Working Paper Submitted by the Russian Federation

On the Procedure for the Management of Microorganisms of the Pathogenicity Groups I-IV in the Territory of the Russian Federation

When considering the procedure for the management of microorganisms of the pathogenicity groups I-IV in the territory of Russia, it should be borne in mind that in the Russian Federation the most pathogenic microorganisms fall into the pathogenicity group I and correspond to the microorganisms of the risk group (of pathogenicity) IV of the World Health Organization.

The procedure for the management of microorganisms of the pathogenicity groups I-IV is specified by a number of federal laws of the Russian Federation, the fundamental among which are the following:

   Federal Law of the Russian Federation No. 52-FZ on the Sanitary and Epidemiological Well-Being of the Population of 30 March 1999 (Article 26. Sanitary and epidemiological requirements and conditions of working with biological substances, biological and microbiological organisms and their toxins);

   Federal Law of the Russian Federation No. 128-FZ on the Licensing of Selected Types of Activities of 8 August 2001 (Article 17. A list of the types of activities, the implementation of which requires a license, – activities related to the use of agents of infections);


Requirements for ensuring safety of conditions of working with biological substances, biological and microbiological organisms and their toxins, including working conditions in the field of genetic engineering, and with agents of infections of humans and the environment are established by the sanitary regulations and other standard-setting acts of the Russian Federation.

Working with biological substances, biological and microbiological organisms and their toxins is permitted subject to a sanitary and epidemiological certificate of compliance of the conditions of carrying out such work with the sanitary regulations.
Activities related to the use of agents of infections, including those that are common both to humans and animals (microorganisms, including genetically modified ones, bacterial toxins, protozoans, helminths and biogenic poisons of the pathogenicity groups I-IV, their production, museum strains and sanitary and demonstrative microorganisms, materials infected or suspected to be infected with the agents of infections of the pathogenicity groups I-IV) are subject to state licensing.

The central role among the license requirements and conditions is assigned to the requirements provided for in the Sanitary Regulations SP 1.3.1285-03 “Safety of working with microorganisms of pathogenicity (severity) groups I-II” and SP 1.2.731-99 “Safety of working with microorganisms of pathogenicity groups III-IV and helminths”, primarily:

- laboratory (production) facilities complying with relevant state sanitary and epidemiological norms and regulations;
- protection equipment, devices and instrumentation;
- relevant vocational and special training of personnel.

Licensee institutions carry out the management of microorganisms of pathogenicity groups I-IV (or pathogenic biological agents) in the territory of the Russian Federation in accordance with the Sanitary Regulations SP 1.2.036-95 “Procedure for registration, storage, transfer and transportation of microorganisms of pathogenicity groups I-IV”. These sanitary regulations are aimed at providing personal and public safety when handling pathogenic biological agents, as well as at precluding storage without special registration or unauthorized access.

In accordance with the sanitary regulations 1.2.036.95 licensees have different powers in handling pathogenic biological agents.

1. Institutions authorized to conduct diagnostic studies only (for example, laboratories at the centers of state sanitary and epidemiological inspections, bacteriological and virological laboratories at the infectious diseases hospitals). These institutions do not have the right to create collections and must hand over the cultures of pathogenic biological agents isolated by them to other institutions specially designated for this purpose.

2. Institutions that are allowed to have collections of pathogenic biological agents necessary to conduct core diagnostic, scientific, educational and production activities but do not enjoy the status of official collection centers.

3. In order to sustain centralized registration, storage and deposit of microorganism strains found in the territory of Russia, ministries and departments designate research institutes to organize specialized collections for information purposes and with exclusive rights to donate industrial and standard pathogenic biological agents.

The most established and important collections often combining the functions of several specialized ones are granted the status of official state collections.

The handling of pathogenic biological agents is thoroughly regulated and appropriately documented as provided for by the Sanitary Regulations No. 1.2.036-95:

Pathogenic biological agents belonging to different groups are stored separately. Strains which serve as a basis for vaccines are stored in separate premises of production units.
Vaccine strains which are part of collections are placed in separate storages: refrigerators or cabinets free of other pathogenic biological agents. The disposal of strains of pathogenic biological agents is registered by a special certificate.

The above-mentioned SP No. 1.2.036-95 also establish the requirements regarding the procedure for the management of pathogenic biological agents within an organization and the requirements regarding the procedure for the transfer of pathogenic biological agents beyond the organization.

Pathogenic biological agents are transferred within an organization from one officer to another upon a written authorization by a head (of the organization). The fact of delivery and receipt of pathogenic biological agents is registered by an appropriate certificate and recorded in the documents maintained by its units.

The transfer of pathogenic biological agents of groups I-IV between organizations is allowed only upon an official request signed by a head of the organization and sealed. In the request a reference is made to the existence of a licence to carry out activities related to the use of microorganisms of pathogenicity groups I-IV with its number and date of issue being specified. The transfer is made only upon a written authorization of a head of the organization who delivers the pathogenic biological agents and an appropriate certificate is drawn up.

Pathogenic biological agents of groups I-II are transported between organizations by special communications or couriers, those of groups III-IV - by mail or couriers.

A covering letter specifying the content of a package with pathogenic biological agents of groups I-IV is drafted on an official form of a sending organization. For pathogenic biological agents of groups I-II a certificate of packaging is additionally drawn up in two copies. The first copies of the said documents are placed into packages containing the pathogenic biological agents. The duplicates are kept by a sender. A consignee organization must draw up a certificate of opening of the package and send it to the organization which has delivered the pathogenic biological agents together with a letter confirming their receipt.

Pathogenic biological agents are transported in air-locked containers. To avoid damaging the containers during the transportation they are wrapped in an absorbent material and placed into metal or plastic cases. The latter, together with the containers therein, are wrapped in paper or covered up with cloth, laced up and wax sealed.

To send the items by mail or special communications the packaged cases are placed within the parcel-boxes while envisaging additional measures to exclude shuffling within the box. Boxes containing pathogenic biological agents of groups I-II are covered up with cloth and sealed.

The address side of the parcel-box is labelled "Danger! Do not open during transportation".

Any emergencies arising during the transportation of pathogenic biological agents of groups I-IV are reported to the bodies of sanitary and epidemiological control and organs of the Ministry of the Interior and the Federal Security Service for appropriate measures to be taken.
Cross-border transfer and receipt of pathogenic biological agents of groups I-IV are authorized only if there is an official request and a transfer permit. The permit is issued by appropriate ministries or departments.

The procedure of export of pathogenic biological agents, the list of which was approved by the Decree of the President of the Russian Federation of August 8, 2001, No 1004, "On the Approval of the List of Agents of Infections (Pathogens) of Humans, Animals and Plants, Genetically Modified Microorganisms, Toxins, Equipment and Technologies Subject to Export Control", is governed by the Decision of the Government of the Russian Federation of August 29, 2001, No 634, "On the Approval of the Regulations of Control over Foreign Economic Activity in Respect of Agents of Infections (Pathogens) of Humans, Animals and Plants, Genetically Modified Microorganisms, Toxins, Equipment and Technologies" (with amendments of October 3, 2002). The Regulations aimed at protecting the Russian Federation's national interests and ensuring the compliance with its obligations under the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction specify the procedure for control over foreign economic activity as regards the products included in the List. The Regulations are binding for all juridical and natural persons under the jurisdiction of the Russian Federation, engaged in foreign economic activity as regards agents of infections, toxins, equipment and technologies subject to control.

Control of fulfilling the requirements under the procedure for the management of the pathogenic biological agents in the territory of Russia is exercised by the units of the State Sanitary and Epidemiological Service of the Russian Federation.