

First Meeting
Geneva, 10 – 14 November 2003

Meeting of Experts
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Items 5 and 6 of the agenda

**PROCEDURE TO CONTROL ACCESS AND WORK WITH BIOLOGICAL AGENTS
AND TOXINS IN UKRAINE**

Prepared by Ukraine

1. The significant attention to the antiepidemic safety issues in the work with the pathogenic microorganisms and toxins always was given in Ukraine. The laws adopted by the Verkhovna Rada as well as others directive documents of the Cabinet of Ministers of Ukraine and Ministry of Health of Ukraine confirm it.
2. The special attention is given to the problem of accounting, storage, work and transfer of cultures of bacteria, viruses, rickettsia, fungi, protozoa, micoplasma, bacterial toxins and poisons of biological origin. The procedure of these actions is determined by the special **"Regulation on Procedure of Storage, Work and Transfer of the Cultures of Bacteria, Viruses, Rickettsia, Fungi, Protozoa, Micoplasma, Bacterial Toxins and Poisons of Biological Origin"** adopted on 18.05.1979.
3. This Regulations provides the strict accounting of materials, safety of work in laboratories, excludes the possibility of non-authorized transfer, unaccounting storage, use, the possibility of distribution of infections outside the limits of laboratories and assure the fulfilment of the rules of transfer of cultures, toxins and poisons in other institutions of the country and outside its borders.
4. In accordance with the degree of danger of infection agents for the persons which work with them as well as for others people and with regard to modern scientific data concerning the etiology and clinics of diseases, and also last achievements in the field of profilactic and treatment of some diseases as well as availability of effective measures of protection of work and safety precautions during the work with BPA, all microorganisms - the agents of antropozoonoze and antropozoonoze infectious diseases, toxins and poisons of animal origin are divided into 4 groups.
5. The State Sanitary Rules **«Safety of Work with Microorganisms of I-II groups of pathogenicity» (ДЧП 9.9.5-035-99)** adopted by the Decree of Chief State Sanitary Doctor of Ukraine of 01.07.1999 №35 contains classification of human pathogenic microorganisms. The division of agents of human infectious diseases into the groups of pathogenicity is based on their affects on workers with normal health. The agents of infectious diseases of animals and plants,

that can not cause human diseases, are not included in the list of microorganisms on groups of pathogenicity.

6. Ukraine as well as other CIS countries has reverse classification of agents of infection diseases comparing with classification of WHO and western countries. For example if in Ukraine classification agents of especially dangerous infectious diseases belong to the I group of pathogenicity, in accordance with classification of EU countries this group is formed by the so-called conditionally pathogenic microorganisms.

7. The I group of pathogenicity is formed by the agents of especially dangerous infectious diseases (plague, viruses of Lassa, Ebola, Marburg, Huanin, Machupo, Crimea-Kongo, smallpox, monkey virus B).

8. The II group of pathogenicity is formed by the agents of highly contagious epidemic bacterial, virus, rickettsia, fungies diseases of human, botulin toxins.

9. The III group of pathogenicity is formed by the agents of bacterial, viruses, fungies, protozoa infectious diseases that are allocated in independent nozological forms, and also by the attenuated strains of agents of I-II groups of pathogenicity.

10. The IV group of pathogenicity is formed by the agents of bacterial, viruses, fungies deseases, septicemices, meningits, pneumonias, enterities, toxicoinfections, acute bacterial poisonings, and also by the attenuated strains of agents of III group of pathogenicity.

11. The procedure of work and storage of BPA is determined in accordance with the division of pathogenic microorganisms into the groups of pathogenicity.

12. Institutions that in accordance with its functional duties carry out bacteriological, virological, immunological researches of pathological material contaminated with the agents of human infectious diseases should receive the permission to work with microorganisms of certain group of patogenicity. The permissions are given out by the regime commissions at the condition of biological safety of work in accordance with the State Sanitary Rules **ДЧП 9.9.5-064-2000 «Procedure to Grant the Permission for the Work with Microorganisms of I-IV Groups of Pathogenicity and Recombinant DNA»**.

13. The above mentioned State Sanitary Rules establish unified procedure to grant permissions for the work with microorganisms of I-IV groups of pathogenicity and recombinant DNA during conduction experimental, diagnostic, production of immunobiological medicines, and procedure to control production on the content of biological pathogenic agents on the territory of Ukraine.

14. Besides granting the permission to work (manufacture, store, transfer, use, destruct, decontaminate) with the biological agents and other products of biotechnologies, **duties of regime commissions are:**

- current state sanitary-epidemiological surveillance for compliance of antiepidemic regime during the work with dangerous biological materials;
- preventive state sanitary-epidemiological surveillance for construction or reconstruction of microbiological laboratories;
- consideration of the projects of reconstruction and construction of microbiological laboratories from point of view of biological safety;

- accounting of laboratories that work with the biological agents in the zone of operation;
- accounting and detailed analysis of each case of accident that occurred during the work with the biologically dangerous material;
- analysis of situation on maintenance of biological and public safety in laboratories of microbiological profile;
- bring forward the proposals on improving the regime of safety.

15. Territorial regime commissions as the working bodies on biological safety are formed of the most qualified experts (epidemiologist, bacteriologist, virologist) and are the part of respective territorial sanitary-epidemiological institutions. Thus, regime commissions are subordinated to the Chief State Sanitary Doctor of the appropriate territory and within the framework of its authorities carry out sanitary-epidemiological surveillance for compliance with the rules of biological safety in laboratories that work with the agents of I-IV groups of pathogenicity on the territory, which is served by this sanitary-epidemiological station.

16. The hierarchical structure of regime commissions looks as follows:

- i. Central Regime Commission of the MOH of Ukraine, which carries out an organisation and methodological management on biological safety in Ukraine;
- ii. Regime Commissions of Autonomous Republic of Crimea, regions, Kiev and Sevastopol;
- iii. District and city regime commissions.

17. Regime Commissions of higher administrative territories carry out an organizational and methodological management of the commissions that work on subordinated administrative territories.

18. The State Sanitary Rules (ДСП 9.9.5-035-99) also precisely determines the procedure of sanitary-epidemiological surveillance for the fulfilment of the rules of biological safety in institutions carrying out the work with agents of I-II groups of pathogenicity.

19. The procedures of work with the biological pathogenic agents of III and IV groups of pathogenicity are determined by the State Sanitary Rules (ДСП 9.9.5-080-2002 "Rules of Organization and Safe Work in Laboratories (Divisions) of Microbiological Profile".

20. The special demands are put forward to the laboratories that work with the biological material of I-II groups of pathogenicity. These demands are determined by the state sanitary rules ДСП 9.9.5-035-99 "Safety of Work with Microorganisms of I-II Groups of Pathogenicity".

21. The rules define the institutions that have the right to work with the BPA of I-II group of pathogenicity and character of researches that could be conducted by the laboratories. With this purpose all researches are divided into 2 groups: diagnostic and experimental. Only antiplague and specialized base institutions have the right to work with BPA of I groups of pathogenicity.

22. The permission on experimental work with each type of biological agent is given out with restriction of term till 5 years, after that the repeated sanction is required. Each 5 years the

microbiological laboratories of sanitary-epidemiological institutions receive the right to realize only the diagnostic researches of BPA of II group of pathogenicity.

23. The special demands are put forward to the material base of laboratories and personnel, which works with the biological material of I-II groups of pathogenicity. In accordance with the degree of safety for the personnel the premises of such laboratories should be divided into 3 zones:

- "Infectious" – where personnel in protective clothes of the appropriate type carry out the work with the material of I-II groups of pathogenicity;
- "Conditionally infectious" – premises of laboratory within the limits of which the infected material only is transferred; the work is carried out in antiplague clothes of IV type;
- "Clean" - premises, where the work with a biological material is not carried out; the personnel can work in personal clothes.

24. The permission to work with a biological material of I-II groups of pathogenicity receive the experts, which have high or secondary medical, biological and veterinary education, finished the appropriate courses of specialization and do not have contra-indications to immunization and treatment with the use of specific medicine. The access to work with experimental and diagnostic material is made out by the order of director of the institution each 2 years after checking the knowledge on antiepidemic regime.

25. Before the disintegration of the USSR special study on laboratory diagnostics of especially dangerous agents was carried out in antiplague institutes. Taking into account that after acquiring of independence Ukraine did not have such institutes the studies were not conducted during some time. In October 1999 Ukrainian Scientific and Research Antiplague Institute was created on the basis of Odesa Antiplague Stations. One of its tasks is the conduction of special study on laboratory diagnostics of BPA of I-II groups of pathogenicity.

26. Now the premises for the educational process are apportioned in the Institute and after their appropriate equipping the studies will be renewed.

27. The obligatory condition of functioning of laboratories that conduct the work with the biological materials of I-II groups of pathogenicity is the day-and-night protection of their premises. This rule is reflected in above mentioned state sanitary rules.

28. The state authorities of Ukraine give the significant attention to the issues of reduction of quantity of institutions where the pathogenic microorganisms and toxins are stored. Taking into account that one of the effective ways of prevention of non-authorized use of biological means is the reduction of number of institutions that have stocks of these agents, the Cabinet of Ministers of Ukraine adopted the **Decrees №705 of 12.10.1994 "On the State System of Deposition of Strains of Microorganisms" and №1300 of 17.08.1999 "On the Development of State System of Deposition of Strains of Microorganisms"**. In accordance with these Decrees the limited number of depositaries of biological materials are created.

29. The L.V.Gromashevskogo Institute of Epidemiology and Infectious Diseases of AMS of Ukraine (Kyiv) is assigned as depositary of human pathogenic microorganisms. As the depositary the Institute has branches in Kharkiv Institute of Microbiology and Immunology of AMS of Ukraine (bacteria, fungies, viruses), Ukrainian Scientific and Research Antiplague Institute of

MOH (Odesa) (especially dangerous bacteria and viruses), Lviv Scientific and Research Institute of Epidemiology and Hygiene of MOH (viruses and rickettsias), Ukrainian Scientific and Research Institute of Venerology (chlamidia), Kyiv Medical University (viruses).

30. State Scientific and Control Institute of Biotechnology and Strains of Microorganisms is the depositary for BPA of animals (fungies, bacteria, viruses).

31. With the purpose of improving of biological and physical protection during the storage of test strains, diagnostic kits, collections of cultures in microbiological and virological laboratories, the MOH of Ukraine adopted the **Decree № 426 of 24.10.2001 «On Improving of Safety of Institutions where the Works with the Microorganisms of I-IV Groups of Pathogenicity are Conducted»**.
