



MOBILIZATION PROJECT FOR SECURING THE BIOSAFETY AT THE NATIONAL AND INTERNATIONAL LEVELS: ORGANIZATIONAL AND LEGAL SUPPORT

PROJETO DE MOBILIZAÇÃO DE BIOSSEGURANÇA EM NÍVEL NACIONAL E INTERNACIONAL: A GARANTIA INSTITUCIONAL E JURÍDICA

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RESUMO

Objetivo: O objetivo do estudo era fundamentar a necessidade de criar um projeto de mobilização, para investigar a correlação entre a economia de mobilização e o projeto de mobilização na área de biossegurança dos estados.

Método: O tema foi explorado utilizando métodos científicos gerais de conhecimento (análise sistemática, teórica), métodos históricos, jurídicos comparativos e lógicos.

Resultados: Foi estudada a experiência russa de mobilização de recursos para resolver projetos estrategicamente importantes para o estado e a sociedade. Os autores fundamentam a necessidade de desenvolvimento de um projeto de "Garantia de Biossegurança", formação de bases científicas, organizacionais e legais do Escudo Sanitário do Estado. Segundo os autores, a pesquisa científica fundamental e aplicada no campo da segurança biológica é uma esfera complicada de atividades científicas, inovadoras e práticas, atuando como um dos motores do desenvolvimento acelerado não



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só do segmento "estreito" de serviços, obras, bens, tecnologias, mas também de biomedicina e biofarmacêuticos.

Conclusões: Sobre a base científica, tecnológica, organizacional e legal, é possível implementar o Projeto Biomédico e, posteriormente, o Projeto Biológico, que forma os contornos da bioeconomia, no futuro.

Palavras-chave: regulamentação legal, biossegurança, escudo sanitário estatal, desenvolvimento biotecnológico, Projeto Biomédico.

ABSTRACT

Objective: The purpose of the study was to substantiate the necessity of the mobilization project, to study the correlations between mobilization economy and the mobilization project in the sphere of biosafety.

Methods: The problem is developed from the standpoint of general scientific research methods (systemic and theoretical analysis), as well as the historical, comparative-legal, and logical.

Results: The article examines the experience of Russia in mobilizing resources for the implementation of projects of strategic importance for society and the state. The authors substantiate the necessity of developing "The Biosafety Securement Project" and the development of scientific, organizational, and legal foundations for the country's Sanitary Shield. It is argued that fundamental and applied research on biosafety securement is a complex area of scientific, innovative, and applied work driving the accelerated development of not only the "narrow" segment of services, activities, goods, and technologies but biomedicine and biopharmaceuticals as well.

Conclusions: The emerging scientific and technological, organizational, and legal base can provide for further realization of the Biomedical Project, and later on – for the Biological Project shaping the outlines of bioeconomy.

Keywords: legal regulation; biosafety; state sanitary shield; biotechnology development; Biomedical Project.

1. INTRODUCTION

The novel coronavirus pandemic has demonstrated to the politicians, governors, and legislators of many world countries the vulnerability of national biosafety and healthcare systems, as well as deficiencies in the scientific and scientific-technical components of biosafety. In many countries, an active search for solutions to these



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problems from the standpoint of biological and other types of security in the context of existing and possible threats and risks has been initiated. In the scientific and technical sense, research in biology, medicine, and pharmaceuticals will have to be conducted to quickly create and reconfigure the existing platforms to meet new challenges in order to mitigate the emerging threats and risks to biosafety. There is a need to reformat the available forces and means in the field of biological, medical, and pharmaceutical science so as to be able to address the problems of biological security in a short time and with sufficient efficiency. It is also necessary to reconfigure law and legislation to address the new biotechnological reality based on the current and projected threats and risks in the area of biosafety. The situation requires the formation of special (pilot, experimental, preferential) legal regimes for subjects engaged in scientific and innovative activities in the field of biosafety. Moreover, there is a need to develop the legal foundations for the functioning of the biosafety securement system and its individual elements in times of extraordinary legal regimes (including epidemics) or in preparation for the introduction or deployment of such regimes.

In connection with the above, literature and practice increasingly often raise the question of the preparation and implementation of the Mobilization Project in the field of biosafety.

2. METHODS

The research process employs general scientific research methods including the principles of objectivity and consistency. The problem is also explored from the position of such methods as historical, comparative-legal, logical, technical-legal analysis, concretization, interpretation, and other methods of research.

3. RESULTS



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The issues of implementation of the Mobilization Project as a whole or its individual components have not received much attention in the Russian legal literature in recent years. At the same time, in the economic literature, authors periodically refer to the problems of the mobilization economy. In this regard, we propose to approach the mobilization project from the standpoint of the mobilization economy. Let us consider the main approaches to understanding the mobilization economy.

L.I. Abalkin (2002) interprets the mobilization economy as an anti-crisis economy associated with extraordinary circumstances. In this definition, a positive indication is the emergency, atypical, extraordinary nature of the circumstances arising, which forces the authorities to look for quick solutions guaranteeing the necessary result.

O.V. Lagutin (2016) points out that a number of historical stages show demand for the mobilization type of economy characterized by the identification of priority economic units (from economic sectors to individual enterprises), centralized management, long-term planning, and major participation of the state in the economic sphere.

According to S.G. Glazev (1999), a mobilization economy is a system of regulation of economic relations that ensures the best, maximum use of its resources. This definition emphasizes a certain combination of resources in the regulation of certain groups of relations. Meanwhile, specific economic, geopolitical, and other factors and conditions of economic management do not always allow discussing an efficient, better use of resources. Uncoincidentally, A.G. Fonotov (1993) understands the mobilization system as development focused on the achievement of emergency goals through extraordinary means and forms. The author argues that the leading priority in such a system is the unconditional achievement of the set goal and deadline. Economic feasibility and efficiency are not major concerns. Later, V.V. Sedov (2003) focused on concentrating resources and counteracting the threat to the existence of the country as a whole. In his opinion, the state is the only entity capable of mobilizing the available resources to solve its own problems.



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Of interest is also the approach proposed by A.G. Dugin (2006), which suggests that the mobilization economy is focused on the development of individual strategic areas in cases where the state needs to make a technological breakthrough.

Due to the scarcity of resources, economic and other breakthroughs are possible only in some and not all areas of technological development. Moreover, such development is not always fully determined by purely economic factors. For example, the implementation of the Atomic Project required from the USSR colossal efforts and the concentration of scientific, technical, financial, military, organizational, medical, and other resources on a separate group of activities. At the same time, the possible prospects for widespread use of the project's anticipated results for the national economy at the time were highly questionable.

In connection with the above, in our view, a mobilization project as a vanguard, advanced project (a relatively isolated part of the economy of a new, innovative type) involves the concentration of available state and society resources on a separate or several interrelated areas of activity that are of strategic importance for the state and (or) ensure its security. In the future, other non-mobilization-type projects can be developed on its basis.

3.1 Historical background

For Russia, with its rather common characteristic of pronounced state intervention in the economy, as well as in the socio-cultural sphere, the question of the mobilization project is not only and not so much of theoretical interest, as of practical interest. Russia almost constantly finds itself at the center of geopolitical, economic, military, and other interests of the world's major players, which could not but affect the most important decisions taken by the authorities in the economy, national defense, and state security.

In the modern understanding, individual elements of the mobilization economy, its organizational, and legal foundations began to take shape in the country a little more than a hundred years ago, with the beginning of the First World War. At that time, four Special



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Meetings were created: on defense, fuel, transport, and food. The jurisdiction of the Special Meetings included the issues of placement and control of the main state orders.

Fixed prices were introduced for certain types of foodstuffs. The ineffectiveness of the policy of price containment on basic foodstuffs during the war led to the introduction of the state monopoly on bread in early 1917. Due to the fact that these institutions and norms of the mobilization economy emerged rather late, their actual efficiency is noted to be low (Bokarev, 2015).

The Bolsheviks, upon coming to power, continued their earlier policy, drawing conclusions about the causes and conditions that contributed to the development of crisis phenomena in the economy in virtually all of its major industries and sectors. The monopoly on foreign trade was introduced at the beginning of 1918. By the middle of the same year, the domestic trade monopoly was introduced. From that moment, the state became the only legal buyer of agricultural products (primarily bread and other crops).

By the end of the civil war, some of the harsh administrative measures started to wind down in one way or another. However, the presence of external and internal threats to the young state forced politicians to search for necessary solutions. It is no coincidence that in 1926, the Regulation on the Preparatory Period for War was drawn up, and the Organizational and Mobilization Department of the Red Army (WPRA) was established.

In 1927, first a commission and then the Ordinary Session of the Council of Labor and Defense and the Defense Sector of the USSR Gosplan were created. The end of 1927 also marked the start of work on the preparation of medium-term plans for the construction of the armed forces of the country and the national economy.

At the November plenum of the Central Committee of the Communist Party of the Soviet Union (Bolshevik) in 1928, Stalin uttered his famous thesis: "We are 50 to 100 years behind the advanced countries. We must run this distance in ten years. Either we do it, or we will be crushed" (Stalin, 1949).

Since 1929 industrialization of the country with an emphasis on mechanical engineering and the production of means of production became a priority. By the end of



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the 1930s, the basis of a mobilization economy had been established, which showed its effectiveness during the Great Patriotic War and the postwar reconstruction period.

In addition, we cannot but note the educational, scientific, and technical components of the mobilization economy.

Russian literature even indicates the formation of the state concept of science mobilization by the 1920s (Berliavskii, 2004). The state scientific policy was being developed at an accelerated pace by the representatives of the party elite and some scientists, the network of educational and scientific organizations of the country was formed based on the main priorities of its development for the upcoming decades.

In the mid-1930s, young specialists started to be assigned to enterprises and organizations. According to the Decree of the Central Election Committee and Council of People's Commissars of the Soviet Union "On Improving the Use of Young Specialists", graduates of universities and technical colleges were obliged to work for five years at production facilities by assignment. They were not allowed to work in jobs other than their specialty. The placement was centralized in the hands of specialized commissariats (ministries).

It should be noted that with the beginning of the Great Patriotic War the system of state administration underwent some changes. In the summer of 1941, the USSR State Defense Committee (SDC USSR) was established as the entity entrusted with solving military and strategic issues and the formation of reserves. It also coordinated the work of all the organs of state power and administration. The activities of the government were also modified: the Council of People's Commissars of the USSR now managed the industries and sectors of the economy not directly related to military production and the provision of the front with weapons and military equipment (Makedonskaia, 2015).

Already in June of 1941, the plan of work of the USSR Academy of Sciences was majorly revised. The main area of its work became the development and introduction of new models of weapons and equipment, the mobilization of available resources, and the search for new materials. In the same period, Soviet scientific institutions and design bureaus began to be evacuated to the rear. The Scientific and Technical Council



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comprised of prominent scientists was created under the SDC USSR. Later on, special commissions were also established in the regions by branches of science and technology. For example, the Military Sanitary Commission (headed by Academician L.A. Orbeli) led the developments in the field of medical support of the troops, anti-epidemic service, and introduction of new methods of treatment of the wounded and sick. During this period, Penicillin and Gramicidin C antibiotics, methods of mass blood transfusion, the method of local anesthesia, the vaccine against tularemia, and a polyvalent vaccine (against seven infections) were developed, improved, and introduced into general practice.

In the army and navy, scientific activity was coordinated from 1940 and after the end of the Great Patriotic War by the Scientific Medical Council created and functioning under the Chief of the Main Military Sanitary Directorate. During the war period, four plenums of the Council were held, as well as a number of meetings of its separate sections. At those meetings, the instructions, methodical recommendations, and other documents were discussed and adopted. In the postwar years, the 35-volume work "Soviet medicine experience in the Great Patriotic War 1941-1945" based on the accumulated experience was prepared and published.

The Atomic Project became the most critical complex mobilization project of the 1940s and mid-1950s in the Soviet Union. As we know today from declassified materials, work on uranium was initiated by a secret order of the State Defense Committee № 2352 of September 28, 1942, which instructed Academician A.F. Ioffe to resume work on the use of atomic energy. The same document established the atomic nucleus laboratory (Kruglov, 1995). I.V. Kurchatov subsequently assumed scientific leadership of the project. The work on the Atomic Project lasted throughout his life. Atomic and hydrogen weapons were created and the world's first nuclear submarine and nuclear icebreaker were built during these years. The foundation of nuclear power was laid. In two decades, the USSR created a reliable nuclear shield and began the process of mastering nuclear energy to solve a wide range of national economic problems (energy, transport, medicine, etc.).

The mobilization regime was gradually phased out in the USSR by the mid-1950s to soon be replaced by a period that historians would later call "stagnation".



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3.2 Characteristics of the modern period

The modern economy and advanced science are in crisis. The problems of innovative development outstripping the development of science and technology are increasingly making themselves felt.

It is enough to look at the documents of the last decade, in which the problems of innovative development are increasingly often identified, but not always solved, for example, the Presidential Decree № 899 of July 7, 2011 “On Approval of Priority Areas for Development of Science, Technology and Engineering in the Russian Federation and the List of Critical Technologies of the Russian Federation” and Resolution № 316 of the Russian Government of April 15, 2014 “On Approval of the State Program of the Russian Federation ‘Economic Development and Innovative Economy’”.

Despite considerable investment in science, the return on the funds invested is extremely low. Business is also reluctant to actively invest in long-term scientific projects and startups. This is especially true in the spheres associated with the provision of certain types of security. Problems in the sphere of the state defense order forced the legislator to adopt Federal Law № 275-FZ of December 29, 2012 “On the State Defense Order”. In this context, the economic literature increasingly points to market failures and the inability of businesses to meet the increasing economic, geopolitical, and social needs on their own without state support.

Attempts are made to single out the “social” economy as a set of new, progressive economic relations. Meanwhile, such an economy is not at all opposed to the mobilization economy. According to Iu. Pavlenko, in modern domestic realities, it is appropriate to talk about the two-sector model of the economy: on the one hand, there is the public sector, whose main task is the implementation of infrastructure and defense projects, on the other – there is private entrepreneurship (Pavlenko, 2020). In our view, in particular spheres, success can be secured through public-private partnership projects. In the context of the



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mobilization economy, T.V. Martynenko (2021) suggests more active state support of industry in strategically important areas.

What can be highlighted as a positive example is the experience of China with its securing rapid economic growth observed in the midst of the global economic crisis of 2008-2010. One of the pivots of China's economic development was investment and innovation activity. In this, state investments in promising innovative projects are the first priority. They are followed by private investments. It is important to note that China has not invented anything new: this is a widely known scheme used by the USA to stimulate innovation activity in the postwar years, which yielded positive results.

The economy of modern states is an economy of constant growth depending primarily on the amount of scientific research in the past. New knowledge embodied in technology in developed countries accounts for 70-90% of GDP growth. This trend is likely to continue in the coming years. Economically developed countries are in search of goal-setting that would allow them to concentrate resources on the most promising areas of technological development. However, this task is not as simple as it may appear at first glance.

The novel coronavirus pandemic creates unique opportunities to initiate serious changes both in the economic development of states and in the security of the population against biological cataclysms. At the first stage, the objective is to meet the most critical goal of ensuring biological security, then comes the implementation of the Biomedical project followed by the Biological project as a general civilizational project of the 21st century.

It is difficult or straight-up impossible to find arguments against the search for a good appropriate solution in securing biological safety (at the national, regional, and international levels). The threats and risks of the spread of both the known and new infections have reached such a level that national economies are stretched to their limits, and the prospect of a return to pre-pandemic levels is largely illusory. Most economic agents and households suffer losses, which leads to their support for the authorities constantly decreasing. The burden on the healthcare and social security (welfare)



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systems has increased significantly, they are dealing with overloads. In view of the above, regardless of the costs of a biosecurity project, these systems will have to deal with it. Technological backwardness can undermine not only the system of biological security but also national security, which cannot be tolerated.

The aforementioned also goes in line with the priorities of the new technological order. Biomedicine and biopharmaceuticals, industrial biotechnology, bioenergy, and ecological entrepreneurship are taking shape (Mokhov, 2021). At their basis lie the most advanced biological, including genetic, technologies. In combination with information, managerial, and other technologies, they can produce noticeable long-term synergistic effects, thus forming the basis for the next technological transition.

It is sufficient to note the following critical documents of recent years: Presidential Decree № 204 of May 7, 2018 “On National Goals and Strategic Development Objectives of the Russian Federation for the Period until 2024”, Presidential Decree № 680 of November 28, 2018 “On the Development of Genetic Technologies in the Russian Federation”, Presidential Decree № 97 of March 11, 2019 “On the Fundamentals of the Russian Federation State Policy in the Field of Chemical and Biological Security for the Period until 2025 and Beyond”, Presidential Decree № 254 of June 6, 2019 “On the Strategy for the Development of Healthcare in the Russian Federation for the period until 2025”, Presidential Decree № 400 of July 2, 2021 “On the National Security Strategy of the Russian Federation”.

There is also a clear understanding of the heterogeneity of development across the areas and sectors of the economy and the socio-cultural sphere of society. A pronounced differentiation of science and technology is also observed. The gap between individual areas is very high and cannot be overcome by administrative measures and in the short term. At the same time, there are no serious organizational and legal obstacles for the concentration of efforts of specialists and the available forces and means (both public sector and business) on solving genuinely important projects.

Legal prerequisites for the creation, development, and differentiation of special legal regimes are being actively created in Russian legislation. We can cite the following



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federal laws that form the organizational and legal basis for scientific, innovative, and other types of activities in certain areas of technological development in certain territories: the Federal Law of September 28, 2010, № 244-FZ “On Innovation Center ‘Skolkovo’”, the Federal Law of June 29, 2015, № 160-FZ “On International Medical Cluster and amendments to certain legislative acts of the Russian Federation”, the Federal Law of July 31, 2020, № 258-FZ “On experimental legal regimes in the sphere of digital innovation in the Russian Federation”, Federal Law № 437-FZ of December 22, 2020 “On the Federal Territory ‘Sirius’”.

Legal regimes enshrined in the legislature are complex (not only sectoral but also inter-branch). In systemic unity, they attempt to solve the main problems arising in the implementation of scientific and innovation activity by general rules based on the norms of the Federal Law of August 23, 1996, № 127-FZ “On Science and State Scientific and Technical Policy”.

In the sphere of biosafety securement as a whole and in its particular directions, legal regimes are only emerging. Federal Law № 492-FZ of December 30, 2020 “On Biological Safety in the Russian Federation” is still of a framework nature and does not provide for the allocation of special and emergency (extraordinary) legal regimes for quite diverse activities in this sphere.

Scientific work in the sphere of biosafety securement is merely mentioned by the legislation among the types of possible activity in this sphere, the indicated Law does not indicate any specialized norms in this regard. In the light of the potential or real emergence of biological risks and threats, from rapid and (or) atypical spread of a previously known or new infection to acts of terrorism with natural or synthetic biological agents, legislators must be concerned about forming a body of special rules.

Within the framework of the general (basic) legal regime, the regime of general can be distinguished. Most of the norms in current legislation are the corpus delicti of the general legal regime in the area of biological security. They define the main forces and means of ensuring biological security, the rights, obligations, and peculiarities of legal responsibility of economic entities, citizens, and officials, aimed at solving the tasks of



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ensuring biological security. The main restrictions, prohibitions, encumbrances, and other means and mechanisms are established, which ensure the current level of biological security in the country in peacetime in the absence of explicit or assumed biological threats.

A special legal regime acts as a kind of modification of the general legal regime characterized either by special benefits and advantages, additional rights, or special restrictions, expressed in additional prohibitions or positive obligations. Special regimes allow within certain boundaries (locality) to establish certain features of social relations, some objects and subjects (flexibility).

Unlike the general regime, special regimes apply to a limited range of subjects (a certain industry, sphere of activity, or even individually defined subjects) defining their legal status (rights, duties, responsibility) differently compared to the general rules. For example, differences in the microorganisms used in scientific, educational, expert, industrial, and other activities (in terms of their pathogenicity, restriction of turnover, etc.) may require business entities and the state to deploy more serious measures, means, and mechanisms to ensure biological safety.

Working with genetically modified organisms that pose a threat to the environment, life, and public health also calls for the development and adoption of biosafety measures at a higher level. Dual, controlled, and other high-risk biological technologies may also require stronger precautionary measures.

Through a set of organizational, legal, and other measures, the biological security system is fine-tuned to allow it to function as planned in the presence of higher risks and threats emanating from certain areas of activity, from certain entities or facilities.

We believe that the stimulation of scientific and innovative activities aimed at solving biological safety problems should follow not only and not so much the general rules, but rather special rules allowing to mobilize resources to solve tasks of overarching importance in the field of securing biosafety. In this connection, as already noted in the literature, it is necessary to create a legal and ethical basis for these activities, including



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those that form a path to a bioethical code (Mokhov, Svirin, Gureev, Posulikhina, Pekchev, 2021).

Other activities needed include mobilizing scientific and scientific-technical elite (biology, medicine, chemistry, etc.) as a necessary prerequisite for economic mobilization and innovative development of the country in a special direction (biosafety securement), concentrating the available property, financial, and other resources in promising areas of development in a particular territory (territories), and accelerated commercialization of the results of research and technological development, as well as applied research (through experimental small-scale production).

Extraordinary or special legal regimes fundamentally differ from both general and special legal regimes. It may be introduced only during the implementation (deployment) of the norms of emergency (reserve) legislation and is limited to the period of the norms of extraordinary legislation (the period of emergency, military legislation).

Emergency legislation is a reserve system of legislation, the norms of which are enacted in the face of peacetime or wartime emergencies. It is in the part of resolving priority tasks for ensuring biological safety that it is possible to apply a wide range of legal means and mechanisms to be used by the state and officials under the conditions of limited time, material, human, and other resources (medicines, medical devices, personal and collective protective equipment, etc.) both in peacetime (when there is a threat of a certain risk (high alert mode)) or when a biological risk or threat presents itself (a natural emergency situation). During a period of aggression or the declaration of martial law, in addition to the “civilian” forces and means, the resources of the state’s armed forces are also actively involved.

Special legal regimes vary both in terms of the tasks they address and the forces and means they employ (regime of high readiness, state of emergency, emergency situations, martial law, etc.). What they have in common is the maximum utilization of forces and means, not only of the biological security system, but also of other resources available to the state. It is during such periods that the advantages, disadvantages, and weaknesses of the given national biological security system become apparent. The



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development of an administrative and legal doctrine in this important area will allow reaching a higher level of understanding of the raised problems in the future from the standpoint of systems theory, as well as making the necessary changes and additions to the existing legislation on biological security in peacetime or wartime.

Examples of this sort are also found in foreign legislation. The USA pays considerable attention to the issues of biosafety securement, which is reflected in such acts as the Public health security and bioterrorism preparedness and response act of 2002 (PHSBPRA), the law on the Project BioShield of 2004, the Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006, 21st Century Cures Act of 2016, and the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019.

4. CONCLUSION

Ensuring biological safety and the formation of an effective Sanitary Shield for the country call for unconventional organizational, legal, and other solutions (regarding the regulation of scientific, scientific-technical, and innovative activities).

This necessitates the mobilization of resources available to the state and society and requires setting and resolving the task of implementing the Mobilization Project as a vanguard, advanced project (a relatively isolated part of the economy of a new, innovative type). Such a project involves the concentration of resources available to the state and society on separate or several interrelated areas of activity, which are of strategic importance for the state and (or) ensure its security.

This avant-garde, cutting-edge base can later serve as the foundation for the Biomedical Project, whose objectives reach beyond ensuring biological safety (increasing the longevity and quality of citizens' life, providing technological biomedical, informational, and other support for the individual at all stages of their life cycle).



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The mobilization project in the sphere of biosafety securement involves a number of measures of an organizational and legal nature allowing to account for the unity of activities in the field of biological security (by their purpose) and their diversity (by the tasks addressed: scientific, implementation, experimental, expert, etc.). For this purpose, along with measures to improve the country's general legal regime in the sphere of biosafety, it is necessary to develop special legal regimes (primarily for science and innovations in the field of biological security) and even extraordinary legal regimes (in times of particular threats and risks of biological nature and taking measures to eliminate the consequences of such threats).

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