

**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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**Responding to and mitigating the effects of suspicious outbreaks of disease**

**System of organization of specific indication of  
bacterial (biological) means**

**Submitted by Ukraine**

1. Significant political, social and economic changes that have taken place in the world and in Ukraine in particular within the last decades, widening of international contacts, scientific achievements in biotechnology and molecular biology, terrorist acts with the use of biological pathogenous agents (BPA), potential threat of emergency situations of man-caused and natural type with the BPA as the dangerous factor stipulate for necessity of improvements in the sphere of provision of biological safety and indication of biological pathogenous agents.
2. With the purpose of detection of biological pathogenous agents in maximum short terms in the system of Ministry of Health since 1979 as part of networks of surveillance and laboratory control the **system of organization of specific indication of bacterial (biological) means** was created.
3. The procedure of functioning of this system on the territory of Ukraine up to 2003 was regulated by the **Decree of MOH of USSR of 10.07.1979 ? 152-c “System of Organization of Specific Indication of Bacteriological (Biological) Means”**.
4. On March 21, 2003 with the purpose of maintenance in Ukraine of reliable level of biological safety, timely indication and identification of type of biological pathogenous agents, MOH of Ukraine and AMS of Ukraine adopted the **new common Decree “On Improvement of System of Indication of Biological Pathogenous Agents”** that replaced the previous Decree of MOH of USSR of 1979.

5. According to this decree the country is divided into 6 regions in accordance with the number of appropriate Centres of indication on the territory of Ukraine. MOH also prepared Regulations on the Centres of Indication and Regulations on Central Institutions of Indications as well as the Methodological Recommendations on Organizing of Functioning of BPA Identification System.

6. Today the system of organization of specific indication of bacterial (biological) means includes three categories of institutions:

(i) **6 Centres of Specific Indication of Biological Pathogenous Agents**, namely: Central Sanitary and Epidemiological Station of MOH, L.V.Gromashevskogo Institute of Epidemiology and Infectious Diseases of AMS of Ukraine (Kyiv), Institute of Microbiology and Immunology of AMS of Ukraine (Kharkiv), Lviv Scientific and Research Institute of Epidemiology and Hygiene of MOH, Ukrainian Scientific and Research Antiplague Institute of MOH (Odesa); Anti-Plague Station of Autonomous Republic of Crimea. The administrative territories, where the Centres carry out indication and identification of all types of BPA, are fixed for each Centre of indication. These Centres also fulfil functions of a profile Centre of indication of BPA on all territory of Ukraine, carrying out identification of non-classified at the previous stages of BPA indications (unknown, new, modernized, transgenic, combined) in accordance with their specialization;

(ii) **Central institutions of BPA indication**, namely: Autonomous Republic of Crimea Sanitary and Epidemiological Station, regional and city sanitary and epidemiological stations of Kyiv and Sevastopol. These institutions conduct indication and identification of all types of biological pathogenous agents within the appropriate territories and provide with methodological recommendations, training of personnel and practical help to the territorial sanitary and epidemiological stations on the issues of organization and carrying out of laboratory research;

(iii) **Institutions of BPA indication** (city, regional, on water, railway and air transport sanitary and epidemiological stations). These institutions carry out surveillance of respective territories, sample collection from different objects, which are suspected on BPA contamination, and send it to the respective territorial Central institution of BPA indication.

## **Annex I**

### **Extract from Regulations on the Centers of Indication of Biological Pathogenous Agents**

#### **General Provisions**

1. Centers of Indication of Biological Pathogenous Agents (CIBPA) are created and function on the basis of research institutes of epidemiological profile of the Ministry of Health, Academy of Medical Sciences of Ukraine, Crimean Anti-Plague Station and Central Sanitary and Epidemiological Station of the MOH of Ukraine as a part of the system of observation and control of the functional subsystem of civil protection of the population and of the territory for the purpose of prevention and response to emergency situations of man-caused, natural and socio-political (including warlike) type.
2. Centers of Indication of Biological Pathogenous Agents consist of structural subunits of the assigned institutions, which are responsible for BPA indication and identification.
3. The Head of the CIBPA is the head of the institution, which became the basis for creation of the Center. The deputy directors of the institution may become the deputies of the Head of the Center, if he chooses to appoint them as such.
4. Performance of the Centers of Indication of Biological Pathogenous Agents is coordinated by the Ministry of Health of Ukraine.
5. Centers of Indication of Biological Pathogenous Agents will function according to the regimes of the system of civil protection of the population and territories, in line with the annual plan approved by the Head of the CIBPA.
6. Reports on CIBPA performance are to be produced for the Ministry of Health annually before February 1st of the subsequent year.
7. Centers of Indication of Biological Pathogenous Agents are to keep primary accounting records according to the forms, approved by the Ministry of Health of Ukraine.
8. Centers of Indication of Biological Pathogenous Agents are to be located in separate isolated facilities, or on the premises of the working area of profile subunits of the assigned institutions (laboratories of prion infections, virology, Rickettsia, bacteriology, mycology, etc). Premises, allotted for the Centers of Indication of Biological Pathogenous Agents need to be sufficient in space, planned and equipped according to standard requirements, in order to ensure optimal working environment.
9. Centers of Indication of Biological Pathogenous Agents will utilize measuring equipment, communication facilities, office equipment, transport, equipment, devices and property of the institutions, which served as basis for creation of the CIBPA, as well as special modern

equipment for BPA indication, which is to be distributed through the system of centralized governmental supply. Immunobiological preparations, nutrient mediums, laboratory animals, means of personal protection for conduction of indication and identification of BPA are purchased on the special funds, provided by the Ministry of Health of Ukraine.

10. Metrological provision of measuring equipment, used in the research, is performed according to the existing normative documents.

11. Accreditation of CIBPA laboratories is performed by the Ministry of Health of Ukraine according to the set procedure. Each laboratory is to have a passport with indication of its profile.

12. Each CIBPA will be assigned with the administrative territory on which they will be performing indication and identification of BPA.

13. Centers of Indication of Biological Pathogenous Agents will perform the profile functions for the whole territory of Ukraine, conducting identification of BPA, which were not classified on the previous stages (unknown, new, modernized, transgene, combined) according to the assigned profile.

**Main functional duties of the Centers of Indication of Biological Pathogenous Agents are:**

- (a) To perform systematic theoretical and practical trainings of:
  - (i) Personnel of the Centers on administrative and methodological issues in indication of all types of BPA and identification of various classes (types) of BPA according to the Center's profile within the programs, approved by CIBPA directors and agreed with the Ministry of Health of Ukraine;
  - (ii) Specialists of the Central Institutions, responsible for indication of all types of BPA and identification of various classes (types) of BPA according to the Center's profile within the programs, approved by the Ministry of Health of Ukraine.
- (b) To carry out measures, providing functionality, antiepidemic mode, Center deployment trainings, perfection of the system of interaction with Central Institutions (laboratories) on the assigned territories and with other CIBPA and bodies of civil protection of the population and territories in case of emergency situations (Committees on Environmental Issues and Emergency Situations);
- (c) To provide consultative, administrative-methodological and practical assistance to Central Institutions (laboratories) in execution of assigned tasks of BPA indication and identification;

(d) To develop new efficient methods of BPA indication and identification, to take part in their testing and introduction them in practical performance of health institutions of the BPA indication system;

(e) To control, analyze and assess the level of readiness of central institutions (laboratories) to perform the set tasks of BPA indication and identification on the assigned territory, to develop recommendation on perfection of their performance, to present the proposals to the Ministry of Health of Ukraine;

(f) To directly perform indication of all classes (types) of BPA and identification of BPA, which were not classified on the previous stages according to the assigned profile. In case of necessity to cooperate with CIBPA of other profiles and pass over the investigated samples or the singled out BPA, which were not classified on the previous stages, in order to receive more accurate results of BPA indication and identification.

## **Annex II**

### **Extract from Regulations about Central Institutions (laboratories) of Indication of Biological Pathogenous Agents**

#### **General Provisions**

1. Central Institutions (laboratories) of indication of Biological Pathogenous Agents are created on the basis of sanitary and epidemiologic station of the AR Crimea, regions, Kiev and Sevastopol, and which are to be powerful enough to cope with the tasks of BPA indication.
2. All microbiological laboratories of the institution will be engaged into work in order to keep up with the principle of investigation performance and identification of all kinds of potential BPA (of prion, viroid, virus, Rickettsia, bacteria and fungus etiology, biochemical action, toxins), and performance of territorial administrative-methodological management.
3. Head Physician of the basis institution is appointed the Head of the Central BPA Indication Institution (laboratory).
4. Central Institution (laboratory) of BPA indication functions in the mode of system of civil protection of the population and of the territory, according to the plan, which provides for logistic support, improvement of the base, personnel training, practical trainings, development of diagnostics methods.
5. Director of the Central Institution (laboratory) of BPA indication will approve the passport, which indicates list of personnel and their functional duties, scheme of the laboratory, succession of pathogen material handling, provision of the basic equipment, diagnostic preparations, nutrient mediums, etc.
6. Central Institutions (laboratories) of BPA indication are to keep primary accounting records according to the forms, approved by the Ministry of Health of Ukraine.
7. Management of the Central Institutions (laboratories) of BPA indication is performed by the Ministry of Health of Ukraine through the Centers of Indication of BPA.

#### **Main functional duties of the Central Institutions (laboratories) of Indication of Biological Pathogenous Agents are:**

- (a) To conduct epidemiological survey of the territories at stake or which are in current state of emergency. Sample collection from people, environmental objects, food, drinking water, other facilities of life support and means of their transportation;

- (b) To perform direct indication and identification of BPA of various samples, prepare and produce stage-by-stage conclusions on presence or absence of pathogens in the offered samples (with indication of BPA type);
- (c) To perform expertise of food, raw material, drinking water and other means of life support and provide conclusion concerning the possibility of their utilization;
- (d) To forward all BPA, singled out in the process of indication, as well as cultures of BPA, which were not identified in the course of indication, or samples of specimens that are infected by an unidentified BPA to the specialized Center of BPA indication for proper research and investigation;
- (e) To perform administrative-methodological management and to provide practical assistance to institutions of health protection and laboratories, irrelative of their subordination on the territory, in epidemiological research, sample collection and laboratory inspection of food, raw material and drinking water for presence of BPA.

### **Annex 3**

#### **Extract from Methodological Recommendations on Organizing of Functioning of BPA Identification System**

##### **1. General Provisions**

1. BPA identification (BPAI) system as an important element in the field of medical and biological protection of population and environment, is a part of state civil protection system from contamination and harmful influence of biologic pathogenous agents.

2. Objectives of BPAI system are: determination and identification of agents (of biotic and abiotic origin), which contaminate people, environment, food, drinking water etc.; analysis and estimation of situation to provide effective administrative, economic, restrictive, antiepidemic, medical and preventive measures concerning prevention or reduction of contamination rate, timely provision of medical assistance.

3. General supervision and control of fulfilment of BPAI tasks is provided by Ministry of Health in co-operation with Ministry of Emergencies and Affairs of Population Protection from Consequences of Chornobyl Catastrophe and other authorities.

4. Methodological supervision of identification of pathogenous agents, laboratory methods and training of staff is provided by Central Sanitary-Epidemiological Station of Ministry of Health of Ukraine.

5. Indication and identification of biological pathogenous agents in railway, air and water transport, administrative territories is a duty of the state sanitary epidemiological services and scientific institutions of Academy of Medical Sciences of Ukraine and Ministry of Health of Ukraine. They collaborate with appropriate organizations and divisions of antiepidemic specialization of Ministry of Defence, Security Service, Ministry for Internal Affairs, State Committee on Protection of State Border, Ministry of Agrarian Policy and other authorities.

6. Sanitary epidemiological services of Ministry of Health of Ukraine and scientific institutions of Academy of Medical Sciences of Ukraine and Ministry of Health of Ukraine, which are the part of BPAI system fulfil their function being guided by Constitution of Ukraine (page 3, 27, 49), Laws of Ukraine "On Civil Protection of Ukraine", "On Legislation Regulations of Emergency Situations", "On Protection of Population and Territories from Emergency Situations of Technogenic and Natural Character", "On Protection of Population from Infectious Diseases", "On Maintenance of Sanitary and Epidemiological Well-Being of Population", by Decree of the Cabinet of Ministers of Ukraine of 03.08.1998 ? 1198 "On Unified State System for Prevention and Reaction on Technogenic and Natural Emergencies".



7. All institutions (laboratories), within BPAI system, are working according to Unified State System of Prevention and Reaction on Technogenic and Natural Emergencies It comprises:

- (a) “State of daily activity”;
- (b) “State of the increased readiness”;
- (c) “State of emergency situation”;
- (d) “State of emergency”.

## 2. Terminology

**Biological Pathogenous Agents (BPA)** – any pathogens of biotic kind (of prion, viroid, virus, Rickettsia, bacteria and fungus etiology, biochemical action, toxins), which are able to cause mass infection among people, animals, plants, and which can cause worsening of environment, considerable economic losses, worsening of living conditions of the population or stipulate illness or death of people.

**Biological safety (BS)** – optimal living conditions, which exclude harmful influence of BPA on people’s health.

**Indication of biological pathogenous agents (IBPA)** – a set of measures consisting of qualified sample collection from people and from objects of environment, and performance of laboratory research according to a special scheme for all kinds of pathogenous biological agents that present a threat for people or animals.

**Biological protection (BP)** – protection from BPA, which encompasses: timely detection of biological pathogens, identification of their kind and of the scope of infection, as well as a set of administrative, regime limiting and antiepidemic, medical and preventive measures.

**Identification of biological pathogenous agents** – complete or sampling laboratory analysis with identification of a kind, species, subspecies, epidemiologic markers of the strain (culture) of organisms of various classes and toxins through implementation of microbiological, virological, biological, immunological, biochemical, genetic and other methods.

**Emergency situation (ES)** – violation of regular living and working conditions of people on the territory, which is caused by accident, catastrophe, natural disaster, epidemic, epizooty, epiphytoty, conflagration, use of means of destruction that have or may lead to human and material losses.

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