

**Enhancing Biosafety and Biosecurity:  
An Agenda for Global Action**  
*A Seminar for Experts from the G-8 Countries*

**18-19 April 2006**  
**I.M. Sechenov Moscow Medical Academy**  
**Moscow, Russia**

**Meeting Summary and  
Recommendations**



**Prepared by:**

**Non Commercial Partnership -The Center of Modern Medical Technology, TEMPO  
International Council for the Life Sciences  
I.M. Sechenov Moscow Medical Academy**

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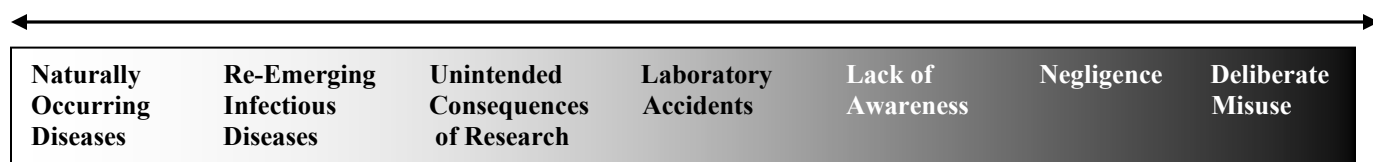
**Canada**

## EXECUTIVE SUMMARY

### Enhancing Biosafety & Biosecurity: an Agenda for Global Action

Experts from the G-8 countries convened in Moscow, Russia on April 18-19, 2006 for a seminar on promoting international cooperation to develop global standards for managing biological risks associated with advances in the life sciences. Life science research and commercial activities are extraordinarily transnational in nature. These activities bring enormous benefits to medicine, public health, the food industry, agriculture, and industrial processes. At the same time, the risks to public health, safety and security from the misuse of this technology are not adequately addressed. This spectrum of biological risks, ranging from emerging infectious disease to premeditated misuse, represents an urgent and overwhelming global challenge. In order for the full humanitarian and economic benefits arising from the advances in the life sciences to be realized, it is essential that the risks are properly identified, understood, and effectively managed.

#### *SPECTRUM OF BIOLOGICAL RISKS*



Improved global standards and increased international cooperation are important contributions in addressing the challenge of biological risks. The International Council for the Life Sciences (ICLS) is a non-profit organization helping to enhance global biological security and safety by directly engaging the life sciences community and governments in the development and promotion of international biosafety and biosecurity standards and the sharing of best practices. Organizations and government agencies operating in the life sciences are welcome to show their support for enhancing biological safety and security by becoming an ICLS member.

As an expression of its global reach and inclusive nature, the ICLS is pleased to have an ongoing partnership with the I.M. Sechenov Moscow Medical Academy (MMA) and the biotechnology consortium Non-Commercial Partnership “Center of Modern Medical Technology” TEMPO. Dr. Mikhail Paltsev, RAMS First Vice-president is the Rector of the MMA and the Chairman of the Scientific Technical Council of TEMPO in addition to being an Academician of the Russian Academy of Sciences (RAS) and Russian Academy of Medical Sciences (RAMS). Academician Paltsev is a member of the ICLS Senior Advisory Panel - a group of international scientific, technical and policy experts.

In this capacity and in the context of the Russian presidency of G-8, Dr. Mikhail Paltsev invited the ICLS to join the MMA and TEMPO in convening *Enhancing Biosafety and Biosecurity: an Agenda for Global Action*, a seminar for experts from the G-8 countries plus Sweden ahead of the G-8 Summit in St. Petersburg in July 2006. The day and a half Seminar brought together scientific experts, government officials and non-proliferation policy experts to discuss global biological risks and contributions from international cooperation. The need for international standards permeated the seminar discussion.

The agenda for the day and a half Seminar had sessions covering

- Global Standards in Biosafety and Biosecurity;
- Raising Awareness: Contributions from Training, Education Curricula and Other Outreach Activities;
- Perspectives on Biological Risk Assessment;
- The Infectious Disease Challenge – Averting Biological Disasters; and
- Enhancing Global Biological Safety and Security through G-8 Leadership.

Seminar participants recommended global action by leaders of the G-8 countries and beyond to:

- 1. Enhance international cooperation in developing scientific research in the field of biosafety and biosecurity to support evidence-based constructive solutions;**
- 2. Develop training programmes in biosafety and biosecurity in accordance with global standards;**
- 3. Develop an International Panel of Experts, based, inter alia, on “groups of excellence”, (National Centres, WHO Collaborating Centres, WHO experts) to create information exchange mechanism between making decisions state organizations, nongovernmental and scientific organizations in the field of biosafety and biosecurity;**
- 4. Create an International Expert Group on developing international glossary on biosafety/biosecurity terminology;**
- 5. Develop common methodological approach on science-based - assessment of biological risks for human health and well-being - biosafety and biosecurity in all types of biological laboratories; and**
- 6. Develop national systems that could be integrated into global geo-information systems (GIS) on data analysis for prognosis, monitoring and preventing introduction and expanding emerging and re-emerging diseases.**

**In order to engender action without delay on these recommendations in the academic, governmental and private sectors, the seminar co-chairs invite the support of the life sciences community in setting up international, multidisciplinary action groups focused on the above issues to support national governments and international organizations in the efforts to enhance biosafety and biosecurity to counter the biological risks faced by the public world-wide.**

The ICLS is actively working to link different organizations working to address the challenge of biological risks. Its ability to convene, in partnership with The International Science and Technology Center (ISTC), the MMA and TEMPO, a group of over 80 individuals with different interests and expertise in biological risks was made possible by the leadership and resources of the Global Partnership Program at Foreign Affairs Canada.

**Tuesday 18 April 2006**

**Welcoming Remarks**

**Dr Mikhail Paltsev**

Seminar Co-Chairman

Rector, I.M. Sechenov Moscow Medical Academy (MMA)

Chairman of the Scientific Council, TEMPO

First Vice-President & Academician, Russian Academy of Medical Sciences (RAMS)

Academician, Russian Academy of Sciences (RAS)

Member, ICLS Senior Advisory Panel

**Mr Terence Taylor**

Seminar Co-Chairman

Director, International Council for the Life Sciences (ICLS) & President of the Board of Directors

**Dr Ronald F. Lehman, II**

Chairman of the Governing Board of the International Science and Technology Center (ISTC)

Director of the Center for Global Security Research, Lawrence Livermore National Laboratory

Dr. Mikhail Paltsev and Mr. Terence Taylor opened the day and a half seminar on the morning of Tuesday April 18, 2006. Dr. Paltsev outlined that the Moscow Medical Academy (MMA) has already positioned itself as an organizer of two international conferences *Molecular Medicine and Biosecurity*, providing a forum for the discussions on applied and fundamental research performed by Russian and international scientists in such areas as medicine, molecular biology, oncology, infectious diseases, and biotechnology. The framework of the II International Conference included an International Seminar entitled *Bioterrorism: Possible Objects for Affection and Counteraction methods* that brought together experts from the U.S., Sweden, Canada, Japan, China, and the U.K. According to Dr. M. A. Paltsev, Rector of the MMA, Academician of the RAS and RAMS, the First Vice-President of RAMS, the discussion was focused on these issues mostly in view of the concerns and interests expressed by the entire community to biosafety/biosecurity and terrorism challenge. The Government of the Russian Federation and President Putin are also aware of the importance of this task.

The program of this seminar, *Enhancing Biosafety and Biosecurity: an Agenda for Global Action*, was formed based on analysis of issues requiring international collaboration. Dr. Paltsev emphasized that the seminar's practical recommendations, which will be elaborated by G8 experts, are to be submitted for the G8 summit in July 2006. In addition, Academician Paltsev stated that the tradition of discussing significant biosafety and biosecurity issues would be followed on within the framework of the third Russian Medical Forum to be held in October 2006.

Mr. Taylor stated that the newly independent International Council for the Life Sciences (ICLS) is working to enhance biological safety and security around the world by helping to develop and promote international standards and the sharing of best practices. The non-governmental ICLS provides a forum for all sectors of the life sciences community - private industry, academia and government – to identify and manage biological risks whatever their origin. The ICLS is based on a Charter, which outlines critical areas of concern for the life sciences community including the safe and secure operation of facilities and the governance of research and development

activities. Companies, government agencies, research laboratories and other organizations operating in the life sciences with an interest in promoting the highest standards for biosafety and biosecurity are welcome to become members of the ICLS and commit to its Charter.

Dr Ronald Lehman emphasized that biosafety and biosecurity are issues now vital to all mankind. Practical solutions, however, are increasingly linked to the very issues that this seminar has been tasked to address; namely, biological risks, global standards, and international cooperation. The magnitude of the emerging challenges fully warrants the G8 focus, and, given the Russian Presidency as we head toward the St. Petersburg Summit in July, meeting here in the Russian Federation is most appropriate.

He stated that this seminar is timely also for reasons more fundamental even a meeting of world leaders. We are in dramatically revolutionary period in terms of: (1) advances in science, (2) political, social, and economic change, and (3) the connectivity, interdependence, and shared vulnerabilities of globalization. Nowhere else is this as clear as in biotechnology. “Embedded engagement” in international biotech programs, both governmental and market oriented, is a win-win strategy. Such intense, detailed cooperation results in the synergistic exchange of technological talent and builds both national scientific capacity and multi-national confidence that we are working together to avoid the dangers associated with proliferation and terrorism. Thus, the sharing of best practices in biosafety and biosecurity will be essential for all of our countries to work together effectively to maximize our mutual benefits from the biological revolution, be they economic, or health, or knowledge.

<b>Session 1: Global Standards in Biosafety and Biosecurity</b>
<p><b>Moderators</b> <b>Dr Alexander Gintsburg</b> Vice-President, Russian Academy of Medical Sciences (RAMS) Director, Gamaleya Institute of Epidemiology &amp; Microbiology <b>Mr Terence Taylor</b> Director, International Council for the Life Sciences &amp; President of the Board of Directors</p>

Speakers and participants addressed the following critical questions:

- How can the World Health Organization (WHO) guidelines for biosafety and biosecurity be developed into agreed global standards?
- How can these guidelines best be promoted globally?
- In what ways can the G-8 nations contribute to global biosafety and biosecurity standards?

**Speaker**

**Dr. Julia Ananyina**

Professor, Deputy Director, Gamaleya Institute of Epidemiology & Microbiology

**Academician Alexander Gintsburg**

Director, Gamaleya Institute of Epidemiology & Microbiology

*Russian View on Biosafety/Biosecurity Challenges*

Dr Julia Ananyina presented a Russian view of biosafety/biosecurity challenges. She drew attention to the basic challenge stems from differences in language and terminology. English, among other languages, uses separate words and separate definitions for biosafety and biosecurity. Other languages, such as Russian and German, have just one word.

<b>Defining Biosecurity and Biosafety</b>	
<u>Biosafety</u> deals with all aspects of containment to prevent any exposure to and accidental release of pathogens.	. . . protection of personnel, external human population and environment from exposure to pathogenic biological agents provided by a system of management, medico-biological measures, facility design, construction and operational practices.
<u>Biosecurity</u> is implemented to prevent the theft, misuse or intentional release of pathogens. <i>Laboratory Biosafety Guidelines. Health Canada 2004.</i>	<i>Russian Ministry of Health Biosafety Regulations 2003</i>

However the issue is defined, biological risks pose a grave threat that could have catastrophic consequences.

**RECOMMENDATION**

**Seminar participants recommend the leaders of the G-8 and beyond create an International Expert Group to develop an international glossary on biosafety/biosecurity terminology.**

Dr Ananyina stated that several inter-governmental agreements impact global biological safety and security. Russia is a State Party to the Biological and Toxin Weapons Convention (BTWC) and is one of the three Depository States for the treaty. The Australia Group is an informal arrangement of countries that cooperate to minimize the risk of biological and chemical weapons proliferation by harmonizing national export controls and promoting information exchange. While not a member of the Australia Group (AG), Russia's list of controlled pathogens<sup>1</sup> is comparable to the AG Common Control Lists. Russia ratified the Convention on Biological Diversity (CBD) in 1995. Biosafety/biosecurity areas of interest for the CBD include updating

<sup>1</sup> Federal Law "On export control" (N183) 1999; List of biological agents for Export Control (human, plant and animal pathogens, GMO, toxins, dual-use biological equipment and related technology)/ (RF Presidential Edict 08.08.2001.№1004); export control of human, animal and plant pathogens, GMO, toxins, equipment and technologies. 2001. Government decree (N634); Federal Law on biosafety, microbiological and biotechnology production facilities and their products. 2006 (draft).

export-control lists, providing maintenance of international and national microbial collections of type strains, and genotyping microbial collections of type strains into genobanks.

The World Health Organization (WHO), through its Biosafety Programme and biosafety collaborating centers (CCs) in Australia, Canada, Sweden, United Kingdom, and the United States, provide guidance and leadership on matters pertaining to biosafety and biosecurity. The WHO provides assistance in biosafety and biocontainment technology in labs, biosafety training and resource centre and applied research programmes on biosafety/biocontainment issues.

The WHO currently has a moratorium on designating additional biosafety collaborating centers. Researchers and individuals in countries outside the five listed above have expressed interest in finding new ways and mechanisms for promoting global dialogue and the exchange of information on biosafety/biosecurity.

### **RECOMMENDATION**

**Seminar participants recommend the leaders of the G-8 and beyond develop a Board of International Experts, inter alia, based on “groups of excellence”, (National Centres, WHO CCs, WHO experts) to create information exchange mechanism between decision-making state organizations, nongovernmental and scientific organizations in the field of biosafety and biosecurity.**

#### *Speaker*

##### **Dr. Rainer Wessel**

President and CEO, GANYMED Pharmaceuticals AG

Member, ICLS Senior Advisory Panel (SAP)

Member, Board of Directors for BIO Deutschland

*Challenges to industry from the lack of global standards?*

Dr. Rainer Wessel outlined the growth of the relatively young biotechnology industry. He stressed the power shift from academia to private industry and that it takes 20-30 years to build a competitive industry. As a reference point, 75% of the global biotechnology workforce is in the United States of America (USA). Biotechnology is revolutionary and some countries will be left behind. Mechanisms must be developed to help these countries keep up, especially in relation to international standards for biosafety and biosecurity. Harmonization and an even competitive landscape are needed between countries.

Dr. Wessel asserted that it is more myth than fact that a country with few regulations provides an incentive for biotechnology companies to re-locate. These locations actually pose a great liability for a company's leadership and also lack other important attributes for private industry, such as qualified personnel.

The risks associated with the biotechnology revolution cannot be dealt with by governments alone. It is in industry's best interest to enhance global biosafety and biosecurity through the highest international standards. If something bad happens somewhere in the world, industry will suffer. Governments may overreact with additional and unhelpful legislation. Action to improve the risk environment should be taken now. Dr Wessel stressed that the ICLS, of which

GANYMED Pharmaceuticals AG is a founding member, contributes by directly engaging the life sciences community and governments in developing and promoting international standards for biological safety and security.

**Dr. Boris Naroditsky**

Professor, Deputy Director, Gamaleya Institute of Epidemiology & Microbiology  
*GMM and biosafety issues*

Dr. Boris Naroditsky gave an overview of the Russian genetically-modified micro-organisms (GMM) safety system and highlighted mechanisms to improve it. Specifically, he advocated the creation of an international database of GMMs, uniform biosafety standards for GMM creation and harmonization of laws on control over their production and use.

<b>Session 2: Raising Awareness</b>
<b>Contributions from Training, Education Curriculum and Other Outreach Activities</b>
<b>Moderators</b>
<b>Dr Beniamin Cherkassky</b> Academician, Russian Academy of Medical Sciences (RAMS) Head of Lab, Central Institute of Epidemiology Head of Chair of Epidemiology, I.M. Sechenov Moscow Medical Academy
<b>Mrs Heather Sheeley</b> Manager of Health and Safety, UK Health Protection Agency

Speakers and participants addressed the following critical questions:

- What are possible approaches for the G-8 to raise awareness of biological risks in the government, business and academic sectors and the general public?
- What are priority areas for training curricula? At what level?
- Can training standards with common elements be developed? Could these standards be recognized internationally?

**Speaker**

**Dr. Yuri Remnev**

Deputy Director, Non-Commercial Partnership TEMPO  
*Educational Program on Biosafety*

Dr Yuri Remnev presented the NP TEMPO's Biosafety Program as a part of Russia's National Biosafety System. This system would help Russia realize a national biosafety policy, promote international cooperation and information exchange, train 150 experts a year and produce a special quarterly bulletin on biosafety and biosecurity issues. Components of a national biosafety system include technical audits of laboratories, monitoring biological research, issuing specialized literature and documentation, and developing specialized education in accordance to international standards.

<b>The Biosafety Program</b>	
<b>Organization</b>	<b>Contribution</b>
NP TEMPO	Coordinate Program
Governmental and educational organizations of the G-8*	Experience and information exchange & audit of education program
I.M. Sechenov Moscow Medical Academy (MMA)	Provide lectures, mentors, educational structures and national expertise of educational programs
Federal Medico-Biological Agency	Help develop specialized educational programs, standard operating procedures (SOPs), and lectures
The State Research Center for Virology and Biotechnology VECTOR	Experimental educational base
The State Research Center for Applied Microbiology, Obolensk	Experimental educational base

*\*The ICLS will assist TEMPO in developing this portion of the Biosafety Program*

Dr Remnev stated that NP TEMPO is uniquely positioned to coordinate this effort and further Russia's biosafety and biosecurity capabilities. The consortium

- Regularly collaborates with international partners – the BioIndustry Initiative of the U.S. Department of State, the International Science and Technology Center, the Regulatory Affairs Professional Society and the International Council for the Life Sciences.
- Is experienced in developing professional educational programs and obtaining accreditation by the Russian Ministry of Education.
- Brings together leading Russian research and development, manufacturing and sales organizations for the development and advancement of innovative biotechnologies, including former biological weapons research facilities in addition to Russia's new and emerging private biotechnology industry.
- Is based at the I.M Sechenov Moscow Medical Academy (MMA), the oldest and the largest national medical higher educational institution in Russia.
- Is led by Academician M.A. Paltsev, the Rector of the MMA, Chair of TEMPO's Scientific Council, Academician of the Russian Academy of Sciences (RAS), Academician of the Russian Academy of Medical Sciences (RAMS), ICLS Senior Advisory Panel (SAP) member and a member of the Governmental Committee on Biological and Chemical Safety.
- Established an annual international biosafety, biosecurity and molecular medicine conference in Moscow, Russia.

***Speaker***

**Ms. Maureen Ellis**

Senior Biosafety Advisor, Biological Non-Proliferation, Global Partnership Program, Foreign Affairs Canada

*Regional Training Centers for Biosafety and Biosecurity*

*Fighting Infectious Disease with International Cooperation*

Maureen Ellis gave an overview of the Canadian government’s effort to develop regional training centers for biosafety and biosecurity around the world. An important component of international cooperation is sharing best practices and learning from each other. Western countries, for example, are extremely reliant on technology to enhance biosafety and biosecurity, while Russia emphasizes human training and procedures. Standardized training materials and practices are critical to enhancing global biological safety and security. A minimum global standard put out by the World Health Organization (WHO) would be a helpful starting point.

Ms Ellis emphasized that effective BioRisk management must include safety and security. Two important inter-governmental initiatives, the World Health Assembly (WHA) Resolution 58.29 (May 2005) and the United Nations Security Council Resolution (UNSCR) 1540 (April 2004), urge member states to address the challenge of biological risks on a national basis.

<b>Relevant United Nations Resolutions</b>	
<p>World Health Assembly Resolution 58.29</p> <ul style="list-style-type: none"> <li>▪ Considering that release of microbiological agents may have global ramifications</li> <li>▪ Acknowledging that the containment of microbiological agents is critical to preventing outbreaks of emerging diseases ...</li> </ul> <p>Urges Member States:</p> <ul style="list-style-type: none"> <li>• to implement specific programmes ... to promote biosafety laboratory practices</li> <li>• to mobilise national and international ... resources to improve laboratory biosafety.</li> </ul>	<p>UNSCR 1540</p> <p>The Security Council ...</p> <p>3. Decides also that all States shall take and enforce effective measures to establish domestic controls to prevent the proliferation of ... biological weapons and their means of delivery, including by establishing appropriate controls over related materials and to this end shall:</p> <ul style="list-style-type: none"> <li>• Develop and maintain appropriate effective measures to account for and secure items in production, use storage or transport.</li> <li>• Develop and maintain appropriate effective physical protection measures.</li> </ul>

UN Security Council resolutions, such as UNSCR 1540, are legally binding for UN member states. Pursuant to its adoption on 28 April 2006, member states were required to submit within 6 months a status report for implementing the measures stated in the resolution. To date, approximately 70 states have yet to submit a report. A special two-year committee was established to monitor countries’ implementation; its mandate was extended on 27 April 2006 to 27 April 2008.

In contrast, United Nation’s General Assembly resolutions are politically binding agreements for member states. The World Health Assembly Resolution 58.29 acknowledges “that the proper containment of microbiological agents is critical to preventing outbreaks of emerging disease...” but the UN is unable to enforce or verify if countries implement the suggested programs to improve biosafety. There is, however, an informal network coordinated via the WHO biosafety program that provides information sharing and other assistance for member states. The WHO also publishes a Laboratory Biosafety Manual, which it hopes “...will continue to encourage

countries to implement biological safety programmes and national codes of practice for the safe handling of potentially infectious materials.”<sup>2</sup> Guidelines for biosecurity are forthcoming.

Ms Ellis drew attention to the additional resources provided by the five research institutes designated as World Health Organization Biosafety Collaborating Centres<sup>3</sup>. These centers provide “guidelines and safety programs for microbiology laboratories worldwide including consultative services in biocontainment technology and biosafety, biosafety training, the dissemination of information, the provision of a biosafety resource centre, surveillance and applied biosafety research programs.”<sup>4</sup>

Helping member states develop biosafety programs, such as promoting the development of national biosafety associations and standardized training materials and curricula, would help strengthen this very important resolution passed by the World Health Assembly and build upon the efforts of the WHO.

## RECOMMENDATION

**Seminar participants recommend the leaders of the G-8 and beyond develop training programmes in biosafety and biosecurity in accordance with global standards.**

Ms Ellis described the numerous organizations from around the world actively promoting improved biosafety. Among these organizations, the leading national and international biosafety associations and the World Health Organization formed the International Biosafety Working Group (IBWG) in 2001. Canada serves as the group’s secretariat.

IBWG is working

- To enhance biosafety and containment awareness;
- To provide a venue for better coordination of biosafety initiatives;
- To facilitate the development of standardized biosafety/biocontainment procedures and practices;
- Provide expert knowledge accessible both nationally and internationally; and
- To improve international biosafety posture.

### **International Biosafety Working Group**

#### ***List of Members***

Asia Pacific Biosafety Association  
ABSA Canada  
Anbio  
ABSA  
EBSA  
JBSA  
WHO Biosafety Program  
International Veterinary Biosafety Association  
International Level 4 Users Group  
Pharmaceutical Biosafety Association

WHAR 58.29 and UNSCR 1540 are two very important UN resolutions that partially address the spectrum of global biological risks. Preventing the deliberate misuse of the life sciences by terrorists and promoting good biosafety practices make major contributions towards enhancing global biological safety and security. Efforts must be made to ensure coordination and collaboration on an international basis between the communities concerned with biosafety, like

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<sup>2</sup> Please see the World Health Organization Laboratory Biosafety Manual at

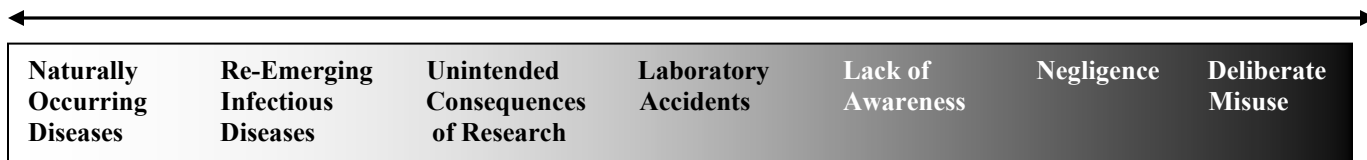
<http://www.who.int/bookorders/anglais/detart1.jsp?sesslan=1&codlan=1&codcol=15&codcch=3213>

<sup>3</sup> The five WHO Biosafety Collaborating centres are the Office of Laboratory Security at the Public Health Agency of Canada, U.S. Centers for Disease Control and Prevention, Swedish Institute for Infectious Disease, the U.S. National Institutes for Health, and the Victorian Infectious Diseases Reference Laboratory in Australia.

<sup>4</sup> According to the WHO Collaborating Centre in Canada at <http://www.phac-aspc.gc.ca/ols-bsl/who-oms/index.html>

the IBWG, and those interested in preventing the deliberate misuse of the life sciences. This will help enable cooperation to address the full spectrum of biological risks and to ensure the best use of resources.

***SPECTRUM OF BIOLOGICAL RISKS***



***Speaker***

**Dr. M. N. Lyapin**, Head of Biosafety Lab

**Professor V. V. Kuttyrev**, Director

**Dr. T. A. Malyukova**

Russian Research Anti-Plague Institute “Microbe” in Saratov

*Experience gained by the RF Anti-Plague Facilities in Biosafety Experts Training*

Since its establishment in 1918, the Anti-Plague Institute has provided specialized education and training for experts. Dr Lyapin gave an overview of the Institute’s current training programs. He described these opportunities as Primary Specialization, which is over 500 hours of training and is available for physicians and biologists specializing in highly dangerous infectious diseases and technicians of anti-plague facilities, and Advanced Training.

<b>Advanced Training Offered at Microbe</b> (72-500 hours)	
<p style="text-align: center;">Professional development for</p> <ul style="list-style-type: none"> <li>• Physicians, technicians and biologists from anti-plague facilities.</li> <li>• Biologists in the specialty of Zoology for zoologists from anti-plague facilities and Central State Sanitary and Epidemiological Inspectorate (TsGSEN).</li> <li>• Physicians in the specialties of bacteriology, epidemiology, allergology and immunology.</li> </ul>	<p style="text-align: center;">Training for</p> <ul style="list-style-type: none"> <li>• Epidemiologists involved in the anti-epidemic teams operating in emergency situations.</li> <li>• The State Sanitary and Epidemiological Inspectorate physicians-bacteriologists in highly dangerous infectious diseases.</li> <li>• Physicians from sanitary-quarantine stations and departments.</li> </ul>

**Session 3: Perspectives on Biological Risk Assessment**

*Moderators*

**Dr Mikhial Kiselev**

Deputy Head, Federal Medico-Biological Agency

**Mr Terence Taylor**

Director, International Council for the Life Sciences & President of the Board of Directors

Speakers and participants addressed the following critical questions:

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- What are priority areas for training curricula? At what level?
- Can training standards with common elements be developed? Could these standards be recognized internationally?

*Speaker*

**Dr Valentin Evstigneev**

Deputy General Director, JSC Biopreparat

*Conception of Acceptable Risk in Assessment of Biosafety Systems*

Dr Evstigneev posed the question when 35 million people have infectious disease, how can acceptable biological risk be defined. He proposed a logical chain of steps for assessing biological risks. Dr Evstigneev stressed that we have highly suspect information on the infectious epidemiology of certain biological agents, such as anthrax, that would be of interest to terrorists. It is known roughly the quantity of diseases that are emerging, but the number and which agents will pose a problem globally, e.g. become a pandemic or would be attractive to a bioterrorist – we do not know.

**RECOMMENDATION**

**Seminar participants recommend the leaders of the G-8 and beyond to develop common methodological approach on science-based - assessment of biological risks for human health and well-being – biosafety and biosecurity in all types of biological laboratories.**

*Speaker*

**Dr. Tim Brooks**

Novel and Dangerous pathogens, Centre for Emergency Preparedness and Response, Porton Down, UK Health Protection Agency

*UK Perspective on Biological Risk Assessment*

Dr. Tim Brooks discussed the UK perspective on the

- Biological threat;
- Biosecurity and who's involved;
- Biosafety and who's involved;
- Risk assessment for Laboratory and Future threats; and
- Containment of an incident.

Dr. Brooks gave an overview of emerging and re-emerging infectious disease and provided examples of new diseases since 1973.

Over 30 new diseases have been recognised since 1973
Rotavirus (1973) – major cause of childhood diarrhoea
<i>Borrelia burgdorferi</i> (1982) – Lyme disease
HIV (1983) – worldwide pandemic
<i>Vibrio cholerae</i> 0139 (1992) – associated with epidemic cholera
vCJD (1995) – human form of “mad cow disease”
SARS (2003)
Avian flu (?) – human form

Diseases that pose the possibility of becoming pandemic, like the bird flu, or that have been highlighted as a biological weapon, like anthrax, become a greater challenge due to the general public’s lack of understanding about infectious diseases. Only one case of suspected human to human transmission has occurred with avian influenza yet individuals are beginning to panic and fear a global pandemic. Dr Brooks stated that this uncertainty is fuelled by the media and reinforced by the public’s high interest. For the popular television period referred to as the May Sweeps in America, ABC aired a made-for-television movie titled "Fatal Contact: Bird Flu in America." Some experts highlight that the movie raises real problems like the probable shortages of goods and services and the need for improved plans. Other experts believe it is an over-dramatization that blurs the line of public information and entertainment.<sup>5</sup>

Following the anthrax mailings in 2001 in the United States, individuals around the world were in an extremely heightened sense of awareness. Numerous reports, which turned out to be false, of anthrax were reported by people who had just handled coffee creamer or ate a powdered jelly doughnut. Dr Brooks advocated that better communication about biological risks to the general public will help in some regard, but this challenge will persist.

The UK Home Office is responsible for internal affairs in England and Wales and is keenly interested when public health problems become a threat to national security. UK actors in Biosecurity include

- Home Office
  - Police
- Department of Health
  - Health Protection Agency
  - Local National Health Service (Primary Care Trusts)
- Ambulance & Fire Service
- Military
- Cabinet Office
- Department for Environment Food and Rural Affairs (DEFRA)

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<sup>5</sup> Please see <http://abcnews.go.com/Entertainment/wireStory?id=1902688&page=3> for more information.

Biosafety in the United Kingdom is led by Health & Safety Executive (HSE) and involves other organizations. Legislation is strict and enforced and relies heavily on risk assessment and containment. UK Authorities include

- Health & Safety Executive (HSE)
  - Provide guidance
  - Inspect sites
  - Enforce law
  - Can bring actions against companies or individuals
  - Can serve improvement or closure notices
- Department for Environment Food and Rural Affairs (DEFRA)
- Environment Agency

UK HSE Biosafety and Biosecurity Publications
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- |   |
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| <ul style="list-style-type: none"><li>• Control of Substances Hazardous to your Health (COSHH): A brief guide to the regulations</li><li>• Biological agents: Managing the risks in laboratories and healthcare premises</li><li>• The Approved List of biological agents</li></ul> |
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Dr Brooks stated that long term planning involves many organizations within the UK government with different functions.

- Health Protection Agency (HPA) research
- Defence Science and Technology Laboratory (DSTL) research
- Regional Health Emergency Planning Adviser (HEPA) and Emergency planning teams
- Cabinet Office Civil Contingencies
- Other government departments
  - Department for Environment Food and Rural Affairs (DEFRA)
  - Department of Health (DH)
  - Ministry of Defence (MoD)

National response plans abound for dealing with public health emergencies due from high profile pathogens such as smallpox and avian influenza. These events have not come to pass and may not. Plans do not exist for illnesses that are more common but do hamper the public health system. In the UK last winter norovirus<sup>6</sup> was a critical concern for hospitals.<sup>7</sup> Individual hospitals were very active in taking steps to reduce the risks of norovirus for their patients and daily operations.<sup>8</sup> This mismatch illustrates the need for additional biological risk assessment. The Health and Safety Executive (HSE) is actively seeking proposals for new scientific-based risk assessment methodology.

### RECOMMENDATION

**Seminar participants recommend the leaders of the G-8 and beyond enhance international cooperation in developing scientific research in the field of biosafety and biosecurity to support evidence-based constructive solutions.**

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<sup>6</sup> <http://www.cdc.gov/ncidod/dvrd/revb/gastro/norovirus-qa.htm>

<sup>7</sup> Wards Shut to Combat Vomit Virus <http://news.bbc.co.uk/1/hi/england/4060145.stm>

<sup>8</sup> Stay away from hospital if you have winter sickness bug, <http://www.stgeorges.nhs.uk/press076.asp>

Dr. Brooks emphasized that many different systems for biosafety and biosecurity exist. Is there any evidence that one system is better than the other? Canada? U.S.? UK? These systems operate with different laboratories and different procedures and have different best practices. He

United Kingdom Containment Legislation
Health & Safety
○ Covers storage and use of pathogens
Prevention of Terrorism legislation 2002
○ Schedule 5 restricts access to some Hazard Group 3 & 4 pathogens
○ Selected list of BT pathogens, includes <i>S. typhi</i>
○ Records have to be kept of stocks
Possible future laws: “Select agent rule”
○ Registered laboratories
○ Secure storage (over and above current law)
○ “Vetted” staff
○ Proscriptive list of pathogens

emphasized that different is not necessarily dangerous. It can be inferred, based upon the small number of problems associated with these facilities, that there are several correct ways for addressing biosafety and biosecurity. Researchers in the UK, for example, do not use class 2 cabinets like their colleagues in the U.S. but do wear protective suits. Canada seals its containment labs while the UK prefers to use a negative pressure system.

The United Kingdom, however, may end up adopting biosecurity standards more similar to

those in the U.S., such as registering Especially Dangerous Pathogens (EDPs) and laboratories, additional security measures for storage and vetting staff. Classifying pathogens as “dangerous” must be supported by a scientific and realistic biological risks assessment. Certain pathogens, *s. typhi* among others, can be bought. Control measures that do not reflect the reality of the life sciences fall short of enhancing security.

The UK has an established system for outbreaks that is multi-agency and led by the Home Office, if national security is threatened. These players conduct regular exercises and have advanced plans in place.

<b>Session 4: The Infectious Disease Challenge</b> <b>Averting Biological Disasters</b>
<b>Moderators</b>
<b>Dr Victor Maleev</b> Academician RAMS Deputy Director, Central Institute of Epidemiology
<b>Dr Stephen Morse</b> Director, Center for Public Health Preparedness at the Mailman School of Public Health, Columbia University

Speakers and participants addressed the following critical questions:

- What are the best methodological approaches for biological risk assessment?
- How can we move towards a shared understanding of biological risks? Is it possible to prioritize biological risks by geographic region, level of development, or type of sector or activity in the life sciences?
- How can the G-8 help to identify and manage biological risks? In what ways can international scientific cooperation and commercial activities assist the process?

**Speaker**

**Dr Vitaly Zverev**

Academician RAMS

Director, The I.I. Mechnikov Institute of Vaccines and Serum

*Vaccines in the Defense System Against New Biological Threats*

Dr Zverev stated that infectious disease has been a topic for discussion by the G-8 for many years. The most wide-spread and most reliable method of fighting infectious disease, and particularly viral disease, is vaccine prophylaxis. Any time and at any place on the planet an epidemic or an outbreak may start. It may be caused by new or re-emerging pathogens or by pathogens migrating to new territories (Monkey Pox and West Nile virus in the U.S.). He emphasized that we are facing 42 new causative agents of infectious disease and the return of childhood diseases, like Pertussis. It was commonly accepted that the vaccine gave life-time immunity, which is not necessarily accurate.

Vaccines are an important element in the defense system against new biological threats. There are a total of 46 vaccine controlled diseases. More than 100 different vaccines developed in the world, with 12 in the 1990s. Over 12 million children die every year from infectious pathology. 4 million from vaccine controlled infections.

<b>Satisfactory vaccines not available</b>		<b>Satisfactory vaccines available</b>	
<b>Infection</b>	<b>Died</b>	<b>Infection</b>	<b>Died</b>
<b>AIDS</b>	<b>2285</b>	<b>Hepatitis B</b>	<b>1000</b>
<b>Tuberculosis</b>	<b>1498</b>	<b>Measles</b>	<b>888</b>
<b>Malaria</b>	<b>1110</b>	<b>Rotaviral</b>	<b>800</b>
<b>Pneumococcus</b>	<b>1100</b>	<b>H. influenza b type</b>	<b>500</b>
<b>Shigellosis</b>	<b>600</b>	<b>Tetanus</b>	<b>410</b>
<b>Colienteritis</b>	<b>500</b>	<b>Pertussis</b>	<b>346</b>
<b>Parasite diseases</b>	<b>232</b>	<b>Cholera</b>	<b>120</b>
<b>PC-viral</b>	<b>160</b>	<b>Diphtheria</b>	<b>5</b>
<b>Dengue</b>	<b>15</b>	<b>Japanese encephalitis</b>	<b>3</b>
<b>Leprosy</b>	<b>2</b>	<b>Poliomyelitis</b>	<b>2</b>
<b>Total</b>	<b>7519</b>	<b>Total</b>	<b>4074</b>

*Childhood deaths per year in millions*

Dr Zverev advocated that international scientific and political cooperation are necessary elements in eliminating infectious disease. There have been some major success, but challenges still exist. Smallpox was eliminated through a global vaccination program. Poliomyelitis has been successfully eliminated in certain continents. The global public health community is working hard to eliminate measles.<sup>9</sup>

Dr Zverev gave an overview of immunoprophylaxis in the event of bioterrorism or biocatastrophe:

1. Planned prophylactic vaccination against dangerous infection;
2. Elaboration of the concept of renewed smallpox vaccination;
3. Prophylactic vaccination of risk groups against smallpox;
4. Development of means for inducing a nonspecific immune response;
5. Traditional vaccine preparations;
6. Therapeutic vaccines;
7. Immunomodulators;
8. Sera; and
9. Antibiotics and antiviral preparations with a broad action spectrum.

He also discussed the available immunological methods for addressing infectious disease, be it a known or unknown pathogen.

#### **Immunological Methods of Fighting Epidemics**

Method	Known pathogen	Unknown pathogen
Vaccination	Yes	No
Immunotherapy	Yes	By the end of the epidemic
Activation of innate immunity	Under discussion	Under development

Innate immunity and acquired immunity are interrelated elements of the integral immune system in 2% of metazoa organisms, including humans. Innate (nonspecific) immunity is

- ✓ Quick (within minutes) recognition of pathogen
- ✓ Recognizes pathogen associated molecular patterns
- ✓ Patterns recognition receptors located on cell surfaces; their diversity allows to recognize any harmful factors (*pathogens, allergens, heat shock proteins*)

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<sup>9</sup> For more on the Measles Mortality Reduction and Regional Global Measles Elimination please see <http://www.cdc.gov/programs/global06.htm>

Having the capability to induce a nonspecific immune response would make a tremendous contribution in the event of bioterrorism or a pandemic outbreak. Dr Zverev described how this emergency protection against pathogens would work.

- Stimulation of immunocompetent cells maturation using immunomodulators of bacterial origin.
- Activation of innate immunity effector mechanisms (24 hours).
- Formation of protective immunity against a concrete pathogen

Dr Zverev stated that vaccines are our greatest tool against infectious disease and offered recommendations for strengthening vaccines.

1. Continuation and expansion of vaccination under national calendar plans;
2. Creation of vaccines to prevent new and reemerging infections, as well as to counter acts of bioterrorism;
3. Development of drugs for immunoprophylaxis and immunotherapy of oncological diseases;
4. Creation of preparations for immunological protection and treatment of drug and smoking addiction;
5. Vaccines that prevent and normalize diseases of the immune system (allergy, autoimmune processes);
6. Therapeutic vaccines for treatment of chronic diseases; and
7. Use of vaccines for prophylaxis of somatic diseases.

***Speaker***

**Dr. Beniamen Cherkassky**

Academician RAMS

Head of Lab, Central Institute of Epidemiology

Head of Chair of Epidemiology, I.M. Sechenov Moscow Medical Academy

*Emerging infections: prevention and control*

Dr. Cherkassky stated that the majority of new and emerging infectious diseases are viruses and zoonotic. There is disagreement over the extent to which new and emerging diseases are hazardous because they are so unpredictable; waiting on the H5N1 avian flu to mutate is a case in point

Emerging diseases can have dire consequences on world economies. Possible impacts for countries affect by an emerging infectious disease include a reduction of the volume of foreign investments, huge damage inflicted to the agricultural industry (e.g. spongious cattle encephalopathy, avian influenza, etc.), catastrophic losses experienced by tourism business, enormous costs of quarantine actions, a reduction in the requirements for raw materials used in industry and transport, particularly aviation fuel, and the devaluation of the currency.

A critical challenge in addressing new infectious disease is the lack of information about

- Pathogen nature and properties;

- Clinical course and epidemiology;
- Rapid methods of pathogen indication and identification;
- Tools and methods of diagnostics and treatment; and
- Tools and methods of prevention and control.

#### **RECOMMENDATION**

**Seminar participants recommend the leaders of the G-8 and beyond develop national systems that could be integrated into global geo-information systems (GIS) on data analysis for prognosis, monitoring and preventing introduction and expanding emerging and re-emerging diseases.**

Dr. Cherkassky advocated for the improved integration of national systems on an international basis into a network to monitor infections. He stressed the need for rapid diagnostics of epidemic outbreaks of infectious diseases (HIV/AIDS, viral hepatitis, animal and avian influenza, SARS, hemorrhagic fevers, etc.) in hard-to-get and remote locations, migratory bird routes, and rural areas. Information and communication technology are powerful tools that for improving disease surveillance.

He highlighted the Russian developed SCAESNet (Satellite Communication Anti Epidemic Screening Network), a telemedicine system to fight HIV/AIDS, tuberculosis and malaria with the help of communication technology. The key element of SCAESNet is represented by mobile self-sustained telemedical labs performing rapid detection of pathogens by advanced methods within 2.5 – 3 hours. It enables to make a real-time “on-site” assessment of the epidemiological situation and to transmit data in a timely manner to the management centers.

Dr. Cherkassky noted that in discussing emerging infectious disease, the question of natural or deliberate has been examined by many; criteria for differentiating the origin of disease have been developed by many groups. The Central Institute of Epidemiology, for example, has a baseline study of all anthrax outbreaks in the last 100 years.

**Reception**  
**18 April 2006**  
**I.M. Sechenov Moscow Medical Academy**

**Speech of Christopher Westdal**  
Canadian Ambassador to the Russian Federation

Canada is co-sponsoring this seminar – but that’s the easy part; for the much harder work of organizing it and for giving me the chance to say a few words at this evening’s reception to open it, I thank the International Council for the Life Sciences, the Moscow Medical Academy, and TEMPO.

This subject of yours is close to my heart.

Before coming to Moscow, I worked in Geneva as Canada’s Ambassador for Disarmament trying to help enforce the ban on biological weapons (the use of which would be, in the unusually stark words of the Biological and Toxin Weapons Convention, “repugnant to the conscience of mankind”).

I was at the same time Canada’s representative to the World Health Organization, where naturally occurring diseases and public health were at the fore.

That time in Geneva left me with profound – and still quite perplexed – respect for national dilemmas of science.

On the one hand, as Robert Oppenheimer wrote, “When you see something that is technically sweet, you go ahead and do it – and you argue about what to do about it only *after* you have had technical success.”

The problem is that that “technically sweet” thing you’ve done – and can’t undo – might save – or might kill – many millions.

Oppenheimer was a nuclear physicist, but the same is true in the biological sciences – where each pathogen holds the keys to both death and life.

You know, at the UN, when you vote, you get three choices, three buttons to push: yes, no, or abstain. Sometimes, like now, I felt I needed a fourth button: too tricky for me.

Whatever, the spread – whether natural or deliberate – of infectious diseases poses grave, global threats to public health, to development, to prosperity and to security.

Such threats command coordinated, multi-faceted responses which harness all of the diverse resources at our disposal.

Canada is actively committed and engaged at home and abroad.

In the Global Partnership Program, we have developed comprehensive bio-safety and bio-security strategies.

They include physical upgrades at vulnerable facilities, the preparation of national guidelines, training and seminars like this one.

We are active as well in the implementation of the Biological and Toxin Weapons Convention.

At its PrepCom next week we will work to enhance the accountability of States Parties, to strengthen national implementation and confidence-building measures and to inaugurate regular annual meetings.

Among your ranks I see scientists and security specialists, biologists and arms controllers, all committed to the same objective: keeping disease beyond the reach of those who would use it as a weapon – and in an environment where it can be worked on in safety by those seeking to unlock its mysteries for the benefit of all.

I also see Maureen Ellis, one of Canada's pre-eminent Biosafety/security experts, who embodies the duality of bio-safety and bio-security.

Maureen serves as Senior Bio-safety Advisor for both Canada's Global Partnership Program and its Public Health Agency. Different starting points – non-proliferation and public health – but same end point.

There's a useful lesson in that. When dealing with biological threats, the stakes are far too high to separate and segregate the means we use to prevent the natural – or the deliberate – spread of disease.

We must let nothing – neither bureaucracy, nor inertia, nor suspicions from an age now past – stand in our way.

I wish every success in this seminar and far beyond.

Thank you.

## Wednesday 19 April

<b>Summary of the First Day &amp; Introducing the Second Day</b>
<p><b>Dr Mikhail Paltsev</b> Seminar Co-Chairman Rector, I.M. Sechenov Moscow Medical Academy (MMA) Chairman of the Scientific Council, TEMPO First Vice-President &amp; Academician, Russian Academy of Medical Sciences (RAMS) Academician, Russian Academy of Sciences (RAS) Member, ICLS Senior Advisory Panel</p> <p><b>Mr Leo Owskiacki</b> Deputy Executive Director, Global Security &amp; Strategic Planning Department, International Science and Technology Center (ISTC)</p> <p><b>Dr Alexander Gintzburg</b> Vice-President, Russian Academy of Medical Sciences (RAMS) Director, Gamaleya Institute of Epidemiology &amp; Microbiology</p> <p><b>Mr Terence Taylor</b> Seminar Co-Chairman Director, International Council for the Life Sciences (ICLS) &amp; President of the Board of Directors</p>

The second day of the seminar was introduced by Academician M.A. Paltsev, Leo Owskiacki, Academician A.L. Gintzburg and Terence Taylor. Academician Paltsev outlined the recommendations from the previous day's discussion, which call for the development of training and educational programs in line with international standards, groups of excellence consisting of international experts - WHO collaborating centres and others - to create a mechanism to share information, an international glossary for biosafety and biosecurity, and international standards to assess biological risks for human health. Mr Owskiacki, the Deputy Executive Director of the Global Security & Strategic Planning Department at The International Science and Technology Center (ISTC) highlighted ISTC activities in promoting biosafety and biosecurity.

Academician Gintzburg noted that it was a matter of top importance to develop international biosafety/biosecurity standards for biological laboratories. The major efforts should be concentrated on the harmonization of the legislation operating in our countries, development of international collaboration, extension of WHO network, and the scientific conferences.

Mr Taylor emphasized the role of the ICLS in promoting international standards for biosafety and biosecurity. He thanked Academician Paltsev, who serves on the ICLS Senior Advisory Panel, for the opportunity to jointly plan and convene the seminar with the MMA and TEMPO. Bringing together scientists and public policy officials to discuss biological risks, whatever their origin, and international cooperation to manage these risks is one way the ICLS helps contribute to enhanced biological safety and security. Mr Taylor invited the seminar participants to be involved in future ICLS activities, which include biosafety and biosecurity education and training curricula for scientists, policymakers and business executives and conducting a global biological risk assessment.

**Plenary Session on the Infectious Disease Challenge  
Averting Biological Disasters**

**Moderators**

**Dr Dmitry Lvov**

Academician RAMS

Director, D.I. Ivanovsky Institute of Virology

Head, Chair of Virology, I.M. Sechenov Moscow Medical Academy

**Dr Ivan Dyatlov**

Professor, Director, State Research Center of Applied Microbiology & Biotechnology Center

Several presentations on avian influenza were given by Russian experts. Dr Ingegerd Kallings of the Swedish Infectious Disease Control Institute gave an overview of the organizations and tools for responding globally to the infectious disease threat.

**Speaker**

**Dr. Dmitry Lvov**

Academician RAMS

Director, D.I. Ivanovsky Institute of Virology

Head, Chair of Virology, I.M. Sechenov Moscow Medical Academy

*Causes and Consequences of the Highly Pathogenic Avian Influenza*

*H5N1 Strain Spread into Russia*

Dr Lvov discussed the reasons and consequences of highly pathogenic (HPAI) H5N1 penetration into Russia: past, present, and future. His research was partially supported by Russian Federal Programs “Defense from pathogens”, “Development of tools and methods for the prevention of bioterrorism” and ISTC project #2800. The main goal of research at the D.I. Ivanovsky Institute of Virology is the study of emerging infections, which are able to provoke extraordinary epidemic situation. Prevention of bioterrorism consequences is important part of this problem.

The Institute performs work it considers as a model for the study of emerging situations appearing as a result of natural or criminal factors. To support this research, the Institute uses an inter-lab group of prompt reaction “by conveyor system”; field materials are quickly and safely collected and examined by classic virological and molecular-genetic methods. Dr Lvov emphasized that the most dangerous threat is Nature.

**Speaker**

**Dr. Oleg Kiselev**

Academician RAMS

Director, Institute of Influenza

National WHO Center

*XX-XXI centuries’ pandemics and biosafety challenges*

Dr. Kiselev noted the emergence of viral infections, such as Hepatitis B and C, HIV/AIDS, coronaviruses, prions, and H5N1 avian flu, which date from the end of 20<sup>th</sup> century and the beginning of the 21<sup>st</sup>. Causes of the frequent emergence of viruses with high epidemic potential include an increased world population number, an increased population density in individual

regions, global warming and the expansion of the artificial farming of fish, poultry and domestic animals.

Dr. Kiselev offered a comparison of global morbidity in 1909 and 1999. He stated that in 1909 overall morbidity from infectious disease was close to 50% versus 20% in 1999. While great strides have been made in treating infectious disease, influenza still remains a global threat.

Dr Kiselev gave an overview of the current World Health Organization (WHO) system of control for handling the 600-1,200 million cases of influenza each year noting that the importance of the influenza vaccine. The vaccine is produced by an analysis of properties of the viruses circulating in a particular epidemic season, recommendations on strains to be used in vaccines for the upcoming epidemic season, production of reassortants or recombinant strains in WHO reference centers, and transferring the production strains to the countries-manufacturers of influenza vaccines.

Dr Kiselev argued that the World Health Organization recommendations for dealing with influenza are not entirely appropriate for the entire world. He cited that the drug Tamiflu can be a problematic medication for influenza treatment and prevention, vaccines proposed by WHO can be compromised by potential efficacy, and the difficulty in reconciling recommendations with the current medical system in many countries.

***Speaker***

**Dr Sergey Netesov**

Corresponding Member RAS

Deputy Director, SRC V&B VECTOR

**Dr. I.G. Drozdov**

Professor, Director, SRC V&B VECTOR

**Dr. G.G. Onischenko**

Academician RAMS

Head of Federal Service for Surveillance in Consumer Rights Protection & Human Well-Being  
*Emerging Infections in Siberia and Far East*

Dr Netesov offered several reasons for the emergence of new infections.

1. Carrying infections with migratory birds (influenza virus of H5 subtype);
2. Invasion of humans to the new territories with previously unknown animals or insects (tick-borne encephalitis in 1937-1940 in Far East);
3. The industrial breeding of new species of animals (palm-civet, SARS-coronavirus);
4. Introduction of the new species of animals to new territories (musk rat – Omsk hemorrhagic fever; Gambian rat in the U.S.);
5. Global warming (West Nile and Japanese encephalitis virus in Siberia);
6. The creation of the new conditions for animals (garbage places, rabies) and insect (used tires, mosquitoes, malaria) breeding; and
7. The introduction of new technologies (air conditioners, legionellosis, Biisk, Altay region).

Dr Netesov expanded on the topic of migratory birds carrying infections (influenza virus of H5 subtype). The H5N1 bird flu outbreak in Russia started in July 2005 in the Novosibirsk region among wild and domestic waterfowl and chicken held in private premises. Similar outbreaks were registered in Omsk, Chelyabinsk, Kurgan, Tyumen, Altai regions and Kalmykia in July and August 2005. The outbreaks were contained within wild birds and poultry in small private premises. Industrial poultry plants were unaffected.

A possible reconstructed sequence of events for the summer of 2005 in the Siberian portion of Russia begins with the arrival of migrating birds from China/Kazakhstan to West Siberia in April/May. In May/June the birds nest, lay eggs, the eggs hatch, and the baby birds are fed in the nest. The baby birds start self feeding and meet with domestic ducks/geese. In July, infected domestic waterfowl bring the virus to private premises, which began the mass infection and death of chickens, ducklings, turkey and other poultry.

<b>Sequence of events engaged with bird flu diagnosis in July 2005 in Russia</b>
11 July – first registration of death of wild birds
15 July – first registration of death of home poultry
17 July – the sampling of organs and feces from birds and its delivery to Vector
20 July – the first results of analysis (influenza virus of H5subtype) were sent to Governor of Novosibirsk Region
22 July – the results of further analysis (H5N1 genotype and high pathogenicity for chicken) were sent to Governor
24 July – information about the potential pathogenicity for humans and phylogenetic similarity to Chinese flu strains was obtained
24 July – the organization of the special commission under the governor for epizooty control

Dr Netesov emphasized that for early detection of emerging infections the monitoring of acute zoonanthropnotic infections of wild animals and birds is highly required in the places close to their entrance to the territory of Russia, CIS countries and Europe. One of the most important entrance, rest and nesting places for migrating birds in Eurasia is located in the south of West Siberia. He stressed that “Vector” is an extremely suitable research institute for the monitoring of infectious agents in migrating birds, wild animals and poultry. Further strengthening its research capacity would be extremely useful for early warning in case of appearance of the new emerging infections for Russia, CIS countries, Europe and, finally, USA and Canada.

***Speaker***

**Dr Ingegerd Kallings**

Biosafety Advisor, Head WHO Collaborating Center on Biological Safety  
Swedish Institute for Infectious Disease Control  
*Global Response to the Infectious Disease Threat*

Dr Ingegerd Kallings gave an overview of the inter-governmental organizations involved in the global response to the infectious disease threat.

- The World Health Organization (WHO)
- The Joint United Nations Programme on HIV/AIDS (UNAIDS)
- United Nations Children’s Fund (UNICEF)
- World Bank
- Food and Agricultural Organization (FAO)
- World Animal Health Organization (OIE)

WHO has several important programs that help address naturally occurring infectious disease and the deliberate misuse of the life sciences. The Epidemic and Pandemic Alert and Response (WHO/EPR) group advocates that “every country should be able to detect, verify rapidly and respond appropriately to epidemic-prone and emerging disease threats when they arise to minimize their impact on the health and economy of the world's population.” Main areas of work for the EPR include Alert and Response Operations, Preparedness for Deliberate Epidemics, and Laboratory and Epidemiology Training, which includes a special project on biosafety.

- WHO/EPR assets for alert and response operations
- ✓ Epidemic intelligence - systematic event detection
  - ✓ Event verification
  - ✓ Information management and dissemination
  - ✓ Real time alert
  - ✓ Coordinated rapid outbreak response
  - ✓ Outbreak response logistics

Dr Kallings stated that the WHO Biosafety Programme is a resource to Member States for information, training and advocacy for laboratory biosafety procedures and practices. It coordinates an informal information-sharing network of international biosafety organizations and liaises with the United Nations on international regulations for transport of biohazardous materials. The programme produces and revises a variety of technical information documents on biosafety. The most well known is the Laboratory Biosafety Manual 3<sup>rd</sup> edition. Laboratory Biosecurity 1<sup>st</sup> edition is forthcoming. The WHO also has a Biosafety Advisory Group composed of experts in biosafety and laboratory safety issues. This group meets regularly and advises the programme on scientific issues.

Another important organization is the European Center for Disease Prevention and Control, which is tasked with strengthening the defence against communicable diseases and increasing public health capacity in Europe. It is composed of three departments: scientific advice, surveillance and communication, and preparedness and response. The organization's main mission is to identify, assess and communicate current and emerging threats to public health:

- ✓ Risk identification and risk assessment
  - Surveillance
  - Epidemic intelligence
- ✓ Preparedness planning
- ✓ Response to health threats
- ✓ Training
- ✓ Communication
- ✓ Scientific opinions and guidelines
- ✓ Advisory role to the European Commission

National biosafety organizations<sup>10</sup> play an important role in promoting biological safety by

- Defining the biosafety profession and professionals (biosafety officer) curriculum and tasks;
- Communicating biosafety best practices;
- Developing national policies, regulations and guidelines; and
- Developing and harmonizing international guidelines and standards.

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<sup>10</sup> Please see page 11 for a list of national biosafety associations.

***Speaker***

**Dr Ivan Dyatlov**

Professor, Director, State Research Center of Applied Microbiology & Biotechnology

*Advanced research in detection, prevention and treatment of newly emerging and re-emerging bacterial infections*

Dr Dyatlov gave an overview of SRCAM and its activities. The key tasks of the organization are to perform fundamental and applied research in the areas of epidemiology, bacteriology, and biotechnology and to provide assurance of sanitary and epidemiological welfare of the public. He discussed the technological platforms used by SRCAM for rapid indication and identification including real-time PCR, immunosensors (optical - plasma resonance, acoustic, magnetometric, etc.), mass-spectrometry sensors, confocal laser scanning microscopy and biochips.

SRCAM preventive products include vaccines for Plague, Tularemia, Anthrax, Tuberculosis and Borreliosis. SRCAM's work also includes therapeutic products such as bacteriophages, plant and animal peptides, and novel compounds produced by combinatorial chemistry. Dr Dyatlov highlighted research on bacteriocins – bacterial peptides synthesized by ribosomes with low-molecular weight that possess antimicrobial activity. Bacteriocins are active against bacteria resistant to antibiotics and there is a very low probability of developing mutants resistant to bacteriocins.

Members of the Mass Media had an opportunity on the second day to attend the seminar and ask speakers and participants questions regarding biological risks and international collaboration. Twenty-four individuals from a variety of media companies were present representing

1. TV & Radio: Voice of Russia, “Zvezda” (Star), 21<sup>st</sup> Office
2. Informational Agencies: ITAR-TASS, RIA “News”
3. Central Press: Moscow News, Moscow Pravda, Pravda, Trud
4. Special medical press: Glavvrach (Chief Doctor), Medical Vestnik, Medical newsletter, Remedium (Russian pharmacies)
5. Other media: Zdorovye (Health), Zdravookhranenie (Public Health), Itogy, Society and we, Parliament newsletter, Poisk (Search), Russian Federation today, Economy and medicine today, News in science and technique, Pro Health

## Concluding Remarks

**Dr Mikhail Paltsev**

Seminar Co-Chairman

Rector, I.M. Sechenov Moscow Medical Academy (MMA)

Chairman of the Scientific Council, TEMPO

First Vice-President & Academician, Russian Academy of Medical Sciences (RAMS)

Academician, Russian Academy of Sciences (RAS)

Member, ICLS Senior Advisory Panel

**Mr Terence Taylor**

Seminar Co-Chairman

Director, International Council for the Life Sciences (ICLS) & President of the Board of Directors

Academician Paltsev and Mr Taylor thanked everyone for their participation. The Seminar Co-Chairmen intend to promote and help carry out the recommendations from the meeting, which are listed below.

## RECOMMENDATIONS FOR GLOBAL ACTION

**The Moscow Medical Academy, TEMPO, ICLS and participants at *Enhancing Biosafety and Biosecurity: An Agenda for Global Action* recommend the following:**

- 1. Enhance international cooperation in developing scientific research in the field of biosafety and biosecurity to support evidence-based constructive solutions;**
- 2. Develop training programmes in biosafety and biosecurity in accordance with global standards;**
- 3. Develop an International Panel of Experts, based, inter alia, on “groups of excellence”, (National Centres, WHO Collaborating Centres, WHO experts) to create information exchange mechanism between making decisions state organizations, nongovernmental and scientific organizations in the field of biosafety and biosecurity;**
- 4. Create an International Expert Group on developing international glossary on biosafety/biosecurity terminology;**
- 5. Develop common methodological approach on science-based - assessment of biological risks for human health and well-being - biosafety and biosecurity in all types of biological laboratories; and**
- 6. Develop national systems that could be integrated into global geo-information systems (GIS) on data analysis for prognosis, monitoring and preventing introduction and expanding emerging and re-emerging diseases.**

**In order to engender action without delay on these recommendations in the academic, governmental and private sectors, the seminar co-chairs invite the support of the life sciences community in setting up international, multidisciplinary action groups focused on the above issues to support national governments and international organizations in the efforts to enhance biosafety and biosecurity to counter the biological risks faced by the public world-wide.**

Organizations and individuals interested in working with the ICLS, TEMPO and the MMA to help implement these recommendations should contact:

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