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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Meeting of Experts
Geneva, 24-28 August 2009
Item 5 of the provisional agenda
Consideration of, with a view to enhancing international
cooperation, assistance and exchange in biological
sciences and technology for peaceful purposes, promoting
capacity building in the fields of disease surveillance,
detection, diagnosis, and containment of infectious diseases

PROJECT PROPOSALS FOR MEETING OF EXPERTS

Submitted by Ukraine

I. Sanitary-and-epidemiological Service of State Department of Punishment

Main tasks

1. According to the Regulation of Ministry of Health of Ukraine sanitary-and-epidemiological service of the State department of punishment has gained the state status.

Description of works

- 2. Works include:
 - (i) Carrying out of state sanitary-and-epidemiological control.
 - (ii) Determination of main tasks in prophylactics of infection diseases and health protection of personal, prisoners and persons taken upon guard from harmful impact of environment factors.
 - (iii) Study, evaluation, prognosis of the infection levels, elaboration of prophylactic and anti epizootic measures.
 - (iv) Timely implementation of anti epizootic measures when outbreaks of mass illness and infection diseases occur.

Results to be achieved

3. At present moment state service is lacking sanitary-chemical, bacteriological and radiological laboratory, which makes it unable to perform the monitoring of infection disease and study the impact of environment factors upon the health of prisoners and persons taken upon guard.

Necessary technical & financial support

- 4. The creation of sanitary-and-epidemiological stations with bacteriologic and radiological laboratories requires the approximate sum of 9 million 400.000 hrivnas (940.000 euros) including:
 - (i) Laboratory equipment and reagents 6 million 825.000 hrivnas (682.500 euros) (cost for one sanitary-and-epidemiological station 271.875 hrivnas (27187 euros)
 - (ii) Forming of staff in sanitary-and-epidemiological stations (salary amount of staff) 2.575.000 hrivnas (257500 euros).

II. Academy of Medical Sciences

Description and objectives of the project

5. Study of the localization and biological properties of little-known bacterial and parasitic agents of transmissible infections (Anaplasma, Bartonella, Babesia, Ehrlichia): To develop a laboratory diagnostic method for anaplasmotic, batonellotic, babesiotic and erlichiotic infections through the use of bacteriological, cultural, immunological and molecular-genetics technologies.

Importance

6. The necessity of this project is conditioned by the expansion of the geographic range (due to global warming) and the growing number of transmitted infectious disease cases from known, new and little-known agents, including bacteria and protozoa. To date, Ukraine does not have any oversight mechanisms or etiological diagnostic methods for anaplasmosis, batonellosis, babesiosis or erlichiosis which hinders their adequate treatment or prevention.

Results to be achieved

7. Advanced laboratory etiological diagnostics methods for anaplasmotic, batonellotic, babesiotic and erlichiotic infections that will be offered for practical application in health care institutions, promoting effective surveillance, etiological diagnosis, treatment and prevention of bacteriological and parasitic diseases.

- 8. Necessary technical &financial support includes:
 - (i) CO₂ incubator (CB 150 "ALCONLABS", USA);
 - (ii) DNA amplifier (ABI PRISM 7500, "APPLIED BIOSYSTEMS, USA)

Preferred foreign partnerships

- 9. Preferred foreign partnerships include:
 - (i) USA Department of Pathology, University of Texas Medical Branch;
 - (ii) Canada National Laboratory for Zoonotic Diseases and Special Pathogens.

III. Academy of Medical Sciences

Description and objectives of the project

10. Unification of molecular-genetic epidemiological typing methods for infectious disease agents. Creating an on-line electronic library of epidemically dominant pathogen strains of diverse taxonomic groups: To improve and implement unified and highly effective agent epidemiological (intraspecific) genotyping methods (various taxonomical groups – viruses, bacteria, microfungi, protozoa) of current infectious diseases.

Importance

11. This project, as part of the global and national effort to combat infectious diseases, stipulates that infectious agent epidemiological (intraspecific) strain typing research results are essential to determining disease origin and spread patterns. Pathogen genetic typing (determining genomic imprints) permits not only to determine the infection's origin, transmission factors and area of circulation, but also promotes the extensive unification of research conduction methods with obtained research results, their accumulation in relevant databases and their global accessibility through the Internet.

Results to be achieved

12. Development and incorporation of advanced molecular-genetic (intraspecific) epidemiological genotyping methods for pathogens of different taxonomical groups onto the infectious disease control system. Establishment of a national genomic fingerprints library (database) of epidemically dominant types of pathogens (protozoan, microfungal, bacterial, viral, including the A H_{1sw}N1 flue virus) and it's subsequent incorporation into an analogous global network with the purpose of strengthening the national and global surveillance frameworks for socially-significant disease spread paths and intensity.

- 13. Necessary technical &financial support includes:
 - (i) DNA sequencer (ABI PRISM 3110, "APPLIED BIOSYSTEMS", USA);
 - (ii) DNA amplifier (ABI PRISM 7500, "APPLIED BIOSYSTEMS, USA);
 - (iii) Pulse-electrophoresis device (CHEF-DR III system, BIO-RAD, USA).

Preferred foreign partnerships

- 14. Preferred foreign partnerships include:
 - (i) USA Center for Disease Control and Prevention;
 - (ii) Canada British Columbia Center for Disease Control (Vancouver), National Microbiology Laboratory (Manitoba).

IV. Academy of Medical Sciences

Description and objectives of the project

15. Acquirement and description of diphtheria, pertussis and tuberculosis agent antigens for new generation vaccine creation with alternative administration methods (peroral, pernasal, transcutaneous, injectional): to develop physical technologies of native antigen acquisition that are identical in chemical structure and molecular weight to corresponding pathogen cell structures (diphtheria, pertussis, tuberculosis agents) and have high immunogenic, adjuvant and, at the same time, negligible pernicious properties.

Importance

16. This project is conditioned by the views that physical methods of acquiring antigens are a possible alternative to chemical technologies. The advantage of these methods lies in the easiness of their acquirement in standard conditions and no need for operations on purifying extracted compositional pathogen structures from ballast substances. Moreover, physical methods open up the possibility of manufacturing native chemically unchanged, and thus more specific, vaccines.

Results to be achieved

17. Diphtheria, pertussis and tuberculosis agent antigen samples for improved vaccines against infections that are relevant to various world nations. The predictable development of inexpensive antigen acquisition methods compared to chemical technologies that will have high immunogenic and safety levels.

- 18. Necessary technical and financial support includes:
 - (i) Liquid chromatograph with full automation and certified software (Agilent 1200, "Agilent technologies, inc.", USA);
 - (ii) Ultrasound microorganism disintegrator (DIGITAL Sonifier® UNITS Models S-450D, "Branson Co.", USA or Ultrasonic Processor UP400S, "Hielscher USA inc.", USA).

Preferred foreign partnerships

- 19. Preferred foreign partnerships include:
 - (i) USA Department of Microbiology, University of Colorado School of Medicine;
 - (ii) Canada Department of Microbiology & Immunology, Queen's University.

V. Academy of Medical Sciences

Description and objectives of the project

20. Unification of molecular-genetic epidemiological typing methods for infectious disease agents. Creating an on-line electronic library of epidemically dominant pathogen strains of diverse taxonomic groups: to improve and implement unified and highly effective agent epidemiological (intraspecific) genotyping methods (various taxonomical groups – viruses, bacteria, microfungi, protozoa) of current infectious diseases.

<u>Importance</u>

21. This project, as part of the global and national effort to combat infectious diseases, stipulates that infectious agent epidemiological (intraspecific) strain typing research results are essential to determining disease origin and spread patterns. Pathogen genetic typing (determining genomic imprints) permits not only to determine the infection's origin, transmission factors and area of circulation, but also promotes the extensive unification of research conduction methods with obtained research results, their accumulation in relevant databases and their global accessibility through the Internet.

Results to be achieved

22. Development and incorporation of advanced molecular-genetic (intraspecific) epidemiological genotyping methods for pathogens of different taxonomical groups onto the infectious disease control system. Establishment of a national genomic fingerprints library (database) of epidemically dominant types of pathogens (protozoan, microfungal, bacterial, viral, including the A H1swN1 flue virus) and it's subsequent incorporation into an analogous global

network with the purpose of strengthening the national and global surveillance frameworks for socially-significant disease spread paths and intensity.

Necessary technical and financial support

- 23. Necessary technical and financial support includes:
 - (i) DNA sequencer (ABI PRISM 3110, "APPLIED BIOSYSTEMS", USA);
 - (ii) DNA amplifier (ABI PRISM 7500, "APPLIED BIOSYSTEMS, USA);
 - (iii) Pulse-electrophoresis device (CHEF-DR III system, BIO-RAD, USA).

Preferred foreign partnerships

- 24. Preferred foreign partnerships include:
 - (i) USA Center for Disease Control and Prevention;
 - (ii) Canada British Columbia Center for Disease Control (Vancouver), National Microbiology Laboratory (Manitoba).

VI. Academy of Medical Sciences

Description and objectives of the project

25. Development of nanosensors for detecting agents of socially-hazardous diseases: To create biosensors and biosensor platforms with bioactive biological membranes for electrochemical detection of relevant agents (viruses, bacteria, microfungi) and antibody avidity evaluation for determining population immunity levels.

Importance

26. This project's significance is conditioned by the need for development and integration into health care practice of express, highly-avid, inexpensive, unified and automated infectious disease agent detection systems and antibody avidity evaluation systems for determining population immunity levels. In recent years the preeminent choice has become the creation of nanobiosensors and use of electro-chemical technologies for conducting specific indication and registration of its results.

Results to be achieved

27. Acquirement and clinical trial of nanobiosensors with bioactive biological membranes for detection of relevant agents (microfungi, bacteria, viruses, including the A H_{1sw}N1 flue virus) using electrochemical methods.

- 28. Necessary technical and financial support include:
 - (i) Impedance spectrometer (FRA 2, "AUTOLAB", Holland);
 - (ii) Potentiostat (PGSTAT302N, "AUTOLAB", Holland);
 - (iii) Langmuir-Blodgett automated bath (Extra, "NIMA TECHNOLOGY", USA);
 - (iv) Monomolecular layer coating device (DC Multi Sample, "NIMA TECHNOLOGY", USA).

Preferred foreign partnerships

- 29. Preferred foreign partnerships include:
 - (i) USA Stanford Genome Technology Center;
 - (ii) Canada Biotechnology Research Institute National Research Council of Canada.

VII. State Committee of Veterinary Medicine

Description and objectives of the project

30. With a view to complete the adaptation process of national legislation with the requirements of WTO and EU agreements, in particular concerning production, circulation and quality control of veterinary drugs, striving to meet full compliance with ISO 17020 and ISO 17025 standards, the National Scientific-Control Institute for Biotechnologies and Microorganism Stams (NCSIBMC) has started work on it's accreditation in the DAP international accreditation body. Technological and/or financial aid is required to ensure the realization of this accreditation process in accordance with the international requirements. Foremost, this concerns the ability to sustain the viability and capacity of production, control and diagnostic stam collections and ensuring the proper conditions for carrying out veterinary immunobiological drug quality control procedures. To ensure work that complies with international standards the NCSIBMC stressed the necessity for the following equipment.

No	Equipment designation	Qty.	Estimated value for unit/sum, UAH	Estimated value for unit/sum, EURO
1	Lyofilisation apparatus for productive microorganism strains Lab. Freeze dryer ("TELSTAR")	1	500 000	50 000
2	Biosafety class II laminar flow hood, ("TELSTAR")	4	80 000/ 240 000	80 00/ 24 000
3	Low-temperature freezing chamber "UltraFREEZE 175 (340)" ("TELSTAR")	2	80 000/ 160 000	8 000/ 16 000
4	Real-time PCR apparatus (Russia)	1	500 000	50 000
5	Biochemical analyzer "Star Fax 3300" + reagents	1	100 000	10 000
6	Air-conditioner with bacterial filter	4	10 000/ 40 000	1 000/ 4 000
7	Binocular microscope "XS-3320" (MICROmed)	5	10 000/ 50 000	1 000/ 5 000
8	Centrifuge "ОПн-3.02" ["OPn-3.02"] (test tube holder speeds, rpm 1000, 1500, 3000; overall size, mm 460x430x270); ("DANSTAN", Bishkek city, Kyrgyzstan)	2	4 000/ 8 000	400/ 800
9	"Eppendorph Research" sampler with variable volume – 100-1000 mcl (autoclavable lower section)	10	1 500/ 15 000	100/ 1 500
10	Water bath without agitation	2	4 000/ 8 000	400/ 800
11	Refrigerator	4	3 500/ 14 000	350/ 1 400
12	Equipment for water cleaning and conditioning "Thermo Scientific Barnstead TII" ("Thermo Fisher Scientific", Germany)	1	100 000	10 000
13	Laboratory vessel washing machine "G 7883 CD" ("Miele", Germany)	1	100 000	10 000

14	Dry heat box "StabiloTherm EU2-234" ("Sanyo", Japan)	1	20 000	2 000
15	Screening-class trinocular light microscope "MC 400AT (P)" ("Micros", Austria)	2	30 000/ 60 000	3 000/ 6 000
16	Research light microscope "NIKON ECLIPSE 90i/80i" (Japan)	1	30 000	3 000
17	Inverted microscope "NIKON ECLIPSE TS100/TS100-F" (Japan)	2	30 000/ 60 000	3 000/ 6 000
18	Inverted fluorescent trinocular microscope "INVERSO – epi flu" with fluorescent unit ("CETI", Great Britain-Belgium)	1	80 000	8 000
19	Dry box "BIII-1.2" ["VSh-1.2"] ("Porsa-Ukraine", Ukraine)	2	7 000/ 14 000	700/ 1 400
20	Centrifuge "Jouan C4i" ("Thermo Fisher Scientific", Germany)	2	20 000/ 40 000	2 000/ 4 000
21	"IEC MicroCL 17/17R" series microcentrifuge ("Thermo Fisher Scientific", Germany)	1	40 000	4 000
22	Analytical scales "AB-S" ("Mettler Toledo", Switzerland)	1	15 000	1 500
23	Compact electronic portion scales "SK-30KD" (Japan)	1	8 000	800
24	Spectrophotometer "UV-2005" ("Selecta", Spain)	1	12 000	1 200
25	Vertical plan-table spectrophotometer "Multiscan Accent" ("Thermo Fisher Scientific", Germany)	1	50 000	5 000
26	Redistillator "Calypso" ("Fistreem", Great Britain)	1	20 000	2 000
27	CO ₂ -incubator "MEMMERT" (INCO2 model) ("GmbH", Germany)	2	40 000/ 80 000	4 000/ 8 000
28	Image analyzer "ВидеоТест-Карио" ["VideoTest-Kario"] (St. Petersburg, Russia)	1	30 000	3 000
29	Freezing chamber (vertical) up to -20°C "ZANUSSI ZFU 17S"	2	5 000/ 10 000	500/ 1 000
30	Egg incubator for 88 eggs "Кварц" ["Quarz"] ("Электрокомфорт" ["Electrocomfort"], Russia)	1	5 000	500
31	Dewar flask "Cryo 200/CryoPlus 2" ("Thermo Fisher Scientific", Germany)	2	40 000/ 80 000	4 000/ 8 000

32	Programmable freezer "Thermo CryoMed 7453/7459" ("Thermo Fisher Scientific", Germany)	1	200 000	20 000
33	autoclave "BK-77" (steam, vertical, semiautomatic) ("Нафтохімгруп" ["Naphtohemgroup"], Kyiv, Ukraine	1	28 000	2 800
34	pH-meter "pH – 150 M" (Belarus) ~ 1042,50	1	2 500	250
35	"Varispenser" dosimeter 1-5 ml ("Макрохім" ["Makrohem"], Kyiv, Ukraine)	10	3 000/ 30 000	300/ 3 000
36	Vacuum pump "TOP – 3 Lio Beta"	2	15 000/ 30 000	1 500/ 3 000
37	Freezing chamber for up to -80°C "UCF 481"	1	190 000	19 000
38	Storage cabinet for reagents with hood "Salex"	2	5 000/ 10 000	500/ 1 000
39	"MedaClave", 220 V – multifunctional medium brewer	1	300 000	30 000
40	Low-temperature refrigerator "ULUF 450"	1	120 000	12 000
41	Vertical electrophoresis chamber with accessories	1	25 000	2 500
42	"BIOREX 3" microscope	1	10 000	1 000
	TOTAL			340 450

VIII. Ukrainian Academy of Agricultural Sciences

Description and objectives of the project

- 31. Harmonization of domestic legal framework concerning biosafety and biosecurity towards international requirements. Establishment of joint expert groups to coordinate positions and elaboration of measures concerning international approval of the domestic reference-laboratory system for controlling extremely dangerous toxins and animal diseases:
 - (i) Ecological and biological interrelationships in the agent–ectoparasitic vector–host systems of extremely dangerous animal diseases.
 - (ii) Paramixvirus and orthomixvirus infection spread risks due to natural and artificial animal and bird migration.

(iii) Transfer detection and control system for toxic agents which may influence the quality and security of animal-derived products.

Importance

- 32. Increase of extremely dangerous diseases spread risks (such as febris catarrhalis ovium virus and African swine flue) caused by transmission vectors (insects and ticks) by means of mechanical agent transfer as well as through biotic interrelation, namely persistency and the reproduction of pathogens within insect organisms. Insect organisms often carry their own viruses (such as baculoviruses classic genetic information transfer vectors in molecular biotechnologies) which potentially may become a driving component for genetic modifications and recombination of animal pathogens. The results of studies regarding the specifics of interrelations in the agent–ectoparasitic vector–host system can be applied in the development and use of biological weapons counteraction programs, as well as control and risk evaluation of extremely dangerous diseases outbreaks.
- 33. Bird flue, swine flue, horse flue and Newcastle disease are targets for intensive monitoring by world veterinary and humane medicine due to their high panzoonotic and pandemic potential. They are very diverse in genetic structure, which causes considerable divergence of their antigenic and pathogenic features.
- 34. In the whole world, when isolating flue factors, molecular-genetic inspection is conducted through sequencing and phylogenetic analysis of flue virus and Newcastle disease genes, which allows to identify factor origin and examine possible mutation and recombination paths. This gives opportunities to create effective control and prevention systems for orthomixvirus infection outbreaks.
- 35. In modern conditions of agricultural intensification, there is an increase in use of anthropogenic environmental chemical pollutants, among which antibiotics, pesticides, microelements, etc. are distinguished. Control of trace amounts of these substances is necessary in regard of their distinct biological potency and their ability to migrate within natural objects. Climatic changes facilitate the accumulation of microfungi and, thus, mycotoxins in plants. The research results of the introduced project may be applied while implementing toxicological weapons spread counteraction programs and to ensure the quality and safety of animal-derived products.

Results to be achieved & necessary technical support

36. With the aim to enact the introduced proposals it is important for Ukraine to gain international aid in the area of improvement of physical parameters of existing biosafety systems of institutions where work with especially dangerous pathogens is carried out. In order to support the proposed research projects it is vital to modernize the physical infrastructure of UAAS institutions: equip them with lacking laminar flow hoods, low-pressure systems, real-time PCR amplifiers, pulse gel electrophoresis equipment, DNA analyzers, chromatographs, mass-spectrographs, standard pathogen samples.
