Working Group on Strengthening the Biosecurity of the United States
Public Consultation Meeting

Hyatt Regency- Bethesda
7400 Wisconsin Ave
One Bethesda Metro Center
Bethesda, MD 20814
May 13-14, 2009

Agenda

Wednesday – May 13

8:30 a.m. **Welcome and Opening Remarks**
Jean D. Reed, Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense and Chemical Demilitarization

8:45 a.m. **Introduction to EO 13486 and the Working Group on Strengthening the Biosecurity of the United States**
Carol D. Linden, Ph.D., Principal Deputy Director, Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

9:15 a.m. **Evolution of Biosecurity**
Jennifer Gaudioso, Ph.D., Technical Staff, International Biological Threat Reduction Program Sandia National Laboratories

10:00 a.m. *Break*

10:15 a.m. **Panel I –Select Agent Regulations**

Moderator: *Freeda E. Isaac, D.V.M. Director, Live Animals, Organisms and Vectors, Select Agents Technical Trade Services Team, National Center for Import/Export, Animal and Plant Health Inspection Service, U.S. Department of Agriculture*

Background:
The possession, use, and transfer of biological agents and toxins that have the potential to pose a severe threat to public health and safety, or animal and plant health and animal and plant products are regulated by HHS and USDA under the *Select Agent Regulations*. In determining whether to include an agent on the Select Agent List, the *Bioterrorism Act* requires that HHS and USDA consider the effect on human health after exposure to the agent or toxin; the effect of exposure to the agent or toxin on animal or plant health, and on the production and marketability of animal or plant products; the infectivity and means of transmission of the agent or toxin to humans; the pathogenicity of the agent or the toxicity of the toxin and the methods by which the agent or toxin is transferred to animals or plants; the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; any other criteria that the Secretary of HHS deems appropriate to protect public health and safety; and any other

criteria that the Secretary of Agriculture deems appropriate to protect animal or plant health or animal or plant products.

The Working Group is seeking individual input on the following questions:

Discussion questions:

- Has the purpose and content of the Select Agent list supported enhancement of biosecurity?
- Are the current select agent regulations sufficiently comprehensive and effective?
- Should the current select agent regulations move away from performance standards to more specific prescriptive standards?
- Do you see any value in a stratification of select agents by risk? If so, which aspects of the current select agent regulations would be most amenable to a stratified approach? Do you currently utilize a stratified approach with the select agents in your facility?
- Do you have access to all select agent registered space in your facility? Do you believe that you have sufficient authority within your organization to effectively implement the select agent regulations?
- Do you find the Security Risk Assessment system currently in use by the federal select agent Program to be effective? If so, why; and if not, why not?
- What type of inventory system do you have in place to maintain for your select agent materials in long term storage? Do you use a centralized database, or separate databases for each principal investigator? Are you satisfied with the current guidance from the CDC/APHIS Select Agent Programs on long term storage? If not, how might this guidance be improved?

Panelists

Ronald M. Atlas, Ph.D., Professor of Biology and Co-director of the Center for the Deterrence of Biowarfare and Bioterrorism, University of Louisville

Gigi Kwik Gronvall, Ph.D., Senior Associate, Center for Biosecurity of UPMC, Assistant Professor of Medicine, University of Pittsburgh

Laura Kahn, M.D., M.P.H., M.P.P., Research Staff, Program on Science and Global Security, Princeton University

Stephen A. Morse, Ph.D., Associate Director of Science, Division of Bioterrorism Preparedness and Response and Director of the Environmental Microbiology Program, U.S. Centers for Disease Control and Prevention

Discussion

12:00 p.m. *Lunch*

1:00 p.m.

Panel II – Physical/Facility Security at Select Agent Program Entities

Moderator: *Pamela Monroe, Office of the Under Secretary of Defense for Intelligence, Office of Security, U.S. Department of Defense*

Background: The *Select Agent Regulations* require that all entities that possess, use and/or transfer select agents and toxins develop *site specific written security plans* that describe how select agents and toxins in their possession are to be safeguarded against unauthorized access, theft, loss, or release. The *Bioterrorism Act* and the *Agricultural Bioterrorism Act* require respectively, the Secretaries of HHS and USDA to by regulation "[E]stablish and enforce safeguard and security measures to prevent access to listed agents and toxins for use in domestic or international terrorism or for any other criminal purpose." *[42 U.S.C. §262a(b)(2), 7U.S.C. §8401(b)(2)]*

The Task Force is seeking individual input on the following questions:

Discussion questions:

- The *Select Agent Regulations* provide a broad requirement that allows physical security requirements to be interpreted by individual or entity. Should the Federal government develop baseline prescriptive physical security requirements (e.g., minimum criteria for structure, facility entrance, interior, security systems, security operations, and administration) based on categorized risk or facility category?
- The *Select Agent Regulations* require development and implementation of a written security plan and require security plans to be designed according to site-specific risk assessments. Are there additional tools or guidance documents that would be helpful to you?
- The *Select Agent Regulations* require drills and exercises to be conducted at least annually to evaluate the written security plan. Is this adequate?

Panelists

William T. Porter, J.D., Director, Office of Security and Emergency Preparedness, U.S. Centers for Disease Control and Prevention

Robert L. Rice, Security Program Officer, Agriculture Select Agent Program, Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture

Austin Smith, Executive Director, Interagency Security Committee, U.S. Department of Homeland Security

Thomas Williams, Director of Operations and Security, Walter Reed Army Institute of Research, U.S. Department of Defense

Discussion

3:00 p.m. *Break*

3:15 p.m. **Panel III – Oversight and Inspection of Select Agent Facilities**

Moderator: *Charles L. Divan, PhD, Senior Agricultural Microbiologist, Agriculture Select Agent Program, U.S. Department of Agriculture*

Background: All entities possessing select agents or toxins are subject to inspection, prior to the issuance of a Certificate of Registration to (1) verify that the facility is accurately represented by the information submitted by the entity to the select agent program, and (2) has in place the procedures and processes necessary to ensure compliance with the *Select Agent Regulations.* In addition to an initial inspection during the application process, every entity may also be inspected during the Certificate of Registration renewal process. Additionally, inspections may be conducted when: 1) modifications are made to the entity's application; 2) a new building or laboratory is added to the registered areas; 3) a higher-risk agent/toxin is added; 4) a change is made in security infrastructure or policy and procedures; 5) a theft, loss, or release incident occurs; and/or 6) a regulatory violation is reported. The *Select Agent Regulations* also permit unannounced inspections (42 C.F.R. § 73.18(a), 9 C.F.R. § 121.18(a), 7 C.F.R. § 331.18(a)). Entities possessing select agents or toxins may experience additional inspections by third parties outside of the select agent program.

The Working Group is seeking individual input on the following questions:

Discussion questions:

- Is the current inspection regimen by the Select Agent Program effective?
- Are inspection programs in need of improvement? If so, are there recommendations for improvement?
- Is there additional guidance that would be helpful to prepare for program reviews and facility inspections?
- How many other "third party" inspection groups have visited your facility, in addition to either the CDC or APHIS Select Agent programs?
- If you've had multiple inspections by various federal government agencies, do you have any thoughts on how these inspections could be better coordinated?
- Do you have recommendations for approaches to enhance institutional implementation, compliance, oversight and accountability?

Panelists

Todd Blose, Chief, Technical Inspections Division, Army Inspector General, U.S. Department of Defense

Michael Ehret, Regional Vice President and Director of Mid-Atlantic Operations, Midwest Research Institute

Richard Henkel, Ph.D., Chief of Policy and Compliance, Division of Select Agents and Toxins, Coordinating Office for Terrorism Preparedness and Emergency Response, U.S. Centers for Disease Control and Prevention

Bruce Whitney, Ph.D., Biological Safety Officer/ Responsible Official, Division of Research and Graduate Studies, Texas A&M University

Discussion

4:30 p.m. Public Comments

5:00 p.m Adjourn

Thursday – May 14

8:30 a.m. Welcome
Carol D. Linden, Ph.D., Principal Deputy Director, Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

8:45 a.m.

Panel IV – Transportation of Select Agents

Moderator: *Bob Richard, Pipeline and Hazardous Materials Administration, U.S. Department of Transportation*

Background: Infectious substances and the materials known or suspected to contain them are regulated as Division 6.2 (infectious) hazardous materials by DOT, under the Pipeline and Hazardous Materials Administration (PHMSA) *Hazardous Materials Regulations* (*HMR*; 49 CFR Parts 171-180). The *HMR* requirements are patterned after those in international transport regulations and include safety and security requirements for the transportation of infectious substances including select agents. DHS's Transportation Security Administration (TSA) recently issued highway security action items that pertain to select agents. TSA will provide an overview of these new requirements. The panel will discuss current regulations that apply to the secure transportation of select agents, potential vulnerabilities, challenges and recommendations for enhancing security while balancing the potential impact on the carrier community.

The Working Group is seeking individual input on the following questions:

Discussion questions:

- Are there vulnerabilities that exist for select agents during transportation? If so, how can they be addressed?
- What challenges do carriers currently face and how might additional security requirements and controls impact their business decision to accept and transport select agents?
- Are the chain of custody requirements sufficient and how are lost or mis-directed shipments handled?
- Should packages containing select agents be packaged or labeled differently than other infectious agents?
- At what point should facilities be held responsible for package? For example, at time of receipt at entity (e.g., shipping area) or at laboratory?
- Are there additional tools and guidance that would be helpful related to the transportation of select agents?
- Should there be a registration program for carriers?

Panelists
Bud Hunt, Chief of Threats, Vulnerabilities and Consequences Branch, Highway and Motor Carrier Programs Office, Office of Transportation Sector Network Management, Transportation Security Administration, U.S. Department of Homeland Security

Lori J. Bane, Compliance Officer, Division of Select Agents and Toxins, U.S. Centers for Disease Control and Prevention

David Littlejohn, Corporate Safety Advisor, FedEx Express

Patrick Oppenheimer, Senior Manager, Safety Programs, Safety Health and Fire Prevention, FedEx Express

Robert L. Rice, Security Program Officer, Agriculture Select Agent Program, Animal and Plant Health Inspection Service, U.S. Department of Agriculture

Discussion

10:15 a.m. *Break*

10:30 a.m.

Panel V – Personnel Security/Reliability Programs

Moderator: *Kenneth A. Cole, Ph.D., Medical Director, Office of the Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense and Chemical Demilitarization Programs, U.S. Department of Defense*

Background: Security procedures at entities with select agents are intended to prevent the theft, loss, or release of an agent from the laboratory. Personnel with access to select agents must be reviewed by the FBI through a Security Risk Assessment (SRA), to ascertain whether they meet certain criteria which would preclude them from inclusion in the Select Agent Program. While the criteria for exclusion are very specific, they do not eliminate the risk posed by an "insider threat." Personnel reliability programs (PRP) are used in other fields, such as nuclear and chemical research programs, to ensure that individuals with access are trustworthy, reliable, and physically and mentally competent. Depending on the type of PRP implemented, components can be voluntarily applied at the local level or mandated nationally to include background checks, credit checks, medical and psychological investigations, random drug testing and polygraph tests. Such a program may require additional staff and resources at the institution to manage the process, and consideration must be given to the additional value and potential loss of scientific progress imposed by any program. While no PRP can completely mitigate the risk of the insider threat, certain steps may be taken to reduce the intentional misuse of biological materials and enhance public confidence in the biodefense research enterprise.

The Working Group is seeking individual input on the following questions:

Discussion questions:

- What type of background investigations, if any, do you do that go beyond those required for compliance with the Select Agent regulations?
- Do you have a Personnel Reliability Program (PRP)? If so, what elements does it contain and who runs it? Do you have a Certifying Official, or equivalent, for your PRP?
- How effective has your PRP been in preventing potential thefts, losses, or release of select agents?

- Do you utilize the "Two person rule"? Do you believe it is of value to your safety or security plans?
- Should extant frameworks for personnel reliability be applied to all select agent research?
- What is the optimal framework for ensuring personnel reliability in a manner that balances the needs for both biosecurity and rapid progress in the life sciences?
- What are the features of an optimal PRP?
- What are the costs of implementing a PRP?
- What are the risks and benefits associated PRP?
- What metrics should be used for evaluating PRPs?

Panelists

Jean L. Patterson, Ph.D., Chair, Department of Virology & Immunology, Southwest Foundation for Biomedical Research

Gregory Saathoff, M.D., Executive Director, Critical Incident Analysis Group, Associate Professor of Research in Psychiatry and Neurobehavioral Sciences, and Associate Professor of Emergency Medicine, University of Virginia

John Humpton, Combating WMD and Proliferation Policy Division G-3/5/7, Headquarters, Department of the Army, U.S. Department of Defense

Murray Cohen, Ph.D., M.P.H., President and Chairman, Frontline Healthcare Workers® Safety Foundation, Ltd.

James LeDuc, Ph.D., Professor, Microbiology and Immunology, Robert E. Shope Chair in Global Health, Director, Program on Global Health, Institute for Human Infections and Immunity, Associate Director, Galveston National Laboratory, University of Texas Medical Branch

Discussion

12:00 p.m. *Lunch*

1:00 p.m. **Panel VI – Culture of Security and Responsibility and Biosecurity Training Programs**

Moderator: *Peter B. Jahrling, Ph.D., Director, Office of the Chief Scientist, Integrated Research Facility, National Institute of Allergy and Infectious Diseases, National Institutes of Health*

Background: Any biosecurity program that is implemented must be done in such a way that it does not unduly burden the researcher or prevent quality research from progressing. For this reason, we need to work within a culture of responsibility and security whereby researchers understand why they're being asked to increase security precautions and awareness. Important components of this discussion include thoughts about implementations of different procedures discussed here over the last two days, the sharing of best practices among institutions, and training in methods related to high and maximum containment level work and security policies and practices.

The Working Groups seeking individual input on the following questions:

Discussion questions:

- What resources would institutions need to implement some of the activities discussed at this meeting?
- How do you currently share best practices regarding safety and security among institutions?
- Do you feel you have enough technical and financial support from Federal agencies to successfully follow Select Agent regulations and any future guidelines set forth on security?
- How many hours of training do employees have to undergo before being allowed access to select agents and toxins? What resources are used in the design of the training module?
- Should minimum competency and biosecurity training standards be developed for all personnel who work in, oversee, or manage high and maximum containment research laboratories? If so, who should develop these standards?
- Are there sufficient training opportunities for personnel in high and maximum containment laboratories to ensure effective biosecurity training of current and projected staff?
- What are the current training practices related to biosecurity at both federal and non-federal institutions?

Panelists

Vickie Sutton, M.P.A, Ph.D., J.D., Robert H. Bean Professor of Law, Director, Center for Biodefense, Law and Public Policy, Director, Law and Science Certificate Program and The JD/MS Program in the Life Sciences, Texas Institute of Environmental and Human Health, Texas Tech University School of Law

Ronald M. Atlas, Ph.D., Professor of Biology and Co-director of the Center for the Deterrence of Biowarfare and Bioterrorism, University of Louisville

Bob Hawley, Senior Advisor, Center for Biological Safety and Security (CBS2), Midwest Research Institute

Debra Sharpe Director, Compliance and Security, Southern Research Institute, President, BioSafety Solutions, LLC

Discussion

2:30 p.m. Public Comments

3:00 p.m. Wrap-up and Concluding Remarks

3:15 p.m. Adjourn