MEETING OF THE STATES PARTIES TO THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND ON THEIR DESTRUCTION

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Consideration of national, regional and international measures to improve biosafety and biosecurity, including laboratory safety and security of pathogens and toxins

OVERVIEW OF MAJOR INTERNATIONAL BIOSECURITY ACTIVITIES SINCE THE 2003 INTERSESSIONAL MEETING

Submitted by the United States of America

1. States Party to the Biological Weapons Convention (BWC) have demonstrated their commitment to and the importance of having an international dialogue on biosecurity. The Fifth Review Conference of the BWC established an extensive intersessional work program with the 2003 intersessional meeting devoted to national implementation measures for the BWC and the security and oversight of pathogens (laboratory biosecurity). The intersessional process was renewed at the Sixth Review Conference. The purpose of the 2008 intersessional meeting is to specifically address national, regional, and international measures to improve biosafety and biosecurity, including laboratory safety and security of pathogens and toxins.[1] This paper provides a brief overview of a few of the most important laboratory biosafety and biosecurity events since the 2003 intersessional meeting. The organizations and events highlighted in this paper are only illustrative examples; the global community has been remarkably active in this area in the last five years.

2. The bioterrorism attacks of the past decade have forced the political world to take notice of the importance of laboratory biosafety and biosecurity. Realization of this threat has prompted many international and national initiatives to minimize the consequences of these biological risks. On 28 April 2004, the United Nations Security Council unanimously passed resolution 1540 (**UNSCR 1540**), which established for the first time binding obligations on all UN member states under Chapter VII of the UN Charter to take and enforce effective measures against the proliferation of weapons of mass destruction, their means of delivery, and related

[1] Department of Peace Studies, University of Bradford. The Biological and Toxin Weapons Convention Website. www.opbw.org.

materials. Control measures cited in the Resolution specifically relating to the support of biosafety and biosecurity measures include securing biological materials in production, use, storage, and transport, and implementing physical protection measures, border controls, and other law enforcement efforts to "detect, deter, prevent and combat, and export and end-user controls."

3. Since 2003, there have been numerous initiatives, events, and publications on these topics, such as the passage of the **World Health Assembly (WHA) Resolution 58.29** in 2005. This resolution specifically urged member states of the World Health Organization (WHO) to take a number of steps to enhance laboratory biosafety. Member states were advised to review protocols for ensuring safe handling of harmful biological agents. States were also instructed to establish biosafety practices in accordance with WHO guidance. Mobilization of national and financial resources sufficient to accomplish these goals, as well as the requisite international support and cooperation, were also recognized as important components. The WHO has also developed a number of benchmark documents, including the third edition of the *Laboratory Biosafety Manual* in 2004.[2] This document serves as a global resource that offers practical guidance on biosafety for all types of laboratories and biosafety levels; the third edition for the first time included a chapter introducing laboratory biosecurity. Other influential WHO documents include **Biorisk management: Laboratory Biosecurity Guidance**,[3] which promotes the protection and control of laboratory biological materials to prevent intentional misuse, and the Guidance on Regulations for the Transport of Infectious Substances.[4] In 2007, the Organization for Economic Cooperation and Development (OECD) published the **OECD Best Practice Guidelines for Biological Resource Centers**.[5] This comprehensive report describes a rationale for establishing a global network for biological resource centers (BRCs) and contains four sets of best practice guidelines, including the Best Practice Guidelines on Biosecurity for BRCs. Other organizations, such as the World Organization for Animal Health (OIE), have also recently published guidelines that endorse good biosafety and biosecurity practices in laboratory environments. Three of the most important include The Terrestrial Animal Health Code (2007), Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (2004), and Quality Standard and Guidelines for Veterinary Laboratories: infectious diseases (2008).[6] All these publications are available online, and have been translated in multiple languages.

4. Conferences, workshops, and trainings have also been important tools in disseminating information and raising awareness internationally. The WHO has been one of the most prolific organizations, hosting six Biosafety and Laboratory Biosecurity Awareness Workshops since 2005 in Africa, Asia, Latin America, and the Middle East, and educating participants from more than 95 countries.[7] Much of this work has been done through the WHO regional offices. The

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[2] World Health Organization, Laboratory Biosafety Manual, 3rd edition. 2004. http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/
[3] World Health Organization, Biorisk management: Laboratory biosecurity guidance. 2006. http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6/en/index.html
[4] World Health Organization, Guidance on regulations for the Transport of Infectious Substances 2007-2008. http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2007_2/en/
[5] Organization for Economic Cooperation and Development, OECD Best Practice Guidelines for Biological Resource Centres, 2007. http://www.oecd.org/document/36/0,3343,en_2649_34537_38777060_1_1_1_1,00.html
[6] World Organization for Animal Health. Standards, 2006. http://www.oie.int/eng/publicat/en_normes.htm
[7] Nicoletta Prevasini, "The WHO Global Biosafety and Laboratory Biosecurity program," Latin America Laboratory Biosafety and Biosecurity Conference, Brazil, May 2008. http://www.biosafetyandbiosecurity.org

International Criminal Police Organization (Interpol) has hosted a number of international bioterrorism conferences that include biosecurity in South Africa, Singapore, Chile, Ukraine, and Oman[8] and a Southeast Asia regional conference in the Philippines. OECD and the International Committee for the Red Cross are examples of other organizations that have hosted similar international conferences. In many cases, successful meetings have resulted in the formation of other resources, such as independent regional associations that address laboratory biosafety and biosecurity. Examples of new associations and organizations since 2003 include the African Biosafety Association (AfBSA), the Asia-Pacific Biosafety Association (APBA), the Biosafety Association for Central Asia and Caucuses (BACAC), the International Advisory Working Group (IAG) on Biosafety and Biosecurity, and the Israeli Biological Safety Association (IBSA). Biosafety associations have also been under development in the Philippines and Pakistan.

5. Many of the recently developed online resources are also indispensible in promoting laboratory biosafety and biosecurity. The OECD launched a biosecurity website in 2004.[9] The site offers a variety of online biosecurity, biotechnology, and biosafety information, with links to international, national, government, academia, industry, and non-profit institutions. The website also offers a list of future and past events, meetings, and conferences. In 2006, Interpol established the **Bioterrorism Prevention Resource Center**,[10] which lists numerous bioterrorism-related websites that promote awareness among member countries, public health officials, customs and law enforcement officials, and international organizations. Similarly, the United Nations Food and Agricultural Organization created the *Biosafety Resources* website[11] in 2003, with links to guidelines, manuals, reports, and toolkits, as well as the WHO's *Laboratory Biosafety Manual*.

6. The United States Government (USG) has been a world leader in promoting laboratory biosafety and biosecurity internationally.[12] A few exemplary programs are discussed here. The US Department of Defense has many relevant programs, including the Biosecurity and Biosafety/Threat Agent Detection and Response program, which works with Russia and the Former Soviet Union to improve biosafety and biosecurity, and to secure dangerous biological material to prevent their accidental release, theft, or exposure.[13] In 2006, the US Department of State established the Biosecurity Engagement Program (BEP),[14] which strives to develop cooperative international programs that promote the safe, secure, and responsible use of biological materials that are at risk of accidental release or intentional misuse. BEP has developed similar programs and trainings in other regions of the world, with its initial efforts primarily focused in Southeast Asia, South Asia, and the Middle East.

7. The USG has also been working to strengthen laboratory biosafety and biosecurity in the United States. For example, the National Science Advisory Board for Biosecurity (NSABB) was

[8] J. B. Tucker. Preventing the Misuse of Pathogens: The Need for Global Biosecurity Standards. Arms Control Today. 2003.
[9] www.biosecuritycodes.org
[10] Interpol Bioterrorism Prevention Resource Centre. 2006.
http://www.interpol.int/Public/BioTerrorism/links/default.asp
[11] http://www.fao.org/sd/2003/biosafety/index.htm
[12] This paper presents only a few illustrative examples as the USG has been heavily active in these areas making it nearly impossible to address all events since 2003.
[13] Cooperative Threat Reduction Annual Report to Congress Fiscal Year 2009.
http://www.dtra.mil/documents/oe/ctr/FY09%20CTR%20Annual%20Report%20to%20Congress.pdf
[14] www.BEPstate.net

established in 2004 to advise all federal departments, including the US Secretary of the Department of Health and Human Services (HHS) and the Director of the US National Institutes of Health (NIH), and recommend specific strategies for the efficient and effective oversight of federally supported, dual-use, biological research.[15] Other noteworthy domestic activities include the release of the 5th edition of the Biosafety in Microbiological and Biomedical Laboratories (BMBL) in 2007 by the US Centers for Disease Control and Prevention (CDC) and the US NIH.[16] This influential document provides practical guidance on biosafety and biosecurity for all types of laboratories and levels, and is used extensively both in the United States and around the world. The 5th edition contains many new topics, including a chapter dedicated to laboratory biosecurity.

8. It is difficult to define or measure the success of the many laboratory biosafety and biosecurity events that have occurred since 2003. While it is clear that the number and scope of these events have increased in the last five years, there is no measurement currently available to assess how exposure to this new information improves implementation at the laboratory level. Furthermore, there is very little information available in the open-source literature that reports the number of biosafety accidents and biosecurity breaches worldwide.

9 There is evidence, however, to suggest these events have made a positive contribution to the field. There have been more national and international legislative initiatives on these issues in the past decade than ever before. There is clearly a greater knowledge and commitment to laboratory biosafety and biosecurity in the scientific community today than ever before. The number of conferences, trainings, courses, and workshops devoted to these issues has grown substantially in the last five years, reaching many under-developed regions of the world for the first time. The internet has become a critical tool providing access to a vast assortment of online resources and is accessible to anyone in the world with internet access. Furthermore, many scientific societies and non-governmental organizations have linked membership and/or privileges to their organization to adherence to the biosecurity and biosafety measures that they officially endorse.

10. Nevertheless, the concept of laboratory biosafety and biosecurity at an international level is still in its infancy, and the international community faces many challenges in achieving comprehensive implementation in this area. Hurdles range from a lack of capacity or necessary financial resources in many regions to operational and oversight laxity, personnel liability, and an overall low-level of awareness or concern.

11. It is an immense challenge to improve international laboratory biosafety and biosecurity. While efforts in the last five years have created more global awareness and education than ever before, much work still needs to be done. To reduce the biological risks associated with infectious disease laboratories, complementary and coordinated international measures are critical.

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[15] National Science Advisory Board for Biosecurity. http://www.biosecurityboard.gov/links.asp
[16] Centers for Disease Control and Prevention, Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition. 2007. http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm