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Facultad Experimental de Ciencias
Departamento de Ciencias Humanas
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State programs for the development of genetic technologies

Saria B. Nanba[1]
[1]Institute of Legislation and Comparative Law under the Government of the Russian Federation, Moscow, Russian Federation
saria.nanba@izak.ru

Oganes A. Akopyan[2]
[2]Institute of Legislation and Comparative Law under the Government of the Russian Federation, Moscow, Russian Federation
oganes.akopyan@izak.ru

Emil V. Alimov[3]
[3]Institute of Legislation and Comparative Law under the Government of the Russian Federation, Moscow, Russian Federation
emil.alimov@izak.ru

Maria A. Garmaeva[4]
[4]Institute of Legislation and Comparative Law under the Government of the Russian Federation, Moscow, Russian Federation
maria.garmaeva@izak.ru

Zarina N. Bedoeva[5]
[5]Institute of Legislation and Comparative Law under the Government of the Russian Federation, Moscow, Russian Federation
zarina.bedoeva@izak.ru

Abstract

The article analyzes state programs for introducing genetic technologies, their goals and development prospects via comparative qualitative research methods. As a result, the Human Genome Project had a significant impact, the completion of which coincided with the development of computer technology. In conclusion, now humankind is at the beginning of a new era, which opens up new prospects for maintaining human health. This is facilitated by the use of genetic testing in personalized medicine. That is why federal and international programs for the introduction of genetic technologies require approval.

Keywords: Genetic, Government, Genome, Regulation, federal.

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Programas estatales para el desarrollo de tecnologías genéticas

Resumen

El artículo analiza los programas estatales para la introducción de tecnologías genéticas, sus objetivos y perspectivas de desarrollo a través de métodos comparativos de investigación cualitativa. Como resultado, el Proyecto Genoma Humano tuvo un impacto significativo, cuya finalización coincidió con el desarrollo de la tecnología informática. En conclusión, ahora la humanidad está al comienzo de una nueva era, que abre nuevas perspectivas para mantener la salud humana. Esto se ve facilitado por el uso de pruebas genéticas en medicina personalizada. Es por eso que los programas federales e internacionales para la introducción de tecnologías genéticas requieren aprobación.

Palabras clave: Genética, Gobierno, Genoma, Regulación, Federal.

1. INTRODUCTION

Genomic research is a relatively new area of science that emerged at the turn of the 1980s and 1990s and gained rapid development because of the medical, biotechnological and informational improvement. As interdisciplinary science genomics is aimed not so much at studying the development, structure, organization and behavior of individual genes as at studying the interaction of a set of genes in a given environment. Thus, genomic research is at the intersection of medicine, general biology, bioengineering, computer science and a number of other disciplines

(PUTILO, 2010). The study of the genome of living organisms opens up great prospects for humanity, both in terms of treating and preventing previously incurable diseases, and in the field of gene family planning and bioengineering (ALIMOV, 2019).

At the same time, genomic research directly affects basic human rights (human dignity, privacy, health protection, etc.), therefore it requires strict observance and adoption of relevant documents. Being a comprehensive scientific industry, genomics studies the full spectrum of interactions between body genes: from the action of one gene on other genes and the genome as a whole to the suppression of genes and the possibility of gene modification of a living organism. Genomics has a close relationship with ethics and jurisprudence, which is reflected both in the texts of regulatory legal acts and in codes of conduct for specialists and scientists conducting genomic research.

With the decoding of the human genome and other organisms, biological sciences have entered a new era. Genome maps have become symbols of comprehensive knowledge of the body at a previously unattainable level of completeness (ROGERS, STOKES, DUNN, CAI, WU, HAQ & BAUMES, 2017).

Major technological advances over the past few years have expanded our knowledge of the role of genetics in occupational diseases and our understanding of the genetic components and interactions between genetic prerequisites and environmental factors.

The use of genetic information, along with all other factors contributing to occupational morbidity and mortality, will play an increasingly important role in the prevention of occupational diseases (ASTASHOVA, BONDYREVA & SMANTSER, 2018). Nevertheless, the use of genetic information in research and practice in the field of labor safety and health is a promising area (MCCANLIES & WESTON, 2004). Using genetic information raises medical, ethical, legal, and social issues (MAKSIMENKO, DEYKIN & GEORGIEV, 2013).

The importance of genetically modified organisms (GMOs) cannot be overestimated. As evidenced by modern pharmaceuticals, in particular, recombinant proteins and vaccines, as well as the increased efficiency of the use of GMO crops in agriculture, which contributed to solving the problem of food supplies, etc. Genetically modified (GM) organisms have gained a place in biotechnology: in particular, in bioreactors for the production of recombinant proteins (ENGELHARD, HAGEN & BOYSEN, 2008).

Today in Russia there is a law that is devoted to the legal regulation of human activities in the field of genetic engineering – Federal Law as of 05 Jul 1996, No. 86-FZ on state regulation in the field of Genetic Engineering. This Federal Law defines and consolidates the legal norms that govern the use of genetic diagnosis and therapy in humans. The law provides that genetic engineering activity is based on the following principles:

- Safety of citizens and the environment; the safety of clinical trials of genetic diagnosis methods and gene therapy methods on a somatic cell level;

- The general availability of information on the safety of genetic engineering activities; certification of products containing the results of genetic engineering activities (BRICKMAN, JASANOFF & ILGEN, 1985). Thus, the legislator at the state level enshrines the requirements to which the procedures for genetic research and the use of genetic technologies must comply. First of all, they must comply with the main ethical principles and standards of modern biomedicine.

In September 2013, the Government of the Russian Federation (hereinafter - RF) approved the Decree on the state registration of genetically modified organisms, as well as products obtained with their use (Decree). The Decree consolidated the process of GMOs' registration that are released into the environment for specific purposes:

- Production of feed and feed additives for animals;

- Production of raw materials and food products;

- The cultivation or breeding of modified plants, animals and microorganisms. Under the condition that such production or

breeding is carried out for agricultural use in RF's territory (Kord et al., 2017).

The Decree establishes the rules that determine the functions of various state bodies in the field of registration and control of genetically modified organisms. In particular, the Federal Service for Consumer Rights Protection and Human Well-Being has the power to register modified organisms that are used to produce raw materials for food. At the same time, the modified plants and animals that are intended for breeding in RF, and modified agricultural microorganisms will be registered and controlled by the Federal Service for Veterinary and Phytosanitary Control. The Ministry of Health will maintain consolidated registration of all genetically modified organisms and genetically modified products. The impact of such organisms and products on the environment is to be assessed before registration. The authority to conduct such an assessment is vested in the Federal Service for Supervision of Natural Resources (BRANUM & WOLF, 2015).

RF's Government approved the Federal Scientific and Technical Program aimed at the development of genetic technologies for 2019–2027. The main objectives of this Program are:

- Increasing development of genetic technologies, including genetic editing technologies;

- Creation of scientific and technological groundwork for medicine, agriculture, and industry;

- Improvement of the system of prevention of biological emergencies and control in this area. (Decree of RF's Government as of 22 Apr 2019, No. 479 On approval of the Federal scientific and technical program for the development of genetic technologies on 2019 – 2027).

The program says that in the field of biotechnology (except biopharmaceutical), Russia is far behind both developed and many developing countries of the world. Russia's share in the global market for biotechnological products is less than 0.1 percent. In the segments of biodegradable materials and biofuels, the share is close to zero. The concept of biotechnology in the program is very general. Thus, biotechnology is described as a technology of living systems, namely:

1) A discipline that studies the possibility of using living organisms, their systems or their metabolic products to solve technological problems, as well as the possibility of creating living organisms with the necessary properties by genetic engineering, and

2) Using biological structures for the production of food and industrial products and for targeted transformation. The biological structures, in this case, are microorganisms, plant and

animal cells, cellular components such as membrane cells, ribosomes, mitochondria, chloroplasts, as well as biological macromolecules (DNA, RNA, proteins - mainly enzymes) (LÉVESQUE, JOLY & SIMARD, 2011).

The program is developing in four directions:

- Biosafety and ensuring technological independence;

- Genetic technologies for the development of the agricultural industry;

- Genetic technologies for biomedicine;

- Genetic technologies for industrial microbiology.

It should be noted that the Decree immediately received many positive reviews from the public.

2. METHODOLOGY

It is vital to provide standardized genetic information that can later be interpreted and verified by a third party. Current genetic testing guidelines emphasize the importance of using standardized terminology from established databases. However, while analyzing

SNP (single nucleotide polymorphism), there is no standard terminology for raw genetic data or for documenting risk assessment models (TYUMASEVA, OREHOVA, VALEEVA, SALAMATOV & KALUGINA, 2018).

Some experts are calling for clarity on how federal agencies will regulate the use of gene technology. The release of genetically modified organisms into the environment is likely to fall under the Agreed Framework for Biotechnology Regulation with the responsible federal agency. Namely, the Environmental Protection Agency and the Food and Drug Administration. Ministry of Agriculture bases on existing governing bodies and the intended use of the product (for example, to suppress the target pest or reduce transmission of the disease). In particular, the Food and Drug Administration regulates genetically modified animals in accordance with the new drug regulations of the Federal Law on Food, Drugs, and Cosmetics, while the US Environmental Protection Agency regulates pesticides through federal regulations regarding insecticides, fungicides and rodenticides. The Animal and Plant Health Inspection Service of the US Department of Agriculture also regulates genetically modified organisms that are harmful weeds or maybe plant pests under the Plant Protection Act.

People have empirically learned how to successfully manipulate higher living organisms with limited undesirable side effects. The discovery of DNA and genes has opened up great opportunities for research and biotechnological use. Indeed, the manipulation of isolated

and known genes makes possible more diverse and better controlled genetic modifications.

The introduction of isolated genes into cells became common practice in the 1970s, shortly after the advent of genetic engineering methods. This is significant progress in understanding the function of genes and mechanisms of action. This method is still widely used, and it began to be supplemented in 1980 and 1983 with gene transfer to animals and plants, respectively, to generate genetically modified organisms, also known as transgenic animals and plants. The first transgenic animals, mice, were obtained by microinjection of genes into the nucleus (pronuclei) of one-day embryos. This method could have been successfully extrapolated to other mammals in 1985, but it soon became clear that other methods had to be used for some species. Another problem arose quickly. Transgenes worked, and they were able to cause some phenotypic modifications in animals. The first example was giant mice overexpressing growth hormone genes. It also turned out that transgene expression was not satisfactory and was not easily controlled in all cases (HOUDEBINE, 2009).

In addition, scientific standards are needed for the following:

- Selection and verification of the genetic variants that are used to assess disease risk;

- Assessing the total risk when considering several options;

- Determining appropriate measures for calculating the prognostic value of genomic profiles based on SNP analysis.

The authors KRAFT, WACHOLDER, CORNELIS, HU, HAYES, THOMAS & CHANOCK (2009) explain that standards are important because, although the test persons cannot interpret the results themselves, the genetic information belongs to them. They should be able to get this information in order to get another opinion, as they could with any other test.

3. RESULTS

The Decree of RF's Government as of 22 Apr 2019 clearly defines the goals that the state plans to achieve in connection with the introduction of genetic technologies:

- Increasing development of genetic technologies, including genetic editing technologies;

- Creation of scientific and technological groundwork for medicine, agriculture, and industry;

- Improving measures for the prevention of emergency situations of a biological nature and control in this area.

The main objectives of the program are identified by the legislator:

- Formation of conditions for the development of scientific and scientific-technical work;

- Obtaining and implementing the results that are necessary for the creation of genetic technologies (including genetic editing technologies in the areas of the Program);

- Development of the personnel potential of Russian science and highly professional competencies of researchers in the field of genetic technologies;

- Reduction of the critical dependence of Russian science on foreign databases of genetic and biological data, as well as on foreign specialized software and devices.

The Strategy for RF's Scientific and Technological Development was approved by RF's Presidential Decree dated 01 Dec 2016, No. 642 On the Strategy for RF's Scientific and Technological Development. The Strategy identifies priorities (for the next 10 to 15 years) of RF's scientific and technological development. The latter will allow obtaining scientific and technical results and creating technologies that will be the basis for innovative development of the domestic market products and services, as well as ensure a stable

position of Russia in foreign markets. (RF's Presidential Decree dated 01 Dec 2016, No. 642 On the Strategy for RF's Scientific and Technological Development).

The development of biotechnology is a priority for RF, as indicated in the Biotechnology Development Program until 2020. The Program was approved by RF's Government in 2012. The Program accompanies roadmap Development of Biotechnology and Genetic Engineering.

The Program defines the Ministry of Economic Development as the coordinator of the Program and describes the role and functions of the coordinator. The Program also determines the federal executive bodies that will cooperate with the coordinator in the implementation of the Program. The Program Coordinator forms an interdepartmental council, which will include leading scientists, representatives of business, government, public organizations who will develop the program's strategy.

Federal Law as of 05 Jul 1996, No. 86-FZ On State Regulation in the Field of Genetic Engineering establishes that the persons working in the field of genetically modified organisms should be responsible for the following:

- Safety of the population and the environment;

- Availability of information on the safety of genetic engineering activities;

- Certification of products that contain the results of genetic engineering;

- State registration of genetically modified organisms that will be released into the environment.

- State registration of products resulting from the use of genetically modified organisms or containing such organisms.

The Law requires the certificates to provide complete information about the methods by which such a product was obtained and its properties. The Law also provides that products and services that are developed through genetic engineering must meet not only environmental safety requirements but also public health and pharmacopeia.

Certain types of new food products, materials that are manufactured and intended for sale in RF's territory or those that are first imported into RF's territory must undergo the state registration procedure. The government has developed a special procedure for the export control of genetically modified microorganisms (GMMs). In accordance with this procedure, RF's President in 2007 approved a periodically updated list of GMMs and genetic elements authorized for

export from Russia. The latest updates on the list were made in July 2013.

Russia is engaged in genome editing. A federal program of 111 billion rubles (1.7 billion US dollars) is aimed at creating 10 new varieties of genetically edited crops and animals by 2020 and another 20 by 2027. Aleksei Kochetov, Director of the Institute of Cytology and Genetics of the Siberian Branch of the Russian Academy of Sciences (RAS), has welcomed the research program, noting that genetics in Russia has been chronically underfunded for decades. Science funding declined sharply in the 1990s after the collapse of the Soviet Union. Russia still lags behind other major states: in 2017, Russia spent 1.11% of its gross domestic product on research, compared with 2.13% in China and 2.79% in the United States.

4. CONCLUSION

Currently, the Russian Federation lags behind the United States or Europe in the implementation of genetic technologies. That is why RF's President and Government have adopted the indicated regulatory legal acts in order to support the development of genetic technologies. For example, medical genetics helps to prevent many genetic diseases through timely diagnosis. Thanks to modern technologies, it is possible to prevent metabolic disorders, congenital malformations, chromosomal abnormalities, and many others. The main goals of

medical genetics are caring for specific people, their families, as well as physically and mentally healthy generation. In Russia, the legal regulation of genomic research currently consists of by-laws, primarily the Decrees of RF's President.

This is due to the possibility of RF's Presidential Decrees to regulate public relations that have not received the relevant regulation by federal law provided for in article 90 of RF's Constitution. The considered sphere of public life, affecting human rights issues, protection of personal data, intellectual property, as well as the strategic development of domestic science should be stated in a special federal law. At the same time, it is impossible to ignore the possibilities of regulating certain aspects of genomic research by RF's administrative subjects, which is justified both from the point of view of federalism and the need to take into account the cultural, national, socio-economic and other specifics of each RF's subject (ALIMOV, 2019).

The United States provides a range of legal guarantees for citizens in the field of genomic research. This relates to the obligation to preserve genomic information, the prohibition of its unauthorized transfer and use (in this case, there is a certain discretion at the national and state levels), as well as the protection of citizens from genetic discrimination, which primarily occurs in labor relations and the field of human insurance. The standards for conducting genetic and genomic research are designed to overcome the deficiency of legal

regulation in this sphere since genomic research can get out of control, which might create multiple problems in law, ethics and human biology (ALIMOV, 2019).

The main tasks of the state are the development of genetic technologies, including genetic editing technologies and the creation of scientific and technological departments in medicine, agriculture, and industry. These tasks can be accomplished by improving the precautionary measures in emergency situations of a biological nature and control in this area.

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