# CHAIRMAN'S SUMMARY

# WORKSHOP ON "BIOSECURITY OF MICROBIAL BIOLOGICAL RESOURCES – COMPLEMENTING INNOVATION"

## 20-21 SEPTEMBER 2006

## MOSCOW, RUSSIAN FEDERATION

**BIOSECURITY OF MICROBIAL BIOLOGICAL RESOURCES – COMPLEMENTING INNOVATION**

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***Chairman's Summary***

## Background

1. On 20-21 September 2006 the OECD and the Russian Federation held a joint workshop in Moscow entitled "*Biosecurity of microbial biological resources – complementing innovation*". Eighty-five participants attended, representing twelve governments, the WHO, several biotechnology industry associations, academic institutions, public research organisations and civil society. The workshop examined three inter-related themes: the health and economic benefits of biomedical innovations derived from research on pathogenic micro-organisms, how to improve pathogen security in response to the menace of bioterrorism and the need to balance pathogen security measures against the need to produce health innovations. The Biotechnology division of the OECD organized the workshop with financial and logistical support from the Russian Ministry of Education and Science and the French G8 Global Partnership programme (PMG8).

2. Since 2004, the OECD has provided an intergovernmental forum to analyse how rapid advances in the life sciences offer significant benefits to mankind while posing new challenges to the scientific and security communities. Whereas biological research has greatly contributed to the improvement of human health, the same methods, materials, technologies, and knowledge bases have a potential dual-use, namely, they may be misused to produce dangerous agents and toxins for malicious purposes.

3. Two OECD activities have addressed particular aspects of the "dual-use" challenge. First, the Working Party on Biotechnology (WPB) is developing biosecurity guidance for culture collections in the maintenance, use and supply of pathogenic micro-organisms under the auspices of its Task Force on Biological Resource Centres (BRCs). Second, OECD hosted a high level meeting of policymakers in Frascati, Italy in 2004 to take stock of efforts for the promotion of responsible stewardship in the biosciences to avoid potential abuse of research and resources.

4. Based on this foundation of institutional expertise, the Russian Federation took the initiative to create synergies in policy analysis with OECD by proposing a joint workshop on biosecurity. WPB had already planned to build on the biosecurity principles being developed for BRCs by taking a broader policy view on the subject in 2007-2008 under its direct authority. It therefore welcomed the opportunity to consult a broader range of experts from a key non-member country in considering topical issues for its future work.

5. The workshop comprised three keynote speeches and three plenary sessions. Each plenary session was chaired by a government policymaker who presided over several presentations by invited experts. Following presentations, a designated discussant introduced key themes for debate and helped the session Chair to steer ensuing deliberations. A wrap-up session was held during which a Rapporteur's report was delivered to draw together the major points of agreement emerging from the keynote speeches, plenary sessions and debate, and to suggest next steps on advancing the workshop's conclusions.

**Keynote addresses**

6. The workshop was privileged to hear from three high-level policymakers with vast expertise in public health, epidemiology and non-proliferation of biological weapons. The three speeches effectively set the stage to discuss how the contribution of life sciences to economic development operates in an environment of opportunities to combat infectious diseases and challenges relating to security.

7. The keynote speakers pointed out how life sciences research in the 21st century holds the key to developing treatments that vastly improve human health, sources of renewable energy and sustainable industrial development. Excellence in scientific research, however, depends on open access to biological resources– including pathogens, open interactions among researchers and the exchange of scientific data and methodologies.

8. Among the drivers for research using pathogenic micro-organisms are new markets for biotechnology applications that provide rapid and accurate point of service detection for infectious diseases and the menace of bioterrorism. The globalisation of biotechnology R&D, however, has raised the number of countries in which such research is taking place. In turn, the frequency of transfer of pathogenic micro-organisms has increased, thereby augmenting the risk of their misappropriation for malicious misuse. While it is widely acknowledged that security of biological materials and information is necessary as a complement to improving access and innovation, national legislative action to this effect has been enacted in only a few countries.

9. The keynote speakers provided an overview of the challenge to securing pathogenic micro-organisms that have dual-use capacity. Economic and societal impacts of a biological weapons attack are not easy to model, but there is no doubt that the potential cost in human lives necessitates concerted action to reduce the probability of such an attack from occurring. While the scientific community has engaged in the process of developing codes of conduct, these efforts remain light-touch and lack verifiable reliability. There is a need for multidisciplinary collaboration due to the fact that scientists are generally not versed in security policy and security experts most often lack hands-on knowledge about how laboratories operate.

10. Not enough countries have taken action specifically intended to reduce the possibility of pathogenic micro-organisms being lost or stolen, but a threshold of awareness about security issues has finally reached the scientific community. The time is ripe for the development of documented and transparent governance frameworks for the identification of dangerous pathogens and how to secure them.

11. Developing such governance frameworks will call for international coordination supported by extensive consultation with the stakeholders who work with pathogenic micro-organisms, *i.e.* government actors, industry and academia. Acceptance of measures prescribed under these governance frameworks and successful implementation by the scientific community will also require taking into account the need to enable research, innovation and an appropriate level of freedom to operate for the facilities concerned.

***Session I – Realising value from pathogenic microbial resources***

12. The speakers in Session I focused on illustrating the value that can be derived from pathogenic micro-organisms, notably in biomedical sciences. The market opportunities for biotechnology products and services in which the research and development process utilizes such pathogens are well established in the fight against infectious diseases and bioterrorist threats (*e.g.* diagnostic kits, vaccines, therapeutics), and new opportunities continue to arise – *e.g.* microchip based biotoxin detection and therapeutic antibodies.

13. The research and development process constitutes the majority of these products' value-added, thus the jobs created to perform this work are relatively well paid. In addition to serving economic policy objectives, speakers emphasized that these products present the additional value of serving important social

goals such as producing direct health benefits. The development of new diagnostics, vaccines and therapeutics to fight naturally occurring or intentionally introduced infectious diseases has the added benefit of strengthening global health protection overall.

14. One of the challenges to better delivery of effective diagnostics and vaccines is the need to improve the reliability of access to a broad range of microbial strains. Participants noted that a complex web of applicable regulations has impeded the international exchange of pathogenic micro-organisms and that this barrier to advancing research activities should be reanalysed in an international forum.

15. A few expert networks are already in place to carry-out biomedical R&D making use of pathogenic micro-organisms (*e.g.* ENIVD). Such networks may provide platforms for developing common research and security methodologies (*e.g.* genetic databases for strain identification), however due to the variance of protocols in traceability and exchange of pathogens within these networks there is scope to compare and evaluate practices across them.

16. Participants discussed the role that management systems designed to ensure the quality of R&D (such as GLPs, GMPs and ISO standards) could play in implementing security management of pathogenic micro-organisms. Integrating security requirements into the certification processes of such well established quality management systems would streamline the regulatory burden for laboratories engaged in biomedical research and development. Broad international implementation would also provide an opportunity to harmonize practice in the secure maintenance and storage of pathogenic micro-organisms. Participants did recognize, however, that quality management systems are unsuited to the full range of pathogen security measures, for example those related to the transport and traceability of pathogens.

***Session II: Establishing biosecurity systems: risk assessment and risk management of dangerous biological material***

17. The second session examined challenges to the research and development supply chain of biological resources due to the dual use capacity of pathogenic micro-organisms and the toxins they may produce. Speakers suggested that new policy responses are necessary to secure against the damage that biological weapons could cause to human beings, crops, livestock, water resources and other valuable infrastructure. Some participants confessed that not enough is being done in their countries to protect against the loss or theft of pathogenic micro-organisms, and expressed keen interest in collaborating at the international level to develop such protective measures.

18. Discussion focused on what policymakers could do better to respond to this threat, and began to frame the issues in terms of a biosecurity risk governance structure for biological materials. An over arching governance structure would address not only biosecurity systems such as hazard identification, risk assessment and risk management, but also the development of detection and decontamination technologies and crisis response. Participants agreed that such a biosecurity risk governance structure should concentrate resources on the most probable risks and guard against jeopardising the advancement of biosciences.

19. Participants clearly distinguished biosecurity systems that lay-out control measures (i.e. risk management) from systems that identify the materials that should be subject to control measures (i.e. hazard assessment and risk assessment). Several international efforts, *e.g.* the Australia Group list on transfer of biological items, provide well established guidance on which materials should be controlled for the purpose of export, but these lists do not identify the materials that laboratories should take caution to secure with extra measures to prevent loss or theft.

20. As is often the case in emerging policy fields, terminology related to biosecurity has sometimes been a source of confusion. Certain policy communities, e.g. agriculture and environmental protection, understand biosecurity to mean mechanisms that detect and respond to invasive species. Further, some languages are prone to associate the concept of biosecurity with biosafety because no linguistic differentiation is made between the two. The term "Pathogen Security" was introduced into the discussion to mean measures intended to prevent the loss or theft of biological materials as distinct from "Biosafety" which covers measures designed to prevent the accidental exposure of workers to dangerous biological materials.

21. There was broad agreement that pathogen security measures should build upon a solid foundation of previously implemented biosafety measures, and ideally the two should be integrated. Participants acknowledged that there are parallels in classifying biological materials for the purpose of pathogen security and laboratory worker safety, but they are not necessarily the same since the former takes into account a material's potential for malicious misuse. Indeed, accidental exposure to certain pathogens in a laboratory may lead to human fatalities, but these same pathogens are not necessarily useful for the production of biological weapons capable of affecting large human populations. Laboratory operations, procedures and structures should take account of this difference, while considering how to produce as little obstruction to laboratory activity as possible. By separating biological materials into groups according to their security risk, as distinct from safety risk, risk management may proportionately guard against loss or theft of materials.

22. Two international projects which aim to address aspects of a biosecurity risk governance structure were presented: the OECD biosecurity principles for Biological Resource Centres (BRCs) and the WHO Biorisk management: Laboratory Biosecurity Guidance. BRCs have as their mission the concentration and supply of biological materials, including pathogens that may pose a biosecurity risk. The activities of BRCs are governed by a series of guidelines, including a set of biosecurity principles. A system of certification for culture collections that choose to become BRCs and ongoing validation of certification is envisaged, and would help BRCs to control compliance with the biosecurity principle's provisions on risk assessment and risk management. The principles have been developed for use by culture collections, thus they do not address the whole scope of entities facing biosecurity challenges.

23. Participants recognized that training laboratory personnel is essential to ensure good managerial practices in facilities handling dangerous biological materials. The scope of facilities working with such materials is so broad that participants questioned how to determine with precision which facilities might require biosecurity measures. Should the target group be determined on the basis of material that the facility possesses, and if so, what kind of material – nucleic acids, proteins, toxins, delivery systems, knowledge/data and/or organisms? It was suggested that some materials (*e.g.* pathology samples) are particularly difficult to control.

24. Participants further debated whether risk assessment should be based solely on the intrinsic properties of the biological material in question, or also take into account external factors such as the competence of the individuals working with the material, the type of activities in which the laboratory is engaged and the laboratory's location. It was suggested that hazard assessment should measure the potential impacts or consequences associated with the misuse of the biological material itself, whereas risk assessment, which encompasses consideration of the probability that the hazard might occur, should take account of external factors.

25. Participants suggested that efforts to develop in-depth pathogen security risk assessment would require multidisciplinary expertise. In this effort, policymakers should consult both the scientific and security communities in developing an effective pathogen security system, and leverage international collaboration where viable to share the burden of work that risk assessment presents. Emerging from this

discussion, a clear demand was articulated for international cooperation in developing a pathogen security system. Once established, pathogen security risk assessment and risk management systems may need to be reassessed periodically to take account of advances in scientific knowledge about biological materials.

26. Several issues in this session were advanced as key considerations: How does an entity integrate a biosafety/pathogen security risk assessment in practice? Who validates risk assessment and how? How can current methodologies be drawn from to arrive at a harmonized approach?

***Session III: Biosecurity regulations implementation and compliance: seeking balance***

27. The disastrous consequences that would result from bio-warfare moved States to prohibit the production, development and stockpiling of bioweapons under the 1972 Biological and Toxin Weapons Convention (BTWC). Recent global developments, however, require strategies that take account of non-state actors who operate outside the control of such agreements, as is evidenced by the deliberate release of *Bacillus anthracis* through the US postal system, fraudulent attempts to obtain cultures of *Clostridium botulinum* and *Clostridium tetani* from the American Type Culture Collection and Al-Qaeda's efforts to establish a biological weapons programme in Afghanistan. Consequently, laboratories that work with biological materials that can be used as arms are increasingly coming under the scrutiny of security policymakers.

28. Several countries have enacted laws and regulations to reinforce pathogen security in recent years, but such legislation is too often missing in OECD countries. A lack of continuity in pathogen security regulations across borders could undermine the effectiveness of measures in countries where preventative efforts are put in place. In addition to the security concerns of States, industrial laboratories also have an interest in assuring that irresponsible competitors do not enjoy an unfair commercial advantage by refusing to implement appropriate pathogen security measures.

29. The OECD has begun to develop a web based repository of such laws and regulations: www.biosecuritycodes.org. This resource also includes information on legislation implementing the Biological Weapons Convention and non-binding codes of conduct written by national science foundations and academies regarding the responsibility of scientists to act ethically with the biological materials entrusted to them. A cursory analysis of the binding and non-binding instruments available reveal a key difficulty facing facilities that maintain and transfer pathogenic micro-organisms: there is neither international consensus on which materials should be secured, nor guidance on how to secure them.

30. Collaboration between policymakers and stakeholders will be necessary for the successful development of practices and procedures to deter and/or detect the misappropriation of dangerous biological materials. The challenge for policymakers and stakeholders resides in striking an appropriate balance between applying security measures to control materials that could be used in a biological weapon and an operational environment conducive to advanced biomedical research. Participants explored what a balanced approach to implementing pathogen security would entail.

31. There was broad agreement that governments have a responsibility to take some action to prevent the loss and theft of pathogenic micro-organisms from laboratories, but there was equal agreement that general prohibition would be unacceptable to the scientific community. Developing a pathogen security approach that is neither too restrictive nor too lax is a moving target for policymakers. Several countries with pathogen security legislation have taken a list based approach to indicate clearly whether or not a facility must take security measures designed to prevent loss and theft of a particular biological material. Under such an approach, if a facility works with a biological material on the list it must register with a government authority and eventually implement a series of security measures such as background checks on personnel working with the material.

32. Several participants suggested that information derived from research also posed a "dual-use" risk and that steps to prevent it from falling into the wrong hands should be taken. To minimize negative impacts of legislative restraints on the scientific community, however, a primary distinction should be made between research activities that could be misused to threaten public health and national security from innocuous types of research.

33. Criteria were discussed for the purpose of classifying research of "dual-use" concern. It was suggested that research may be considered a risk if, for example, it: renders an immunization ineffective or disrupts immunity; confers to a pathogenic agent or toxin resistance to useful prophylaxes or therapeutics; enhances the pathologic consequences of an agent or toxin; increases the transmissibility of a pathogenic agent; increases the capability of a pathogenic agent or toxin to be disseminated; alters the host range or tropism of a pathogenic agent or toxin; enhances the susceptibility of a host population; generates a novel pathogenic agent or toxin, or reconstitutes an eradicated pathogenic agent.

34. Participants questioned how pathogen security could be efficiently implemented by means in addition to legislation and regulation. The fundamental proposals were to make training in pathogen security a requisite for users/stakeholders and to increase awareness in laboratories whether they are public institutes, commercial labs or universities. Aspects that must be considered when instituting comprehensive pathogen security practices include, but are not limited to: physical security, information security, personnel reliability, and accountability for biological materials. Accountability not only applies within facilities that maintain dangerous pathogens, but must also be ensured when transfer of biological materials occurs between such facilities.

35. Participants recognized that creating and maintaining an ethical scientific community with an acute consciousness of security risks should serve as the first line of defence against pathogen security concerns. Pathogen security needs to become part of the culture of science – not an afterthought. Top-down legislative and regulatory approaches are never self-executing and should be accompanied by bottom-up codes of conduct in the scientific community.

36. The key statement emerging from Session III was that it is important to strengthen pathogen security initiatives and prevent misuse of legitimate life science research while enhancing public health more generally. Policymakers face the challenge of crafting and implementing multi-disciplinary approaches to pathogen security that serve to bolster non-proliferation while promoting the development of prophylactic technologies that make society a safer, healthier place. Investing in such a policy approach will pay off in overall improvements to global health even if there is never again a bioterrorist attack. Developing remedies to an eventual bioterrorist attack provides "dual benefits" by increasing society's capacity to survive such an event while simultaneously creating valuable technologies with market value.

**Emerging Conclusions**

37. The theft of pathogen strains to build biological weapons is a genuine risk to global security, and needs to be addressed more systematically at an international level. Governments, industry, academia and the broader scientific community have a responsibility to strengthen pathogen security. Co-coordinating efforts through top-down policy tools and bottom-up codes of conduct will be invaluable to their effective and broad implementation.

38. A principle challenge facing policymakers is how to strike balance between open innovation and security to maintain progress in scientific research. The policy goal should be to derive the "dual benefits" of security and biotechnological advances.

39. There was broad agreement that mechanisms for the rapid and efficient transfer of biological materials need to improve. Among the challenges facing international transport of biological materials are adequate protection and enforcement of intellectual property rights.

40. Quality management practices provide a partial platform for implementing pathogen security measures, as do well established biosafety measures. Integration of pathogen security with biosafety is necessary, but developing practical means to achieve this remains a key challenge.

41. Harmonisation in some areas of biosecurity systems, such as risk assessment and risk management is both possible and beneficial, including: agreement on common terminology (*e.g.* to distinguish policies that aim to prevent loss and theft of biological materials from those which prevent humans to accidental exposure or the agriculture sector to invasive species); development of risk assessment methodologies for pathogens; and scientific networks to exchange information on the hazard of particular pathogens.

42. Recognition that bio-safety and biosecurity are different issues has been slow to emerge, but a critical mass of awareness has grown throughout relevant communities that both types of measures are needed in the maintenance and transfer of pathogenic micro-organisms. International organizations (*e.g.* OECD and WHO) should be encouraged to continue to promote and roll out their work on biosafety and biosecurity in laboratories.

**Next steps**

43. The OECD's Working Party on Biotechnology should take forward work on biosecurity risk governance frameworks by conducting policy analysis of current approaches to pathogen security systems in line with the notion of dual benefit. OECD could produce a valuable tool for policymakers in the form of a report that is built on:

- A multiple stakeholder survey (covering public research institutes, industry, academia, etc.) to compile data on the number, type and location of facilities working with pathogenic micro-organisms, the range of products and services that require use of such materials, approximation of their market value and identification of barriers to market entry. Such data might be used to assess the regulatory burden of pathogen security systems and to measure the economic impact of a bioterrorist attack.

- Analysis of legally binding, national and international policy instruments designed to secure against the loss or theft of pathogenic micro-organisms for the purpose of identifying cross jurisdictional gaps and barriers to the international exchange of pathogens.

- Raising awareness among relevant policy circles and stakeholders about the distinctions between pathogen security and biosafety, while investigating how they may be successfully integrated.

- Development of best practice guidelines on pathogen security systems (*e.g.* risk assessment and risk management).