

## **On biological safety of the Republic of Kazakhstan**

### *Unofficial translation*

The Law of the Republic of Kazakhstan dated May 21, 2022 № 122-VII LRK.

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This Law shall determine the legal framework for state regulation in the field of biological safety of the Republic of Kazakhstan and is aimed at preventing biological threats.

## **Chapter 1. MAIN PROVISIONS**

### **Article 1. Basic concepts used in this Law**

The following basic concepts are used in this Law:

1) a susceptible organism - a human, animal, or plant organism that reacts to a pathogenic biological agent by developing an infectious and (or) parasitic disease or becomes its carrier;

2) social distancing - the optimal distance between people necessary to reduce the risk of infection;

3) biological safety - the state of protection of people and individual components of the natural environment (atmospheric air, surface and ground waters, the earth's surface and soil layer, flora, and fauna, and other organisms (hereinafter - individual components of the natural environment) from dangerous biological factors, including those provided by biological protection measures;

4) requirements in the field of biological safety - the norms governing the issues of ensuring biological safety contained in the legislation of the Republic of Kazakhstan, as well as regulatory technical documents, national and (or) interstate standards included in the list approved in accordance with subparagraph 11) of Article 9 of this Law;

5) an authorized body in the field of biological safety - a state body, carrying out management and intersectoral coordination in the field of biological safety;

6) biological protection - a set of measures to ensure biological safety, implemented through physical protection against the misuse of pathogenic biological agents (a set of organizational measures, engineering and technical means and actions for their protection), control, accounting, and ensuring the safe handling of pathogenic biological agents, taking measures to prevent their loss, theft, unauthorized access to them or handling of them, as well as acts of terrorism and (or) sabotage using pathogenic biological agents and (or) in relation to potentially dangerous biological objects;

7) biological risk - the probability of causing harm to the health of people, animals, and plants by pathogenic biological agents, as well as the probability of their entry into individual components of the natural environment;

8) support personnel - employees of entities handling pathogenic biological agents, performing an auxiliary function in the handling of pathogenic biological agents;

9) hazardous biological factor - an event, condition, property, and (or) process, entailing an increase in the risks of the negative impact of pathogenic biological agents and objects containing them, carriers, and vectors on the health of people, animals, plants, as well as the ingress of pathogenic biological agents into individual components natural environment;

10) strain of a microorganism - a homogeneous culture of a microorganism type with certain biological properties;

11) pathogenic biological agent - microorganisms, poisons of biological and plant origin (toxins), helminths, nematodes capable of causing an infectious and (or) parasitic process in a human, animal, or plant body;

12) handling of pathogenic biological agents - processes (stages) of working with pathogenic biological agents, directly aimed at isolation (detection), development (creation), production (manufacturing), circulation (including import (export), storage, transportation) of pathogenic biological agents for the purpose of their research, destruction and (or) development of immunobiological drugs;

13) a specialist handling pathogenic biological agents (hereinafter-a specialist) - an individual who has a technical and vocational and (or) post-secondary education and (or) higher and (or) postgraduate education, and (or) an academic degree and is admitted in accordance with the established procedure for handling of pathogenic biological agents;

14) an entity handling pathogenic biological agents - a legal entity handling pathogenic biological agents in the manner and under the conditions established by this Law;

15) chemoprophylaxis - prescribing chemicals to humans or animals to prevent infectious and (or) parasitic diseases;

16) potentially dangerous biological object - an immovable (stationary) or deployable mobile object, where activities are carried out for the handling of pathogenic biological agents

## **Article 2. Legislation of the Republic of Kazakhstan in the field of biological safety**

1. The legislation of the Republic of Kazakhstan in the field of biological safety shall be based on the Constitution of the Republic of Kazakhstan and consist of this Law and other regulatory legal acts of the Republic of Kazakhstan.

2. If an international treaty ratified by the Republic of Kazakhstan establishes other rules than those contained in this Law, then the rules of the international treaty shall be applied.

## **Article 3. Scope of application of this Law**

This law shall regulate public relations related to the handling of pathogenic biological agents in order to ensure biological safety.

## **Article 4. Principles of ensuring biological safety**

Biological safety shall be ensured on the basis of the following principles:

1) handling of pathogenic biological agents exclusively for non-military purposes: handling of pathogenic biological agents for the purposes of development (creation), production (manufacturing), and (or) stockpiling, use of bacteriological (biological) and toxin weapons shall be prohibited;

2) advanced recognition of biological threats: when exercising powers in the field of biological safety, state bodies should be guided by the need to prevent biological threats, analyze and predict biological threats based on accounting and monitoring data in the field of biological safety;

3) controllability of the handling of pathogenic biological agents: handling of pathogenic biological agents shall be carried out in accordance with the requirements in the field of biological safety, compliance with which is ensured as part of the management of biological risks, the application of a permit procedure for handling of pathogenic biological agents, accounting, monitoring and forecasting (modeling) in the field of biological safety, state control and supervision of compliance with the requirements in the field of biological safety;

4) proportionality of state regulation measures: preventive measures in the field of biological safety must be proportionate to the degree of danger of biological factors, including in accordance with the criteria and classification in the field of biological safety;

5) priority of the national interests of the Republic of Kazakhstan: it is not allowed to accept obligations within the framework of international cooperation not corresponding to the national interests of the Republic of Kazakhstan, which may damage the national security of the Republic of Kazakhstan or lead to the loss of independence of the Republic of Kazakhstan

## **Article 5. Main biological threats**

1. The main biological threats shall be:

1) the occurrence of an emergency situation of a natural, man-made and social nature ( hereinafter- an emergency situation) affecting potentially dangerous biological objects;

2) a case of a particularly dangerous infectious disease of humans and (or) animals;

3) excess of the average level of infectious morbidity of the population, animals;

4) excess of the average level of mortality (lethality) from infectious diseases;

5) the spread of plant diseases above the economic threshold of harmfulness;

6) the spread of plant quarantine diseases included in the unified list of quarantine objects of the Eurasian Economic Union and (or) the list of quarantine objects and alien species, in relation to which plant quarantine measures are established and implemented;

7) a situation that has arisen when handling pathogenic biological agents that creates a real or potential possibility of biological risk;

8) violation of the requirements for the handling of pathogenic biological agents, including the concealment of information on the handling of pathogenic biological agents;

9) unauthorized access to pathogenic biological agents;

10) unregulated free handling of pathogenic biological agents;

11) acts of terrorism and (or) sabotage using pathogenic biological agents and (or) in relation to potentially dangerous biological objects, the use of biological technologies and other related technologies for the development (creation), production (manufacturing), and use of pathogenic biological agents as a bacteriological (biological) and toxin weapons;

12) formation of stability (resistance) of pathogenic biological agents to the effects of medicinal, chemical, and (or) biological agents;

13) low qualification of specialists, lack of personnel in the field of biological safety;

14) displacement of the population and changes in the habitat of animals and plants that are vectors and (or) carriers of especially dangerous infectious and (or) parasitic diseases;

15) military operations on the territory of the Republic of Kazakhstan affecting potentially dangerous biological objects and (or) associated with the use of pathogenic biological agents.

2. State bodies, when developing regulatory legal acts and documents of the state planning System of the Republic of Kazakhstan, as well as entities handling pathogenic biological agents, when developing organizational measures shall be obliged to ensure the development of provisions providing for mechanisms aimed at preventing biological threats listed in paragraph 1 of this Article.

## **Chapter 2. STATE REGULATION IN THE FIELD OF BIOLOGICAL SAFETY**

### **Article 6. State regulation in the field of biological safety**

1. The main problems and threats, strategic goals, main directions, target indicators, tasks and performance indicators, and interdepartmental interaction in the field of biological safety shall be determined by the National Security Strategy of the Republic of Kazakhstan.

2. Ensuring prompt interdepartmental exchange of information and taking coordinated measures in the field of biological safety shall be carried out through the state information system in the field of biological safety and in other ways in accordance with the legislation of the Republic of Kazakhstan.

3. State regulation in the field of biological safety shall be carried out by:

1) implementation of a unified state policy in the field of biological safety;

2) introduction of a permissive procedure for handling pathogenic biological agents;

3) carrying out state control and supervision over compliance with the requirements in the field of biological safety;

4) biological risk management;

5) accounting, monitoring and forecasting (modeling) in the field of biological safety.

### **Article 7. Interdepartmental coordination**

1. Interdepartmental coordination of activities on ensuring biological safety shall be carried out by the authorized body in the field of biological safety. In order to implement the state policy in the field of biological safety, state bodies, and organizations shall be obliged to assist the authorized body in the field of biological safety and state bodies that regulate and implement measures aimed at ensuring biological safety.

2. The State Security Service of the Republic of Kazakhstan shall carry out interdepartmental coordination and organization of activities on ensuring the biological safety of protected persons and objects in the places of security measures in accordance with the Law of the Republic of Kazakhstan "On the State Security Service of the Republic of Kazakhstan".

3. Interdepartmental coordination of activities in the field of countering terrorism and extremism, including with the use of pathogenic biological agents and (or) in relation to potentially dangerous biological objects shall be carried out by the national security bodies of the Republic of Kazakhstan in accordance with the legislation of the Republic of Kazakhstan on countering terrorism and extremism.

4. In emergency situations affecting potentially dangerous biological objects and (or) caused by exposure to pathogenic biological agents, management and intersectoral coordination, implementation of measures to prevent and eliminate emergency situations, and provision of emergency medical and psychological assistance to the population shall be carried out by the authorized body in the field of civil protection in accordance with the legislation of the Republic of Kazakhstan on civil protection.

Action plans for liquidation of emergency situations of global, regional, and local scales, developed in accordance with the legislation of the Republic of Kazakhstan on civil protection, should also include protocols (scenarios) of response in the field of biological safety, providing algorithms for the actions of state bodies, organizations, interdepartmental interaction in the field of biological security.

The authorized body in the field of biological safety and state bodies, within their competence shall provide assistance in the prevention and elimination of emergency situations affecting potentially dangerous biological objects and (or) caused by the impact of pathogenic biological agents, including through the implementation of protocols (scenarios) of response in the field biological safety.

5. Interdepartmental coordination of measures to ensure biological security under martial law and within the framework of military security and defense of the Republic of Kazakhstan shall be carried out by the Ministry of Defence of the Republic of Kazakhstan in accordance with the legislation of the Republic of Kazakhstan on defense and the Armed Forces.

#### **Article 8. Competence of the Government of the Republic of Kazakhstan in the field of biological safety**

The competence of the Government of the Republic of Kazakhstan includes:

1) development of the main directions of the state policy in the field of biological safety and organization of their implementation;

2) approval of the rules for the formation, conduct, and maintenance of national collections of pathogenic and industrial microorganisms and the list of organizations authorized to form, conduct and maintain them;

3) excluded by the Law of the Republic of Kazakhstan dated 19.04.2023 No. 223-VII (shall be enforced ten calendar days after the date of its first official publication);

4) excluded by the Law of the Republic of Kazakhstan dated 19.04.2023 No. 223-VII (shall be enforced ten calendar days after the date of its first official publication).

Footnote. Article 8 as amended by the Law of the Republic of Kazakhstan dated 19.04.2023 No. 223-VII (shall be enforced ten calendar days after the date of its first official publication).

## **Article 9. Competence of the authorized body in the field of biological safety**

The competence of the authorized body in the field of biological safety includes:

1) coordination of draft regulatory legal acts, regulatory technical documents, national and (or) interstate standards related to the issues of ensuring biological safety;

1-1) formation and implementation of the state policy in the field of biological safety and organization of its implementation;

2) maintenance of the state information system in the field of biological safety;

3) development and approval of rules for accounting, monitoring, and forecasting (modeling) in the field of biological safety;

4) monitoring the implementation of accounting of subjects handling pathogenic biological agents, potentially dangerous biological objects, pathogenic biological agents of pathogenicity groups I and II, and specialists handling them;

5) development of rules for the formation, conduct, and maintenance of national collections of pathogenic and industrial microorganisms and a list of organizations authorized to form, conduct and maintain them;

6) coordination of standard programs for professional training, retraining, and advanced training of personnel in the field of biological safety;

7) development of criteria for classifying pathogenic biological agents as causing especially dangerous infectious diseases and a list of pathogenic biological agents, taking into account the classification of pathogenic biological agents according to pathogenicity and degree of danger;

8) development and approval of rules for the formation of a personnel reserve of specialists for handling pathogenic biological agents of I and II pathogenicity groups;

9) development and approval of the rules for ensuring biological protection;

10) coordination of biological risk management techniques;

11) development and approval of a list of regulatory technical documents, national and (or) interstate standards in the field of biological safety;

12) development and approval of the rules for monitoring the effectiveness of the external assessment of biological risks;

13) monitoring the effectiveness of the external assessment of biological risks carried out by the state bodies specified in paragraph 3 of Article 10 of this Law;

14) analysis and forecasting of biological threats;

15) coordination of targeted scientific, scientific-technical projects and programs in the field of biological safety;

16) representation of the Republic of Kazakhstan in international organizations on the issues of ensuring biological safety;

17) informing the public about the state of biological safety of the Republic of Kazakhstan in accordance with the legislation of the Republic of Kazakhstan on access to information;

17-1) approval of criteria for classifying pathogenic biological agents as causing particularly dangerous infectious diseases and a list of pathogenic biological agents, taking into account the classification of pathogenic biological agents by pathogenicity and degree of danger;

18) exercise of other powers provided for by this Law, other laws of the Republic of Kazakhstan, acts of the President of the Republic of Kazakhstan, and the Government of the Republic of Kazakhstan.

**Footnote. Article 9 as amended by the Law of the Republic of Kazakhstan dated 19.04.2023 No. 223-VII (shall be enforced ten calendar days after the date of its first official publication).**

#### **Article 10. Competence of state bodies in the field of biological safety**

1. Ensuring biological safety shall be carried out by the following state bodies within the competence established by the legislation of the Republic of Kazakhstan:

- 1) state body in the field of sanitary and epidemiological welfare of the population;
- 2) an authorized body in the field of veterinary medicine;
- 3) an authorized body for plant quarantine;
- 4) an authorized body in the field of plant protection;
- 5) an authorized body in the field of environmental protection;
- 6) an authorized body in the field of civil protection;
- 7) an authorized body in the field of science;
- 8) Ministry of Defence of the Republic of Kazakhstan;
- 9) state revenue bodies;
- 10) an authorized body in the field of healthcare;
- 11) national security bodies of the Republic of Kazakhstan;
- 12) bodies of internal affairs of the Republic of Kazakhstan;
- 13) State Security Service of the Republic of Kazakhstan.

2. Ensuring biological safety shall be carried out within the competence established by the legislation of the Republic of Kazakhstan by the state bodies specified in paragraph 1 of this Article, including through:

- 1) participation in the implementation of state policy in the field of biological safety;
- 2) informing the public about situations involving risks of biological threats, in accordance with the legislation of the Republic of Kazakhstan on access to information;

3) providing statistical information and other accounting and reporting documentation (information) in the field of biological safety in accordance with the rules for accounting, monitoring, and forecasting (modeling) in the field of biological safety;

4) coordination with the authorized body in the field of biological safety of draft regulatory legal acts, regulatory technical documents, national and (or) interstate standards related to the issues of ensuring biological safety;

5) development and approval of biological risk management techniques;

6) exercising other powers provided for by this Law, other laws of the Republic of Kazakhstan, acts of the President of the Republic of Kazakhstan, and the Government of the Republic of Kazakhstan.

3. The state body in the field of sanitary-epidemiological welfare of the population, the authorized bodies in the field of veterinary medicine, plants protection, science, and plants quarantine, in addition to the functions specified in paragraph 2 of this Article, within the competence established by the legislation of the Republic of Kazakhstan shall carry out:

1) maintaining registers of entities handling pathogenic biological agents, and potentially hazardous biological objects;

2) maintaining registers of pathogenic biological agents of pathogenicity groups I and II, specialists handling pathogenic biological agents of pathogenicity groups I and II;

3) carrying out preventive measures in the field of biological safety in accordance with this Law and the legislation of the Republic of Kazakhstan;

4) accounting and monitoring in the field of biological safety in accordance with this Law and the legislation of the Republic of Kazakhstan;

5) state control and supervision over compliance with the requirements in the field of biological safety;

6) development and approval of standard programs for professional training, retraining, and advanced training of personnel in the field of biological safety;

7) development and approval of a model remuneration system for specialists and support personnel of state enterprises on the right of economic management, handling (performing an auxiliary function in handling) pathogenic biological agents of pathogenicity groups I and II;

8) organization of scientific research in the field of biological safety in the manner prescribed by the legislation of the Republic of Kazakhstan;

9) external assessment of biological risks;

10) accounting and monitoring of collectors' activities;

11) development and approval of the rules for implementation and admission to the implementation of referent (reference-) studies;

12) ensuring the activities of organizations authorized to form, conduct and maintain national collections of pathogenic and industrial microorganisms, at the expense of budgetary funds.



The functions provided for in subparagraphs 2) and 7) of part one of this paragraph shall not be carried out by the authorized bodies for plant quarantine and in the field of plant protection.

4. The state body in the field of sanitary and epidemiological welfare of the population, in addition to the functions specified in paragraphs 2 and 3 of this Article, within the competence established by the legislation of the Republic of Kazakhstan shall carry out accounting of biological substances recognized as hazardous to human health or future generations by the results of sanitary and epidemiological expertise and scientific expertise.

**Article 11. Competence of local executive bodies of regions, cities of republican significance, and the capital in the field of biological safety**

Local executive bodies of regions, cities of republican significance, and the capital within the competence established by the legislation of the Republic of Kazakhstan shall:

- 1) take measures and organize work to ensure biological safety;
- 2) provide measures to prevent biological threats and eliminate their consequences within the framework of operational headquarters, created in accordance with the legislation of the Republic of Kazakhstan on civil protection, in emergency situations on a local scale;
- 3) carry out interregional cooperation and interaction in the field of biological safety;
- 4) exercise in the interests of local government other powers assigned to local executive bodies in accordance with the legislation of the Republic of Kazakhstan.

**Article 12. International cooperation in the field of biological safety**

1. The priorities of international cooperation in the field of biological safety shall be:

- 1) protection of national interests of the Republic of Kazakhstan in the field of biological safety;
- 2) ensuring the sanitary-epidemiological welfare of the population, veterinary and sanitary safety, and favorable phytosanitary situation in the Republic of Kazakhstan;
- 3) application of international experience in the field of biological safety.

2. Directions of international cooperation in the field of biological safety shall be:

- 1) participation in international initiatives in the field of biological safety;
- 2) attraction and provision of technical assistance in the field of biological safety at the interstate level;
- 3) introduction of international innovative technologies and modernization of the biological safety and biological protection system;
- 4) prevention of acts of terrorism and (or) sabotage using pathogenic biological agents and (or) in relation to potentially dangerous biological objects and elimination of their consequences;
- 5) integration of the Republic of Kazakhstan into interstate and international biological safety systems and other international integration associations, participation in international scientific exchange;

- 6) representing the interests of the Republic of Kazakhstan in international organizations on the issues of ensuring biological safety;
  - 7) participation in the international deposit of strains of microorganisms in the manner prescribed by the legislation of the Republic of Kazakhstan;
  - 8) participation in the localization and liquidation of emergency situations of an international nature affecting potentially dangerous biological objects and (or) caused by the impact of pathogenic biological agents;
  - 9) interstate cooperation in the field of professional training, retraining, and advanced training of personnel in the field of biological safety;
  - 10) regulation of transboundary movement of pathogenic biological agents;
  - 11) exchange of information in accordance with international treaties in order to prevent biological threats.
3. International cooperation in the field of biological safety shall be based on openness and non-direction against other states.

### **Chapter 3. GENERAL REQUIREMENTS FOR ENSURING BIOLOGICAL SAFETY**

#### **Article 13. Criteria and classifications in the field of biological safety**

1. Handling of pathogenic biological agents shall be based on the classification of pathogenic biological agents by pathogenicity and degree of danger:
  - 1) pathogenicity group I - pathogenic biological agents that cause especially dangerous infectious diseases of humans and (or) animals with a high level of mortality (lethality), easily spreading from an infected organism to a healthy one, as a rule, for which there are no vaccines and effective therapies;
  - 2) pathogenicity group II - pathogenic biological agents that cause infectious and (or) parasitic diseases of humans and (or) animals, easily spreading from an infected organism to a healthy one, for which effective means and methods of treatment and prevention are available, including vaccines. This group is subdivided into pathogenic biological agents that cause:
    - especially dangerous infectious diseases;
    - infectious and (or) parasitic diseases;
  - 3) pathogenicity group III - pathogenic biological agents that cause infectious and (or) parasitic diseases of humans and (or) animals or capable of causing significant harm to plants, characterized by minimal spread from an infected organism to a healthy one, for which effective means and methods of treatment and prevention, including vaccines, are available;
  - 4) pathogenicity group IV - pathogenic biological agents that cause infectious and (or) parasitic diseases of humans and (or) animals or capable of causing harm to plants, as a rule, not spreading from an infected organism to a healthy one, for which effective means and methods of treatment and prevention, including vaccines, are available.

2. Attenuated (weakened) strains of microorganisms, which are pathogenic biological agents of pathogenicity group II, belong to pathogenic biological agents of pathogenicity group III.

Attenuated (weakened) strains of microorganisms, which are pathogenic biological agents of pathogenicity group III, belong to pathogenic biological agents of pathogenicity group IV.

3. The criteria for classifying pathogenic biological agents as causing especially dangerous infectious diseases and the list of pathogenic biological agents shall be formed taking into account their classification by pathogenicity and the degree of danger specified in this Article, as well as taking into account the recommendations in the field of biological safety of international organizations, the results of the assessment of biological risks.

#### **Article 14 Management of biological risks**

1. Management of biological risks shall be used to reduce the likelihood of negative consequences of exposure to hazardous biological factors.

2. An assessment of biological risks is an element of biological risks management and represents a set of organizational, analytical, and practical measures aimed at preventing the occurrence of negative consequences of exposure to hazardous biological factors, means, methods, technologies, and services in various fields of activity related to the handling of pathogenic biological agents.

3. An assessment of biological risks shall be carried out in relation to the handling of pathogenic biological agents, potentially hazardous biological objects, epidemic and epizootic foci of infectious and (or) parasitic diseases, and a potentially focal area.

Assessment of biological risks is divided into external and internal.

4. An external assessment of biological risks shall be carried out by state bodies within the established competence.

To conduct an external assessment of biological risks, state bodies shall have the right to involve their subordinate organizations.

5. An internal assessment of biological risks shall be conducted by the entities carrying out activities for the handling of pathogenic biological agents in relation to their own activities for the handling of pathogenic biological agents.

6. Assessment of biological risks shall be carried out in accordance with the biological risk management methodology. The methodology for managing biological risks shall be developed, among other things, taking into account the scientific and methodological base and should provide for the gradation of biological risks according to their levels.

7. The results of the assessment of biological risks, depending on their level, should be used to develop measures to reduce the biological risk to a permissible (acceptable) level, which provides conditions for protecting the population and protecting individual components of the natural environment from the impact of hazardous biological factors.

8. Control over the effectiveness of measures to reduce biological risk, as well as the effectiveness of the internal assessment of biological risks shall be carried out in accordance with the biological risks management methodology.

9. Depending on the level of biological risk, authorized state bodies, within their competence shall develop mandatory requirements for the entities handling pathogenic biological agents.

#### **Article 15. Carrying out activities for the handling of pathogenic biological agents**

1. The process of handling pathogenic biological agents includes their detection, carried out by selecting and examining substances and materials, including those from individual components of the natural environment, vectors and carriers of especially dangerous infectious and (or) parasitic diseases (including products of their activity) that may contain pathogenic biological agents (potentially hazardous biological substances).

2. Subjects handling pathogenic biological agents shall be obliged to:

1) obtain a permit for the handling of pathogenic biological agents and an annex to it;

2) comply with the requirements in the field of biological safety;

3) undergo the accreditation procedure in the field of conformity assessment in the manner prescribed by the legislation of the Republic of Kazakhstan on accreditation in the field of conformity assessment;

4) comply with the requirements of the legislation of the Republic of Kazakhstan when working with information of restricted access;

5) provide statistical information and other accounting and reporting documentation (information) in the field of biological safety in accordance with the rules for accounting, monitoring, and forecasting (modeling) in the field of biological safety;

6) organize and carry out activities to ensure the biological protection of potentially hazardous biological objects, taking into account the level of biological risks in accordance with the rules for ensuring biological protection;

7) exercise control over the safe handling of pathogenic biological agents at all stages of their handling;

8) assist the authorized body in the field of biological safety, state bodies specified in Article 10 of this Law, on the issues of ensuring biological safety;

9) immediately inform the territorial subdivisions of the state body in the field of sanitary and epidemiological welfare of the population, authorized bodies in the field of veterinary medicine, plants protection, plants quarantine, civil protection, the authorized body in the field of science about the facts of accidents (emergency situations), infection of workers with infectious diseases in the process of handling pathogenic biological agents;

10) organize, in accordance with the legislation of the Republic of Kazakhstan, the passage of periodic medical examinations and checkups, training, and testing of knowledge on the issues of ensuring biological safety and labor protection of managers, specialists, and auxiliary personnel;

11) comply with the requirements of the legislation of the Republic of Kazakhstan on export control when importing, exporting, re-exporting, or transiting pathogenic biological agents subject to export control through the territory of the Republic of Kazakhstan.

3. Subjects handling pathogenic biological agents of pathogenicity groups I and (or) II, in addition to the duties provided for in paragraph 2 of this Article, shall be obliged to:

1) ensure the availability of trained specialists handling pathogenic biological agents of pathogenicity groups I and (or) II;

2) provide a regime of limited access to potentially hazardous biological objects in accordance with the legislation of the Republic of Kazakhstan;

3) in the manner determined by the rules for accounting, monitoring, and forecasting (modeling) in the field of biological safety:

integrate information systems used in carrying out activities with the state information system in the field of biological safety;

provide information on the specialists handling pathogenic biological agents of pathogenicity groups I and (or) II to the state body in the field of sanitary and epidemiological welfare of the population, authorized bodies in the field of veterinary medicine, and science for inclusion in the appropriate register.

4. Based on the conclusion of the commission for monitoring compliance with requirements in the field of biological safety (regime commission) in accordance with the Code of the Republic of Kazakhstan "On Public Health and the Healthcare System" and the Law of the Republic of Kazakhstan "On Permits and Notifications" a permit for the handling of pathogenic biological agents and an appendix to it shall be issued by the state body in the field of sanitary and epidemiological welfare of the population.

5. The handling of pathogenic biological agents causing especially dangerous infectious diseases shall be carried out by state enterprises and state institutions, as well as other legal entities, one hundred percent of the voting shares (stakes in the authorized capital) of which belong to the national holding.

6. Referent (reference-) studies in the field of biological safety shall be carried out:

1) in diagnostically complex and expert cases;

2) for the purpose of identifying pathogenic biological agents, including conducting research in particularly difficult cases;

3) for the purpose of studying newly identified pathogenic biological agents;

4) to issue an expert opinion in doubtful or controversial cases.

7. Referent (reference-) studies in the field of biological safety shall be carried out by organizations admitted to this activity in accordance with the rules for the implementation and admission to the implementation of referent (reference-) studies.

8. Subjects carrying out referent (reference-) studies in the field of biological safety must comply with national standards and carry out organizational-methodological work on the

implementation and operation of the external quality assessment system, as well as external quality assessment of activities for the handling of pathogenic biological agents.

#### **Article 16. Accounting and monitoring in the field of biological safety**

1. Accounting and monitoring in the field of biological safety shall be the elements of biological risk management and aimed at preventing the occurrence of negative consequences of exposure to hazardous biological factors.

2. Accounting and monitoring in the field of biological safety shall be carried out at all stages of handling pathogenic biological agents by:

1) maintaining registers:

subjects handling pathogenic biological agents;

potentially hazardous biological objects;

pathogenic biological agents of pathogenicity groups I and II;

specialists handling pathogenic biological agents of pathogenicity groups I and II;

2) collection and analysis of statistical information and other accounting and reporting documentation (information);

3) conducting a survey of the territory, individual components of the natural environment, vectors and carriers of especially dangerous infectious and (or) parasitic diseases (including their metabolic products), substances, and materials, establishing the causes and conditions for the occurrence of infectious and (or) parasitic diseases of the population, animals, plants;

4) interdepartmental exchange of information;

5) exchange of information within the framework of international cooperation;

6) collection, generalization, and analysis of information from open sources.

3. The procedure for the formation and maintenance of registers specified in subparagraph 1) of paragraph 2 of this Article, the types of statistical information and other accounting and reporting documentation (information) in the field of biological safety, the procedure for the formation and maintenance of the state information system in the field of biological safety, as well as the procedure for collection, processing, storage and transmission of information shall be determined by the rules of accounting, monitoring and forecasting (modeling) in the field of biological safety.

#### **Article 17. State information system in the field of biological safety**

1. The state information system in the field of biological safety shall be created for the purpose of analyzing the situation, forecasting and modeling biological risks, developing coordinated and prompt response measures through centralized accounting and monitoring in the field of biological safety, managing biological risks, and exchanging information between state bodies and local executive bodies of regions, cities of republican significance, the capital

2. The objects of informatization in the field of biological safety shall be electronic information resources, software, Internet resource, and information-communication infrastructure in the field of biological safety.

3. The subjects of informatization in the field of biological safety shall be state bodies (their subordinate organizations) carrying out state regulation (activities) in the fields, affecting the issues of biological safety, as well as subjects handling pathogenic biological agents.

4. The state information system in the field of biological safety shall be formed on the basis of statistical information and other accounting and reporting documentation (information) provided by informatization subjects.

5. Information entering the state information system in the field of biological safety shall be accumulated in a unified form and forms a single national database in the field of biological safety.

6. Creation, improvement, and operation of the state information system in the field of biological safety and ensuring the protection of information stored and processed in it shall be carried out by the authorized body in the field of biological safety in accordance with the legislation of the Republic of Kazakhstan.

#### **Article 18. Rights and obligations of individuals and legal entities in the field of biological safety**

1. Individuals and legal entities shall have the right to:

1) protection from exposure to hazardous biological factors;  
2) obtaining information about potential biological risks associated with a planned visit to foreign countries and regions of the Republic of Kazakhstan endemic for infectious and (or) parasitic morbidity, and measures for their prevention;

3) obtaining reliable and timely information on sanitary-epidemiological and veterinary-sanitary situations, as well as measures taken aimed at protecting the population and protecting individual components of the natural environment from the impact of dangerous biological factors, preventing biological threats, in accordance with the legislation of the Republic of Kazakhstan;

4) appeal on the issues of ensuring biological safety to the relevant state bodies;

5) participation in activities aimed at ensuring biological safety, taking into account the fulfillment of the requirements for individual protection in cases established by the legislation of the Republic of Kazakhstan;

6) other rights in accordance with the laws of the Republic of Kazakhstan.

2. Individuals and legal entities shall be obliged:

1) to report all known facts of illegal (unauthorized) use of pathogenic biological agents or their free circulation to state bodies, provided for in paragraph 1 of Article 10 of this Law, in accordance with their competence;

2) to prevent the dissemination of deliberately false information related to the handling of pathogenic biological agents;

3) to comply with the requirements for restricted information related to the handling of pathogenic biological agents in case of acceptance of restrictions established by the legislation of the Republic of Kazakhstan on access to information;

4) not to carry out actions entailing a violation of the rights of other individuals and legal entities to protection from the impact of hazardous biological factors.

Activities for the handling of pathogenic biological agents without a permit for the handling of pathogenic biological agents and annexes to it, provided for by the Law of the Republic of Kazakhstan "On Permits and Notifications" shall be prohibited.

3. In addition to the obligations specified in paragraph 2 of this Article, individuals shall be obliged to:

1) apply in a timely manner to medical organizations at the location upon the fact of a deterioration in the state of health, accompanied by signs characteristic of an infectious and (or) parasitic disease;

2) inform about the previous stay abroad and (or) on the territory of the Republic of Kazakhstan that is endemic in terms of infectious and (or) parasitic morbidity in case of applying for medical care for an infectious and (or) parasitic disease;

3) promptly inform medical organizations at the location of information about contacts preceding such diagnosis in case of diagnosing an infectious and (or) parasitic disease that poses a danger to others.

#### **Article 19. Prevention in the field of biological safety**

1. Prevention in the field of biological safety shall be carried out in accordance with the legislation of the Republic of Kazakhstan and includes a set of anti-epidemic, veterinary, phytosanitary measures, plant quarantine measures, and other measures aimed at managing biological risks, preventing and containing biological threats.

Preventive measures in the field of biological safety shall be carried out by state bodies within the competence established by the legislation of the Republic of Kazakhstan.

2. Prevention in the field of biological safety shall be divided into the following preventive measures:

1) general;

2) aimed at a source of biological threat;

3) aimed at a hazardous biological factor;

4) aimed at a susceptible organism.

3. General preventive measures include:

1) monitoring and analysis of biological risks, including forecasting of infectious and (or) parasitic morbidity, monitoring of individual components of the natural environment, neutralization or reduction of the level of biological threats;

2) ensuring the readiness of the relevant services to carry out activities aimed at identifying and localizing the source of a biological threat, managing the situation, and



developing protocols (scenarios) for responding to biological safety within the framework of action plans for eliminating emergencies of global, regional and local scales;

3) compliance with the requirements in the field of biological safety by persons interacting with pathogenic biological agents as part of their activities;

4) compliance with the requirements in the field of biological safety when placing, designing, building, reconstructing, carrying out technical re-equipment, expansion, overhaul, and commissioning of facilities located on the territory and in close proximity to potentially dangerous biological objects, natural foci of infectious diseases and (or) outbreaks of plant diseases;

5) mobilization of human resources from the personnel reserve of specialists for handling pathogenic biological agents of I and II pathogenicity groups;

6) mobilization of reserves of medicines and medical devices, re-profiling of facilities for the needs of preventive measures in the field of biological safety;

7) implementation of state control and supervision over compliance with the requirements in the field of biological safety;

8) activities aimed at increasing the level of awareness of the population and its readiness to respond to the impact of dangerous biological factors;

9) inclusion of the study of biological safety issues in general education curricula.

4. Measures aimed at the source of a biological threat include:

1) timely detection of the infected and people, and animals that have been in contact with them, identification of damaged (infected) plants, their accounting, and registration, isolation (observation), diagnosis, treatment, as well as the removal, destruction of plants and animals;

2) identification, localization, examination, and elimination of foci of infections and (or) foci of the spread of plant diseases;

3) prevention of the occurrence, import, and spread of infectious and (or) parasitic diseases of people and animals, plant diseases throughout the territory of the Republic of Kazakhstan;

4) development and improvement of methods for early detection (express diagnostics) of biological threats, including through the use of collections of pathogenic and industrial microorganisms;

5) state registration of a medicinal product or a medical device under an accelerated examination procedure in accordance with the Code of the Republic of Kazakhstan "On Public Health and the Healthcare System";

6) ensuring biological protection measures for potentially hazardous biological objects in accordance with the rules for ensuring biological protection;

7) interdepartmental interaction, including for the purpose of promptly responding to the emergence of biological threats, including taking measures to prevent illegal (unauthorized)

handling of pathogenic biological agents, their loss, theft, concealment (non-provision) of information about their illegal handling, as well as acts of terrorism and (or) sabotage using pathogenic biological agents and (or) against potentially hazardous biological objects.

5. Measures aimed at a hazardous biological factor include:

- 1) introduction of restrictive measures, including quarantine;
- 2) compliance with individual and public protection measures, including the use of personal protective equipment, personal hygiene, and social distancing;
- 3) conducting disinfection, disinfestation and deratization, and treatment of plants with protection products;
- 4) sanitary and preventive measures and improvement of social and living conditions;
- 5) carrying out anti-epidemic, anti-epizootic, phytosanitary measures, and plant quarantine measures.

6. Measures aimed at a susceptible organism include:

- 1) conducting preventive medical examinations of the population;
- 2) assistance in the formation of a healthy lifestyle and healthy nutrition for the population ;
- 3) immunoprophylaxis and chemoprophylaxis in order to prevent the spread of human and (or) animal infections, the use of plant protection products;
- 4) provision with personal protective equipment in accordance with the requirements in the field of biological safety of persons engaged in the framework of medical, veterinary, and scientific activities, interaction with pathogenic biological agents that cause especially dangerous infectious diseases.

#### **Chapter 4. STATE CONTROL AND SUPERVISION OVER COMPLIANCE WITH REQUIREMENTS IN THE FIELD OF BIOLOGICAL SAFETY**

##### **Article 20. State control and supervision over compliance with requirements in the field of biological safety**

1. State control and supervision over compliance with requirements in the field of biological safety (hereinafter-state control and supervision) shall be aimed at preventing, detecting, suppressing, and eliminating their violations and shall be carried out in accordance with the Entrepreneurial Code of the Republic of Kazakhstan, taking into account the specifics provided for by this Law, legislation Republic of Kazakhstan in the field of sanitary and epidemiological welfare of the population, in the field of veterinary medicine, plants protection, plants quarantine, countering terrorism.

2. The subjects or objects of state control and supervision shall be legal entities handling pathogenic biological agents, or facilities where handling of pathogenic biological agents is carried out (hereinafter-subjects (objects) of control and supervision).

3. The objects of state control and supervision, where handling of pathogenic biological agents is carried out, belong to the objects of a high epidemic, epizootic, and epiphytotic risk.

The objects of high epidemic, epizootic, and epiphytotic risk are divided into two groups:

- 1) potentially hazardous biological objects where pathogenic biological agents of I and (or) II pathogenicity groups are handled;
- 2) potentially hazardous biological objects where pathogenic biological agents of III and (or) IV pathogenicity groups are handled.

The assignment of objects of state control and supervision to these groups shall be carried out on the basis of the criteria for classifying pathogenic biological agents as causing especially dangerous infectious diseases and the list of pathogenic biological agents, taking into account the classification of pathogenic biological agents by pathogenicity and degree of danger.

4. In relation to the subjects (objects) of control and supervision, state control shall be carried out in the forms provided for by the Entrepreneurial Code of the Republic of Kazakhstan.

5. Within the framework of state control and supervision, measures of prompt response may be applied to the subjects (objects) of control and supervision in accordance with Article 21 of this Law.

#### **Article 21. Procedure for applying prompt response measures**

1. Measures of prompt response provide for the right of officials of control and supervision bodies to suspend the implementation of activities for the handling of pathogenic biological agents or their individual types on one of the following grounds:

- 1) non-provision, concealment, and (or) provision of false information on the handling of especially dangerous pathogenic biological agents of I and (or) II pathogenicity groups;
- 2) violation of the requirements for the physical protection of potentially hazardous biological objects, where especially dangerous pathogenic biological agents of I and (or) II pathogenicity groups are handled, prevention of unauthorized movement of pathogenic biological agents and their removal outside these objects;
- 3) violation of the requirements for the protection of personnel of potentially hazardous biological objects from the harmful effects of pathogenic biological agents, including the absence or insufficient number of personal protective equipment for personnel;
- 4) faulty condition of the ventilation system or air conditioning system during work with pathogenic biological agents of I and (or) II pathogenicity groups at the facilities handling them;
- 5) non-compliance with the requirements for disinfection of wastewater (septic tank, pits), faulty condition of the sewer network at facilities handling pathogenic biological agents of I and (or) II pathogenicity groups;
- 6) violation of the requirements for the disposal of waste generated as a result of handling pathogenic biological agents of I and (or) II pathogenicity groups;
- 7) gross violations of the requirements for the flow of movement of pathogenic biological agents of I and (or) II groups of pathogenicity and potentially infected material;

8) absence, faulty or non-working condition of technological equipment (containers and low-temperature cabinets for storing pathogenic biological agents, fume hood, autoclave, thermostat, water bath) necessary for carrying out activities related to the handling of pathogenic biological agents;

9) implementation of the handling of pathogenic biological agents by personnel who do not have access in accordance with the established procedure;

10) violation of the requirements for transportation and (or) storage of pathogenic biological agents of I and (or) II pathogenicity groups.

2. Measures of prompt response provide for the right of officials of control and supervision bodies to prohibit activities for the handling of pathogenic biological agents or their individual types on one of the following grounds:

1) lack of permission to handle pathogenic biological agents and an appendix to it;

2) the absence of a sanitary and epidemiological conclusion for an object of high epidemic risk;

3) the absence of separate isolated rooms (boxes) with a vestibule (pre-box) for the "infectious" zone, designed to work with each type of pathogenic biological agents of I and (or) II pathogenicity groups that cause especially dangerous infectious diseases;

4) the absence of a ventilation system or an air conditioning system at facilities handling pathogenic biological agents of I and (or) II pathogenicity groups;

5) non-elimination of the circumstances, the reasons that served as the basis for the suspension of the implementation of activities for the handling of pathogenic biological agents or their individual types within the established time limits.

3. The body of control and supervision in the course of preventive control or inspection upon detection of a violation of the requirements, which is the basis for applying prompt response measures shall draw up an order (act, resolution) on the application of a prompt response measure.

4. The order (act, resolution) on the application of prompt response measures shall indicate:

1) the date, time, and place of drawing up the order (act, resolution);

2) the name of the control and supervision body;

3) surname, name, patronymic (if it is indicated in the identity document), and position of the person (persons) who carried out preventive control with a visit to the subject (object) of control and supervision and (or) inspection;

4) the name or surname, name, patronymic (if it is indicated in the identity document) of the subject (object) of control and supervision, the position of the representative of an individual or a legal entity who was present during the preventive control with a visit to the subject (object) of control and supervision and (or) inspection;

5) the date, place, and period of preventive control with a visit to the subject (object) of control and supervision and (or) inspection;

6) a list of identified violations in accordance with the checklist with a mandatory indication of the severity of the violation in accordance with the criteria for assessing the degree of risk;

7) a measure of prompt response (suspension with terms of its validity or prohibition of activities);

8) recommendations and instructions on possible actions to eliminate the identified violations, indicating the timing of their elimination;

9) information about familiarization or refusal to familiarize with the instruction (act, resolution) of the representative of the subject of control and supervision (the head of a legal entity or his/her authorized person), persons involved in preventive control with a visit to the subject (object) of control and supervision and (or) inspection, their signatures or refusal to sign;

10) position, surname, name, patronymic (if it is indicated in the identity document), and signature of the head of the control and supervision body.

The forms of order (act, resolution) on the application of prompt response measures shall be approved by the state bodies specified in paragraph 3 of Article 10 of this Law.

5. An order (act, resolution) on the application of a prompt response measure shall be signed by the head of the control and supervision body and handed over to the head of the subject of control and supervision or his/her authorized person against signature.

6. The head of the subject of control and supervision or his/her authorized person shall have the right to refuse to accept the order (act, resolution), giving a written explanation of the reason for the refusal.

In case of refusal to accept an order (act, resolution) on the application of a prompt response measure, an appropriate entry shall be made in it and a protocol shall be drawn up, which is signed by the official exercising state control and supervision and the head of the subject of control and supervision or his/her authorized person. The order (act, resolution) on the application of a prompt response measure shall be considered to have been handed over from the moment the protocol is drawn up.

7. Refusal to receive an order (act, resolution) on the application of a prompt response measure shall not be a reason for its non-execution.

8. An order (act, resolution) on the application of a prompt response measure shall be subject to execution by the subject of control and supervision immediately. The filing of a complaint by the subject of control and supervision shall not suspend the execution of the order (act, resolution) on the application of a prompt response measure.

9. In case of the elimination of the identified violations, the subject of control and supervision shall be obliged to provide the relevant body of control and supervision with information on the elimination of the identified violations for further resumption of its activities.

The body of control and supervision shall carry out control over the execution of instructions (acts, resolutions) on the application of a prompt response measure in the manner prescribed by the Entrepreneurial Code of the Republic of Kazakhstan.

10. Based on the act on the results of the inspection, confirming the elimination of the identified violations, the subject of control and supervision shall resume its activities in the handling of pathogenic biological agents or their individual types.

11. The implementation of prohibited activities for handling pathogenic biological agents shall entail liability established by the laws of the Republic of Kazakhstan.

## **Chapter 5. COLLECTIONS OF MICROORGANISMS**

### **Article 22. Collection activity**

1. In order to study and determine the uniqueness of pathogenic microorganisms, their scientific, educational, and practical value, the possibility of applied use in scientific, research, and production activities, conducting international and national patent procedures in relation to them, collection activities shall be carried out.

2. Collection activities shall be carried out by collecting, identifying, studying, accounting, certification, storage (deposit), and maintenance of pathogenic and industrial microorganisms in national and working collections of pathogenic and industrial microorganisms.

3. Responsibility for the safety of national and working collections of pathogenic and industrial microorganisms shall be borne by the first heads of organizations engaged in collection activities.

### **Article 23. National collections of pathogenic and industrial microorganisms**

1. The formation, replenishment, accounting, and centralized storage of unique pathogenic and industrial microorganisms, including those used as a reference, isolated from various sources, test strains for standardization and control of immunobiological preparations and nutrient media, production, deposited, patented and reference strains of microorganisms, as well as other strains of microorganisms of scientific, educational and practical value shall be carried out in the national collections of pathogenic and industrial microorganisms.

2. National collections of pathogenic and industrial microorganisms contain strains of microorganisms, the composition of which is formed according to the characteristics of origin, species relationship, and method of exposure to the human, animal, or plant organism and is maintained in a viable state with the preservation of the original characteristics.

3. Microorganism strains that are unique, as well as used in the manufacture of medicines and immunobiological preparations, duly registered and approved for circulation, shall be subject to mandatory deposit in the national collections of pathogenic and industrial microorganisms.

The procedure for assigning strains of pathogenic and industrial microorganisms to national collections on the basis of their pathogenicity, degree of danger, and purpose shall be

determined by the rules for the formation, conduct, and maintenance of national collections of pathogenic and industrial microorganisms.

4. Subjects handling pathogenic biological agents, when allocating, acquiring, and (or) importing samples of especially dangerous pathogenic microorganisms into the territory of the Republic of Kazakhstan shall be obliged to submit their samples to the national collection of pathogenic or industrial microorganisms in accordance with the rules for the formation, conduct, and maintenance of national collections of pathogenic and industrial microorganisms

5. National collections of pathogenic and industrial microorganisms shall be the property of the state and shall not be subject to privatization. Financial provision of national collections of pathogenic and industrial microorganisms shall be carried out at the expense of budgetary funds.

6. Organizations authorized to form, conduct, and maintain national collections of pathogenic and industrial microorganisms shall provide advisory and scientific-methodological assistance to individuals and legal entities on the systematization, study, search, and selection of strains of microorganisms according to established criteria, taking into account the requirements for distribution restricted access information in accordance with the legislation of the Republic of Kazakhstan.

7. Organizations authorized to form, conduct, and maintain national collections of microorganisms shall identify a sample of a particularly dangerous pathogenic microorganism, deposit it or send it to the appropriate national collection of microorganisms.

8. Biological protection of national collections of pathogenic and industrial microorganisms shall be carried out in accordance with the rules for ensuring biological protection.

#### **Article 24. Working collections of pathogenic and industrial microorganisms**

1. Working collections of pathogenic and industrial microorganisms shall be created, if necessary, by the subjects handling pathogenic biological agents for scientific, industrial, diagnostic, and research purposes and shall be maintained in a viable state with the preservation of initial characteristics.

2. The procedure for the formation, conduct, and maintenance of working collections of pathogenic and (or) industrial microorganisms shall be determined by the legislation of the Republic of Kazakhstan.

### **Chapter 6. SOCIAL PROTECTION OF SPECIALISTS AND SUPPORT PERSONNEL**

#### **Article 25 Social protection of specialists and support personnel handling (performing an auxiliary function in handling) pathogenic biological agents of I and (or) II pathogenicity groups**

1. Specialists and support personnel of state enterprises and state institutions, as well as legal entities, one hundred percent of the voting shares (stakes in the authorized capital) of

which belong to the national holding, handling (performing an auxiliary function in handling) with pathogenic biological agents of the I and (or) II pathogenicity groups shall be subject to social protection, taking into account harmful and (or) dangerous working conditions and the risk of acquiring occupational diseases, as well as the features provided for by this Law.

2. Specialists and support personnel of state enterprises and state institutions, as well as legal entities, one hundred percent of the voting shares (stakes in the authorized capital) of which belong to the national holding, handling (performing an auxiliary function in handling) with pathogenic biological agents of the I and (or) II pathogenicity groups shall have the right to:

- 1) wages taking into account the level of biological risks;
- 2) health protection and working conditions that meet the requirements in the field of biological safety;
- 3) compensation for harm caused to life and health in the performance of official duties, in the manner prescribed by the legislation of the Republic of Kazakhstan;
- 4) other rights provided for by the legislation of the Republic of Kazakhstan.

3. Remuneration of labor of specialists and support personnel of state enterprises and state institutions, as well as legal entities, one hundred percent of the voting shares (stakes in the authorized capital) of which belong to the national holding, handling (performing an auxiliary function in the process of handling) with pathogenic biological agents of the I and (or) II pathogenicity groups in the field of sanitary and epidemiological welfare of the population, in the field of veterinary medicine and science, includes an official salary, allowances, and additional payments, taking into account harmful and (or) dangerous working conditions, an increased risk of acquiring occupational diseases.

4. When granting the main annual labor leave to specialists and support personnel of state enterprises and state institutions, as well as legal entities, one hundred percent of the voting shares (stakes in the authorized capital) of which belong to the national holding, handling (performing an auxiliary function in the process of handling) with pathogenic biological agents of the I and (or) II pathogenicity groups, a health improvement allowance shall be paid in the amount of at least two official salaries.

5. Specialists and support personnel of state enterprises and state institutions, as well as legal entities, one hundred percent of the voting shares (stakes in the authorized capital) of which belong to the national holding, handling (performing an auxiliary function in handling) with pathogenic biological agents of the I and (or) II pathogenicity groups, when performing tasks for the selection and transportation of vectors and carriers of infectious and (or) parasitic diseases (including their metabolic products), potentially hazardous substances and materials, including from individual components of the natural environment, in order to detect pathogenic biological agents and their fragments, payment shall be made, provided for employees sent on business trips, in accordance with the legislation of the Republic of Kazakhstan.



Persons provided for in part one of this paragraph, when performing tasks in the field for the selection and study of vectors and carriers of infectious and (or) parasitic diseases (including their metabolic products), potentially hazardous substances and materials, including from individual components of the natural environment, in order to detect pathogenic biological agents and their fragments, if it is impossible to provide documents confirming the costs of renting a dwelling, reimbursement of the costs of renting a dwelling shall be carried out in accordance with the standards established by the legislation of the Republic of Kazakhstan, without confirming documents.

#### **Article 26 Personnel reserve of specialists for handling pathogenic biological agents of the I and II pathogenicity groups, conditions for their mobilization**

1. In order to ensure sufficient human resources in the field of biological safety, and readiness for an adequate response to biological threats, including in emergency situations, a personnel reserve of specialists shall be created to handle pathogenic biological agents of pathogenicity groups I and II.

2. Specialists included in the personnel reserve of specialists for handling pathogenic biological agents of pathogenicity groups I and II shall have a priority right to employment in state enterprises and state institutions, as well as in legal entities, one hundred percent of voting shares (stakes in the authorized capital ) which belong to the national holding, to carry out activities for the handling of pathogenic biological agents of I and II pathogenicity groups

3. Specialists included in the personnel reserve of specialists for handling pathogenic biological agents of pathogenicity groups I and II, if necessary, can be involved in the implementation of preventive measures in the field of biological safety.

4. The register of specialists handling pathogenic biological agents of pathogenicity groups I and II includes a personnel reserve of specialists for handling pathogenic biological agents of pathogenicity groups I and II.

### **Chapter 7. SCIENTIFIC AND EDUCATIONAL ACTIVITIES IN THE FIELD OF BIOLOGICAL SAFETY**

#### **Article 27. Priority areas of science in the field of biological safety**

1. Priority scientific-research areas in the field of biological safety shall be determined in the documents of the State Planning System of the Republic of Kazakhstan, developed and adopted for the implementation of the state policy in the field of biological safety.

2. Priority scientific-research areas in the field of biological safety, among other things, should include:

1) development and implementation of targeted scientific, scientific-technical projects and programs;

2) introduction of advanced international innovative technologies;

3) development and implementation of national standards in the field of biological safety in accordance with the legislation of the Republic of Kazakhstan in the field of standardization;

4) development and production of immunobiological, medicinal and diagnostic products for the prevention, treatment and diagnosis of infectious and (or) parasitic diseases.

3. The development and production of immunobiological, medicinal and diagnostic products for the prevention, treatment and diagnosis of infectious and (or) parasitic diseases must be scientifically substantiated.

4. Scientific research in the field of biological safety, transfer, publication of their results and applied use shall be carried out in accordance with the legislation of the Republic of Kazakhstan.

#### **Article 28. Training in the field of biological safety**

1. Training in the field of biological safety includes training of personnel within the framework of technical and professional, additional, post-secondary, higher and (or) postgraduate education, their professional training, retraining, and advanced training and is aimed at developing and strengthening human resources in the field of biological safety.

2. Professional training, retraining, and advanced training of personnel in the field of biological safety shall be organized by the subjects handling pathogenic biological agents.

3. In the event of an emergency, professional training and retraining of the necessary personnel in the field of biological safety shall be ensured, providing training in handling the pathogenic biological agent that caused the emergency.

4. Training, professional training, retraining, and advanced training of personnel in the field of biological safety shall be carried out by organizations accredited in accordance with the legislation of the Republic of Kazakhstan.

#### **Article 29. State support of scientific-technical potential and resources in the field of biological safety**

1. Priority areas of state support for scientific-technical potential in the field of biological safety shall be:

1) support for domestic scientific research aimed at ensuring the biological safety of the Republic of Kazakhstan, including the prevention of biological threats and the management of biological risks;

2) support for the development of production of immunobiological, medicinal and diagnostic products, means of disinfection, disinfestation, deratization, plants protection and personal protection, laboratory equipment in accordance with the legislation of the Republic of Kazakhstan;

3) ensuring the transfer of the results of scientific-research works in the field of biological safety for practical application.

2. In order to preserve the scientific and human potential, state support for applied scientific research and programs aimed at ensuring the biological safety of the Republic of Kazakhstan shall be carried out taking into account stability and continuity.

3. State support for fundamental and applied scientific research and programs shall be aimed at ensuring the biological safety of the Republic of Kazakhstan, solving strategically important state tasks and shall be carried out on the basis of program-targeted funding on a competitive basis or by decision of the Government of the Republic of Kazakhstan outside competitive procedures, as well as in other forms provided by the laws of the Republic of Kazakhstan.

## **Chapter 8. FINAL AND TRANSITIONAL PROVISIONS**

### **Article 30. Responsibility for violation of the legislation of the Republic of Kazakhstan in the field of biological safety**

Violation of the legislation of the Republic of Kazakhstan in the field of biological safety shall entail liability established by the laws of the Republic of Kazakhstan.

### **Article 31. Transitional provisions**

1. Subjects handling pathogenic biological agents and having permits to work with microorganisms of I-IV pathogenicity groups and helminths shall be required to reissue permits in accordance with subparagraph 1) of paragraph 2 of Article 15 of this Law within six months after the date of entry into force of this Law.

2. Permits for work with microorganisms of I-IV pathogenicity groups and helminths that are not reissued within the period specified in paragraph 1 of this Article shall cease to be valid.

### **Article 32. Procedure for the entry into force of this Law**

This Law shall enter into force upon expiry of six months after the day of its first official publication.

*President of the Republic of Kazakhstan*

*K. TOKAYEV*