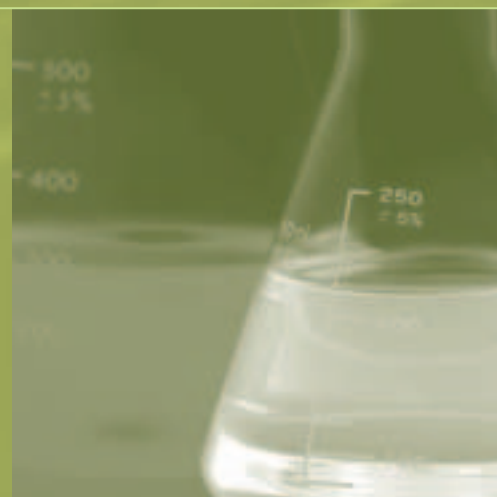


# Advancing International Cooperation on Bio-Initiatives in Russia and the CIS



**FINDINGS AND REPORT  
FROM AN INTERNATIONAL CONFERENCE ORGANIZED BY:**

**RANSAC**

**Landau Network-Centro Volta**

# Advancing International Cooperation on Bio-Initiatives in Russia and the CIS

Findings and Report from the April 26-27, 2005 Conference

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# Introduction

In April 2005, RANSAC and LNCV held a meeting titled *Advancing International Cooperation on Bio-Initiatives in Russia and the CIS* in Rome, Italy. The event was held with the support of the governments of the United States, Canada, Italy, and the United Kingdom, and with the cooperation of the International Science and Technology Center (ISTC) in Moscow, Russia. The participants included government officials and academic experts from key Western countries, and biological scientists and biosecurity experts from Russia, Kazakhstan, and Uzbekistan.

The event was the second in a series of meetings on how to further cooperation between these governments and non-governmental organizations (NGOs) to prevent biological terrorism by promoting biosecurity, biosafety, and the involvement of commercial entities in key biological institutes. The event provided for the discussion of a broad range of topics from a spectrum of specialists. The following is a digest of the findings from the RANSAC and LNCV organizers of the meeting and the conference proceedings.



# Findings

## ■ THERE IS NO AGREEMENT ON THE PRIORITIZATION OF THE BIOLOGICAL THREAT

Western governments have become much more concerned about terrorist biological attacks in the 21st century, but Russian and CIS governments seem to rate this danger as a lower priority. This dichotomy is evidenced by the growth in Western budgets for biological attack preparedness and also, on a much smaller scale, for bioproliferation prevention. In Russia and the CIS, however, the lack of aggressive funding for the maintenance, security, safety, and commercial conversion of their biological institutes is evidence that those threats do not rank as highly as others. The Russian government, for example, under the G8 Global Partnership, has continued to prioritize nuclear and chemical threat reduction over biosecurity issues. The sensitivity, especially in Russia, about biological security issues, activities, and cooperation with the West on these issues, has retarded international cooperation in this area.

There is, in addition, limited agreement among Western nations on how to best develop a strategy for the prevention of bioproliferation. Some key governments see the need for the creation of a better connection between the BWC and the goals of the Global Partnership. Others are more concerned that the threat is not coming necessarily from “classical” biological weapons models or pathogens, but rather from the growing threat of hostile use, or accidental misapplication, of the life sciences. The current BWC protocol is inadequate for today’s radically changed life sciences environment, and technology has advanced far beyond the parameters of what is covered by the BWC. The international discussion on controlling pathogens and technology needs to recognize what the BWC process has to offer but also move beyond the idea of a BWC verification protocol as a “silver bullet” to prevent bioproliferation.

## ■ PROGRESS IS BEING MADE ON BIO-THREAT REDUCTION

Since the first RANSAC-LNCV meeting on bio-threat reduction, in November 2003, a number of steps have been taken to enhance bioproliferation prevention (BPP) activities. In particular, some Global Partnership nations have elevated the priority of bio-threat reduction projects. The United States is dedicating more attention to converting bio-facilities to market-oriented, demand-driven technology suppliers. The government of Canada is emphasizing

biosafety and biosecurity as priorities under the Global Partnership and is linking existing global public health, biosafety, and biosecurity improvements to threat reduction goals. The government of France has identified eight bio-projects it will fund through the ISTC. The government of Ukraine has reached agreement with the U.S. to allow bilateral cooperation at biological institutes including anti-plague institutes. Agreements between the U.S. and other CIS countries have also been established. The European Commission has launched a number of international research initiatives in health, counterterrorism, security, science, and technology, and is actively seeking to deepen its engagement with key biological institutes in Russia and the CIS on these issues.

## ■ NUMEROUS OBSTACLES TO EXPANDED ENGAGEMENT REMAIN

While progress is being made between Western and CIS nations on bioproliferation prevention, numerous obstacles remain. A number of priority issues identified at the 2003 RANSAC-LNCV meeting remain unresolved.

- *Russia’s Reticence:* Transparency within the Russian bio-institute network remains a key issue, and facilities managed by the Russian Ministry of Defense and an array of Russian anti-plague research institutes remain off-limits, which hinders the amount of investment that can be made by Western governments. The true scope of the risks posed by the network of Soviet-era anti-plague facilities is not yet known in detail, and greater attention must be paid to securing, consolidating, or destroying any inventories of pathogens these sites may have. Of greater concern is the fact that there are few “champions” for bioproliferation prevention activities in the higher levels of the Russian government, although a number of dedicated supporters of cooperation do exist at the individual and institute levels. This situation retards efforts to promote expanded engagement with Russia on bioproliferation prevention efforts and also generates negative political and budgeting consequences.
- *Limited Funding:* U.S. funding for bio-threat reduction projects managed by the departments of Defense, State, and Energy is rising slowly, but those funds are being used in a variety of ways. Defense Department projects are shifting away from infrastructure elimination work towards biosafety and biosecurity, and establishing disease-monitoring networks, while the



Department of Energy (DOE) and State Department programs are switching from market studies and preparatory work to more concrete facility conversion activities. The U.S. DTRA is shifting a large portion of its bio-threat reduction funds from Russia to the CIS activities, because of long-standing problems with implementing bio-projects in Russia. Canadian funding for BPP is maximized at \$C 18 million per year at present, and other G8 nations are contributing modest amounts to bio-projects of specific interest to those nations. Also, the EU budget for 2007–2013 does not appear as if it will offer substantial increases in its nonproliferation budget in this area.

- *Need for Better Coordination:* Coordination is needed in two basic areas: (1) among the Global Partnership donors, as there is not yet an integrated strategy among its members, and (2) among the bio-industry, the scientific community, and government agencies on bio-issues, who all have unique priorities and approaches. There have been few efforts to build support for or consensus on the need for bioproliferation prevention efforts among the press and public.
- *Limited Industry Involvement:* While the Russian side asserts that cooperation with bio-industry is the pathway to transforming their institutes, much more needs to be done to make industry aware of the opportunities, and the Russian side needs to project to the West a more inviting environment. In most cases, industry has opted out of Russia in favor of investing in more promising countries like India and China, where facilities are more transparent, access is less restricted, and the sites have achieved, or are nearing, compliance with international biosafety standards.

#### ■ OPPORTUNITIES FOR EXPANDED COOPERATION EXIST

Despite the daunting list of problems, there are still a number of areas where cooperation with Russia and the CIS nations could be intensified in the bioproliferation area.

- *Focus on CIS Institutes:* While the vast majority of the former Soviet Union's bio-institutes of concern are located in Russia, there are also a number of sites in the CIS countries that are equally or more deserving of attention, and in fact may be greater causes of concern because of poor security, inadequate levels of assistance, and lack of broad workforce redirection opportunities.

Sites in the former Soviet republics of Kazakhstan, Georgia, and Uzbekistan have begun to receive support from Western BPP initiatives, but much more assistance is needed. These sites may ultimately prove more receptive to assistance than those in Russia, given their strong interest in securing their pathogens and technologies. Creating success stories elsewhere in the CIS is possibly one way to stimulate greater openness from Russia.

- *Build a Global Consensus:* There is a need to build global consensus on key bioproliferation and biotechnology issues. There is no global consensus on the levels of security that are required, no common agreement on biosafety levels, and a lack of transparency on how bioethics and regulations are implemented across nations and regions. Also, the window for control of pathogen development may quickly be closing, and there may be only 10–20 years before technology has completely outpaced any measures to control it. While governments and the science community are concerned about the potential misapplication of biological research, there is no international consensus on what measures of oversight are required. Nor is there a common understanding of what the best approach to bio-defense is—be it broad-spectrum protection from multiple pathogens, export control, scientist education and monitoring, or even preemption vs. post-event response.
- *Intensify Biosafety and Security Training:* The lack of conformity with international biosafety and security standards by Russian and CIS institutes is a leading factor in Western industry avoiding cooperation with them on pharmaceutical and biotechnology development. Training and certification efforts are being funded by Western governments, and are greatly appreciated by Russian and CIS recipients. Workshop participants urged that an even greater emphasis be placed on these sorts of training activities. An added benefit of sustained biosafety and security training in the FSU is that it can help develop trust between facility personnel and Western entities, and serve as a starting point for deeper cooperation on more business-sensitive or proprietary efforts.

#### ■ COMMERCIALIZATION IS A DIFFICULT OBJECTIVE

There is very limited funding input from private entity partners in the biological area in Russia and the CIS. Therefore, there is a growing recognition that commercial ventures alone are not the sole or even best conduit to redirect biological scientists. Efforts to



pull industry into ventures in these areas have largely been unsuccessful as the numerous regulatory, safety and security, and political challenges in these nations loom as serious impediments. Russian and CIS governments can best help to facilitate commercial ventures by creating the right conditions for investment in their emerging biotechnology sector, including providing strategic funding for projects such as infrastructure development, training to meet international biosafety and security requirements, and providing initial support for industry to provide it with the confidence required to make additional investments in the future.

#### ■ WORKFORCE REDIRECTION INSTITUTIONS MUST EVOLVE

There is waning interest and support for WMD expertise redirection, as evidenced by decreasing U.S. government budget support, and rumors of an EU budget decrease as well. As a result, there are many questions regarding the future of the ISTC. There was some substantial debate about whether the ISTC should be focusing on graduating more scientists to self-sustaining activities or whether its project financing and incubation roles for biological scientists should continue as currently practiced. One obvious problem is that ISTC funding for bio-projects is largely provided by U.S. government agencies and other Western governments. In fact, many key U.S. government agencies are partners in the ISTC program, and, therefore, bio-project funding reflects those partners' priorities, not necessarily the priorities of the host nation.

The question was also raised of whether the ISTC's function of providing short-term grants to scientists is now less relevant. The U.S. and U.K. are beginning to place emphasis on eliminating the threat and "graduating" the scientific workforce from their dependence on Western support through the science centers and other programs. Others believe the ISTC should become a "bridge that should be

stepped on toward direct collaboration with scientists." For the EU, the emphasis is on integrating the Russian scientific community into the global science arena. The EU is focusing on increasing its direct contact with experts, rather than relying exclusively on the bridge provided by the ISTC and other multilateral entities. ISTC continues to provide critical support to Russian science, in the absence of adequate alternative sources of funding. However, some Russian participants suggested ISTC funding is like a narcotic, so the question becomes one of "how to wean the addict."

All of this debate foreshadowed a more serious discussion regarding the future survival and composition of WMD workforce redirection programs.

#### ■ ISSUES FOR FUTURE MEETINGS

Future international meetings and workshops should be tailored to specific interests of the Russian and CIS scientific and technical community, to provide an alternative approach to bioproliferation prevention. Topics could include:

- Airing the views of key parties on their views of the biological threat to help to establish the groundwork for expanded cooperation.
- Infrastructure development, training, creating a security culture.
- Establishing international labs for monitoring emerging infectious diseases.
- Developing a global ethical culture.
- Eliminating surplus biological facilities' infrastructure.
- Setting up the needed GXP levels to support international investment or customer base. A center for GXP is needed in Russia which has multiple sources of support, can shape a common language for international standards, and provide regulatory guidance.

**Advancing  
International Cooperation on  
Bio-Initiatives in Russia and the CIS  
Conference Proceedings**

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**Spring 2006**



## Welcome and Introductory Remarks

Panel: **Maurizio Martellini**, *Secretary General*, Landau Network-Centro Volta (LNCV)

**Umberto La Rocca**, *President*, SIOI

**Giulio Terzi di Sant'Agata**, *Director General of Political Affairs*, Ministry of Foreign Affairs, Italy

**Kenneth N. Luongo**, *Executive Director*, RANSAC

**Sue McClaren**, UK Ministry of Defence

**Jason Rao**, *Senior NWMDE Program Coordinator & Director*, Bio-Industry Initiative, U.S. Department of State

**Barbara Rhode**, *Director of Multilateral Cooperation*, DG Research, European Commission

**Cindy Vestergaard**, *Global Partnership Program*, Foreign Affairs Canada

The organizers of the conference acknowledged the generous financial and moral support of the sponsors and the interest shown by the participants, especially those from Russia, Kazakhstan, and Uzbekistan. The aims of this initiative were, first, to highlight the needs of recipient facilities and opportunities presented by bioproliferation prevention programs; second, to bring policy practitioners, NGOs, and facilities together and thereby inform policy choices; and third, to encourage more extensive funding for bioproliferation prevention and where possible bring in new states and private organizations. It was highlighted in particular that at forthcoming, major biotechnology conferences in the U.S., no sessions on biosecurity or codes of conduct are offered for scientists, and there was a clear disconnect between the interests of the bioscience and industry community on the one hand and the security policy community on the other.

The speakers agreed that bioproliferation prevention is a key area of international security and receives far less attention than it merits. Article X of the BWC enshrines the rights of states to access to biotechnology, but various factors mean that it presents a spectrum of risks and problems which the search for an effective verification protocol and the establishment of export control regimes has only partially addressed; other strategies, including cooperative proliferation prevention, need to be pursued. The great tradition of biotechnology in Russia and the CIS makes them necessary partners in this process, and several of the participants of this conference have already contributed a great deal to implementing existing programs.

The sponsors described the initiatives pursued in their own countries. In the U.S., several programs are funded by the U.S. Department of State. The efforts of ICCEB in Italy, which focuses on biosafety and biosecurity issues and has organized training for scientists from 30 countries, provides a model for integrating programs for the benefit of the scientific community worldwide. The UK's program is currently focused on scientist redirection in the area of plant and animal biotechnology; a plant health project in Georgia is taking up the majority of the budget and the UK is engaging the Georgian government to help with the reform of the biosector. The UK is also currently chairing the G8 and has a leading role in codes of conduct negotiations. The EU considers this conference especially timely as the European Commission is thinking ahead to the next budget cycle from 2007 and is seeking to restructure its approach to disarmament and nonproliferation. Finally, Canada, a founding member of the STCU and which recently acceded to Founding Member status in the ISTC, has developed its policy to include redirection of biological scientists as a priority. The representatives of donor programs emphasized that, within a limited funding environment, more effective and coordinated financial assistance is required for bioproliferation prevention and they welcomed the opportunity to resume or initiate discussion with colleagues from other countries at this conference.

# Session 1 Status of Bio-Cooperation in International Programs

Chair: **Maurizio Martellini**, *Secretary General*, Landau Network-Centro Volta

Panel: **Uwe Meyer**, *Deputy Executive Director*, ISTC

**Jason Rao**, *Senior NWMDE Program Coordinator & Director*, Bio-Industry Initiative, U.S. State Department

**Barbara Rhode**, *Director of Multilateral Cooperation*, DG Research, European Commission

**Cindy Vestergaard**, *Global Partnership Program*, Foreign Affairs Canada

## Uwe Meyer:

ISTC programs have to date reached over 60,000 scientists from 700 institutes across the CIS, with around \$660 million invested in 2140 projects. 35 nations are engaged in threat reduction programs. It was emphasized that the ISTC makes use of its position as an intergovernmental organization with diplomatic status and its reputation as a “clean” organization to maximize the successful implementation of proliferation prevention. The ISTC wants to be part of a product and technology “road map” with the aim of long-term sustainable partnership between Western and CIS scientists.

In the biotechnology/life sciences sector, a variety of scientific fields are covered. \$180 million, or roughly 30 percent of ISTC total funding, has reached 9,000 biological scientists, and this sector is experiencing the most rapid growth, with an increasing share of partner funding. There are five key areas of activity, each of which is supported by specific funding agencies: control of highly infectious diseases; surveillance, monitoring, and risk assessment; food safety; biosafety and biosecurity upgrades at key institutions with pathogen collections; and commercialization and sustainability, including industrial and training programs.

## Jason Rao:

The U.S. State Department now provides the main part of the U.S. budget for basic science projects but also contributes to applied science and technology projects. The avian flu surveillance project is a typical new development. The Nonproliferation of WMD Expertise program at the U.S. State Department focuses on people rather than eliminating infrastructure, perceives CIS scientists not as a source of threat but as partners in stemming threats and addressing risks and problems, and considers scientist redirection a critical component of self-sustainability. Rao cited the example of Stepnogorsk as a scenario to avoid, wherein the infrastructure was dismantled but where little thought had been given to redirecting

those scientists unemployed following the sites’ dismantlement, until the initiation of State programs. Congress has mandated the State Department to reconfigure former bio-weapons facilities and engage scientists in collaborative R&D projects in drug and vaccine development against highly infectious diseases. The State Department channels funding through the ISTC and STCU but also works through other organizations, for example, through CRDF for marketing, business training, and infrastructure development and through CIMIT to encourage the uptake of novel scientific products. The State Department’s Bio-Chem Redirect Program has the USDA, EPA, and HHS as partners.

The Bio-Industry Initiative, created in the wake of 9/11, is being expanded to include new countries but without an increase in budget, hence the emphasis on the need for greater coordination and effectiveness within an overall environment of decreasing funding. It was emphasized that the ISTC and STCU have done an excellent job but need to develop to meet new problems: assisting facilities to “graduate” and become self-sustainable is becoming more important as donor countries are seeking an “exit strategy” for these programs.

Examples of typical “catalyst” projects and key projects for strategic funding include a DNA vaccine that has been developed and patented at Vector, which should begin to make money in the near future. A business development center at Pushchino, the Kirov environmental laboratory, Georgia Biokombinat, Bifida production, the Vector Hepatitis C laboratory and CRDF clinical trials have all been established in the recent period.

The speaker emphasized two key program goals for BII: First, transparency and the need to open up facilities: access, and even permission to set up business space at some facilities—are still being denied. For example, State is working with part of the Kirov



facility but access to the other half of the facility is denied to them. Second, sustainability, as there is too much emphasis on commercialization and more attention should be directed to strategic funding for basic research and to preparatory steps to commercial activity with the emphasis on self-sustainability. As well as funding key strategic projects, priorities are: reconfiguring some production facilities, obtaining access to anti-plague institutes, and improving the work of the ISTC and STCU with these goals in mind. Coordination with global partners, especially the EU, UK, and Canada, in a limited funding environment is an important way forward. Other urgent tasks include finding a way to operate within a changing political environment in Russia, meeting common metrics in terms of sustainability of R&D, commercialization, and assessing the bioterrorist threat.

#### **Barbara Rhode:**

DG Research within the European Commission runs research for EU member states and is providing funding of €17 billion over four years through the 6th Framework Programme, working together with DG Health and Consumer Protection, DG Justice, Freedom and Security, and DG Environment. Its budget comes from DG External Relations, which is not an EU foreign policy-making body but coordinates national foreign policies and acts via the practical application and implementation of agreed instruments. The Commission is currently looking forward to the next budget cycle and welcomes the opportunity to discuss initiatives that might be coordinated with those of the U.S. DG Research is open to international collaboration, including Russia and the CIS; health and life sciences, biotechnology, and food security are areas they want to develop.

There are six relevant lines of activity:

- The Health and Security Committee (SANCO), incorporating the Global Health Security Initiative and Global Health Security Action Group, are tasked with developing proposals and actions to improve global health security;
- Security research, which was started in 2003 but will operate fully from 2007 under the 7th Framework Programme, and includes protection against terrorism and crime, security of infrastructure and facilities, border security and reconstruction of affected facilities;
- The EU R&D expert group on countering terrorism, including chem/bioterrorism, is inventorying research in member states, identifying gaps, and making recommendations;
- A social science research “foresight” platform is investigating innovative research and the future of Common Foreign and

Security Policy and governance;

- Ethics policies in S&T, including international research on SARS, codes of conduct, support for a model law on bioethics in the CIS (a conference was held in Baku in October 2004), working together with the parliamentary assembly of the CIS;
- A new initiative in biosecurity through the ISTC and STCU; a 6th Framework Programme conference was held in March 2005 on biotechnology partnership, and a workshop in July 2005 will create an expert group on biosecurity with the aim of securing the participation of more CIS scientists.

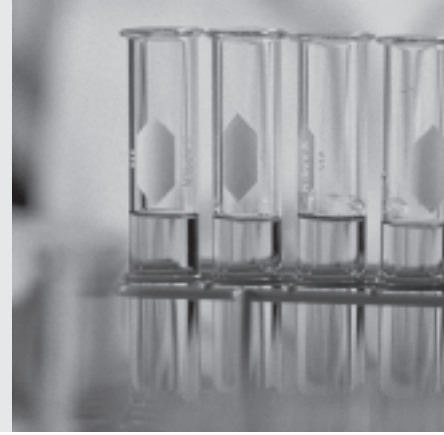
#### **Cindy Vestergaard:**

Curbing the proliferation of biological weapons is an essential element of the \$20 billion Global Partnership Against the Spread of Weapons and Materials of Mass Destruction, which was launched at the G8 Summit in Kananaskis, Canada in June 2002 to prevent terrorists, or countries of proliferation concern, from acquiring or developing biological, chemical, nuclear, or radiological weapons, and related materials, equipment, and technology. As Chair of the G8 for 2002, Canada reinforced its leadership on the initiative by committing up to \$C 1 billion over 10 years, beginning in 2003, to this initiative.

At Kananaskis, four priority areas were identified: dismantlement of decommissioned nuclear-powered submarines; destruction of chemical weapons; nuclear and radiological security; and the reemployment of former weapons scientists.

Canada is addressing the reemployment of former weapons scientists and biological nonproliferation through the ISTC, which it joined in March 2004. Canada contributes up to \$C 18 million annually to the ISTC to fund science projects, workshops, travel support, training, partner projects, and communications support projects. Canada’s biosafety/biosecurity initiatives include developing guidelines, associations and training and carrying out upgrades.

To date, Canada and the ISTC have held biological nonproliferation events and activities in Canada, Kazakhstan, and Russia. A Canadian biosciences colloquium was held in Moscow in September 2004, as well as a biosafety/biosecurity workshop for Central Asia/Caucasus in Almaty and an International Plague Surveillance Workshop in the same month. In October 2004, a Biosafety Workshop in High Containment Laboratories was held at the Canadian Science Centre for Human and Animal Health that houses Canada’s BSL-4 lab.



Canada places high value on BWC and the international norms against biological weapons, continuing to take steps to further these international norms and strengthen the BWC, and strongly encourages all countries not Party to join.

**Discussion:**

It was emphasized that existing mechanisms such as those provided by the WHO for monitoring disease should be used and more thought should be given to coordinating U.S. and EU efforts. There is no international watchdog agency, such as the IAEA in the nuclear sphere, to monitor developments in the biotechnology/life sciences field, improve physical protection of materials, and develop a trigger list of materials and equipment. Global bioproliferation prevention is better presented as part of extending efforts against natural outbreaks of disease, such as those the WHO monitors, making it both a health and security issue.

A decrease in external funding to Russia/CIS is both inevitable and appropriate, and the transition to sustainability requires a “road map,” based on a demand-side approach, for the involvement of the biopharmaceutical industry. One participant argued that instead of trying to sell “used cars”—i.e., outdated technologies from the CIS—it was important to support their efforts to develop high-tech marketable technologies. This conference should aim to shape a new vision, and NGOs have an important coordinating role to play.

Concerning the public health perspective, a U.S. government representative mentioned that he had met the Russian Minister of Health and tried to obtain an entry point or “champion” at the Russian government level for bioproliferation prevention programs; the need for a champion was emphasized by other participants. Champions exist at individual facilities, partnership with which has reverberated upwards.

A representative of the European Commission underlined that the EU would not necessarily be increasing the budget of the ISTC but would use the latter as a bridge to reach facilities and encourage them to develop independently of support funding. The EU has had good experience of this in the nuclear field. One Russian participant warned that, while donor countries are seeking to decrease funding, the ISTC still has an important role in distributing international assistance as there is simply nobody else—given the lack of attention to this of the Russian Academy of Sciences or Ministry of Health—to do so. Withdrawal of ISTC support, which has brought together Russian institutes which otherwise would have struggled to link up, would be ruinous.

# Session 2 Improving the Global Biosafety and Security Network

Chair: **Ken Luongo**, *Executive Director*, RANSAC

Panel: **Maureen Ellis**, *Senior Biosafety Adviser*, Canadian Global Partnership Program

**Evgenii Grishin**, *Deputy Director for Science*, Institute of Bioorganic Chemistry

**Giles Merritt**, *Director*, New Defence Agenda

**Leonid Ryabikhin**, *Executive Secretary*, Center for Scientific Research, Committee of Scientists for Global Security

## **Maureen Ellis:**

It is important to approach the bioproliferation prevention issue through coordination with public health issues and by linking Russia and the CIS with existing international biosecurity networks. Global public health vulnerability requires the integrating of biosafety and biosecurity and the partnering of security, human and animal health entities. For example, the Global Partnership is encouraged to work with the WHO, OIE, the International Biosafety Working Group, and others to achieve this. Key government agencies should be brought together to promote regulatory and legislative initiatives, biosecurity guidelines, training, and the creation of regional biosafety associations. Some countries have existing biosafety legislation while others may face the challenge of establishing new standards. The creation of scientifically sound, cost-effective, common international standards is the goal of the WHO's third edition of the Laboratory Biosafety Manual. Other areas of legislation (e.g., transport of biological agents) must also be incorporated into the overall biosecurity issue to ensure mechanisms are enforced. Russia and some countries within the CIS do have existing standards that may or may not require modification. It would be important to determine the existing conditions in facilities in Russia/CIS and work from there, defining minimum criteria and encouraging local scientists to become involved. The International Biosafety Working Group, consisting of the WHO and biosafety associations from all regions of the world, provides a forum where the Russian delegation can meet others. The International Veterinary Biosafety Working Group would also be important for Russian/CIS facilities to get involved in. The Russians have already made a significant contribution to the BSL-4 Users Group. The need for laboratory specialists trained in biosecurity has led to the initiative of developing sustainable regional training centers in all areas of the globe, and should include Russian/CIS sites.

## **Evgenii Grishin:**

International interest in the biotechnology sector was welcomed and the hope expressed that existing expertise in addressing the nuclear field can be adapted to the bio-sector. Outlining the "academic perspective", the speaker explained that his institute has created a biosafety committee and is dealing with a number of new biotechnologies and carrying out some production, notably of recombinant human insulin. The institute has 1,200 employees, including 470 research staff. The site has received a number of international grants from the ISTC and CRDF, among other organizations.

Main trends and activities at the institute include the structure and function of proteins and peptides; biocatalysis; the structure and function of nucleic acids; molecular mechanisms of genetic processes; the structure and function of carbohydrates, lipids, and low-molecular bioregulators; mechanisms of biomolecular recognition; assembly and functioning of supramolecular structures; signal transduction in biological systems; the molecular and cell basis of immunity; biotechnology; biomedical research, novel technologies, and materials; molecular mechanisms of cell processes and intercellular interactions; and molecular ecology. New technologies include human interferons b and g; recombinant interleukin-3; recombinant oxytocin; Likopid immunomodulator; myelopeptides (immunoregulators); Deltaran (neuromodulator); recombinant human insulin; DNA diagnostics of thrombophilias; and synthetic vaccine against foot-and-mouth disease. The advantages of gel-based protein microchips are also being investigated at the institute.

## **Giles Merritt:**

The speaker outlined the activities of the New Defence Agenda



(NDA) and in particular its Bioterrorism Reporting Group (BRG). The NDA is building a constituency of people involved or interested in political aspects of security issues. The BRG is concentrating on how to establish effective U.S.-Europe networks to manage bioterrorism risks; the culture of communication is foreign to key players in the biotechnology field in governments and bureaucracies, though scientists are exempted from this criticism. There are five main stages involved: common threat analysis; assessment of defenses; consensus building on those defenses; best practice in improving defenses; and political and financial cost-benefit calculations.

A key observation is that, while policy makers are in denial about informing the public about what managing bioterrorism entails, public opinion is crucial—both as a moral issue, since people have a right to know the facts relating to their security, and to make any strategies work, as it mobilizes pressure to access budgets and secure funding for nonproliferation strategies. Key questions yet to be answered are: What do we tell the media and how do we present it? Are all parties going to deliver a consistent message? Governments and organizations have disparate views but these need to be brought together and presented as a consensus, in order to inform the public properly in a way that local constituencies can understand and relate to. Also, signals need to be sent to potential aggressors. The NDA is planning to use forthcoming BRG meetings to address the external communications issue, identify key elements of the threat and raise their profile so as to harness public opinion, and examine constraints in various countries to making strategies work.

#### **Leonid Ryabikhin:**

The Committee of Scientists for Global Security is an NGO providing information and policy recommendations on issues of strategic stability and security. The biological threat is perceived as one of the most dangerous, and the Committee has formed a section dealing with it, which is involved in collaboration with the Center for

International Security and Cooperation at the Stanford University Institute for International Studies. They are currently planning meetings in Silicon Valley with U.S. partners and in Stockholm with the Europeans, to give Russian scientists the opportunity to talk to the biopharmaceutical industry. Concerning global networking in biosafety/biosecurity, the Committee is working on modeling terrorist actions and how to deal with them, and on the use of pathogens in terrorist attacks, and invites cooperation on these issues.

#### **Discussion:**

Concerning the comments of the last speaker, it was pointed out that the Russian policy community's views about the bio-threat and what can be done in terms of international cooperation and partnership remain obscure. It was acknowledged on the Russian side that, while the Russian government has taken steps to improve biosecurity in Russia, its lack of attention to it in terms of building international partnerships is a concern. There is a debate in progress on a national program for biosecurity and on international cooperation, from which some conclusions are expected to be made public.



# Session 3

## Creating New Biotech Ventures at Key Institutes—Russia

Chair: **Maurizio Martellini**, *Secretary General*, Landau Network-Centro Volta

Panel: **Vladimir Kolesnikov**, *General Director*, Biopreparat

**Gennadii Lepeshkin**, *General Director*, Russian-American Center for Ecological Monitoring

**Sergei Netesov**, *Deputy Director*, State Research Center of Virology and Biotechnology, Vector

**Sergei Pchelintsev**, *General Director*, Institute of Immunology Engineering

**Yuri Remnev**, *Deputy Director*, TEMPO

### **Vladimir Kolesnikov:**

The speaker outlined the biosecurity program initiated by the Russian government and the government commission for chemical and biological security headed by the Russian Minister of Health. Biopreparat, a joint-stock company with a majority state shareholding, incorporates 24 companies located throughout Russia. These facilities have undergone dramatic changes since 1990 and are now private entities seeking to attain GMP standards. Russia plans to join all international standards for pharmaceuticals and medicines.

It was emphasized, in response to questions about the difficulty potential Western investors face with access to Biopreparat facilities (which might discourage investment), that they are private companies and have a duty to protect commercial confidentiality. However, these facilities are open to mutually beneficial cooperation, and there is already one U.S.-Russian joint venture company.

Concerning the absence of financing through ISTC programs for equipment purchases, it was pointed out that, while at a large company like Vector, expenditure on scientific programs is assured, the low level of financial support for equipment means that the facility degrades. International assistance should take into consideration both this issue and that of financing services, on the grounds that if a facility's infrastructure is being used on a collaborative project it should be included in overhead costs.

### **Gennadii Lepeshkin:**

The Russian-American Center for Ecological Monitoring (RACEM) operates in the Kirov region where there are numerous chemical and biological institutes and former weapons facilities. Its approach is to invest in capital and personnel; conduct market

research to identify business opportunities; and design, implement, and market strategic projects. Criteria for an acceptable strategic project were outlined: RACEM proposals must satisfy U.S. policy objectives for commercially sustainable efforts and productive employment of former weapons scientists; be able to leverage investment in laboratory equipment and personnel; expedite accreditation and licensing; and rapidly train personnel. Potential strategic projects were described: research, assessment, and quality control of bioactive substances; creation of a regional information reference database system for biotechnology in the Kirov region; environmental monitoring of food and water in Kirov; and evaluation of soil and water pollution levels around pesticide burial and storage sites. Customer needs have been identified as sophisticated analysis, rapid detection, and an accredited laboratory. Proposed business opportunities exist in the area of environmental services, contract R&D and remediation, product support and technical training. A projected 5-year financial plan was presented, as well as projected revenues by business area.

### **Sergei Netesov:**

Vector has created new ventures at the institute, the site of Russia's only high-containment BSL-4 facility for the most dangerous pathogens. The economic changes over the last 15 years were described, including decline in government funding and corresponding search for, and increase of, commercial income and international investment. Vector's main strategic goals are: to establish laboratories for the study of emerging/re-emerging diseases; to develop and implement GLP-level standards; and to finalize GMP-level manufacturing capabilities.

The speaker pointed out that the term "biosecurity" (biobezopasnost) in Russian can cover different concepts including biosafety,



biosecurity and bio-protection of the population, and as such there is a need to be more precise in how the term “biosecurity” is applied. Vector understands the need for constant improvement of biosafety and biosecurity systems, and international funding has addressed these needs, but some second- and third-phase funding—including requests made to the Russian government beginning in 2003—have not yet been provided. Vector has elaborated some key main principles, important both in terms of science and business, and initiated some important regional developments such as the Koltsovo innovation center/science city, which began operation in 2002–2003.

#### **Sergei Pchelintsev:**

The Institute of Immunology Engineering (IIE) is now an economically viable company, working mainly in the field of protecting the armed forces from biological warfare agents. Bioterrorism has raised the problem of BW to another level and the extent of the threat is more difficult to determine; the potential for terrorist access to BW has switched attention from sophisticated BW systems, of which only a few countries were capable and which were directed against states, to the wider security threat of pathogens which can be used against any country’s population by smaller groups. Factors to take into account are the availability of materials, generally restricted; motivation of potential users; and the availability of vaccines. There was a vaccination program in the Russian and Soviet army, and revaccination would be problematic. There are two types of bioterrorism—a hidden attack, and an attempt to sow panic; the IIE is working on mathematical modeling of both these threats.

#### **Yuri Remnev:**

Noncommercial organizations can contribute in a number of ways to enhance biosafety. The speaker emphasized that what we generically call biosecurity can embrace many aspects—bioterrorism, biosafety at biological research centers, biosecurity, microbiological biosafety; and medical, agricultural, veterinary, genetic, and ecological security. The last of these in itself can cover several areas, such as energy, industry, water provision, transport, and eco-terrorism. Remnev offered a working international definition of biosafety: “realization of efforts of the world community aimed at the preservation of the biological specific uniqueness of the human organism.”

TEMPO is a noncommercial organization, involved in monitoring the development and production of biotechnology preparations on

the basis of recombinant strains of micro-organisms; production and quality control of pharmaceutical production; implementation of new medical technologies involving the use of human and animal cells; and the ethical aspects of biotechnology development. Its aim is to improve the state of human health in Russia and consolidate the efforts of scientists and technologists in implementing health technologies. TEMPO links 14 participating facilities with considerable scientific expertise in the areas of: research in virology, microbiology, biotechnology, immunology, and diagnostics; development and introduction of means and methods of diagnostics; preclinical research of biopreparations using animals according to GLP; clinical trials of medical preparations according to GCP; safe plant protection agents; development and manufacture of immunochemical and biochemical testing kits; manufacture of biotechnology equipment; training in medicine, biotechnology, and pharmacology; and manufacture of medical preparations. Its management structure incorporates committees for legal/governmental matters, the Russian biopharmaceutical market, cooperation in production and registration of biopreparations, and S&T developments and financing, as well as a coordinating group on tuberculosis. It runs a center for training of specialists in GXP, to encourage a common language among the international scientific community and develop and implement education and training in the area of GLP for preclinical trials in Russia, as well as good management and corporate practices.

International programs such as those delivered by the ISTC remain important, but the speaker warned of negative aspects that might result from the discontinuation of international support: Russian scientists who have become dependent upon these programs may suffer “withdrawal symptoms.”

#### **Discussion:**

In response to questions about Biopreparat’s links with the Russian government, it was stated that it carries out projects based on government contracts but has an independent management structure and has representatives on the management of the Penza, Saransk, Kurgan, and other facilities. It was re-emphasized that the organization places no restrictions on its companies other than those commonly established in international practice and that it is open for constructive business. Biopreparat subcontracts out some work to Vector on a commercial basis. A Russian participant asserted that, while Russia has introduced elements of an overall biosecurity strategy, certain aspects are still lacking and the situation requires further investigation.

# Session 4 Creating New Biotech Ventures at Key Institutes—CIS

Chair: **Raphael Della Ratta**, *Bioproliferation Prevention Project Manager*, RANSAC

Panel: **Shakhnoza Azimova**, *Director*, Institute of Chemistry of Plant Substances, Uzbek Academy of Sciences

**Evgenii Kalmykov**, *JSC Biomedpreparat*, Engineering Center Monitoring Laboratory

**Valerii Shimanaev**, *Director*, Stepnogorsk Technology Park Industrial Site

## **Shakhnoza Azimova:**

The presentation focused on the development of new biotechnologies and manufacturing of new biologically active products based on plant substances in Uzbekistan. The speaker's institute is both a research center and manufacturing facility for plant-based substances. It contributes to the Global Biosafety Program and has projects with CRDF and other U.S. scientific collaborators, working in the areas the ISTC has identified as important, such as new drugs and diagnostics. It was emphasized that we need to pay attention not only to former weapons scientists but also to the younger generation of biotechnologists emerging in the CIS.

## **Evgenii Kalmykov:**

The speaker introduced the commercial activity of laboratories in Kazakhstan and described those operating in the chem/bio fields as well as the prospects for establishing joint ventures with overseas laboratories. Modernization of the speaker's own facility has been carried out with U.S. and other support and a monitoring laboratory was created. Many chem/bio labs are still under government auspices but some have become private.

The big gap between science and industry in Kazakhstan was emphasized—few scientists can translate their R&D into industrial production and become self-sustaining. The main developing branches of industry in Kazakhstan are the oil/gas and refining industry, the construction industry, and plant and animal agriculture. There is official support for these sectors, especially agriculture where there are opportunities since the state is providing legal, tax, and credit privileges and it also attracts the largest share of private capital. Scientific services are not internationally competitive in high-tech areas but can meet the local needs of Kazakhstan and result in the employment of scientists and technicians. The main problems are: poor equipment in labs (there are few local suppliers of modern equipment); the lack of local suppliers

of actives and reagents; the absence of a proper laboratory comparison system (like ISO), although these are demanded by state control agencies; and little training of staff in analytical methods due to the absence of mentors.

## **Valerii Shimanaev:**

The presentation focused on concepts for the development of the Stepnogorsk Biotechnology Park. The speaker reiterated earlier comments about the difficulty of commercialization of R&D and in linking science and business. Technology parks could provide a model for development. The future competitiveness of the Park is based on converting the current manufacturing structure into a regional cluster structure, with high-tech goods—for example, biotechnology at one end of the spectrum, and materials production on the other. Three development stages were outlined: the first entailed completion of creation of a regional biotechnology cluster, the second (currently under way) involves its transformation into an economically sustainable cluster, and the third (2008–2010) is expected to focus on bringing manufacture up to sustainability and profitability level and transforming the Park into a trans-national bio-information cluster. Sustainability of the biotechnology cluster will be based on revenues generated by the sale and export of gluten, food starch, purified enzymes, antibiotics, pharmaceuticals, and biological and chemical plant protection agents. A decision was also made to establish special economic zones with privileges for investors. The Park has good transportation facilities and infrastructure, and possesses innovation potential in the Institute of Industrial Biotechnology, the Biomedpreparat Engineering Center, and the Educational Center for Biotechnologies. They envisage it as a venture cooperation center attracting private investment. Negotiations are being held with the International Technopark in Pushchino, and good scientific collaboration has been established based on transfer of advanced technologies with Alfa-Laval and Bayer.



#### **Discussion:**

Although some CIS organizations have had commercial success, this was rarely due to market research, which was very weak, sometimes amounting to little more than word of mouth of former colleagues. Support for business development, rather than just threat reduction, is thus invaluable. The knowledge of former weapons scientists is potentially applicable in a range of scientific areas. Young scientists obtain their knowledge from former weapons scientists and are very capable but need to be attracted into modern science and given incentives to remain in science-based careers.

Concerning implementation of a biosecurity program, in Kazakhstan there is a biosecurity concept adapted to local needs, and state entities and institutes are addressing these problems. In Uzbekistan, the Institute of Chemistry of Plant Substances is informing the Uzbek Ministry of Health about these issues; a biosecurity concept has not yet been adopted, and making matters worse, the instruments to enforce it are lacking. Regarding reporting to government authorities, the Institute of Chemistry of Plant Substances reports both to the Uzbek Academy of Sciences and the Ministry of Health, while in Kazakhstan, Biomedpreparat reports to the Kazakh Ministry of Education and Science. A European participant pointed out that one solution lies in educating new generations of scientists on proliferation prevention issues, both in the CIS and in Western countries as well.

## Session 5 Strengthening the Global Ban on Biological Weapons

Chair: **Maurizio Martellini**, *Secretary General*, Landau Network-Centro Volta

Panel: **Don Avery**, *Professor of Social Science*, University of Western Ontario

**Robin Coupland**, *Advisor on Armed Violence and Effects of Weapons*, Legal Division, International Committee of the Red Cross

**Sarah Price**, *Deputy Head, Counter-Proliferation Department*, Defence & Strategic Threats Directorate, UK Foreign and Commonwealth Office

### Don Avery:

The presentation stressed the symbiotic relationship between the BWC and the Global Partnership, while suggesting that greater efforts should be made in utilizing the biological aspects of the Global Partnership, as part of a global response to BW proliferation. Such a program would not only apply to Russia and the CIS, but also for other countries which have phased out their weapons of mass destruction. Since 2002, the BWC expert groups have met to discuss important verification issues such as national legislation/penal enforcement; biosafety/biosecurity; and the transport and storage of pathogens. These meetings demonstrated a noticeable improvement in global cooperation after the bitter debates of 2001–2002; and the involvement of the WHO and other international organizations helped the process recover. The June 2005 BWC review meeting on codes of conduct is particularly important. Although the issue has been raised many times in the past, the pace of the biotechnology revolution has greatly accelerated, with large-scale genomic sequencing of many of the world's most menacing pathogens. Problems of dual-use complicate efforts to control potentially dangerous R&D, which could result in both intentional and unintended outbreaks of disease.

Russia and the CIS have played an important role in this debate, within the context of the BWC experts meetings, and as members of the WHO. But there are still concerns over possible proliferation from these countries because of outdated biosafety/biosecurity standards, and problems of transparency and accountability, particularly in the military-run laboratories. Moreover, it is not clear how these countries are dealing with new technologies and regulations on the development of new pathogens, especially genetically altered ones, or to what extent discussion of BWC codes of conduct are taking place in Russia/CIS. In addition, there is the question of whether the Global Partnership should be concerned with monitoring adherence to BWC standards.

Future Global Partnership priorities should include upgrades of biosafety/biosecurity standards in laboratories and anti-plague institutes, improvements in efforts to enlist Russian/CIS scientists in the WHO campaigns against HIV/AIDS and pandemic influenza, and greater involvement with the Global Health Security Initiative. Above all, there should be better coordination of BWC and Global Partnership approaches, and of national, regional, and international measures, in preventing the spread of WMD.

### Robin Coupland:

The international community should keep in mind that any advance in science can be turned to hostile use, and the biotechnology revolution is no exception. The ICRC appeal of 2002 dealt with this; there was a precedent in 1918, following the use of poison gas in the First World War. The risk lies in the following factors: existing diseases are more harmful; new, more attractive agents are being developed; advances in technology make for easier and safer delivery; there have been advances towards targeting of specific ethnic groups; and the danger is not just of bio-terror sown by sub-state groups but also state actors. These remain as a great—if not a greater—risk. The rules are based in the 1925 Geneva Protocol, the BWC, and the Chemical Weapons Convention, as well as in customary law which dictates that the use of chemical and biological weapons is prohibited even if a country is not a signatory to conventions. This is implemented at national level, where there is often legislation to criminalize it. UN Security Council Resolution 1540 crystallizes the prohibition.

The life sciences community bears a responsibility to not misapply new technologies although even eminent scientific bodies are often not aware of their legal responsibilities. How are laws and ethics linked with codes of conduct? The issues fall into clusters—conflict of interests, legal responsibilities, diligence, governance of research and publication, a culture of transparency, speed of

advance of biotechnology, establishing a web of prevention, voicing concern, the specific characteristics of BW, the dual-use problem, and diffusion of materials and technologies—each of which was taken and an attempt made by the ICRC to establish principles and action points which would create a bridge between laws/ethics and codes of conduct for best practice. For example, research must be compatible with law; we must ensure this remains the case both through science education and work with governments to reinforce convention commitments. A parallel was drawn with the rules governing bio-research and mechanisms to deal with outbreaks of fire. The reaction has been that these ideas lack a hard edge, but the aim is to produce a framework for discussion.

**Sarah Price:**

As chair of the G8 and the 2005 BWC codes of conduct meetings, and as president of the EU in the second half of 2005, the UK will be working on a number of fronts to strengthen the BWC. Work in the Global Partnership framework has not focused on bioproliferation prevention, but the UK is trying to get some forward planning for the next few years and produce concrete action. The G8 can impart impetus to other processes by stating at heads of government level what needs doing, and in fact that UK is working on a statement on nonproliferation for the Gleneagles summit. Russia will take over the chair of the G8 next year, and the hope is that it will carry this process on.

The BWC codes of conduct meeting is likely to be difficult since there is no agreement on what they should constitute, though a great deal of work has been done on it by the ICRC, UNESCO, and medical associations. The UK is trying to bring these efforts together, but is unlikely to obtain a draft code of conduct as it would be difficult to produce one to suit all countries. A more likely result is a list of elements recommended for inclusion. The intangible outcome is that the issue is being discussed with the involvement of academia, government scientists, and industry, and encouraging outreach to and feedback from them on what they are doing and might be done. It should also raise awareness of the BWC in universities. The aim is to have sessions open to NGOs, academia, and industry to canvas a broad range of opinions, and to obtain a good geographical spread, including Russia and the CIS whose governments have been lobbied. At the BWC Review Conference in 2006, the UK wants a continuation of the BWC process and agreement on further meetings. There has been internal EU reflection, involving ideas from a high-level UN panel, which demonstrates growing high-level awareness of the BW prob-

lem. Insisting on a verification protocol as a “magic bullet” is pointless, and it may not even be the right answer to the problem of the biotechnology revolution. Confidence-building measures (CBM) are badly implemented; the UK will try to obtain CBM returns and encourage other states to make them. A small secretariat is needed to start this process. The UN Secretary General’s call to pick up on and investigate outbreaks may be a good start in this direction.





### Discussion:

It was pointed out that it is hard to know what can be expected from the 2005 BWC codes of conduct expert group meeting, but it is unlikely to result in firm and binding mechanisms. It was pointed out that there is an assumption that codes of conduct apply only to scientists, but their employers and professional associations also have responsibilities to uphold. Technicians and other personnel should also be included, since some technologies are pursued more in big industrial laboratories. The definition of scientists of proliferation concern should be expanded to include technicians and other specialists, and it is expected that it will include life sciences workers whose work is relevant to BWC issues.

The Global Partnership program emphasizes the importance of treaties: specifically, the first nonproliferation principle in the Kananaskis statement commits all Partnership states to “strengthen the international nonproliferation regime through its treaties and other instruments.” A Russian participant felt that Russia is often singled out, contending that in Russia there has been no proliferation, while suggesting that there had been incidents in the U.S. In this regard, the difficulty of distinguishing between offensive and defensive R&D, given the dual-use aspects of biotechnology, was reiterated. There has never been any intention to single out Russia/CIS, as proliferation threats are global in scope. The speaker agreed with these viewpoints, citing the historical experience of the 1992–1994 Trilateral Agreement, when all sides contributed to its dissolution and demise. The role of the U.S. in defeating the 2001–2002 BWC verification protocol was also mentioned.

A number of non-treaty mechanisms exist that are linked to the BWC, and the intention was to view the Global Partnership within overall BWC aims, which are similar. It was also suggested that separating the goals of the Global Partnership from the similar goals of other treaty mechanisms would also negate any connection between the Global Partnership and the Chemical Weapons Convention, as well as preventing cooperation between the BWC and organizations such as the Australia Group and the Global Health Security Initiative.

European participants argued that the Global Partnership is an important commitment made by several countries and should not be distrusted, but rather supported. Strengthening the BWC depends on the states parties, but a catalyst to activate them is provided by a range of organizations and mechanisms, including the Global Partnership. It was suggested that the Global Partnership working groups be structured on thematic issues, rather than be organized by country.

It was recalled that courts spent two years debating the morality of nuclear weapons, and suggested that the ICRC take the issue to the International Court and ask its opinion. However, the ICRC is not allowed to ask for an advisory opinion, and a ruling was made by the International Court that even the WHO could not do so.

Concerning developing a framework where international law can incorporate a mechanism for codes of conduct, the notion was raised at the World Conference of Science in 1996 and work is going on in UNESCO, but it is likely to take until at least 2010 to complete. Other groups have also considered this. The use of genetic data should be compatible with laws on human rights. The link between ethics and dual-use biotechnologies is difficult, particularly when linked with other technological breakthroughs—scientists might not accept that the threat exists in science itself since they see themselves as bringing benefits to mankind. This situation differs from the nuclear field where clearer boundaries can be drawn.

# Session 6 Advancing Bio-Threat Reduction and Expanding International Cooperation

Chair: **Ken Luongo**, *Executive Director*, RANSAC

Panel: **Ken Luongo**, *Executive Director*, RANSAC

**Derek Averre**, *Centre for Russian and East European Studies*, University of Birmingham

**Maurizio Martellini**, *Secretary General*, Landau Network-Centro Volta

## **Ken Luongo:**

The U.S. response to concerns raised by the Aum Shinrikyo attacks, the U.S. anthrax incident, and the upsurge in terrorism has been excessive and skewed towards biodefense, while important threats such as new biotechnology R&D have not received much attention. The BWC process has also suffered. Issues related to transparency, monitoring, biosafety/biosecurity, and export controls should form the theme of this initiative; and the vulnerabilities that still exist in Russia/CIS must be recognized. Existing institutions will need to adapt to new funding realities and deliver programs in a more effective way, though Western governments are funding bioproliferation prevention inadequately and doubling the current budget could be a target. The next EU budget cycle is crucial in this respect. It is important to coordinate this strategy through the Global Partnership, though divergent views make this difficult, and it is not clear where it is going. On the Russian side, lack of transparency remains a problem as it impedes funding by U.S. agencies. Something to consider is what time frame we are contemplating: the U.S. and other countries are pushing for an exit strategy; the Global Partnership expires seven years from now; and political trends in Russia may mean that the window of opportunity may not be open for too long. The bioproliferation issue is complex and subject to many factors, not least the biotechnology revolution.

## **Derek Averre:**

Bioproliferation issues incorporate a spectrum of problems, risks, and threats which go beyond traditional arms control/disarmament paradigms; as previous speakers have underlined, there is no single solution or "magic bullet," but the number of factors (the dual-use problem, the biotechnology revolution, globalization and the increase in trade, the weakness of the BWC and a general crisis of legitimacy, the potential threat of use by sub-state actors) requires ongoing and permanent management. Bioproliferation prevention programs have an important role to play in halting or reducing the risks of bioproliferation at source, but in the Russian/CIS context it is also crucial to promote a long-term scientific and cultural shift

towards a sustainable civilian/commercial science and technology partnership based on the needs of Russian/CIS facilities. This requires a long-term need for reemployment, education, and economic diversification. Information, which remains fragmented, is key to this process and to understanding and acting upon the perceptions and needs of the Russian/CIS governments, the scientific and business community, and recipient facilities. Further work on considering alternative mechanisms/sources of finance to underpin a strategic plan or "road map" should be considered; the experiences provided in the International Working Group (IWG) framework of international cooperation with Russia's nuclear sector (organized by LNCV) might be taken as useful models to build on. An informal BPP contact working group should be established to study the methodology and mechanisms to accelerate reemployment/economic diversification, paralleling the work of the IWG in the nuclear field, and to carry out an initial scoping study.

## **Maurizio Martellini:**

The speaker has been working on issues of reemployment and economic diversification for 10 years. The difficulty of this task was emphasized: establishing new mechanisms tends to conflict with the existing rules of the game as understood by governments and the science community, and it is hard to change minds. This is not just applicable to Russia/CIS; the Los Alamos National Laboratory had to face these issues at the end of the Cold War, and it proved a very difficult transition. We do not need complicated solutions, but something simpler, particularly how to produce a service sector. The RANSAC-LNCV initiative is trying to bring in new ideas based on what is happening in Russia/CIS. The general problems it faces are the lack of real partnership between the West and Russia/CIS, whereas the approach should be based on the principle that the latter are not just recipients of assistance but partners; also, the political agenda is changing 15 years after the end of the Cold War and the outlook is uncertain. Part of the solution is to create a think-tank, comprising a range of experts from interested countries, to initiate dialogue on the range of risks, threats, and problems involved.



### Discussion:

A Russian participant emphasized that over a period of 10 years, the ISTC has worked very productively in stemming bioproliferation from Russia. Biosafety/biosecurity upgrades have been carried out, but more importantly, new working relationships have been established with the West and trust created. There are still gaps in biosafety/biosecurity, but collaboration is occurring. Russia needs an upgrading of ethical education rather than codes of conduct; a dedicated educational center for this would be a good idea but the issue has not been given enough attention. There are several new projects at Vector which will be developed more rapidly with Western collaboration.

A second Russian participant argued that bioproliferation is not just an academic problem but a problem for society overall. At a recent meeting between the Russian Academies of Science and Medical Sciences, the state program for biosecurity/biosafety, and education were discussed. The 2004 Russian government restructuring has reduced the focus on biosecurity but there has been some progress—in particular, strong regulation in the area of genetic engineering and genetically modified organisms. Much remains to be done, however. Many different organizations and government agencies are dealing with aspects of bioproliferation prevention but there is not enough communication and understanding. Another problem is old-fashioned thinking on biosafety/security; every day, new threats appear. The last big conference on medical toxicology discussed bioterrorism and how to prevent information concerning dangerous developments being transmitted via the Internet.

One speaker stated that biosecurity is not really discussed in Russia and there is little public involvement. Conferences on biosecurity in Russia produced a committee on new medical technologies within the Ministry of Health. A pilot international project focusing on management of biosecurity risks and national biosecurity in Russia, covering scientific and clinical laboratories and industrial facilities would be a good idea. This project could identify weak links in the Russian biosecurity strategy, bring them to the attention of the government, and provide advice on where international support could be directed.

It was argued that any forum needs a specific focus and to think of how to present conclusions to the policy community. This conference had focused more on crucial, sensitive, and political issues, and less on reemployment and economic diversification and problems in developing sustainable biotechnology in a competitive international environment.

An American participant echoed previous comments on the need for trust and transparency. Representatives of Russian and CIS facilities are “champions” of these BPP activities, but how to find a champion in the Russian policy community is much more difficult – this problem exists in Western countries as well. Expertise exists in Canada both within and outside of government to deal with bioproliferation issues. Seeking complementary approaches is important, and it was highlighted that to this end, representatives from U.S., Canada, and UK agencies hold trilateral consultations annually or biannually to discuss implementation.

A European participant expressed appreciation of the open debate at this conference and stated that these issues definitely need further consideration and discussion. The EU is planning some new measures in proliferation prevention. Concern about the concept of an “exit strategy” was expressed—the nonproliferation/science community may need to be sustained in order to achieve its aims. Future funding is uncertain but the EU is seeking guidance to make the right decisions. Particularly important is developing a strategic approach for the future of biotechnology in Russia/CIS, and the EU open to debate and to provide support for this. A complex, disaggregated approach is definitely needed to deal with the issues discussed in this panel. How to organize collaboration with Western industry is an important task, and something within an EU framework would be invaluable.

### Concluding Comments:

A European participant stated that his agency welcomed the opportunity to support this initiative since bioproliferation is a complex security, scientific-technological, economic, and ethical issue on which there is still a great deal to be done; dialogue with Russia/CIS participants has been valuable. There are conflicting priorities among governments and bureaucracies, and they need the kind of input this initiative supplies if resources are to be accessed.

Russian and CIS speakers asserted that, while the conference may have conveyed the impression that there is biosecurity chaos in Russia, this is not the case. In Russia, a federal agency for biotechnology and medical research has been created which certifies the work of biotechnology institutes; measures had also been taken in Uzbekistan. Also, the BWC represents only a small part of attempts to address bioproliferation and this RANSAC-LNCV forum should aim to formulate the main tasks which the BWC should address. The problems of how to bring Russian/CIS biotechnology to the market and of reemployment are still to be addressed, but the call to integrate scientists into international efforts to solve global health problems is more crucial than ever.

# Conference Agenda

## Advancing International Cooperation on Bio-Initiatives in Russia and the CIS

Società Italiana per l'Organizzazione Internazionale (SIOI)

Piazza San Marco 51, Rome, Italy

April 26–27, 2005

Organized by: **RANSAC**

**Landau Network-Centro Volta (LNCV)**

With the support of: **Bio-Industry Initiative**, Department of State, USA

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**Italian Ministry of Foreign Affairs (MFA)**, Italy

**Ministry of Defence**, UK

**International Science and Technology Center (ISTC)**, Russia

**European Commission (EC)**, DG Research, Belgium

**Società Italiana per l'Organizzazione Internazionale (SIOI)**, Italy

## Day 1

### 9:15–10:00 am: Welcome and Objectives

- Amb. Umberto La Rocca, SIOI
- Amb. Giulio Terzi di Sant'Agata, Director General of Political Affairs, Italian MFA
- Ken Luongo, RANSAC
- Maurizio Martellini, Landau Network-Centro Volta (LNCV)
- Sue McLaren, UK Ministry of Defence
- Jason Rao, U.S. Bio-Industry Initiative, U.S. Department of State
- Barbara Rhode, EC DG Research

### 10:00–11:30 am: Status of Bio-Cooperation in International Programs

- Uwe Meyer, International Science and Technology Center
- Jason Rao, U.S. Bio-Industry Initiative, U.S. Department of State
- Barbara Rhode, EC DG Research
- Cindy Vestergaard, Global Partnership Program, Canada

### 11:30–11:45 am: Coffee Break

### 11:45 am–1:00 pm: Improving the Global Biosafety and Security Network

- Maureen Ellis, Global Partnership Program, Canada
- Eugene Grishin, Institute of Bioorganic Chemistry
- Giles Merritt, New Defence Agenda
- Leonid Ryabikhin, Committee of Scientists for Global Security and Arms Control

### 1:00–2:00 pm: Lunch Break



## Day 2

### **2:00–3:45 pm: Creating New Biotech Ventures at Key Institutes—Russia**

- Vladimir N. Kolesnikov, Biopreparat
- Gennady Lepeshkin, Russian-American Center for Ecological Monitoring, Kirov, Russia
- Sergey Netesov, Vector
- Sergei Pchelintsev, Institute of Immunology Engineering
- Yuri Remnev, TEMPO Consortium

### **3:00–3:45 pm: Coffee Break**

### **3:45–5:45 pm: Creating New Biotech Ventures at Key Institutes—CIS**

- Shakhnoza Azimova, Uzbek Institute of Chemistry of Plant Substances
- Evgeny Kalmykov, Stepnogorsk Environmental Monitoring Laboratory
- Valery Shimanaev, Stepnogorsk Technology Park

### **9:15–10:45 am: Strengthening the Global Ban on Biological Weapons**

- Don Avery, University of Western Ontario
- Robin Coupland, International Committee of the Red Cross
- Sarah Price, UK Foreign Commonwealth Office

### **10:45–11:00 am: Coffee Break**

### **11:00–2:00 pm: Advancing Bio-Threat Reduction and Expanding International Cooperation**

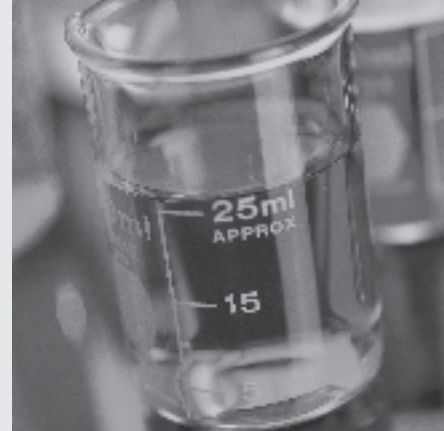
- Ken Luongo, RANSAC
- Derek Averre, University of Birmingham
- Maurizio Martellini, Landau Network-Centro Volta (LNCV)

### **12:00–12:30 pm: Roundtable Discussion; Conclusions and Next Steps**

### **12:30–1:30 pm: Adjourn and Lunch Break**



# Conference Participants



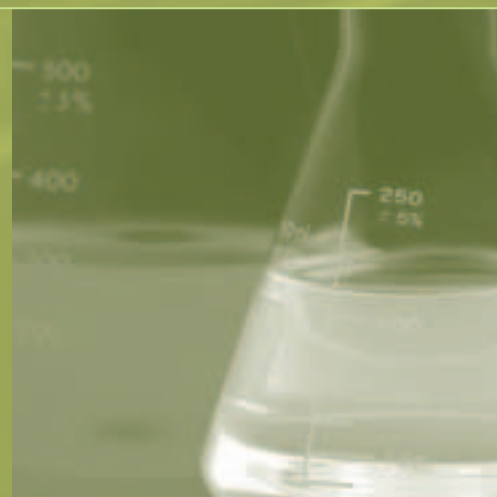
- Don Avery**, University of Western Ontario
- Derek Averre**, University of Birmingham
- Shakhnoza Azimova**, Institute of Chemistry of Plant Substances
- Marc Baril**, TDV Global, Inc.
- Roman Borovick**, Research Center for Toxicology and Hygienic Regulation of Biopreparations
- Gaia Caverzasio**, LNCV
- Robin Coupland**, International Committee of the Red Cross
- Camile De Walder**, U.S. Civilian Research and Development Foundation
- Raphael Della Ratta**, RANSAC
- Maureen Ellis**, *Senior Biosafety Advisor*, Global Partnership Program, Canada
- Evgeneii Grishin**, Institute of Biorganic Chemistry
- Evgeneii Kalmykov**, Engineering Center Monitoring Laboratory, Kazakhstan
- Vladimir Kolesnikov**, Biopreperat
- Umberto La Rocca**, *President*, SIOI
- Gennady Lepeshkin**, Kirov Russian-American Center for Ecological Monitoring
- Ken Luongo**, RANSAC
- Jenifer Mackby**, Center for Strategic and International Studies
- Maurizio Martellini**, LNCV
- Sue McLaren**, UK Ministry of Defence
- Min. Andrea Meloni**, Analysis and Policy Planning Unit, Ministry of Foreign Affairs, Italy
- Giles Merritt**, New Defence Agenda
- Uwe Meyer**, *Deputy Executive Director*, ISTC
- Sergei Netesov**, Vector
- Sergei Pchelintsev**, Institute of Immunology Engineering
- Viktor Popov**, Institute of Immunology Engineering
- Sarah Price**, *Deputy Head, Counter-Proliferation Department*, Defence & Strategic Threats Directorate,  
UK Foreign and Commonwealth Office
- Jason Rao**, *Acting Senior NWMDE Program Coordinator and Director*, Bio-Industry Initiative, U.S. Department of State
- Frank Rapoport**, McKenna, Long, and Aldridge LLP
- Riccardo Redaelli**, LNCV
- Yuri Remnev**, TEMPO
- Barbara Rhode**, *Director of Multilateral Cooperation*, DG Research, European Commission
- Roger Roffey**, Swedish Defence Research Agency
- Leonid Ryabkhin**, Center for Scientific Research, Committee of Scientists for Global Security
- Marina Shilkina**, *Science Workshop Program Manager*, ISTC
- Valerii Shimanaev**, Stepnogorsk Technology Park Industrial Site, Kazakhstan
- Amb. Giulio Terzi di Sant'Agata**, *Director General of Political Affairs*, Ministry of Foreign Affairs, Italy
- Cindy Vestergaard**, Global Partnership Program, Foreign Affairs Canada



# Glossary of Abbreviations

<b>BII</b>	Bio-Industry Initiative	<b>NDA</b>	New Defence Agenda
<b>BPP</b>	bioproliferation prevention	<b>NIS</b>	Newly Independent States of the former Soviet Union
<b>BRG</b>	Bioterrorism Reporting Group	<b>NIH</b>	U.S. National Institutes of Health
<b>BWC</b>	Biological and Toxin Weapons Convention	<b>NWMDE</b>	Nonproliferation of WMD Expertise program at U.S. State Department
<b>BW</b>	biological weapons	<b>OIE</b>	International Office of Epizootics
<b>CBM</b>	confidence-building measures	<b>RACEM</b>	Russian-American Center for Environmental Monitoring, Kirov
<b>CBW</b>	chemical and biological weapons	<b>RANSAC</b>	Russian-American Nuclear Security Advisory Council
<b>CGMP</b>	current good manufacturing practice	<b>R&amp;D</b>	research and development
<b>CIMIT</b>	Center for Integration of Medicine and Innovative Technologies	<b>SANCO</b>	Health and Security Committee of the European Commission
<b>CIS</b>	Commonwealth of Independent States	<b>S&amp;T</b>	scientific and technical
<b>CRDF</b>	Civilian Research & Development Foundation	<b>SIOI</b>	Italian Society for International Organizations
<b>CTR</b>	cooperative threat reduction	<b>STCU</b>	Science & Technology Center in Ukraine
<b>DOD</b>	U.S. Department of Defense	<b>TACIS</b>	Technical Assistance to the Commonwealth of Independent States
<b>DOE</b>	U.S. Department of Energy	<b>UNESCO</b>	United Nations Education, Scientific, and Cultural Organization
<b>DOS</b>	U.S. Department of State	<b>USDA</b>	U.S. Department of Agriculture
<b>DTRA</b>	U.S. Defense Threat Reduction Agency	<b>WHO</b>	World Health Organization
<b>EPA</b>	U.S. Environmental Protection Agency	<b>WMD</b>	weapons of mass destruction
<b>FSU</b>	Former Soviet Union		
<b>GCP</b>	good clinical practice		
<b>GLP</b>	good laboratory practice		
<b>GMP</b>	good management practice		
<b>GXP</b>	generalized term for pharmaceutical quality guidelines		
<b>HHS</b>	U.S. Department of Health and Human Services		
<b>IAEA</b>	International Atomic Energy Agency		
<b>ICGEB</b>	International Center for Genetic Engineering and Biotechnology		
<b>ICRC</b>	International Committee of the Red Cross		
<b>IIE</b>	Institute for Immunological Engineering		
<b>IPP</b>	Initiatives for Proliferation Prevention		
<b>IPR</b>	intellectual property rights		
<b>ISO</b>	International Standards Organization		
<b>ISTC</b>	International Science and Technology Center		
<b>IT</b>	information technology		
<b>IWG</b>	International Working Group		
<b>LNCV</b>	Landau Network-Centro Volta		
<b>MOD</b>	Russian Ministry of Defence		

# Advancing International Cooperation on Bio-Initiatives in Russia and the CIS



**FINDINGS AND REPORT  
FROM AN INTERNATIONAL CONFERENCE ORGANIZED BY:**

**RANSAC**

**Landau Network-Centro Volta**