

**MEETING OF THE STATES PARTIES TO
THE CONVENTION ON THE
PROHIBITION OF THE DEVELOPMENT,
PRODUCTION AND STOCKPILING OF
BACTERIOLOGICAL (BIOLOGICAL) AND
TOXIN WEAPONS AND ON THEIR
DESTRUCTION**

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**Mechanism for implementation of state control over dangerous infectious human diseases in
the Russian Federation***

Submitted by the Russian Federation

1. Particularly dangerous diseases in the Russian Federation are infectious diseases capable of epidemic spread affecting large masses of population and/or causing individual diseases that assume extremely serious course resulting in heavy mortality or disability. The Annex contains a list of relevant etiological agents identified by national classification as Pathogenic Biological Agents of the pathogenicity groups I - II (PBA pathogenicity groups I - II). Other pathogenic microorganisms constitute pathogenicity groups III and IV.

2. All events related to manifestation and realization of pathogenic properties of the said microorganisms liable to registration are under control of the National Health Service. The existing system of national control over dangerous infectious human diseases in the Russian Federation is state-organised, systematic and specialised. Efficient state control depends on two main mechanisms:

- (i) improvement of legal regulation and regulation of sanitary and epidemiological procedures;
- (ii) integrated control over compliance with regulatory and legal requirements.

3. The State Sanitary and Epidemiological Service of the Russian Federation is charged with executive powers to implement these two mechanisms pursuant to Federal Law No. 52 of the Russian Federation "On Public Sanitary and Epidemiological Well-being" of March 30, 1999, and the Decree of the Russian Government No. 554 "On approval of the Regulation of the State Sanitary Epidemiological Service of the Russian Federation and the Regulation of the State Sanitary Epidemiological Norms Application", of July 24, 2000.

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4. The structure of the State Sanitary and Epidemiological Service of the Russian Federation follows the administrative-territorial division of the country into federal districts, constituents, municipal formations, cities, district centers, rural communities and involves a system of ministerial centers of state sanitary-epidemiological control, specialised scientific field anti-plague units and epidemiological and microbiological research institutions. Besides the above-mentioned elements, the Service incorporates sanitary-epidemiological institutes of the country's other agencies.

5. The framework of the first of the above mentioned mechanisms responsible for improvement of legal regulation and regulation of sanitary-epidemiological procedures provides for the establishment and development of a normative base to guide the procedures for its implementation first of all. Basic documents that provide for the implementation of relevant mechanism are the said Decree "Regulation of the State Sanitary Epidemiological Norms Application" and Guidelines P 1.1.001-96 "General requirements for elaboration of regulatory documents of the state sanitary-epidemiological regulating system".

6. In accordance with the procedure provided for in those documents specialised scientific field anti-plague agencies and epidemiological and microbiological research institutes under the State Sanitary and Epidemiological Service of the Russian Federation have developed a set of special federal normative and legal acts providing for licensing of any activity within the Russian Federation related to shedding of pathogenic microorganisms by humans, animals or by the environment, detection and treatment of people displaying symptoms of infectious diseases, as well as scientific, educational and productive activities involving use of agents of infection.

7. "Procedure for licensing of the activity related to the use of infectious agents" ratified by the Government of the Russian Federation by Resolution No. 501 of July 4, 2002, established designation of certain kinds of activity, licensing body, licensing requirements, licensing procedure and control over licensee's compliance with licensing requirements.

8. In the center of licensing requirements and conditions for conducting activities related to the use of infectious agents there are the following specific requirements stipulated by the sanitary rules SP 1.3.1285-03 "Safety procedures for handling microorganisms of the pathogenicity (risk) groups I - II":

- (i) Facilities equipped in conformity with relevant state sanitary-epidemiological norms and rules;
- (ii) Safety equipment, devices and tools;
- (iii) Appropriate professional and special training of personnel.

9. A specific mechanism for handling by license holding institutions of dangerous infectious-disease pathogens (as well as materials, infected or suspected to be infected by infectious-disease pathogens) is established by sanitary regulations SP - 1.2.036 - 95 "Procedure for the record-keeping, storage, transfer and transportation of microorganisms of pathogenicity groups I-IV". These sanitary regulations are aimed to maintain individual and public safety when handling dangerous infectious-disease pathogens, as well as preventing their unrecorded storage and unauthorised possession.

10. PBA groups I-IV may be transferred abroad and received only under an official request and transfer authorisation. An authorisation is granted by appropriate ministries and agencies based on an opinion of specialised collections.
11. Institutions, having received PBA from abroad, are obliged to inform the specialised collections thereof.
12. Procedure for exporting PBA, whose list is approved by the Decree of the President of the Russian Federation of August 8, 2001, No. 1004, is established by Resolution of the Government of the Russian Federation of August 29, 2001, No. 634.
13. The second out of the above mentioned mechanisms for public monitoring of dangerous infectious diseases involves a comprehensive control over compliance with the said regulatory requirements.
14. Sanitary Rules SP 1.3.1285-03 "Safety work with microorganisms of pathogenicity (risk) groups I - II" establish a two-level - i.e. internal and external ones - monitoring over activities, which involve handling of dangerous infectious-disease pathogens.
15. An internal monitoring is ensured through a required establishment and functioning in each license-holding institution of a monitoring executive and advisory body – a commission that monitors compliance with biological safety requirements.
16. An external monitoring involves routine and extraordinary checks of how actual conditions of activities involving handling dangerous infectious-disease pathogens conform to the conditions declared in license applications. It is carried out by the following specialised and authorised bodies and institutions of the State Sanitary and Epidemiological Service:
 - (i) the Anti-Plague Centre of the Ministry of Health and Social Development of Russia (MHSD) - in all institutions which carry out activities involving handling the most biologically dangerous microorganisms (PBA pathogenicity group I);
 - (ii) anti-plague institutions (Anti-Plague Center of the MHSD of Russia, anti-plague field stations, anti-plague research institutes) - at the centres of the State Committee for Health and Epidemiological Monitoring of the Russian Federation which carry out activities involving handling the pathogenic biological agents of the pathogenicity group II in the attached constituent entities of the Russian Federation (under Order of the MHSD of Russia ? 37 of February 5, 2004 "On interaction to ensure sanitary protection of the territory of the Russian Federation and measures to prevent quarantine and other especially dangerous infections");
 - (iii) Centers for public health and epidemiological oversight in the constituent entities of the Russian Federation - in the territorial monitored institutions which carry out activities involving handling pathogenic biological agents of the pathogenicity group II.
17. Besides the above mentioned mechanisms for epidemiological monitoring, modalities of identification of first patients suspected to have the well-known dangerous nosological forms and unknown illnesses with signs of controlled emergencies, as well as assessment of quantitative and

qualitative criteria of an anti-epidemic readiness of preventive care facilities and the State Committee for Health and Epidemiological Monitoring of the Russian Federation have been developed and are effectively operating in Russia. Those modalities are governed by the following federal normative and methodical documents:

- (i) instructional guidelines “Organisation and execution of primary measures in case of identification of a patient suspected to have quarantine infections, contagious virus haemorrhagic fevers, malaria and infectious diseases of an unclear etiology, which are internationally significant” (? U 3.4.1028-01);
- (ii) instructional guidelines “Organisation, maintenance and assessment of anti-epidemic readiness of medical facilities to take measures in case of imported or emerging quarantine infections, contagious virus haemorrhagic fevers (CVHF), infectious diseases of an unknown etiology which pose danger for the population of the Russian Federation and international community” (? U 3.4.1030 - 01)

18. The sanitary and epidemiological regulations “Sanitary protection of the territory of the Russian Federation (SP 3.4.1328 - 03)” are also an important set of documents which determine the model of national epidemiological monitoring of quarantine diseases.

19. An algorithm of public monitoring of infectious disease in Russia (47 items) is very similar and includes such elements as: 1) screening the signs of potential and actual epidemic danger of a specific disease consistently based on the clinical and epidemiological analysis and verification of a suspected specific nosological form when identifying its etiology, 2) step-by-step (vertically and horizontally) transfer of information on the territorial, regional, national and international levels, 3) application of primary anti-epidemic measures, 4) application of measures to localize and suppress an epidemic nidus, application of sanitary preventive measures.

20. The Russian Federation maintains state control over infectious diseases based on its three-level system including territorial, regional and federal levels.

21. On the territorial level an epidemiological monitoring and control are ensured through an interaction of the centers for public epidemiological monitoring, preventive care and anti-plague institutions, as well as agency services in line with territorial comprehensive and operational plans of actions in case of identification of patients who suffer from quarantine infections (plague, cholera, yellow fever) approved by the heads of administration for every 5 year periods with their annual update.

22. State control over infectious diseases on the regional level is carried out by the centers for public sanitary and epidemiological monitoring in the constituent entities of the Russian Federation, regional centers for public sanitary and epidemiological monitoring on means of transportation (water and air) and anti-plague institutions.

23. Epidemiological monitoring and control over infectious diseases at the federal level is carried out by the MHSD of Russia which co-ordinates activities of all health care bodies and institutions, the Federal Center for Public Sanitary and Epidemiological Monitoring of the MHSD of Russia, the Anti-Plague Center of the MHSD of Russia, centers for public sanitary and epidemiological

monitoring of the constituent entities of the Russian Federation and centers for public sanitary and epidemiological monitoring on water and air transport, as well as their interaction with anti-plague institutes.

24. Respectively, an information support system which makes it possible to identify epidemic emergencies based on the well-developed criteria, determines an extent of their national and international impact, promptly responds to them and develops rational set of measures to localise and suppress epidemic nidus.

25. The Russian Federation exercises state control over import and proliferation of dangerous infectious diseases in accordance with the list of infectious diseases which require actions to maintain sanitary protection of the territory including plague, cholera, yellow fever, virus haemorrhagic fevers (Marburg, Ebola, Lassa, Junin, Machupo, malaria and severe acute respiratory syndrome (SARS).

26. Each case of a disease (or a suspected disease) placed on the list maintained in force in the Russian Federation (especially groups of cases and detection of unknown infectious diseases) is viewed as an emergency and requires to transfer an urgent information in the form of two consecutive messages: extraordinary (a preliminary one, provided urgently, within 24 hours) and final (within 15 days after an emergency situation was restored back to normal).

27. The information on identification of a sick person (suspected to be ill) is communicated upward in accordance with the infrastructure of therapeutic and sanitary-epidemiological services. The first level of its collection and accumulation is a regional sanitary body (CGSEN in the constituent entity of the Russian Federation), the second one is a national sanitary body - the Department of State Sanitary and Epidemiological Service of the MHSD of Russia. Only reliable and etiologically verified information is communicated to the WHO.

28. The national system of state monitoring of and control over contagious diseases in the Russian Federation is functionally linked to the global system of epidemiological monitoring and control. The global epidemiological surveillance is managed by the International Health Regulations in force, now under revision and the Russian Federation takes an active part in this process. The draft International Health Regulations prepared by the WHO defines a generic notion as an object of the global epidemiological surveillance - emergency situations in matters of public health having international consequences. In this case Article 41 of the draft International Health Regulations provides for an immediate exchange of medical and sanitary information concerning the suspicion about a deliberate release of a biological, chemical or radiological agent, that is to say the issues of biological terrorism become as well an integral part of the object of global epidemiological control which should be regulated at the level of the largest representative body of countries.

Annex

**List of human pathogens of the pathogenicity groups I-II
(the most dangerous micro-organisms)**

Bacteria

Group I

1. *Yersinia pestis* - pest

Group II

1. *Bacillus anthracis* - Siberian plague
2. *Brucella abortus*
Brucella melitensis - brucellosis
Brucella suis
3. *Francisella tularensis* - tularemia
4. *Burkholderia mallei* - glanders
5. *Burkholderia pseudomallei* - pseudoglanders
6. *Vibrio cholerae* O1 toxicogenic - cholera
7. *Vibrio cholerae* non O1 (0139) toxicogenic - cholera

Rickettsiae

Group II

1. *Rickettsia prowazeki* - epidemic typhus fever and Brill's disease
2. *Rickettsia typhi* - flea-borne typhus fever
3. *Rickettsia rickettsii* - Kew Gardens spotted fever
4. *Rickettsia tsutsugamushi* - tsutsugamushi fever
5. *Coxiella burnetii* - coxiellosis (Q-fever)

Viruses

(Names of viruses have been given in Russian transcription as the binominal list does not exist)

Group I

1. Filoviridae:
Marburg and Ebola viruses - haemorrhagic fevers
2. Arenaviridae:
Lassa fever, Junin, Machupo, Sabia,
Guanarito viruses - haemorrhagic fevers
3. Poxviridae:
Ortopoxvirine type
natural smallpox virus (Variola) - human natural smallpox
monkey pox virus (Monkeypox) - monkey pox
4. Herpesviridae:
monkey virus B - chronic encephalitis and encephalitis

Group II

1. Togaviridae:
equine encephalomyelitis viruses - mosquito encephalitis, encephalomyelitis,
(Venezuelan equine encephalitis virus, blind-staggers
Eastern equine encephalitis virus, Western
equine encephalitis virus)

Semlica, Bibaru, Evergladis, - fever diseases
Chikungunya, O'Njong-Njong, Karelia,
Sindbis, Ross-river, Mayaro, Mucambo,
Sagiuma fever viruses
2. Flaviviridae:
tick-borne type encephalitis viruses, - encephalitis, encephalomyelitis
Alma-Arassan, Apoi, Langat, Neguishi,
Povassan, Scotland sheep
encephalomyelitis

Kyasanur Forest diseases, Omsk - haemorrhagic fevers
haemorrhagic fever virus

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| Japanese encephalitis type viruses,
Western Nile, Ilyelus, Rocio, St Louis
encephalitis, Murray Valley encephalitis
virus | - encephalomyelitis, blind-staggers |
| Carshi, Cungin, Sepic, Wesselborn, Zica,
Riobravo, Dengue, Soculuc | - fever diseases |
| Yellow fever | - haemorrhagic fever |
| Hepatitis C virus | - parenteral hepatitis, hepatocellular liver
carcinoma |
| 3. Bunyaviridae:
Bunyavirus type
California encephalitis type, La-Cross,
James-Town, canyon, lepus, Inco, Tiaguin | - encephalitis, encephalomyelitis, blind-
staggers and fever diseases with
meningeal syndrome and arthritis |
| C-type Apey, Madrid, Oriboca, Ossa,
Restan etc. Viruses | - fever diseases with myositis and arthritis |
| Phlebovirus type:
mosquito fever viruses of Sicily, Naples,
Rift Valley, Toscana etc. | - encephalitis and fever diseases with
myositis and arthritis |
| Nairovirus type:
Congo-Crimean haemorrhagic fever virus;
diseases of sheep of Nairobi, Gandjam | - haemorrhagic fever, fever with meningeal
syndrome |
| Dugbe | - encephalitis |
| Hantavirus type:
Hantaan, Seoul, Puumala, Chile, Aido
viruses and others | - renal (RSHF) and pulmonary syndrome -
haemorrhagic fevers |
| 4. Reoviridae,
Orbivirus type:
Kemerevo, Colorado tick-borne fever,
Bluetongue of sheep, Changuinola,
Orungo viruses and others | - meningeal syndrome and arthrities fevers |
| 5. Rhabdoviridae,
Lyssavirus type:
street mice virus
Dikovania, Lagos-bat | - fury
- pseudofury and encephalopathy |
| 6. Picornaviridae | |

- Aphthovirus type:
Foot-and-mouth disease virus - foot-and-mouth disease
7. Arenaviridae:
lymphocytic choro-meningitic viruses, Takaribe, Pichinde - asthenic meningitis and meningoencephalitis
8. Hepadnaviridae:
hepatitis B virus - parenteral hepatitis
9. Retroviridae:
human immunodeficiency virus (HIV-1, HIV-2) - AIDS
T-cellular human leukemia (HT_{LV}) - T-cellular human leukemia
10. Nodaviridae:
hepatitis D (delta) and E viruses - infectious hepatitis
11. Unconventional agents:
- Tardy neuroinfections pathogens = subacute spongy encephalopathies (Prion Diseases)
Kuru - subacute encephalopathy
- CJD agent – Creutzfeldt-Jacob disease pathogen - Creutzfeldt-Jacob disease, Gerstmann-Straussler syndrome
- Pathogen of human vector-borne spongy encephalopathy - amiotrophic leuc ospongiosis (Belarus)
- Pathogen of Dejerine-Thomas human atrophy - I type Dejerine-Thomas atrophy (Yakutia, Eastern Siberia)
- Scrapie - sheep and goats subacute encephalopathy
- Pathogen of the mink encephalopathy - mink vector-borne encephalopathy
- Chronic wasting disease of hoofeds - chronic weariness diseases of deers and elks in captivity
- Pathogen of the cattle spongy encephalopathy - “mad cow disease”

Chlamydia

Group II

1. *Chlamydomphila psittaci* - parrot fever – psittacosis

Fungi

Group II

1. *Blastomyces dermatitidis* - blastomycosis
 2. *Histoplasma capsulatum* - histoplasmosis
 3. *Coccidioides immitis* - coccidioidomycosis
 4. *Paracoccidioides brasiliensis* - paracoccidioidomycosis
(Brazilian blastomycosis)
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