Biotechnology as a Type of Converged Technologies in Industry 4.0 and a Source of Increased Danger in Civil Law of the Russian Federation

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Abstract. Purpose: the research of the significance, positive and negative socio-economic factors, features of scientific, technological and legal development of biotechnology in Russia and in the world; the identification of the existing problems of the legal regulation of biotechnology in Russia; studying the experience of foreign countries in the legal regulation of biotechnological activities; studying the characteristics of biotechnological objects to correlate them with the sources of increased danger, including the activities related to the development, creation and testing of viruses, as having increased danger to others.

Design/Methodology/Approach: Industry 4.0 leads to the mass introduction of cyber-physical systems in production, to the automation of most of the production processes, to the endowment of devices with artificial intelligence and the introduction of many other modern technologies. Biotechnology is an integral part of Industry 4.0, which involves a rapid breakthrough in the research of medicines, diagnostic methods, finding new vaccines, creating the ways to protect human organisms and biosystems, and creating artificially modified biological microorganisms. The demand for biotechnology creates the need to create and improve the legal framework for biotechnological developments. The authors used the methods of systematic analysis and comparative legal analysis to identify and consider the existing problems of the legal regulation of biotechnology in Russia.

Findings: biotechnology implies significant changes in various spheres of society’s activity, including a positive modification of the medical sphere, due to the wide spread of new methods of personalized medicine, and an increase in the efficiency of treatment. The issue of recognizing the increased harmfulness of certain objects or activities in relation to such areas of biotechnology as the energy waste management, biofuel production, bioenergy engineering, the prevention and elimination of environmental pollution, bioengineering, breeding technology, production of electrical energy from biomaterials, etc. remains
unresolved. The liability for causing harm by activities that create increased
danger, due to the inability of a person to fully control it, is one of the gaps in
the current civil law regulation. The justification and assessment of recognizing
certain specific types of biotechnology as a source of increased danger have yet
to be objectively justified by the doctrinal basis, judicial practice and the
regulations.

**Originality/Value:** it is concluded that the high prospects of the theoretical
biotechnological developments cause the need for their legalization and leg-
islative regulation. Based on the danger, harmfulness and uncontrollability
of viruses, any activity related to viruses, from their creation to the work of medical
staff to treat an infected person, is recommended to be recognized as a source of
increased danger.

The definition of the source of increased danger is given, and the criteria for
classifying an object as a source of increased danger are called. The identified
criteria are compared with the characteristic features of biotechnological objects.
It is suggested that the activities associated with the risk of infection with
infectious diseases be considered a priori as a source of increased danger. The
inability of a person to control the spread of viruses, including infection,
harmfulness and increased probability of causing harm, prove the need for a
separate indication in the legislation of this source and the adoption of appro-
priate measures for any activity in which a person is directly exposed to the
contact with infection and the threat of infection and spread of the disease.

**Keywords:** The fourth industrial revolution · Industry 4.0 · Cyber physical
systems · Digital technology · Biotechnology · Bioterrorism · Viruses · Civil
law · Source of increased danger

**JEL Code:** F63 · K13 · K15 · K32 · K24 · K42 · L65 · O14 · O31 · O33

1 Introduction

The technological progress has an impact on all spheres of society’s life. Industry 4.0 is
the fourth industrial revolution, as a result of which the cyberphysical systems con-
ected to the single Internet network will be implemented in the countries’economy
and in a number of other functional areas. It is supposed to automate the existing
processes, expand and use completely new models and technologies. Such factors as
urbanization, technological progress, and environmental crises can be considered
the prerequisites for the formation of the fourth industrial revolution. One of the main tasks
of the fourth industrial revolution is to create the digital systems that will change the
traditional economic, social, political and other processes through the digital mod-
ernization (Babkin, et al. 2013). The basis of the concept is the achievement of such
goals as the unification of all subjects in the single network “Internet”, the transparency
of information, the bifurcation of the functional human systems into the digital and real
(physical) ones, where the digital one replaces and complements the imperfect func-
tions of reality; (Ustinova 2018) remote communication and human control of
machines and mechanisms; replacing human functions with automated systems, sim-
plifying a number of control combinations and enabling the technologies to
autonomously regulate a given process. In the context of the global economic crisis, it is necessary to maintain and develop the existing trend of transformation of production which can ensure the stability of economic competitiveness. Such a tool is the multifunctional use of the digital technologies that lead to the beginning of a new period of economic activity of mankind.

One of the important elements directly related to the preservation of biological health and the fullness of human life in the new economic, social and environmental realities is the development of biotechnology. The world community is actively developing this industry, considering it vital, so it is quite natural to make a large scale of investment in this area. The replacement of the traditional production with the biotechnological production is becoming more and more noticeable. However, Russia does not take a leading position in the bioindustry development. The highest percentage of the use of biotechnology has on the development of biopharmaceuticals.

Biotechnology is a form of consolidation of biology and technology aimed at meeting the needs of humanity with the help of the environment. The demand for biotechnology creates the need to create and improve the legal framework for biotechnological developments.

2 Materials and Methods

The normative basis of the study was made up of the international and national legal acts, as well as various documents of a programmatic nature. In particular, the Comprehensive Program for the Development of Biotechnology in the Russian Federation until 2020 approved by the RF Government Decree No. 1853p-P8 of April 24, 2012 on the priority areas of biotechnology development in Russia. The study also examined the norms of the national legal acts that indirectly regulate biotechnology, including: Federal law No. 323-FZ “On the Basics of Public Health Protection in the Russian Federation”, Federal law No. 86-FZ “On State Regulation of the Field of Genetic Engineering”, and others. The norms of the Civil Code of the Russian Federation served as the basis for the analysis of the criteria for sources of increased danger and the possibility of assigning biotechnological objects to this category.

The theoretical basis of the research is made up of the works of the Russian researchers who consider certain issues related to the technological development, the emergence and legal regulation of biotechnology, the recognition of biotechnological objects as a source of increased danger Babkin et al. (2013), (Onishchenko 2000), Krasavchikov (2005), (Rakhmanova et al. 2001), (Sergiev et al. 2000), (Supotnitskiy 2000), Ustinova (2018), Vanchukhina et al. (2019).

The main methodological step of the research is a systematic analysis of the current civil law regulation of sources of increased danger and the possibility of assigning biotechnology to this category in a comparative law comparison with the complex approaches to the legal regulation of biotechnology demonstrated in the international and foreign normative legal acts.
3 Results

The effects of introduction of biotechnology in public life.

Let’s consider the expected effects due to the use of biotechnology in public life in order to give a correct legal assessment of its legal nature. Biotechnology, following the prospects of development after the active implementation, assumes the presence of significant changes in various areas of the company’s activities. Thus, a positive modification of the medical sphere is expected, due to the wide spread of new methods of personalized medicine, increasing the treatment efficacy. Considering the industrial and agricultural production, we expect an increase in food and industrial products, their reliability and safety. The positive dynamics of the environmental area is assessed, which is mediated by the modern methods of eliminating pollution and preventing it, as well as other spheres of social activities.

Biotechnology is based on the science of genetic engineering and cellular technology for the production and application of transformed biological substances obtained with the help of natural biological objects (microorganisms, cells, molecules, etc.) in order to produce new biological systems for various purposes.

There are the following main areas of biotechnology:

– biotechnology of pharmaceutical products;
– biotechnology of food products;
– biotechnology of industrial and household products (extraction, processing of natural resources);
– biotechnology of objects for agriculture (the creation of new types of fertile crops, animal breeds);
– ecological biotechnology (the biological cleaning of polluted soil, reservoirs);
– bioenergetics;
– genetic engineering (the creation of new DNA and RNA molecules);
– biochemistry, etc.

Biotechnology, as a process, has the unique properties that make it possible to obtain products for health care, industry, agriculture and other industries, including the products that arose only at the expense of biotechnology. Using the methods of biotechnology, it became possible to construct in genetic and cellular engineering, which directly forms the heredity and vital activity of living organisms. It becomes possible to create new substances and organisms with the useful properties that have not existed before. Biotechnology is highly useful, because the profitability of its use has a positive impact on the productivity and environmental friendliness of the processes. Biotechnology allows us to create new industrial productions, ensures the rationalization of the natural resources consumption, positively influences the environment and significantly improves the system of reproduction of objects known to society.

However, when analyzing the problems of the current legal regulation of biotechnology, it is impossible not to take into account the risks of the negative consequences of the use of biotechnology. In particular, it should be noted that the doctrine of Russian law, confirmed by the judicial practice, recognizes biological
objects and materials as a source of increased danger (Krasavchikov 2005). However, the limits of application of the norms of article 1079 of the Civil Code of the Russian Federation, which contains the characteristic of a source of increased danger, are limited by the ambiguous interpretation in science and judicial practice. Let’s study this question in more detail.

3.1 The Legal Regulation of Biotechnology in the Current Russian Legislation

The international regulation of biomedical research is based on the 1997 Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine. The Convention is the only international legal instrument for the protection of human rights in the field of biomedical innovation. This legal act is aimed at protecting the interests and benefits of the person, the individual, and not society as a whole. The Russian Federation have not signed this Convention for unfounded reasons, but an alternative legal act has been adopted within the framework of the CIS cooperation: the Model law “On the Protection of Human Rights and Dignity in Biomedical Research in the CIS Member States”. The law provides for the protection of the rights and dignity of participants in biomedical research in all countries of the world and applies to all citizens of the states conducting biotechnological activities and all the institutions and legal entities engaged in this specific activity. This law specifies the need for an ethical component to be evaluated by a specialized ethics committee when developing the biotechnological tools.

The principles contained in these acts are disclosed in the Federal law of 22.12.1992 “On Transplantation of Human Organs and Tissues”, which regulates the procedure for transplantation of human organs and tissues, excluding the organs related to human reproduction, blood and its components.

It is noteworthy that the Russian Federation does not have a single statutory regulation of biotechnology as a separate institution of law. Russia is not a party to the important European Convention for Human Rights and Biomedicine and its existing three additional Protocols: the 1998 Additional Protocol on the Prohibition of Human Cloning; the 2002 Additional Protocol on Human Organ and Tissue Transplantation; and the 2005 additional Protocol on Biomedical Research. An alternative to these acts was Federal law No. 54-FZ dated 20.05.2002 “On the Temporary Ban on Human Cloning”, which, accordingly, contains the provisions prohibiting human cloning until the adoption of a normative act regulating this process, as well as prohibiting the import of cloned human embryos to Russia.

Given that there is currently no existing law approving the development program or other provisions related to the regulation of biotechnology one should be guided by the Comprehensive Program for the Development of Biotechnology in the Russian Federation until 2020, approved by the RF Government Decree No. 1853p-P8 of April 24, 2012. This program highlights the priority areas for the development of biotechnology, such as (“VP-P8–2322. Comprehensive Program for the Development of Biotechnology in the Russian Federation until 2020” (appr.by the Government of the Russian Federation 24.04.2012 No.1853p-P8)): biopharmaceutics and biomedicine; industrial
biotechnology and bioenergy; agricultural biotechnology; forest biotechnology; environmental biotechnology; marine biotechnology.

Along with the legislative provisions that regulate the development of biotechnology, various regulations that indirectly regulate biotechnology in Russia are indirectly applied, for example, Federal law No. 323-FZ “On the basics of public health protection in the Russian Federation”, Federal law No. 86-FZ “On state regulation of the field of genetic engineering”, etc.

3.2 Biotechnology as a Source of Increased Danger in the Scientific Doctrine, Judicial Practice and the Legislation

Let’s return to the question of the limits of application of the norms of Article 1079 of the Civil Code of the Russian Federation, which contains a characteristic of the source of increased danger. The difficulty of interpreting the source of increased danger lies in the heterogeneity of its definition. The specified source can be either an activity that has a specifically dangerous character, while an activity with the same material object is safe, or a material object, whose use in any type of activity without exception carries a danger to the surrounding world. If you literally interpret the concept under study, then the source of increased danger is understood as the method of occurrence of the possibility of harming the individual, society, and the state.

The identification of types of sources of increased danger indirectly affects the law enforcement in Russia (for example, the legal regime of these objects depends on whether viruses can be classified as sources of increased danger or not). At the moment, the Russian legislation does not contain an exhaustive list of objects or activities that can be classified as a source of increased danger. A number of legal acts classify certain specific groups of material objects or activities as sources of increased danger, but this list is not consolidated or specified.

The judicial practice requires the adoption of a general list of cases involving civil liability arising from the infliction of harm by a source of increased danger and the establishment of criteria for classifying a specific jural fact as increased danger.

The definition of the essence and degree of concretization of the criteria for attributing a certain material object or activity to a source of increased danger gives rise to a lengthy discussion in the field of doctrinal law.

The source of increased danger can be clearly recognized as an activity or material object that directly poses a danger to the surrounding world. In accordance with the definition of the Supreme Court of the Russian Federation, increased danger is recognized as such if there is a high probability of harm. Thus, the main criterion for classifying a certain object of the material world or activity as a source of increased danger can be recognized as an increased probability of harmful consequences, in contrast to ordinary objects and non-dangerous activities. From this point of view, a number of biological objects can be recognized as sources of increased danger, including viruses, harmful bacteria and infections.

The objective category of a source of increased danger implies the occurrence of a malicious situation directly due to the operation of the source in question while an important distinguishing feature of the source of increased danger can be recognized as the lack of full human control over the malicious object. Namely, the operation of the
source of increased danger that complies with all the technical regulations does not provide a proper guarantee of safety for both the operator and the environment.

The modern legislation provides for an open and approximate list of sources of increased danger, summarized in Article 1079 of the Civil Code of the Russian Federation. Resolution No. 1 of the Supreme Court of the Russian Federation clarified that the court, taking into account the specific properties of the object, can recognize a specific activity that is not provided for by law.

The most universal and generally accepted concept for determining the types of sources of increased danger is the classification proposed by O.A. Krasavchikov (Krasavchikov 2005). According to the classification presented in the twentieth century, the sources of increased danger have a gradation of four types:

1. Physical objects, which include mechanical, thermal, and electrical objects;
2. Physical and chemical (radioactive materials);
3. Chemical, for example, certain gases, poisons, fuels;
4. Biological, which are divided into microbiological and zoological objects.

This list is generalizing and is widely used in the doctrine of civil law, however, given the current specific conditions of the development of the world production, based on the rapid growth of new technologies, methods and means of production, the discovery of new types of microorganisms and their development, etc., it is becoming increasingly urgent to improve the criteria and classification of the sources of increased danger.

The absence of a legal definition of the source of increased danger characterizes the attempts to systematize the object under study as useless.

The cases of attributing an object to a source of increased danger are reduced to obvious and difficult to identify. An example of the sources of increased danger which are difficult to determine, are biological, including microbiological substances and matter (bacteria, viruses). However, not all microbiological organisms, such as bacteria, are dangerous and harmful to the surrounding world.

Biotechnology is an integral part of Industry 4.0, which involves a rapid breakthrough in the research of medicines, diagnostic methods, finding new vaccines, creating the ways to protect human organisms and biosystems, creating artificially modified biological microorganisms, etc. Viruses, as objects of biotechnology, occupy a special place in modern innovations (Onishchenko 2000). The use of unique properties of viruses in the process of biotechnological activities has led to a new stage in the development of pharmaceutical production, the emergence of new methods of using the biological systems and industrial production. Virus biotechnology makes it possible to make a big leap in the formation of the latest medical system.

It should be noted that a number of authoritative scientists adhere to the general form of classification proposed by O. A. Krasavchikov (Krasavchikov 2005). Expanding the interpretation of the proposed concept, it is necessary to pay attention to the biological type of sources of increased danger, which contains, in particular, such biological materials as viruses. Thus, in the last century, the understanding of viruses as a source of increased danger was established.
3.3 The Objects of Biotechnology as an Effective Means of Bioterrorism: The Concept and Criteria for Classification as a Source of Increased Danger

Biotechnology involves activities related directly to the genetic engineering modification of viruses, which allows you to create effective vaccines and recreate new treatments. However, the issue of recognizing activities related to the development, creation and testing of viruses as activities that have increased danger to others remains unresolved (Supotnitsky 2000). There is no denying that the level of development of this industry is significantly behind the pace of foreign countries (the USA, China etc.), and, accordingly, is characterized by the lack of scalability of this activity, which leads to the effective regulation by the state.

The infectious diseases caused by viruses pose a great threat to human life and health (Sergiev, et al. 2000); they cause pandemics and epidemics (for example, the pandemic of 2020 due to the spread of the COVID-19 virus (coronovirus)). At the moment, especially dangerous viruses can be recognized as a number of 10–15 pieces, which include artificially created ones. Such viruses are evaluated as an effective means of bioterrorism.

Bioterrorism is a malicious, deadly, uncontrolled threat to humanity. A malicious situation is one in which the activity of using the source of danger is not under the full control of the person who is carrying it out, and by its very nature, even the correct use of it cannot guarantee that there will be no socially dangerous consequences. Therefore, based on the danger, harmfulness and uncontrollability of viruses, any activity related to viruses, from their creation to the work of medical staff to treat an infected person, it should be recognized as a source of increased danger.

The activities associated with the risk of infection with infectious diseases are a priori characterized as a source of increased danger. The lack of human control over the spread of viruses, including infection, harmfulness and increased likelihood of harm, proves the need for a separate indication in the legislation on this source and the adoption of the appropriate measures for any activity in which a person is directly exposed to contact with the infection and the threat of infection and spread of the disease. The activity of a legal entity associated with the risk of infection carries a large uncontrolled threat of causing serious consequences to an indefinite circle of persons (Rakhmanova, et al. 2001).

There is no denying that not all biotechnologies can be considered a source of increased danger. The issue of recognizing the increased harmfulness of certain objects or activities in relation to such areas of biotechnology as the energy waste management, biofuel production, bioenergy engineering, the prevention and elimination of environmental pollution, bioengineering, breeding technologies, the production of electrical energy from biomaterials, etc. is unresolved. The justification and assessment of the recognition of certain specific types of biotechnology as a source of increased danger has yet to be objectively supported by a doctrinal basis, judicial practice and the regulations.
4 Conclusion

It can be concluded that biotechnology as a type of convergent technologies and an integral part of Industry 4.0 involves the creation and development of biological materials based on the latest chemical technologies, as well as the production of biological objects necessary for society using living organisms and biological processes. Biotechnology, solving specific problems of science and production, accelerates the scale of human impact on nature, acting as an anthropogenic factor in the adaptation of the biological world to the modern level of human evolution.

The identification of types of sources of increased danger indirectly affects the law enforcement in Russia (for example, the legal regime of these objects depends on whether viruses can be classified as sources of increased danger or not). At the moment, the Russian legislation does not contain an exhaustive list of objects or activities that can be classified as a source of increased danger; this list is not consolidated or specified. The judicial practice requires the adoption of a general list of cases involving civil liability arising from the infliction of harm by a source of increased danger and the establishment of criteria for classifying a specific juridical fact as increased danger. The doctrine of Russian law confirmed by the judicial practice recognizes biological objects and materials as the source of danger, but the difficulty of interpreting the source of danger, as well as determining the nature and extent of concretizing the criteria for classifying a particular material object or activity as a source of danger gives rise to discussion.

Thus, we believe that the high prospects of the theoretical biotechnological developments cause the need for their legalization and legislative regulation. The source of increased danger should be recognized as an activity or material object that directly poses a danger to the surrounding world and is more likely to cause harm.

The following factors are recommended as the main - unconditional criteria for assigning a certain object of the material world or activity, and in this case, the object of biotechnology, to a source of increased danger:

- the presence of an increased probability of malicious consequences;
- the possibility of a malicious situation occurring directly due to the exploitation of the source in question;
- the lack of guarantees of occurrence of socially dangerous consequences even in the case of proper operation and proper use of the object;
- the lack of full human control over a malicious object.

It is proposed that article 1079 of the Civil Code of the Russian Federation, which establishes the rules on the liability for harm caused by activities that create increased danger to others, make additions to the definition of a source of increased danger, as well as the main criteria for the object's being classified as a source of increased danger.

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