

International Council for the Life Sciences



Enhancing Biosafety and Biosecurity: An Agenda for Global Action



Meeting Summary and Recommendations

Summer 2006

This report and its findings are based on the international seminar:

***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**

This seminar was convened by:



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

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The International Science and Technology Center

The International Council for the Life Sciences (ICLS) is a non-profit organization headquartered in Washington, DC, USA. The ICLS is helping to enhancing biological security and biological safety and reducing biological weapons proliferation risks. It is a membership-based organization that brings together life sciences organizations from academia, private industry, nongovernmental organizations, and governments from around the world to identify critical biological risks and to develop and promote international guidelines, best practices, codes of conduct and/or regulations to manage these risks. For more information on the ICLS visit www.iclscharter.org.

The I.M. Sechenov Moscow Medical Academy (MMA), established in 1765, is the largest educational institution in Russia in medicine and pharmacology, as well as a center of excellence in research and development in the biomedical sciences. The Moscow Medical Academy brings together an education center, clinical center, and a research center, including 61 laboratories and 5 research institutes. MMA, together with TEMPO and MMA's Institute of Molecular Medicine, run the annual International Conference on Molecular Medicine and Biosafety. For more information visit www.mmascience.ru.

The Non Commercial Partnership “Center of Modern Medical Technology” TEMPO is the Biotechnology Consortium that brings together leading Russian research & development and manufacturing & sales organizations for the development and advancement of innovative biotechnologies. TEMPO focuses on providing leadership in regulatory affairs, industry outreach, and innovation support to its member institutions. TEMPO is currently a dynamic consortium that unites 17 organizations. TEMPO member institutions' areas of specialization include research and development, the manufacture of diagnostics and biopharmaceuticals against human diseases, veterinary products, space biotechnology, and biological instrumentation. For more information on TEMPO visit www.nptemp.ru.

The Global Partnership Program, Department of Foreign Affairs and International Trade, Government of Canada is intended to address one of the most serious security threats facing our world today by preventing terrorist groups from obtaining weapons and materials of mass destruction (WMD) to carry out their campaigns. For more information visit www.dfait-maeci.gc.ca/foreign_policy/global_partnership/menu-en.asp

The International Science and Technology Center (ISTC) was established by an international agreement in November 1992 as a nonproliferation program. The ISTC coordinates the efforts of numerous governments, international organizations, and private sector industries, providing weapons scientists from Russia and the Commonwealth of Independent States (CIS) new opportunities in international partnership. Through its political, legal, and financial frameworks, the ISTC contributes to Fundamental Research, International Programs and Innovation and Commercialization, by linking the demands of international markets with the exceptional pool of scientific talent available in Russian and CIS institutes. For more information on the ISTC visit www.istc.ru.

Foreword

by, Terence Taylor

Having dedicated a substantial portion of my professional career examining the security implications of scientific advances, I can fully appreciate the significant need for an independent non-profit organization focused on biological risks, whatever their origin. Traditional governance structures of national governments and international organizations are overwhelmed by the fast-paced developments and dissemination of the life sciences and associated technologies. While governments will remain an important component in addressing biological risks, effectively meeting this challenge requires a new approach. It must be inclusive of the entire risk spectrum - ranging from naturally occurring infectious disease to deliberate misuse - and directly engage the global life sciences community. By promoting the International Council for the Life Sciences (ICLS), I hope to provide a forum for exactly that.

Reaping the rewards and reducing the risks of innovations in the life sciences and related technologies serves as the foundation for the ICLS and its activities. While such advances offer new medicines and extraordinary benefits to industrial processes, they can pose serious threats to public health, safety and security. I firmly believe that the best course of action to reduce the misuse of the life sciences is to raise awareness of the full spectrum of biological risks, promote international safety and security standards worldwide, and provide a forum for the safe exchange of information and best practices.

More than seventy experts from the G8 countries plus Sweden, representing government, academia and industry, participated in a two day seminar on *Enhancing Biological Safety and Security: An Agenda for Global Action* in April 2006. This meeting summary provides their recommendations to reduce biological risks through improved disease surveillance, widely accepted standards for biosafety and biosecurity, education and training curricula for scientists and policy officials, increased international

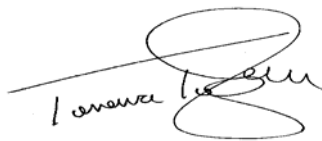
cooperation, greater exchange of information and best practices, and developing a common methodological approach for biological risk assessment. Implementing these recommendations will not only require the sustained engagement of the global life sciences community but a firm commitment by governments and international organizations. While the 2006 Russian Presidency of the G8 and President Putin's stated interest in infectious disease provided an incentive for the seminar, the resulting report and recommendations are global in scope.

The International Council for the Life Sciences was greatly pleased to partner with the Non-Commercial Partnership TEMPO and the I.M. Sechenov Moscow Medical Academy in planning and conducting the Seminar, and I look forward to continuing collaboration. The support of the Global Partnership Program at Foreign Affairs Canada and the International Science and Technology Center were invaluable to the success of the seminar. The efforts by Canada to reduce biological proliferation risks and to promote international cooperation are of paramount importance.

The seminar conducted in Moscow is a demonstration of the cooperation that is needed to manage biological risks and is truly a step in the right direction. I look forward to welcoming new partners and members into the ICLS network to promote advances in the life sciences and collaboratively identify and manage biological risks to public health, safety and security.

This report is our effort to provide a comprehensive overview of the seminar. The authors endeavored to accurately convey the information and ideas given by the participants and we take full responsibility for the final content of the report.

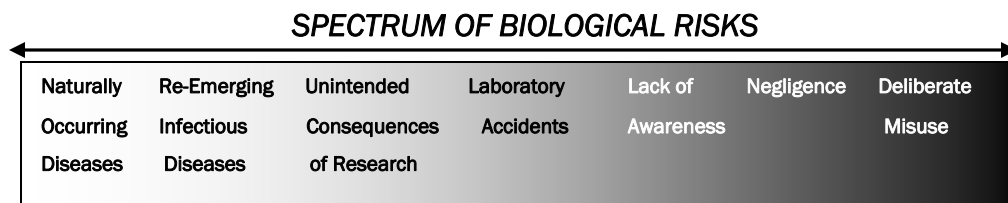
Sincerely,

A handwritten signature in black ink, appearing to read "Terence Taylor", with a large, stylized flourish at the end.

Terence Taylor
Director, ICLS

EXECUTIVE SUMMARY

Experts from the G8 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.



Improved global standards and increased international cooperation are important contributions in addressing the challenges 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, training and education 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 also 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 G8, 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 G8 countries plus Sweden ahead of the G8 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 covered:

- 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 G8 Leadership.

RECOMMENDATIONS

Seminar participants recommended global action by leaders of the G8 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 an information exchange mechanism between [decision making] state organizations, nongovernmental and scientific organizations in the field of biosafety and biosecurity;**

4. Create an International Expert Group on developing an international glossary on biosafety/biosecurity terminology;
5. Develop a common methodological approach on science-based - assessments 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
<p>Dr. Mikhail Paltsev Seminar Co-Chairman Rector, I.M. Sechenov Moscow Medical Academy (MMA) Chairman of the Scientific Technical Council, TEMPO First Vice-President & Academician, Russian Academy of Medical Sciences (RAMS) Academician, Russian Academy of Sciences (RAS) Member, ICLS Senior Advisory Panel</p>
<p>Mr. Terence Taylor Seminar Co-Chairman Director, International Council for the Life Sciences (ICLS) & President of the Board of Directors</p>
<p>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</p>

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 on *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 second International Conference included an International Seminar entitled *Bioterrorism: Possible Objects for Affection and Counteraction Methods* that brought together experts from the US, Sweden, Canada, Japan, China, and the UK. According to Dr. 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 on enhanced biosafety/biosecurity and terrorism challenges. 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 and at a joint meeting with the ICLS in November 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 organization is supported by a Charter containing obligations for responsible conduct in the life sciences 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 than even a meeting of world leaders. We are in a 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 biotechnology 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, health, or knowledge.

Session 1: Global Standards in Biosafety and Biosecurity

Moderators

Dr. Alexander Gintsburg

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

Director, Gamaleya Institute of Epidemiology & Microbiology

Mr. Terence Taylor

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

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 G8 nations contribute to global biosafety and biosecurity standards?

Speaker

Dr. Julia Ananyina

Professor, Deputy 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 stemming 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.

Defining Biosecurity and Biosafety	
<p><u>Biosafety</u> deals with all aspects of containment to prevent any exposure to and accidental release of pathogens.</p> <p><u>Biosecurity</u> is implemented to prevent the theft, misuse or intentional release of pathogens.</p> <p><i>Laboratory Biosafety Guidelines. Health Canada 2004.</i></p>	<p>. ... 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.</p> <p><i>Russian Ministry of Health Biosafety Regulations 2003</i></p>

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

RECOMMENDATION

Seminar participants recommend the leaders of the G8 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

¹ 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).

the Australia Group (AG), Russia's list of controlled pathogens¹ 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 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 for research organizations on matters pertaining to biosafety and biosecurity. The WHO provides assistance in biosafety and biocontainment technology, biosafety training and education, and applied research programmes on biosafety/biocontainment issues.

Dr. Ananyina stated that 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 G8 and beyond develop a Board of International Experts, inter alia, based on "groups of excellence", (National Centres, WHO CCs, WHO experts) to create an 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. He emphasized that 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 countries with few regulations provide an incentive for biotechnology companies to relocate. On the contrary, 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.

Session 2: Raising Awareness
Contributions from Training, Education Curriculum and
Other Outreach Activities

Moderators

Dr. Benjamin Cherkassky

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

Mrs. Heather Sheeley

Manager of Health and Safety, UK Health Protection Agency

Speakers and participants addressed the following critical questions:

- What are possible approaches for the G8 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.

The Biosafety Program	
Organization	Contribution
NP TEMPO	Coordinate Program
Governmental and educational organizations of the G8*	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 US 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 Russian Governmental Council on Biological and Chemical Safety.
- Established an annual international biosafety, biosecurity and molecular medicine conference in Moscow, Russia.

Speaker

Mrs. 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. She stressed that 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.

Mrs. Ellis emphasized that effective biological risk 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.

Relevant United Nations Resolutions	
<p>World Health Assembly Resolution 58.29</p> <ul style="list-style-type: none"> • Considering that release of microbiological agents may have global ramifications • Acknowledging that the containment of microbiological agents is critical to preventing outbreaks of emerging diseases ... <p>Urges Member States:</p> <ul style="list-style-type: none"> • to implement specific programmes ... to promote biosafety laboratory practices • to mobilise national and international ... resources to improve laboratory biosafety. 	<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"> • Develop and maintain appropriate effective measures to account for and secure items in production, use storage or transport. • Develop and maintain appropriate effective physical protection measures.

UN Security Council resolutions, such as UNSCR 1540, are legally binding for UN member states. Pursuant to its adoption on 28 April 2004, 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.”² WHO guidelines for biosecurity are forthcoming.

Mrs. Ellis drew attention to the additional resources provided by the five research institutes designated as World Health Organization Biosafety Collaborating Centres.”³ As mentioned by Dr. Ananyina, 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.”⁴

Helping member states develop biosafety programs, such as promoting the development of national biosafety associations and standardized training materials and curricula, would help strengthen World Health Assembly Resolution 58.29 and build upon the efforts of the WHO.

RECOMMENDATION

Seminar participants recommend the leaders of the G8 and beyond develop training programmes in biosafety and biosecurity in accordance with global standards.

² 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>

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

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

Mrs. Ellis gave an overview of the IBWG, which was founded in 2001 and consists of national biosafety associations and the World Health Organization. Health 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

www.internationalbiosafety.org

List of Members

Asia Pacific Biosafety Association
Assiciacao Nacional de Biosseguranc, Brazil (ANBio)
American Biological Safety Association (ABSA)
ABSA Canada
European Biological Safety Association (EBSA)
Japanese Biological Safety Association (JBSA)
International Veterinary Biosafety Working Group (IVBWG)
International Level 4 Users Group
Pharmaceutical Biosafety Group

WHAR 58.29 and UNSCR 1540 are two very important UN resolutions that address separate parts of 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 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.

Speaker

M. N. Lyapin

V. V. Kutyrev

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 and advanced training, which is described in the table below. Primary Specialization 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.

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

Session 3: Perspectives on Biological Risk Assessment

Moderators

Dr. Mikhail 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:

- 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 G8 help to identify and manage biological risks? In what ways can international scientific cooperation and commercial activities assist the process?

Speaker

Dr. Valentin Evstigneev

Deputy General Director, JSC Biopreparat

Conception of Acceptable Risk in Assessment of Biosafety Systems

Dr. Evstigneev posed the following question: When 35 million people have an 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 G8 and beyond to develop a common methodological approach on science-based - assessments 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 is involved;
- Biosafety and who is 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

Borrelia burgdorferi (1982) – Lyme disease

HIV (1983) – worldwide pandemic

Vibrio cholerae 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 or have been branded biological weapons, often take the spotlight with the general public. Improving how the full spectrum of biological risks is communicated to the public is extremely important. Only a few cases of suspected human to human transmission have occurred with avian influenza, yet individuals are beginning to panic and fear a global pandemic is days away. Many Americans, however, do not realize that 30,000 people die annually in the U.S. from influenza and in most years the vaccination has to be discarded from a lack of interest.

Dr. Brooks stated that the public’s heightened sense of awareness and lack of proper information help lead to a skewed perception of risks. He stressed that better communication about biological risks to the general public will help in some regard, but this challenge will persist. Dr. Brooks advocated that better communication about biological risks to the general public will help in some regard, but this challenge will persist.

⁵ Bridges, Andrew. “Bird Flu Hitting TV Screens May .” ABC News. 28 April 2006.

<http://abcnews.go.com/Entertainment/wireStory?id=1902688&page=3>

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)

Biosafety in the United Kingdom is led by the 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

Dr. Brooks stated that long term planning for dealing with biological risks and infectious disease 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)

UK HSE Biosafety and Biosecurity Publications
<ul style="list-style-type: none">• Control of Substances Hazardous to your Health (COSHH): A brief guide to the regulations• Biological agents: Managing the risks in laboratories and healthcare premises• The Approved List of biological agents

National response plans abound for dealing with public health emergencies due to 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 norovirus⁶, which causes upset stomach, among other symptoms, was a critical concern for hospitals.⁷ Individual hospitals were very active in taking steps to reduce the risks of norovirus for their patients and daily operations.⁸ 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 G8 and beyond enhance international cooperation in developing scientific research in the field of biosafety and biosecurity to support evidence-based constructive solutions.

⁶ For the US Center for Disease Control and Prevention's definition of norovirus visit <http://www.cdc.gov/ncidod/dvrd/revb/gastro/norovirus-qa.htm>

⁷ "Wards Shut to Combat Vomit Virus." *BBC News*. 1 Dec. 2004 <http://news.bbc.co.uk/1/hi/england/4060145.stm>

⁸ "Stay away from hospital if you have winter sickness bug." St. George's Healthcare NHS Trust. 22 Feb. 2006

<http://www.stgeorges.nhs.uk/press076.asp>

Dr. Brooks emphasized that many different systems for biosafety and biosecurity exist. He offered the question: Is there any evidence that one system is better than the other? Canada? US? UK? These systems operate with different laboratories and different procedures and have different best practices. He 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 US, 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 US, such as registering Especially Dangerous Pathogens (EDPs) and laboratories, additional security measures for storage and vetting staff. He stresses that classifying pathogens as “dangerous” must be supported by a scientific and realistic

United Kingdom Containment Legislation
Health & Safety <ul style="list-style-type: none"> o Covers storage and use of pathogens
Prevention of Terrorism legislation 2002 <ul style="list-style-type: none"> o Schedule 5 restricts access to some Hazard Group 3 & 4 pathogens o Selected list of BT pathogens, includes <i>S. typhi</i> o Records have to be kept of stocks
Possible future laws: “Select agent rule” <ul style="list-style-type: none"> o Registered laboratories o Secure storage (over and above current law) o “Vetted” staff o Proscriptive list of pathogens

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.

Session 4: The Infectious Disease Challenge
Averting Biological Disasters

Moderators

Dr. Victor Maleev

Academician, RAMS

Deputy Director, Central Institute of Epidemiology

Dr. Stephen Morse

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 major concerns?
- What are possible ways for the G-8 to address the global challenge of infectious disease? What are priority areas for cooperation?
- How can global biosafety and biosecurity standards help the G-8 and other countries manage the infectious disease challenge?

Speaker

Dr. Vitaly Zverev

Academician, RAMS

Director, 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 G8 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 US). 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 for this disease gave life-time immunity, which, we are learning, is not necessarily accurate.

Dr. Zverev stressed that 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 have been developed in the world, with 12 in the 1990s. Over 12 million children, however, die every year from infectious pathology, including 4 million from vaccine controlled infections.

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

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 successes, 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.⁹

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

Dr. Zverev gave an overview of immunoprophylaxis that could be used 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 possible 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; and
- ✓ Patterns recognition receptors located on cell surfaces; their diversity allows to recognize any harmful factors (*pathogens, allergens, heat shock proteins*).

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); and
- 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 zoonotic viruses, which are transmissible from animals to humans . 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 affected 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 the 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 G8 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 necessary and powerful tools 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 is able to make a real-time “on-site” assessment of the epidemiological situation and 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 cause has been examined by many; criteria for differentiating the origin of disease has 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.

The first day of the seminar was followed by a reception, which featured remarks by Canadian Ambassador to the Russian Federation, Christopher Westdal.

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 “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

Summary of the First Day & Introducing the Second Day
<p>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</p> <p>Mr. Leo Owsicki Deputy Executive Director, Global Security & Strategic Planning Department, International Science and Technology Center (ISTC)</p> <p>Dr. Alexander Gintsburg Vice-President, Russian Academy of Medical Sciences (RAMS) Director, Gamaleya Institute of Epidemiology & Microbiology</p> <p>Mr. Terence Taylor Seminar Co-Chairman Director, International Council for the Life Sciences (ICLS) & President of the Board of Directors</p>

The second day of the seminar was introduced by Academician M.A. Paltsev, Leo Owsicki, Academician A.L. Gintsburg 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 Gintsburg 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, expanding the WHO network, and more 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, conducting a global biological risk assessment and working with partners to implement the recommendations from the meeting.

**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 situations. Prevention of bioterrorism consequences is an 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 viruses, such as Hepatitis B and C, HIV/AIDS, corona viruses, prions, and H5N1 avian flu, which date from the end of 20th century and the beginning of the 21st. He stated there are several causes for the frequent emergence of viruses with high epidemic potential including an increase in world population, increases 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 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 every region of the 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 US);
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

Sequence of events engaged with bird flu diagnosis in July 2005 in Russia
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

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.

Dr. Netesov emphasized that for early detection of emerging infections the monitoring of acute zoonotic 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 an 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

- | |
|--|
| 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 |

Operations, Preparedness for Deliberate Epidemics, and Laboratory and Epidemiology Training, which includes a special project on biosafety.

Dr. Kallings stated that the WHO Biosafety Programme is a resource to Member States for information and training 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 3rd edition. Laboratory Biosecurity 1st 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 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.

Speaker

Dr. Ivan Dyatlov

Professor & Director, State Research Center of Applied Microbiology & Biotechnology (SRCAM)

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), 21st 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.

A joint meeting in November 2006 is being planned on education and training.

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 an information

exchange mechanism between [decision-making] state organizations, nongovernmental and scientific organizations in the field of biosafety and biosecurity;

4. Create an International Expert Group on developing an international glossary on biosafety/biosecurity terminology;

5. Develop a common methodological approach on science-based - assessments 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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