

**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**

BIOSECURITY: MOVING BEYOND THE LABORATORY

Submitted by the United States of America

1. There are documented cases of rogue groups attempting to perpetrate bioterrorism. For example, Aum Shinrikyo released anthrax or botulinum around Tokyo up to 12 times during the 1990s.¹ Thankfully, none of the attempts was successful because of their inability to acquire viable and virulent pathogens, but this demonstrates that those who wish to do harm can and will try to use pathogens for nefarious means. Individuals who want to maliciously disseminate infectious disease to cause harm would likely attempt to acquire pathogens or toxins as well-characterized isolates, rather than try to isolate them directly from the environment. The technical difficulties associated with isolation, strain identification, and characterization of virulence make acquiring well-characterized isolates much more desirable than environmental isolation.

2. Well-characterized isolates can be found in bioscience laboratories, as positive controls in some diagnostic laboratories, at vaccine production facilities for use as seed stock or in efficacy studies, and in culture collections. The World Health Organization defines laboratory biosecurity as the institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins.² Since the 2003 Experts Group Meeting of the Biological Weapons Convention, much attention has been devoted by the United States and the international community to raising awareness about the importance of laboratory biosecurity for bioscience laboratories. However, the concept of biosecurity needs to be extended beyond the laboratory to other facilities and institutions with pathogens and toxins.

¹ Carus WS. Bioterrorism and Biocrimes: The illicit use of biological agents since 1900. Washington, D.C.: Center for Counterproliferation Research, National Defense University, 2001

² World Health Organization, "Laboratory Biosafety Manual, 3rd edition," Geneva, 2004.

3. As libraries of pure isolated biological organisms, ensuring effective implementation of laboratory biosecurity for culture collections should be a priority. Access to materials in these repositories and the exchange of organisms has historically been built on trust between scientists and institutions for the common purpose of advancing basic science and public health. A culture collection's main purpose is to acquire, characterize, propagate, preserve, and distribute biological material to legitimate researchers and users. The biological material contained in these collections may be comprised of animal and plant cell lines, bacteria, fungi, viruses, protozoa, and antisera. Culture collections vary widely, from the American Type Culture Collection (ATCC), the world's largest and most extensive repository, to smaller "boutique" collections of microbial strains at universities, federal agencies, and private companies.³

4. It is unclear how many culture collections exist globally, but the World Data Center for Microorganisms (WDCM), an international database of registered collections maintained by the World Federation for Culture Collections (WFCC), has 536 collections registered in 67 countries as of August 9, 2008.⁴ Another estimate suggests approximately 1,500 state-owned and commercial culture collections are in operation worldwide.⁵ The total number of organisms in these collections is reportedly exceeds 1.3 million, and is likely more than that. Asia contains the highest number of collections (178 collections, 328,825 cultures), and Western and Eastern Europe hold the most biological cultures (180 collections, 619,862 cultures, or approximately 45% of the world's total). Many of these facilities contain and distribute such high-risk biological agents as *Bacillus anthracis*, *Clostridium botulinum*, *Yersinia pestis*, *Salmonella* serotypes typhus and typhimurium, and *Brucella abortus*.

5. Culture collections are indispensable in the promotion of basic science and public health. In recent years, the ATCC and several other culture collections have tightened security standards in response to the threat of bioterrorism. They can also be, however, extremely vulnerable to exploitation by terrorist groups or others with malicious intent. Examples of past incidents of exploitation include: Larry Wayne Harris, a former neo-Nazi sympathizer and trained microbiologist from Oklahoma State University, who purchased three cultures of *Yersinia pestis* from the ATCC using falsified documents in 1995;⁶ Iraqi government purchases of *Bacillus anthracis*, *Clostridium perfringens*, *Clostridium botulinum*, *Clostridium tetani*, *Brucella melitensis*, *Brucella abortus*, *Salmonella choleraesuis*, *Escherichia coli*, and *Aspergillus* spp. fungal cultures from the ATCC between 1985-1989 that were later reportedly incorporated into the Iraqi biological weapons program;⁷ and the purchase of *Salmonella typhimurium* by the

³ Tucker JB. Biosecurity: Limiting Terrorist Access to Deadly Pathogens. Peaceworks 2003.

⁴ WDCM Statistics. 2007. World Data Center for Microorganisms.

⁵ Tucker, J. B. Preventing the Misuse of Pathogens: The Need for Global Biosecurity Standards. 2003. Arms Control Today.

⁶ Tucker JB. Bioterrorism: Threats and Responses. In: Lederberg J, ed. Biological Weapons: Limiting the Threat MIT Press, 2001.

⁷ Barletta, M. and Ellington, C. Foreign Suppliers to Iraq's Biological Weapons Program Obtain Microbial Seed Stock for Standard or Novel Agent. 1998. Center for Nonproliferation Studies, Monterey Institute of International Studies.; Central Intelligence Agency. Comprehensive Report of the Special Advisor to the Director of Central Intelligence on Iraq's WMD. 2004. https://www.cia.gov/library/reports/general-reports-1/iraq_wmd_2004/index.html; Shenon, P. Threats and Responses: The Bioterror Threat; Iraq Links Germs for Weapons to U.S. and France. 2003. The New York Times.

Rajneeshees, an East Indian religious cult operating in Oregon, USA, who in 1984 successfully disseminated the pathogen and caused sickness in 751 people.⁸

6. Over the last decade, the US government enacted extensive legislation, including criminal and civil penalties, to control the possession, use, and transfer of biological agents. The Antiterrorism and Effective Death Penalty Act of 1996, crafted partly in response to the arrest of Larry Wayne Harris, makes culture collection acquisition much more difficult by requiring shippers and receivers of select biological agents and toxins to register with the Centers for Disease Control and Prevention (CDC), an agency of the Department of Health and Human Services (DHHS). Furthermore, this registration information may be shared with state and local law enforcement authorities, if requested. Any individual who orders an agent from a US facility is also responsible for obtaining the necessary permits to transfer and receive the order. In addition to the DHHS and the CDC, distribution of infectious materials is subject to regulations from several federal departments and agencies, including the Animal and Plant Health Inspection Service (APHIS) of the US Department of Agriculture (USDA), the Department of Commerce (DOC), the Department of State (DOS), and the Department of Transportation (DOT).

7. Moreover, the Public Health Security and Bioterrorism Preparedness and Response Act of 2001 further requires US facilities that possess select agents to inventory the holdings in their culture collection, and report to CDC or APHIS the possession of any select agents. The USA PATRIOT Act of 2001 makes it an offense to “possess an agent that is not justified by prophylactic, protective, bona fide research or other peaceful purposes.” This law also specifies certain categories of “restricted persons” who are prohibited from access to select agents altogether, such as citizens of countries on the State Department’s list of states that sponsor terrorism, as well as individuals with a criminal record, unlawful users of controlled substances, illegal aliens, those previously admitted to a mental institution, and fugitives from the law.

8. The ATCC has introduced measures to improve the security of its distribution practices, and adhere to national and international regulations and best practices. For example, the transfers of its biological materials are now governed by Material Transfer Agreements (MTA), which allow ATCC to track materials to a specific end user; the ATCC also specifies that the “purchaser is solely responsible for compliance with all foreign and domestic, federal, state, and local statutes, ordinances and regulations applicable to use of the biological materials.”

9. The Organization for Economic Cooperation and Development (OECD) has been very active in addressing biosecurity in culture collections. Since 2001, the OECD has been working toward the establishment of a global network for biological resource centers (BRCs), or “facilities that house, control, test or use biological materials,” that abides by harmonized national standards and regulations to ensure availability of rare biological resources to legitimate scientists and institutions and free exchange of microbial cultures, to prevent illegitimate individuals from acquiring organisms for malicious purposes. In February 2007, OECD Best Practice Guidelines for Biological Resource Centers⁹ was published. In general, this report presents a series of best practices or guidance for the management of biological resource centers (culture collections). This document states that all participants should adhere to a system that

⁸ Carus WS. Bioterrorism and Biocrimes: The illicit use of biological agents since 1900. Washington, D.C.: Center for Counterproliferation Research, National Defense University, 2001.

⁹ *OECD Best Practice Guidelines for Biological Resource Centers*, <http://www.oecd.org/dataoecd/7/13/38777417.pdf>

ensures biological quality and security; the benefits of the network should only be accessible to those collections that meet these requirements.

10. Globally, there have been improvements in security of those culture collections that contain dangerous pathogens. (Many culture collections do not in fact contain dangerous pathogens.) However, very little is known about the status of biosecurity in most culture collections around the world. In reality, most of the biological material is exchanged in culture collections that are not commercial suppliers, but rather are small, unregulated laboratories that may not be aware of any regulations or security implications, and whose activity is not monitored or subject to oversight. While stricter regulations have been enacted by some countries, many culture collections may be vulnerable targets for those who seek to acquire characterized pathogens or toxins for malicious use. Much work remains for states to establish necessary oversight of facilities holding dangerous pathogens and for the international community to increase its cooperative efforts to promote security of such facilities wherever they are located.
