synergies in science, law and management. Environmental law (Northwestern School of Law). 2011;41(2):447-534.
[11] Abdallah N.A., Prakash C.S., McHughen A.G. Genome editing for crop improvement: Challenges and opportunities. GM Crops & Food. 2015; 6(4):183-205.
[12] Wolt J.D., Wang K., Yang B. The Regulatory Status of Genome- edited Crops. Plant Biotechnology Journal. 2016;14(2):510-518.
[13] Sovová T, Kerins G, Demnerová K, Ovesná J. Genome editing with engineered nucleases in economically important animals and plants: state of the art in the research pipeline. Curr. Issues Mol. Biol. 2016;21(21):41-62.
[14] Anonymous UNITED NATIONS ACTIVITIES Environmental Policy and Law, 2011. V. 41(2). P. 56-93.
[15] Tsioumani E. Progress on Genetic Resources for Food and Agriculture. Environmental Policy and Law, 2018;48(1):15-18.
[16] Fatkudinov Z.M., Salieva R.N. Problems of legal regulation of public relations in biotechnology, Law and Economics. 2015;6:4-7.
[17] Sheverdin A.V. Creation and use of biotechnology: background,Journal of Russian Law. 2012;6:118-126.
[18] Miroliubova S.Iu. Cultivated biological resources: concept and legal regulation of use, Environmental Law. 2015;3:37-39.
[19] Bogoliubov S.A., Galinovskaia E.A., Gorokhov D.B. et al. Legal regulation of the use and protection of biological resources: a scientific and practical guide / S.A. Bogoliubov, E.A. Galinovskaia, D.B. Gorokhov, et al.; chief ed. E.L. Minin. M.: IZiSP, INFRA-M, 2016:328.
[20] Malofeev A.O. Legal regulation of the turnover of genetically modified organisms in the Russian Federation // Law and Economics. 2015;4:25-29.
[21] Huttin C. Perspectives of biologists, epidemiologists and geneticists' controversies in sciences and health system reforms, Technology and Health Care, 2015;23(1):103-108.
[22] Lickliter R. Modeling Psychobiological Development in the Post-Genomic Era International Journal of Developmental Science, 2013;7(2):79-82.
[23] Nirmala GS, Muruganandam L. Hydrodynamics in a Liquid Solid Circulating Fluidized Bed–A Review. Journal of Chemical Reviews. 2019 Mar 1;1(2. pp. 78-170):114-29.
[24] Taheri A, Mohammadi S. Ultrasensitive and selective non-enzymatic glucose detection based on pt electrode modified by carbon nanotubes@ graphene oxide/nickel hydroxide-Nafion hybrid composite in alkaline media. Progress in Chemical and Biochemical Research. 2018 Oct 1;1(1, pp. 1-80):1-0.
[24] Haquea TA, Tabassuma M, Rahmana MJ, Siddiqueb MN, Mostafab MG, Khalaquea MA, Abedinea Z, Hamidic H. Environmental Analysis of Arsenic in Water, Soil and Food Materials from Highly Contaminated Area of Alampur Village, Amjhupi Union, Meherpur. Advanced Journal of Chemistry, Section A: Theoretical, Engineering and Applied Chemistry. 2019 Aug 23:181-91.
[25] Vafaei-Nezhad M, Ghiasi R, Shafiei F. Conformational Analysis of 2-halo-1, 3, 2-dioxaphosphinanes: A Density Functional Theory (DFT) Investigation. Chemical Methodologies. 2020 Mar 1;4(2. pp. 115-219):161-71.
[26] Yadav S, Sharma M, Ganesh N, Srivastava S, Srivastava MM. Bioactive principle loaded gold nanoparticles as potent anti-melanoma agent: green synthesis, characterization, and in vitro bioefficacy. Asian Journal of Green Chemistry. 2019 Oct 1;3(4, pp. 418-549):492-507.
[27] Mohamadi S, Borhani F, Nikravan-Mofrad M, Abbaszadeh A, Monajemi F, Moghaddam HR. Assessing of the learning needs of nurses in medical and surgical and emergency wards: nursing continuing education requirements. EurAsian Journal of BioSciences. 2019 Aug 1;13(2).