

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)¹ and ensure their proper registration, safe stewardship, and secure storage or disposal [Tab A]². United States Government departments and agencies have agreed to complete this sweep by October 1, 2014.

¹ See 42 CFR §§ 73.3, 73.4; 9 CFR §§ 121.3, 121.4; and 7 CFR § 331.3

² 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

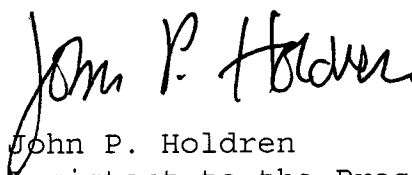
recommendations from previous reports made by and for the Federal government on biosafety and biosecurity, corrective actions identified as a result of the Safety Stand-Down, and the after-action assessments from the three recent U.S. biosafety and biosecurity incidents. The committee will also identify 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 (GHSA), 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

Abrin
Botulinum neurotoxins
Botulinum neurotoxin producing species of *Clostridium*
Conotoxins (Short, paralytic alpha conotoxins)
Coxsackie burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxycirpenol
Eastern Equine Encephalitis virus¹
Ebola virus
Francisella tularensis
Lassa fever virus
Lujo 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
Omsk hemorrhagic fever virus
Variola major virus (Smallpox virus)
Variola minor virus (Alastrim)
Yersinia pestis

Bacillus anthracis
Bacillus anthracis Pasteur strain
Brevetia abortus
Brevetia melitensis
Brevetia suis
Burkholderia mallei
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 glycimicola (formerly *Pyrenochaeta glycines*)
Ralstonia solanaceorum
Rathayibacter toxicus
Sclerotinia reyesiae
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

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

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.

