

**2008 Meeting
Geneva, 1-5 December 2008**

**Meeting of Experts
Geneva, 18-22 August 2008**
Item 5 of the provisional agenda
**Consideration of national, regional and
international measures to improve biosafety
and biosecurity, including laboratory safety
and security of pathogens and toxins**

EFFORTS TO PROMOTE GLOBAL BIOSECURITY AND PATHOGEN SECURITY STANDARDS

Submitted by the United States of America

1. While international standards for biosafety have existed for some time, prior to the work of the Biological Weapons Convention Meetings of Experts there were no standards for pathogen security. As a result, the United States, in support of the work of the Biological Weapons Convention, has undertaken efforts to fund the development of global standards in pathogen security and updating and training of efforts to improve both biosafety and pathogen security.

2. In 2004 the United States provided funding to the World Health Organization (WHO) to develop guidelines for laboratory biosecurity. This led to the development of the “Biorisk Management Laboratory Biosecurity Guidance” document that is now available on the WHO website:

www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf

3. Following the development of the new biosecurity guidance, the United States funded (and continues to fund) WHO to develop and offer a Train the Trainers program using their biosafety and biosecurity materials. This program is based on the materials in the guidance mentioned above, as well as the 3rd. Edition of the “Laboratory Biosafety Manual”. This resource can be found on the WHO website at the following address:

www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en

4. In the summer of 2007 WHO offered a trial run (a Beta test) of its new training program in Singapore. The workshop consisted on intensive training over a two week period. Based on the feedback from that test program, curricula and materials have been modified to offer an improved course. WHO is now organizing Train the Trainer programs through its regional offices. Training is anticipated to begin in September, 2008.

5. The United States worked with the Organization for Economic Cooperation and Development (OECD) to develop “Best Practices Guidelines on Biosecurity for Biological Resource Centers” (BRCs). These best practices are now recommended to all thirty of OECD’s member economies and to those economies that adopt OECD guidelines and practices. While the best practices guidelines were particularly designed for facilities and store and share microbial culture collections, they are becoming widely accepted by laboratories throughout OECD member economies and other countries that ascribe to OECD standards. The link to the OECD best practices guidelines can be found at the following address:

www.oecd.org/dataoecd/6/27/38778261.pdf

6. After the development of the best practices for BRCs, the OECD realized that a risk assessment based approach to biosecurity was essential. Many laboratories are unsure how to conduct risk assessments and resources and guidance for doing so are limited. The United States is currently providing funding to the OECD to develop guidelines for conducting laboratory risk assessments.

7. Effective implementation of laboratory biosecurity practices requires the commitment of institutional management. Until recently there has been no guidance for management in the implementation of this process. The European Committee for Standardization (CEN) convened a three-meeting workshop in 2007 that involved participants from around the world. The outcome of these workshops is an International Standards Organization (ISO)-like management standard for laboratory biosecurity. CEN hopes to release its laboratory management standard soon. It will serve as a guide for certification of laboratories containing dangerous pathogens. It is important to note that CEN does not propose to be a certification organization. Each interested country that adopts the CEN standards would be responsible for identifying its own method for certification and its acceptable certification body or bodies.

8. Pathogen security (biosecurity) guidelines are also beginning to appear in other national and international standards for laboratory practice. The “Biosafety in Microbiological and Biomedical Laboratories”, prepared by the United States Department of Health and Human Services’ (HHS) Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH), has recently been released electronically in its 5th. Edition. This new addition has added chapters on biosecurity and microbial laboratory risk assessment. Persons interested in obtaining a copy of this new edition may do so at:

www.cdc.gov/od/ohs/biosfty/bmbl5/BMBL_5th_Edition.pdf

Conclusions

9. The two global standards in biosafety, the WHO “Laboratory Biosafety Manual”, and the CDC/NIH “Biosafety in Microbiological and Biomedical Laboratories”, have both been modified, either directly or by compendium, to now address biosecurity issues as an integral component of Biosafety. These new standards are currently available. OECD and CEN have established best practices and management standards for implementing biosecurity in laboratories around the world.

10. Training opportunities are being made available through the WHO to promote new biosafety and biosecurity standards. Interested countries and individuals should contact their regional offices of the WHO for information on when training may be available in their areas.
