

Biosafety when Handling Pathogenic Biological Agents

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The humanity entered the XXI century while being exposed to pathogenic viruses, bacteria, microscopic protozoa, and other pathogenic and nominally-pathogenic biological agents. This is why the biosafety issue has revealed itself acutely these days. The World Health Organization (WHO) considers that “underestimating the threat that bacteria and viruses pose to biosafety and economic growth might soon prevent states from protecting their nations from the threat”.

At present it is beyond doubt that the health of the population is a defining factor for ensuring national safety of the Russian Federation, the objectives of which include fostering the economy, overcoming scientific-and-engineering as well as technological dependence on external sources, improving the economical situation in the country, etc.

Biologically hazardous organisms and their products pose threat to the existence of not only humans, but also plants, animals, and useful microorganisms by causing different levels of exposure or lethal effect depriving humans of food and other sources and means of existence. World biosafety issues are of long standing, since in both nature and industry one often comes across hazards in this or that matter necessary for humans and the society.



Analytical data evidence of the fact that concerns are caused by infectious disease incidence. Suffice it to list the following facts. According to the WHO data, annually around 51 million people die in the world, of whom 16 million – of infectious and parasitic diseases. Currently over 200 diseases can be found in both humans and animals, cross-transmitted and caused by viruses, bacteria, fungi, protozoa, helminthes, etc. According to OIE and WHO data, annually over 500 thousand pathogens foci are registered in the world, and one of the conditions for emergence of the diseases is emergencies resulting from natural, environmental, and man-caused catastrophes in different locations on the globe.

In the Russian Federation, around 40 million cases of infectious diseases are annually recorded. That being said, the economic loss caused by infectious diseases makes over 18 billion rubles a year. Over the past 10 years, increase in the morbidity rate has been marked, and in certain regions of the Russian Federations for nearly all known infectious and parasitic diseases. Emergence of over 20 new pathogens was recorded in the country, with the pathogens being unknown to the science 10-20 years ago. On a continuous basis, 5-6 select agents pose threat to the wellbeing of the country, this being connected with the activation of enzootic, epizootic outbreaks and potential environmental catastrophes in numerous natural foci within the Russian Federation area, as well as around 10 select agents and pathogens exotic for the Russian Federation, that can be imported from foreign countries due to intense business and economic as well as cultural exchange. Finally, at this stage, it is emergency biological situations due to unforeseen emergency failures at modern biotechnological industries or deliberate bioterrorist attacks of transnational nature that cause real threat. The above-mentioned and a range of other factors allow affirming that in the coming years pathogens will hold lead positions in the overall structure of pathology of the nation. This being said, economic losses from animal diseases make up to 20% of the cost of products in developed (in terms of industry) countries and up to 40% in developing countries.

In our country there is a large base of regulatory documents that covers, to a large extent, all areas in the field of handling pathogenic biological agents and that has traditionally become the only control tool; specifically:

- SP 1.3.1285-03 “Safe Handling of Microorganisms of I-II Pathogenicity (Hazard) Groups”;
- SP 1.3.23.22-08 “ Safe Handling of Microorganisms of III- IV Pathogenicity (Hazard) Groups and Parasitic Diseases Pathogens”;
- SP 1.2.036-95 “Procedure for Registering, Storing, and Transporting Microorganisms of I- IV Pathogenicity Groups”;
- SP 1.2.1318-03 “Procedure for Issuing Sanitary-and-epidemiological Findings Reports on the Possibility to Handle Human Diseases Pathogens of I- IV Pathogenicity (Hazard) Groups, microorganisms modified through gene engineering, biological toxins and helminthes”.

Observing the above sanitary regulations is a basis for safe handling of pathogenic biological agents in the Russian Federation. These documents are to be observed without exception and serve as a basis for the prevention of loss related to the spread of harmful microorganisms. Alongside with this, it should be noted that in the mentioned regulatory documents applying to PBA's, no such terms as biological risk, risk assessment, biorisk management have been used. And for this very reason, these documents by their nature cannot contain any requirements as to voluntary introduction of a system approach to ensuring biosafety when handling PBA's.

Based on the above documents, respective work is in progress at the Federal Center for Toxicological, Radiation, and Biological Safety –the Lead Institute of the RF Ministry of Agriculture. It is fundamental, applied science developments at the Federal Center that food, biological, toxicological, radiation, environmental safety of the country depends on in many respects.

The Federal Center for Toxicological, Radiation, and Biological Safety, Federal State Budget Institution, until 2004 being FSSI “All-Russian Research Veterinary Institute” (ARRVI [VNIVI]) was established by the USSR Ministry of Agriculture in 1960 in pursuance of the Decree of the USSR Cabinet Council and was identified as the main science institution for toxicological, radiobiological safety, and biosafety in specific areas. The center is depositing select agents for state purposes and serves as a precision center for the development of detection methods and radiation exposure assessment, hard toxins and bacterial agents indication in environmental objects, pathological material, food and forage raw material of local and foreign make.

The Federal Center acts in accordance with the Charter and licenses authorizing the following: the education of postgraduates, refresher trainings for managers and subject matter experts, and processing of microorganisms of 2-4 pathogenicity groups, production of drugs and pharmaceuticals, maintenance of units hosting radioactive substances. The Federal Center is accredited as a competent and independent Trial Center for the certification of agricultural and drug materials, and food products, and as a Radiation Control Laboratory.

Research at Federal Center is conducted in four activity-specific areas: toxicological, radiation, biosafety; and bionanotechnology development. A scientific institution of bio-and-nanotechnologies has been established to help support fundamental and applied research as well as the introduction of developed products with the focus on environmental and industrial safety of the country, and development of bionanotechnology.

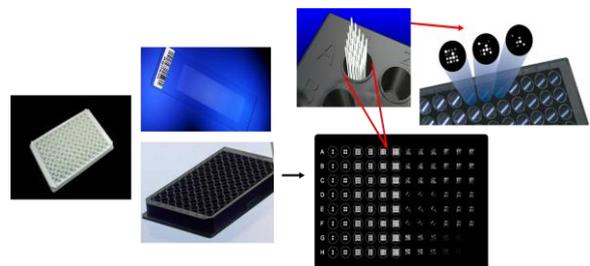
Over the past years a number of international and all-Russian symposia, congresses and conferences have been conducted by FGBU “FTsTRB-VNIVI” accompanied with published handouts. Federal Center is a founder and publisher of “Veterinarny vrach” (“the Veterinarian”) research and practical journal that is referred to the Higher Attestation Commission of the Ministry of Education of the Russian Federation.

Center's achievements have been awarded diplomas of the Russian Agricultural Products Exhibition “Zolotaya Osen”, and diplomas of international exhibitions “Complex Safety”, “Interpolytech” and “World of Biotechnology”, and others; honorary diplomas of 100 best scientific institutions and organizations of Russia, etc.

It is worth mentioning that the problem biosafety can't be effectively resolved without a focused fundamental and applied research requiring maximum possible enhancements which will result not only in an advanced study of living systems processes but in creating favorable conditions for research teams mastering necessary skills and technologies. An attribute of the biosafety management is its infrastructure to ensure economic benefits. All universities and scientific institutions have to work very closely with enterprises. Their joint effort will result in a necessary tool which will transmit advanced technologies and interpret them for medium-sized enterprises first, and then for large businesses.

Owing to joint work with ISTC, International Project # 2434 “Comparative Studies of Immunobiological Properties of Live Tuberculosis Vaccines” was implemented. Comparative testing of immunogenic properties of 7 strains of the Brucellosis pathogen (2 strains from the USA and 5 strains from Russia) has been conducted. The research resulted in 5 articles published in the Vaccine journal, Volume 28, Supplement 5, 1 October 2010, ISSN 0264-410X (USA).

The Federal Center is taking part in International Project 3126: “Upgrade of the Biosecurity and Biosafety Systems to Secure the Biological Material in the All-Russian Research Veterinary Institute (VNIVI)”, which is quite pressing and important in terms of ensuring biosafety.



Currently joint research in the development of new monitoring test-kits is in progress to ensure biosafety. Jointly with Enfer Scientific, Ireland, research is being conducted in the development of multiplex test-kits. The distinctive feature of the multiplex immune analysis is its capability to be used in immune screening for several antigens at a time. In the long term it is planned to create diagnosticums, which would allow screening of animals and humans for several diseases by using one test-kit, which in its turn would reduce the prime cost of the analyses, would increase the efficiency of infectious diseases monitoring. It is towards this target that cooperation is being developed by institutes and state facilities in different countries, particularly UCD (Ireland), VLA (Great Britain), USDA (USA), CFIA (Canada), UCM (Spain), etc. FTsTRB-VNIVI is also merging into this cooperation, since ensuring biosafety is a common cause for all the countries, and there is a key component in this area globally.

When processing select agents international standards on biorisks, biorisk management on the basis of extensive international integration of scientific centers associated with biosafety issues shall be introduced to ensure safety.