

**THE WHITE HOUSE**

WASHINGTON

August 18, 2014

MEMORANDUM FOR DEPUTY SECRETARY OF STATE  
DEPUTY SECRETARY OF DEFENSE  
DEPUTY ATTORNEY GENERAL  
DEPUTY SECRETARY OF AGRICULTURE  
DEPUTY SECRETARY OF TRANSPORTATION  
DEPUTY SECRETARY OF COMMERCE  
DEPUTY SECRETARY OF HEALTH AND HUMAN SERVICES  
DEPUTY SECRETARY OF ENERGY  
DEPUTY SECRETARY OF VETERANS AFFAIRS  
DEPUTY SECRETARY OF HOMELAND SECURITY  
DEPUTY ADMINISTRATOR OF THE ENVIRONMENTAL  
PROTECTION AGENCY  
PRINCIPAL DEPUTY DIRECTOR OF NATIONAL INTELLIGENCE  
DEPUTY DIRECTOR OF THE NATIONAL SCIENCE FOUNDATION  
DEPUTY DIRECTOR OF INTERIOR  
ASSISTANT ADMINISTRATOR OF THE UNITED STATES AGENCY  
FOR INTERNATIONAL DEVELOPMENT  
VICE CHAIRMAN OF THE JOINT CHIEFS OF STAFF  
DEPUTY DIRECTOR OF THE FEDERAL BUREAU OF  
INVESTIGATION

SUBJECT: ENHANCING BIOSAFETY AND BIOSECURITY IN THE  
UNITED STATES

It is essential for the United States Government to conduct life sciences research to prevent, detect, and respond to infectious disease threats posed by natural events or deliberate acts of bioterrorism. It is also the government's responsibility to ensure that infectious disease research in the United States is conducted safely and securely. The United States Government has acted swiftly to address three recent U.S. biosafety and biosecurity incidents. To improve U.S. preparedness for such threats and incidents, it is imperative that infectious disease researchers: (1) conduct a comprehensive review of current biosafety and biosecurity protocols and procedures to ensure they are adequate and appropriate for today's infectious disease research; (2) inventory and document their culture collections; and (3) increase attentiveness throughout the research community

to ensure the safety of laboratory researchers and the American public. To maximize the positive effect of lessons learned from the recent incidents, we are urging all United States Government departments and agencies that work with infectious agents to take immediate and long-term steps to enhance safety and security of research to minimize the potential for future incidents. While immediate action is necessary, United States Government departments and agencies are also urged to continuously review, implement and where appropriate, refine sustainable stewardship practices for biosafety and biosecurity.

#### **Immediate Steps:**

- Within 30 days of the release of this memorandum, all United States Government departments and agencies that operate facilities that possess, use, or transfer human, animal, or plant infectious agents or toxins are urged to perform a "Safety Stand-Down." During the Safety Stand-Down period, senior leaders will devote significant, dedicated time to review laboratory biosafety and biosecurity best practices and protocols, as well as to develop and implement plans for sustained inventory monitoring. Senior leaders should confer with local and agency management and staff to identify opportunities for improving research safety and local oversight systems. In practical terms, this review may take place over several days to ensure that scientific endeavors and clinical care are not adversely affected and to permit safe and efficient laboratory management. Leaders should use this Safety Stand-Down to kick-off an immediate sweep of their facilities that possess, use, or transfer human, animal, or plant infectious agent or toxin holdings to identify Biological Select Agents and Toxins (BSAT)<sup>1</sup> and ensure their proper registration, safe stewardship, and secure storage or disposal [Tab A]<sup>2</sup>. United States Government departments and agencies have agreed to complete this sweep by October 1, 2014.

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<sup>1</sup> See 42 CFR §§ 73.3, 73.4; 9 CFR §§ 121.3, 121.4; and 7 CFR § 331.3

<sup>2</sup> In accordance with Federal regulations (see 42 CFR §§ 73.5, 73.6, 73.9; 9 CFR §§ 121.5, 121.6, 121.9; and 7 CFR §§ 331.5, 331.9), departments and agencies will notify the appropriate authorities if any BSAT is located out of regulatory control. Any identified BSAT that requires movement will be reported to the Federal Select Agent Program in accordance with Federal regulations (see <http://www.selectagents.gov/CDForm.html>), transferred in accordance with Federal regulations (see <http://www.selectagents.gov/TransferForm.html>); and, where appropriate, transported in accordance with Department of Transportation Hazardous Material Regulations (49 C.F.R. parts 171-180.)

- Extramural facilities receiving United States Government funding that possess, use, or transfer human, animal, or plant infectious agents or toxins are encouraged to hold similar events and should be supported in these activities by United States Government departments and agencies to the greatest extent possible, such as by providing instructional materials on safety and security best practices. Departments and agencies providing funding to extramural facilities have agreed to coordinate to provide uniform guidance.
- Department and agency officials who are responsible for oversight of infectious disease research programs or who have safety oversight responsibilities, but are not part of a laboratory facility, are urged to participate in the Safety Stand-Down to demonstrate their commitment, and that of their organization, to safety and security.
- Departments and agencies are urged to provide written documentation of activities taken in support of the aforementioned objectives to the Interagency Policy Committee on BSAT by October 15, 2014. Departments and agencies are urged to provide progress reports, including any identified corrective actions or barriers to success, to National Security Council (NSC) and Office of Science and Technology Policy (OSTP).

#### **Longer-Term Efforts to Improve Biosafety and Biosecurity**

##### **Measures:**

To strengthen United States Government oversight for work with pathogens, including BSAT, we are establishing parallel Federal and non-Federal reviews that will result in specific recommendations to strengthen the government's biosafety and biosecurity practices and oversight system for Federally funded activities, consistent with the need to realize the public, animal, and plant health and security benefits of such work. These United States Government-wide reviews will be coordinated with reviews initiated independently by the Department of Health and Human Services.

- Federal: United States departments and agencies have agreed to conduct a coordinated Federal review through an existing interagency committee to identify needs and gaps and make recommendations to optimize biosafety, biosecurity, oversight, and inventory management and control for BSAT and identify actions and any regulatory changes necessary to improve biosafety and biosecurity. The committee will build on

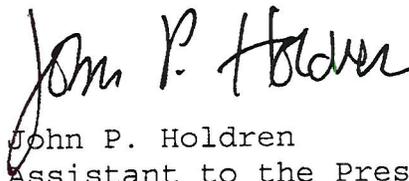
recommendations from previous reports made by and for the Federal government on biosafety and biosecurity, corrective actions identified as a result of the Safety Stand-Down, and the after-action assessments from the three recent U.S. biosafety and biosecurity incidents. The committee will also identify an approach to determine the appropriate number of high-containment U.S. laboratories required to possess, use, or transfer BSAT. United States Government departments and agencies have agreed that the committee will provide a set of recommended actions to the Assistant to the President for Homeland Security and Counterterrorism and the Assistant to the President for Science and Technology within 90 days of the receipt of this tasking.

- Broad Stakeholder Engagement: In response to the three recent U.S. biosafety and biosecurity incidents, the National Science and Technology Council (NSTC) will establish an interagency group to conduct a comprehensive review of the impact that the Select Agent Regulations (SAR) have had on science, technology, and national security. The group should include in its review an analysis of benefits, costs, and limitations of the SAR, as well as offer recommendations to address any identified challenges or gaps. To support this process, the NSTC will convene a public meeting of SAR stakeholders to inform and support the NSTC-led process. The NSTC body will be identified or created within 30 days of the date of this memorandum and will provide recommendations directly to the Assistant to the President for Science and Technology within 180 days of identification.
- Global: The United States will promote transparency concerning the recent biosafety and biosecurity incidents. This will include:
  - Developing a clear and consistent message to international partners for deployment bilaterally by individual agencies and programs, which deliver biological assistance. This message will describe U.S. biorisk management "lessons learned" and highlight the prompt U.S. action taken to address the recent U.S. biosafety and biosecurity incidents;
  - Utilizing multilateral venues, including the Global Health Security Agenda (GHS), the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction, and the Biological Weapons Convention, to promote transparency, address potential international concerns, and, as appropriate, encourage similar actions; and

- In the context of the GHSA, the United States will commit to achieve domestically the objective, "Promoting national biosafety and biosecurity systems," consistent with the target that we have set for our international engagement to include:
  1. A whole-of-government national biosecurity system is in place that ensures collections of especially dangerous pathogens are identified, held, secured and monitored in a minimal number of facilities with biosafety and biosecurity best practices in place;
  2. Biorisk management training and educational outreach is conducted to promote a shared culture of responsibility, reduce dual use biological risks and ensure safe transfer of biological agents; and
  3. Country-specific biosecurity legislation, laboratory certification, and pathogen control measures are in place, as appropriate.



Lisa O. Monaco  
 Assistant to the President for  
 Homeland Security and  
 Counterterrorism



John P. Holdren  
 Assistant to the President for  
 Science and Technology

Attachment

Tab A Guidance on Select Agent Reporting

cc:

Assistant to the President and Counsel to the President  
 Assistant to the President and Deputy Chief of Staff for Policy  
 Assistant to the President and Director of the Domestic Policy  
 Council  
 Assistant to the President and Director of the Office of  
 Legislative Affairs  
 Deputy Assistant to the President and National Security Advisor  
 to the Vice President  
 Associate Director for National Security Programs of the Office  
 of Management and Budget

## Federal Select Agent Program

# Select Agents are Reportable

### Select Agents and Toxins

Abon  
Botulinum neurotoxins  
Botulinum neurotoxin producing species of *Clostridium*  
Conotoxins (Short, paralytic alpha conotoxins)  
*Coxsackie burnetii*  
Cinmean-Congo haemorrhagic fever virus  
Diacetoxyscirpenol  
Eastern Equine Encephalitis virus<sup>1</sup>  
Ebola virus  
*Francisella tularensis*  
Lassa fever virus  
Lujjo virus  
Marburg virus  
Monkeypox virus

Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)

Ricin  
*Rickettsia prowazekii*  
SARS-associated coronavirus (SARS-CoV)  
Saxitoxin

South American Haemorrhagic Fever viruses:  
Chapare  
Guanarito  
Junin  
Machupo  
Sabia

Staphylococcal enterotoxins A,B,C,D,E subtypes  
T 2 toxin  
Tetrodotoxin

Tick-borne encephalitis complex (flavi) viruses:  
Far Eastern subtype  
Siberian subtype

Kyasanur Forest disease virus  
Ornsk hemorrhagic fever virus  
Variola major virus (Smallpox virus)  
Variola minor virus (Alastrim)  
*Yersinia pestis*

*Bacillus anthracis*  
*Bacillus anthracis* Pasteur strain  
*Brucella abortus*  
*Brucella melitensis*  
*Brucella suis*  
*Burkholderia mullii*  
*Burkholderia pseudomallei*  
Hendra virus  
Nipah virus  
Rift Valley fever virus  
Venezuelan equine encephalitis virus  
African horse sickness virus  
African swine fever virus  
Avian influenza virus  
Classical swine fever virus  
Foot and-mouth disease virus  
Goat pox virus  
Lumpy skin disease virus  
*Mycoplasma capricolum*  
*Mycoplasma mycoides*  
Newcastle disease virus  
Peste des petits ruminants virus  
Rinderpest virus  
Sheep pox virus  
Swine vesicular disease virus  
*Peronosclerospora philippinensis* (*Peronosclerospora sacchari*)  
*Phoma glycicola* (formerly *Pyrenochaeta glycine*)  
*Ralstonia solanacearum*  
*Rhizobacter toxicum*  
*Sclerotinia rotinaria*  
*Synchytrium endobioticum*  
*Xanthomonas oryzae*

## What To Do If You Encounter A Select Agent

### What is a Select Agent or Toxin?

Select agents and toxins are biological agents and toxins that could pose a severe threat to public health, animal and plant health, or to animal or plant products. The U.S. list of Select Agents and Toxins is maintained by the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS), and are found in the select agent regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331).

### What to do?

- Immediately contain the select or toxin in a location to ensure the safety and security of the material.
- Immediately contact the Federal Select Agent Program to report the findings and wait for further instructions.

Animal and Plant Health Inspection Service  
Agriculture Select Agent Services  
Email: [AgSAS@aphis.usda.gov](mailto:AgSAS@aphis.usda.gov)  
Phone: 301-851-3300 (option 3) (Normal business hours Mon - Fri)

Centers for Disease Control and Prevention  
Division of Select Agents and Toxins  
Email: [Irsat@cdc.gov](mailto:Irsat@cdc.gov)  
Phone: 404-718-2000 (Normal business hours Mon - Fri)

- Secure the location where the material was discovered until such a time as it can be reviewed by safety and law enforcement personnel. If any suspicious activity is observed that may pose a risk to the security of the facility, its personnel, or the select agents or toxins, please immediately notify the FBI Weapons of Mass Destruction Coordinator. For information on the coordinator please call (202) 323-3300 or visit <http://www.fbi.gov/contact-us/field>.
- After material has been tested and a select agent or toxin identified, the institution should submit the APHIS/CDC Form 4, Report of the Identification of a Select Agent or Toxin within 7 calendar days to the Federal Select Agent Program.

For more information about the Federal Select Agent Program, go to [www.selectagents.gov](http://www.selectagents.gov).

