



## **ON BIOSAFETY AND BIOSECURITY**

This Law governs the public relations connected with controlled biological agents and toxins in order to strengthen the biological safety and biological security system.

### **CHAPTER 1. GENERAL PROVISIONS**

#### **Article 1. Basic concepts**

This Law contains the following basic concepts:

- biological agent shall mean any microorganisms, viruses or infectious substance capable of causing disease or death of a human being, death of an animal, plant and other live organism, quality degradation of food, equipment, supplies or other materials and adverse change of the environment;
- controlled biological agents and toxins shall mean causative agents of infectious diseases and their toxins posing serious threat for health and safety of the population, animals, plants, environment and livestock products or crop production, which can be used as biological weapon;
- biosafety shall mean safety measures in combination with biosecurity procedures for mitigating the risk of loss, plunder or use of controlled biological agents and toxins as biological weapon, diversion, bioterrorism or technology, and practices preventing their distribution and inadvertent release;
- assessment of biological risk shall mean a biological hazard-related risk assessment process considering appropriateness of any existing control mechanisms, and also including decision-making on whether this biological risk is acceptable;
- delivery systems shall mean a strategic weapon and other unmanned systems capable of delivering biological and toxin weapon and specially designed for such application;
- biological risk management shall mean ensuring the organizational management at potentially hazardous biological facilities in order to minimize the risks caused by controlled biological agents and toxins;
- product shall mean the result of activities provided in tangible form and intended for further use for economic and other purposes;
- biosecurity shall mean a set of organizational, legal sanitary engineering and individual protective measures aimed at prevention of loss, plunder, leakage, transfer, misuse or deliberate release of controlled biological agents and toxins, and also unauthorized access;
- biosafety indicator shall mean a feature of human habitat factor found by modern research methods implying no direct or indirect adverse effects on health of the population in these or subsequent generations, no decrease in human performance and no deterioration of sanitary living conditions;

- potentially hazardous biological facilities shall mean organizations and institutions engaged in manufacturing activities related to controlled biological agents and toxins and handling of them;
- accident shall mean an emergency situation at potentially hazardous biological facility creating a potential hazard of inadvertent release of controlled biological agents and toxins into the production zone and the environment, which may cause immediate or postponed negative consequences for human health and their habitat;
- biological or toxin weapon shall mean controlled biological agents and toxins intended for mass destruction of enemy fighters, animals, plantings of agricultural crops, infection of food and water sources, as well as damage to certain types of military equipment and military materials;
- dual-use equipment and technologies shall mean equipment and technologies that are used for peaceful purposes, but can be used to create weapons of mass destruction;
- toxin shall mean a poisonous organic substance produced by microorganisms and plants, capable of causing body malfunctions;
- biological risk shall mean a combination of likelihood of harmful effect and its severity where the source of such effect is a controlled biological agent and toxin;
- biological hazard shall mean potential for hazardous biological factors to affect human beings, the environment, including animals and plants, which may result in a hazardous biological situation and its further development into biological emergency.

#### Article 2. Legislation of the Republic of Tajikistan on ensuring biosafety and biosecurity

The legislation of the Republic of Tajikistan on ensuring biosafety and biosecurity shall be based on the Constitution of the Republic of Tajikistan and shall consist of the Law, other regulatory legal acts of the Republic of Tajikistan and the international legal acts recognized by Tajikistan.

#### Article 3. Principles for ensuring biosafety and biosecurity

Biosafety and biosecurity shall be ensured according to the following principles:

- legality;
- regulation;
- optimization;
- prevention.

#### Article 4. Ensuring biosafety and biosecurity

1. Ensuring biosafety and biosecurity shall include a package of measures and means (organizational, legal, technical, technological, medical and preventive) aimed at public health care during production, transportation, operation, storage, sales, consumption, disposal of products, performance of works and rendering of services.

2. Ensuring biosecurity shall include protection, control and reporting measures applied to prevent loss, plunder, misuse, leakage or inadvertent release of controlled biological agents and toxins and related resources, as well as unauthorized access, storage or transfer of such material.

3. Biosafety and biosecurity shall be ensured through:

- state regulation of research activities, production, transportation, movement, transfer and other activities related to controlled biological agents and toxins, as well as dual-use equipment and technologies;

- control over development, production, acquisition, transportation, storage, transfer and use of controlled biological agents and toxins, as well as transfer of the dual-use biological equipment and technologies;
- delineation of duties and responsibilities of state bodies, rights and responsibilities of individuals and legal entities;
- coordination of activities of state executive authorities;
- ensuring the protection of the population and environment, animals and plants, protection of potentially hazardous biological facilities according to regulatory requirements;
- ensuring, monitoring and regularly reviewing the national list of controlled biological agents and toxins, as well as dual-use equipment and technologies;
- availability of information and increase in the level of public awareness;
- scientific justification in decision-making;
- prohibiting any non-state actor to manufacture, acquire, possess, develop, transport, transfer or use biological or toxin weapons and their delivery systems, as well as to engage in the above activities as an accomplice, to assist or finance them.

#### Article 5. Biosafety indicators

1. To ensure the biosafety of the population and the environment, the following indicators shall be established:

- maximum permissible concentrations (levels) of biological agents in the environment and product composition;
- organoleptic indicators (taste, smell typical for a product);
- visual indicators (package integrity, consistency and color, absence of foreign particles, insects, larvae) typical for biological agents and products;
- toxicity (degree of health hazard);
- virulence (features of vulnerability to disease or destruction of the body);
- contagiousness (features of infectious disease dissemination);
- carcinogenicity (ability to stimulate malignant tumors);
- mutagenicity (ability to change the body);
- teratogenicity (features of tissue and embryo arrested (deterred) development).

2. Elaboration of biosafety indicators for potentially hazardous biological facilities and products shall be provided by legal entities engaged in their production, operation, storage, transportation, sales and disposal.

3. Biosafety indicators shall be governed by regulatory documents approved in accordance with the procedure established by the legislation of the Republic of Tajikistan.

## CHAPTER 2. PROHIBITING MEASURES IN BIOSAFETY AND BIOSECURITY

Article 6. Prohibition of unauthorized activities related to controlled biological agents and toxins

Legal entities shall be prohibited from:

1) developing, producing, acquiring, stockpiling, transporting, storing biological or toxin weapons, as well as transferring, directly or indirectly, any controlled biological agents and toxins to non-state actors suspected of committing unauthorized actions;

2) engaging in the developments on the use of controlled biological agents or toxins as biological or toxin weapons;

3) building, acquiring facilities intended to produce biological or toxin weapons;

4) engaging in unauthorized activities at potentially hazardous biological facilities, as well as actions with package or biologically isolated reservoir containing controlled biological agents or toxins for the purpose of their release into the environment;

5) plundering controlled biological agents or toxins from a potentially hazardous biological facility, a vehicle and distributing them for sabotage purposes;

6) assisting, encouraging, or supporting legal entities and officials in unauthorized activities involving the use of controlled biological agents and toxins;

7) making orders, directions, attempting and threatening to commit illegal acts, as well as acting as an accomplice and providing funding for unauthorized activities involving the use of controlled biological agents or toxins as biological or toxin weapons.

## CHAPTER 3. STATE MANAGEMENT ON BIOSAFETY AND BIOSECURITY

Article 7. Competence of the Government of the Republic of Tajikistan in ensuring biosafety and biosecurity

The Government of the Republic of Tajikistan shall have the following competencies in ensuring biosafety and biosecurity:

1) determine an authorized state body in charge of ensuring biosafety and biosecurity;

2) coordinate the activities of state bodies on biosafety and biosecurity issues;

3) adopt regulatory legal acts prescribing requirements and procedures for authorization to transfer controlled biological agents and toxins, dual-use equipment and technologies;

4) determine the powers of state bodies, rights and obligations of legal entities on ensuring biosafety and biosecurity;

5) introduce biosafety and biosecurity issues into the training and retraining program in higher and secondary vocational institutions;

6) adopt public policies, funding and logistics, approve the list of controlled biological agents and toxins, as well as dual-use equipment and technologies;

7) exercise other competencies in accordance with the legislation of the Republic of Tajikistan.

Article 8. Powers of authorized state bodies on ensuring biosafety and biosecurity

Powers of the authorized state bodies on ensuring biosafety and biosecurity shall be as follows:

1) conduct the state policy and coordinate the activities of ministries, departments and local state authorities;

- 2) within the scope of their powers, take control over compliance with the requirements of the Law and other regulatory legal acts of the Republic of Tajikistan on biosafety and biosecurity;
- 3) develop and apply programs, strategies, national action plan, projects and undertake cooperation with international organizations within the framework of the legislation of the Republic of Tajikistan;
- 4) conduct biological risk assessment and analysis concerning the release and dissemination of controlled biological agents and toxins into the environment;
- 5) develop and timely update national lists of controlled biological agents and toxins, as well as dual-use equipment and technologies;
- 6) issue licenses for activities related to infectious agents and dual-use equipment and technologies;
- 7) issue import, export and transit permits for infectious agents and dual-use equipment and technology;
- 8) take administrative measures (suspension, revocation and cancellation of license to engage in activities related to the use, research and testing, production, release, as well as import and export of infectious agents) against legal entities for violation of the requirements of the Law, regulations and rules in biosafety and biosecurity, including international requirements and regulations;
- 9) supervise the enforcement of regulations prescribing the requirements and procedures for obtaining a permit to transfer controlled biological agents and toxins, as well as dual-use equipment or technologies;
- 10) adopt regulatory documents and instructions prescribing the requirements and procedures for import, export or transit of controlled biological agents and toxins, as well as dual-use equipment and technologies through the territory of the Republic of Tajikistan;
- 11) adopt instructions for the inland transportation of hazardous biological materials and requirements for their packaging and labeling;
- 12) develop basic principles for the analysis, assessment and management of biological risks associated with the release of controlled biological agents and toxins into the environment and mitigation of their effects;
- 13) develop criteria for assessing and ranking potentially hazardous biological facilities;
- 14) undertake a range of activities, including quarantine measures, to destroy controlled biological agents and toxins, to minimize the risks of adverse effects, to increase the security of the population and environment, as well as to assess the effectiveness of such activities;
- 15) conduct a comprehensive analysis of situations, identify new biological threats and predict their possible consequences;
- 16) introduce modern methods for indication and identification of controlled biological agents and toxins in accordance with the international classification;
- 17) create and protect national collections of pathogenic microorganisms from unauthorized access and plunder;
- 18) develop hygienic standards for the content of controlled biological agents and toxins in foodstuff and the environment;
- 19) improve methods for assessing the safety of newly created products, including those derived from living modified organisms, bio- and nanotechnologies;

- 20) categorize and create a register of operating potentially hazardous biological facilities, as well as territories of abandoned facilities;
- 21) ensure in-process control and state supervision over biological waste management;
- 22) establish a state biosafety information system;
- 23) prepare a health and veterinary passport for potentially hazardous biological facilities and conduct biological monitoring of their sanitary areas, as well as prepare a feasibility study on risk mitigation;
- 24) conduct bioprospecting for the use of controlled biological agents and toxins, as well as those genetically engineered, as biological and toxin weapons to develop responses and minimize possible negative effects;
- 25) strengthen the border control over controlled biological agents and toxins, dual-use equipment and technologies in order to prevent terrorist threats within the framework of the adopted international agreements;
- 26) approve accounting and reporting forms for submitting information to an authorized state body or other state authorities;
- 27) engage in accounting and reporting during the development, acquisition, production, possession, storage, transportation, transfer or use of controlled biological agents and toxins, as well as when ensuring the protection of potentially hazardous biological facilities;
- 28) share information with other states and international organizations within the framework of signed agreements;
- 29) conduct training and retraining of professionals in biosafety and biosecurity;
- 30) submit annual reports on the implementation of international obligations in biosafety and biosecurity to the Government of the Republic of Tajikistan;
- 31) appoint inspectors trained in biosafety and biosecurity and engage in inspection activities;
- 32) following the legislation of the Republic of Tajikistan submit proposals for the seizure of controlled biological agents and toxins, dual-use equipment and technologies, and freezing and forfeiture of any funds associated with any activities prohibited by the Law;
- 33) exercise other powers stipulated by the legislation of the Republic of Tajikistan.

## CHAPTER 4. ENSURING BIOSAFETY AND BIOSECURITY REQUIREMENTS

### Article 9. Biosafety and biosecurity inspections

Biosafety and biosecurity inspections shall be provided in accordance with the Law of the Republic of Tajikistan “On inspections of the activities of economic entities.”

### Article 10. Licensing of biosafety and biosecurity activities

Licensing of biosafety and biosecurity activities shall be provided in accordance with the Law of the Republic of Tajikistan “On licensing certain types of activities.”

Article 11. State accounting and control of controlled biological agents, toxins, and potentially hazardous biological facilities

1. Controlled biological agents, toxins, and potentially hazardous biological facilities shall be subject to state accounting and control.

2. State accounting and control system shall ensure taking measures related to the determination of quantity, location, the prevention of losses, plunder and unauthorized access, the provision of the up-to-date information on the availability and their movements, as well as information on the destruction, import and export of controlled agents and toxins provided for by international treaties and obligations.

3. Licensees shall be required to keep records of controlled biological agents, toxins in accordance with their authorized activities.

4. Licensees shall be required to account for controlled biological agents and toxins at all stages from their arrival at the facility until they are destroyed or transferred to another licensee.

5. Licensees shall be accountable to an authorized state body determining the required information and reporting frequency.

6. The form of the accounting and reporting documents, as well as their retention periods, shall be approved by the authorized state body.

7. The procedure for organizing the state accounting and control system for controlled biological agents, toxins and potentially hazardous biological facilities shall be established by the Government of the Republic of Tajikistan.

Article 12. Requirements for ensuring physical security of potentially hazardous biological facilities

1. Requirements for ensuring physical security of potentially hazardous biological facilities shall be established by regulatory legal acts of the Republic of Tajikistan.

2. Rules and regulations for physical security of potentially hazardous biological facilities shall be established by the Government of the Republic of Tajikistan depending on the hazard criteria of microorganisms.

3. Physical security of potentially hazardous biological facilities shall be provided in accordance with the requirements of regulatory legal acts of the Republic of Tajikistan and international legal acts recognized by Tajikistan.

### Article 13. Transportation of controlled biological agents and toxins

1. Controlled biological agents and toxins shall be allowed to be transported by transport organizations licensed to render such types of work and services.

2. Domestic and international transportation of controlled biological agents and toxins shall be provided in accordance with international regulations, as well as regulatory legal acts of the Republic of Tajikistan on the transportation of hazardous materials in compliance with the requirements for their packaging and labeling.

3. Transport organizations involved in domestic and international transportation of controlled biological agents and toxins shall comply with transportation, packaging and labeling requirements, as well as take measures on cargo tracking, security, protection of personnel and vehicles.

Article 14. Import, export and transit of controlled biological agents and toxins, dual-use equipment and technologies

1. Import, export and transit of controlled biological agents and toxins, dual-use equipment and technologies, works and services related to the development, production, procurement, collection, transportation of biological or toxin weapons shall be carried out in accordance with the legislation of the Republic of Tajikistan.

2. Regulatory legal acts establishing requirements and procedures for import, export or transit of controlled biological agents and toxins, dual-use equipment and technologies shall be approved by the Government of the Republic of Tajikistan.

Article 15. Control over internal transfers of controlled biological agents and toxins

1. Within the territory of the Republic of Tajikistan, controlled biological agents and toxins shall be transferred between licensed legal entities and facilities in accordance with the Law and other regulatory legal acts of the Republic of Tajikistan.

2. The transfer of controlled biological agents or toxins within the territory of the Republic of Tajikistan shall be subject to authorization in accordance with the legislation of the Republic of Tajikistan.

3. Regulatory legal acts shall establish additional technical requirements for ensuring protection during transfer, measures for tracing controlled biological agents and toxins, and confirming the receipt of materials by the recipient to ensure strict accounting of the controlled biological agents and toxins.

Article 16. Packaging and labeling requirements for controlled biological agents and toxins

1. The packaging of controlled biological agents and toxins shall ensure the appropriate requirements and conditions (temperature regime) for domestic and international transportation and prevent their release into the environment.

2. Each package shall be accompanied by supporting documentation giving relevant information on the characteristics of the controlled biological agents and toxins contained therein, in accordance with their hazard classification and labeling. The packaging and labeling requirements for controlled biological agents and toxins shall be established in accordance with the regulatory legal acts of the Republic of Tajikistan.

Article 17. Rights and obligations of legal entities in the field of biosafety and biosecurity

1. Legal entities in the field of biosafety and biosecurity shall have the right to:

1) ensure biosafety and biosecurity at potentially hazardous biological facilities under their jurisdiction;

2) develop, produce, store, transport controlled biological agents and toxins in compliance with the established regulations and requirements.

2. Legal entities involved in the development, production, storage, transportation of controlled biological agents and toxins shall be obliged to:

1) comply with the requirements of the Law and other regulatory legal acts of the Republic of Tajikistan in the field of biosafety and biosecurity, as well as with international legal acts recognized by Tajikistan;

2) ensure in-process control at potentially hazardous biological facilities handling controlled biological agents and toxins;

3) store the data, information and documents specified in regulatory legal acts in an appropriate state in the place of organization's or carrier's activities, in the prescribed form and within the time period specified in the regulatory legal acts;

4) provide, at the request of the authorized state body, the necessary information and documents under their jurisdiction or their control, in the specified format and within specified time frame;

5) inform the ministries and departments concerned in the field of biosafety and biosecurity of emergency situations, halting of production and violations of processes that pose a threat to health and safety of the population and environment in a timely manner;

6) provide product batches with proper information about possible harm and factors causing harm to human life or health, including those resulting from long-term use and storage;

7) assist the inspector and the expert in their duties and, upon their reasonable request, provide the necessary information relating to the fulfillment of the requirements stipulated in the Law and other regulatory documents;

8) compensate in full for damage caused to the health and property of individuals and legal entities in accordance with the legislation of the Republic of Tajikistan;

9) bar those employees who have not completed preliminary and periodic training courses on biosafety and biosecurity from working at potentially hazardous biological facilities.

#### Article 18. Obligations of the heads of biosafety and biosecurity organizations

The heads of biosafety and biosecurity organizations shall be obliged to:

- appoint a person responsible for ensuring biosafety and biosecurity;
- ensure their employees undergo special retraining courses on biosafety and biosecurity in accordance with the procedure established by the authorized state body;
- develop and approve job descriptions for employees and persons responsible for biosafety and biosecurity and agree them with the authorized state body.

#### Article 19. Biological emergency response and investigation procedures

Response to and investigation of biological emergencies affecting human health, animals, the environment, and plants shall be provided in compliance with the legislation of the Republic of Tajikistan.

Article 20. International cooperation on biosafety and biosecurity

International cooperation on biosafety and biosecurity with international organizations and relevant agencies of foreign states shall be provided in compliance with the regulatory legal acts of the Republic of Tajikistan and international legal acts recognized by Tajikistan.

CHAPTER 5. FINAL PROVISIONS

Article 21. Liability for non-compliance with the requirements of the Law

Individuals and legal entities shall be liable for violation of the requirements of the Law in the manner prescribed by the legislation of the Republic of Tajikistan.

Article 22. Procedure for putting the Law into force

The Law shall enter into force upon the expiry of six months after the official publication.

President of the Republic of Tajikistan

Emomali Rahmon

*/Seal: Executive Office of the President of the Republic of Tajikistan, Records Management and Control Division/*

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