December 16, 2014

FACT SHEET: Biosafety and Biosecurity in the United States

In the summer of 2014, lapses in biosafety practices in Federal laboratories served as a reminder of the importance of constant vigilance over the implementation of biosafety standards.

As a result of these biosafety lapses, on August 18, 2014, Assistant to the President for Homeland Security and Counterterrorism Lisa Monaco and Assistant to the President for Science and Technology John Holdren issued a memorandum, titled, "*Enhancing Biosafety and Biosecurity in the United States*," which urged 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. All United States Government departments and agencies that possess, use, or transfer human, animal, or plant infectious agents or toxins were urged to perform a Safety Stand-Down, to include an immediate sweep of their facilities to verify that all Biological Select Agents and Toxins (BSAT) in their possession were appropriately registered, stored, and disposed of in accordance with applicable regulations.

Departments and agencies provided written documentation of activities, including facility sweeps, comprehensive safety, security and inventory activities, and captured best practices and plans for systemic strengthening of biosafety oversight. These results are summarized below. Staff from across the United States Government embraced this effort. Going forward, the United States Government will support and reinforce this strong culture of responsibility, which is essential to protecting laboratory personnel and the public.

Overall findings
During the Safety Stand-Down, departments and agencies conducted sweeps at over 4,000 facilities across the United States and in U.S. facilities abroad, which included examining inventory and documentation for over 40 million samples. As a result of this comprehensive review, there were 27 instances in which BSAT materials, while safely and securely stored, were not properly registered with the United States Federal Select Agent Program (FSAP). In each instance, departments and agencies reported the adjudication and final disposition for the materials, and there were no indications of human exposure, including staff or the general public, to any of these agents or toxins. In accordance with standing protocol, the FSAP shared information about the select agent material that was identified during the Safety Stand-Down period with the Federal Bureau of Investigation (FBI), and none of the reported violations resulted in an FBI investigation.

Plans for Sustained Inventory Monitoring
As part of the Safety Stand-Down, departments and agencies were requested to report actions taken to improve inventory management practices and to identify excess biological agents and equipment for disposal. Examples include:

- The Food and Drug Administration (FDA) will implement a new data management system to facilitate automated inventory of long-term stored biological materials, creating a uniform inventory system at FDA that will document and monitor specimens maintained by FDA laboratories in a single database.

- The Centers for Disease Control and Prevention (CDC) is now implementing revised procedures to improve inventory management and will implement enhanced out-processing procedures for departing staff that will include accounting for samples put into storage during that person's tenure, to ensure proper subsequent disposition of samples.

- CDC's laboratories are also implementing an electronic inventory system for all diagnostic specimens, human and animal sera, and potentially hazardous biological materials requiring biosafety level-2 (BSL-2) or greater containment that are not BSAT.

- The National Institutes of Health (NIH) will develop a method to maintain inventories, institute spot checks during annual laboratory inspections, and develop a procedure for the transfer of ownership/responsibility for an inventory should a researcher leave the NIH facility. Quality assurance is an important purpose of these activities, which will aim to validate initial findings and to ensure nothing was missed during the first phase of the inventory.

- Department of Defense (DOD) laboratory leadership re-assessed biosafety and biosecurity operating procedures, training, and inventory management practices, and many DOD laboratories have decided to increase the frequency of their inventory sweeps and add monitoring of inventory sweeps to their quality control programs.

- The Department of Homeland Security (DHS) has updated inventory software and is evaluating additional ways to improve the effectiveness of inventory management going forward.

- The Department of Energy (DOE) improved standardization for elements of its inventory management process and DOE National Laboratories paused BSAT activities until a comprehensive sweep was conducted.

- As a result of rigorous effort to advance biosafety and inventory management, the Department of Commerce National Institute of Standards and Technology tracks all chemical and biological samples on campus and conducts an annual audit of the database contents.

In addition to reports received from federal agencies, the United States Government also received reports from entities outside of the federal government, which conducted independent inventory reviews during the 2014 Federal Safety Stand Down period, and some reported updates for training and inventory management and undertook campus-wide sweeps. The United States Government received 15 of these reports from 13 different organizations. In all cases, the FSAP worked with these organizations to ensure that all select agents and toxins discovered were either destroyed on site or transferred to an organization registered to possess select agents and toxins.

Comprehensive Review of Current Biosafety and Biosecurity Protocols
As a result of the Safety Stand-Down, departments and agencies are updating laboratory protocols and expanding training programs to advance best practices in biosafety and biosecurity. Examples include:

- An audit of all training records performed by the DHS National Biodefense Analysis and Countermeasure Center verified 100 percent completion of mandatory training and mentorship participation, and all staff at the Plum Island Animal Disease Center completed additional training even though no improperly stored BSAT was discovered.

- CDC ceased all transfers of biological materials from all BSL-3 and BSL-4 laboratories at all CDC facilities until each laboratory individually documented its practices and received approval to resume transfers of biological materials. In addition, CDC established an external workgroup to examine laboratory safety and security.

- NIH performed a review of NIH policies that govern the use of biological materials, and NIH will finalize a new manual chapter on internal biosafety and biosecurity policy to strengthen and enhance the oversight of high risk biological materials.

- The Department of Veterans Affairs (VA) convened a Biosafety and Biosecurity Advisory Group to identify best practices and areas for enhancement of the existing VA Research Safety and Security Programs, including an existing centralized system for reporting research noncompliance and/or unexpected adverse events and plans to clarify oversight for VA research conducted in non-VA facilities.

- The U.S. Department of Agriculture reported strengthened awareness about biosafety, biosecurity, and inventory management as a result of Safety Stand-Down, including participation from both management and staff.

- The Environmental Protection Agency (EPA) is evaluating procedural and operational enhancements to its existing laboratory-safety and security program. Currently, EPA laboratories are required to complete an annual safety, health and environmental self-assessment including the topics of proper handling, storage, inventory and disposal of infectious and hazardous materials.

- The FDA has established an agency-wide Laboratory Safety Policies and Practices Workgroup to conduct a comprehensive review of laboratory safety and security policies and procedures, including inventory management, identify and address any gaps in policies and procedures, and standardize safety and security practices across the agency's laboratories.

Opportunities for Improving Research Safety and Local Oversight Systems
Departments and agencies also hosted sessions with laboratory researchers and other staff to elicit input and to emphasize the importance of rigorously adhering to established practices for storing, handling, and working with infectious agents, toxins, and other biological derived materials. For example:

- During the month of September 2014, CDC, NIH, and FDA featured a National Biosafety Stewardship Month to raise awareness of activities undertaken during the Safety Stand-Down, and to promote safety programs and initiatives for all employees, including an HHS Safety Managers Meeting, a Biological Risk Mitigation Strategies online training course for 200 safety personnel, and provided laboratory-specific fora to elicit suggestions and concerns from staff regarding laboratory safety.

- The DHS Plum Island Animal Disease Center is implementing a program to track training requirements and completion, expanding information technology infrastructure to biocontainment areas for real-time select agent tracking, improving oversight of shared biosafety level 2 facilities and cold storage areas, and updating their security and laboratory access policies. DHS has also developed an "Accountability" module to be added to annual performance evaluations and appraisal trainings for supervisors.

- OSTP is coordinating across the interagency on the implementation of key actions called for in a memorandum sent by Assistant to the President for Science and Technology John Holdren in March 2014 to all departments and agencies that hold scientific collections, including infectious disease agents, including to develop a comprehensive electronic management policy and systems to improve collection, long-term preservation, and accessibility. Full federal implementation of this policy allows for transparent accountability of federally owned scientific collections and serves as platform for advancing inventory management and strengthening federal biosafety and biosecurity.

Next Steps to Implement Best Practices
Moving forward, departments and agencies will work to implement the lessons learned from the Safety Stand-Down, including:

- Identifying best practices to standardize electronic inventory documentation and management systems in BSAT and non-BSAT laboratories;
- Enhancing biosafety and biosecurity training for laboratory staff, leadership, students, and management;
- Clarifying policies regarding handling and disposition of remaining laboratory samples when researchers, staff members or trainees depart from positions overseeing BSAT; and
- Implementing mechanisms to designate responsible individuals to oversee samples stored in common storage areas, including for non-BSAT facilities.

In addition, the United States Government is conducting 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. Through the Federal Experts Security Advisory Panel (FESAP), the United States Government is conducting a coordinated Federal review to: 1) identify needs and gaps and make recommendations to optimize biosafety, biosecurity, oversight and inventory management and control for BSAT; 2) identify actions and any regulatory changes necessary to improve biosafety and biosecurity; and 3) identify an approach to determine the appropriate number of high-containment U.S. laboratories required to possess, use, or transfer BSAT. In addition, the National Science and Technology Council has established an interagency Fast Track Action Committee to conduct a comprehensive review of the impact that the Select Agent Regulations have had on science, technology, and national security. The recommendations from these reviews will inform future policy to advance biosafety and biosecurity. Finally, the United States Government is committed to advancing biosafety and biosecurity in the United States and around the world as an integral component of the Global Health Security Agenda (GHSA). The Ebola epidemic has highlighted the importance of this effort, and we will achieve – domestically and with partners around the world – the measurable target we have set forward through the GHSA to advance national biosafety and biosecurity systems.

2014 Federal Safety Stand Down: Summary of Biological Select Agent and Toxin Materials Reported to the Federal Select Agent Program

During the "Safety Stand Down" period, multiple government institutions identified biological select agents and toxins (BSAT) in areas not registered with the Federal Select Agent Program (FSAP). The FSAP is a collaboration between the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) and the Animal and Plant Health Inspection Service (APHIS) Agriculture Select Agent Services (AgSAS) to regulate the possession, use, and transfer of BSAT listed in 7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73 (select agents and toxins). In accordance with the select agent regulations, these discoveries were reported to the FSAP.

During the Safety Stand-Down, the FSAP received a total of 38 discovery reports from federal entities. Departments and agencies conducted sweeps at over 4,000 facilities across the United States and overseas, which included examining inventory and documentation for over 40 million samples. As a result of this comprehensive review, there were 27 instances in which BSAT materials, while safely and securely stored, were not properly registered with the United States FSAP. In each instance, departments and agencies reported the adjudication and final disposition for the materials, and there were no indications of human exposure, including staff or the general public, to any of these agents or toxins. All discovered BSAT were located in secure laboratory space with multiple layers of access control and there were no indications of human exposure to any of these agents or toxins. Many of the agents and toxins identified were from studies associated with personnel who have left their agencies and the custodianship of the samples was not reassigned. Some of these materials were labeled with obsolete pathogen names, while other material was found in laboratories where their active use had ceased, in some cases, decades prior to the establishment of the select agent regulations. All of these materials have been either safely destroyed on site or transferred to either registered areas or a registered facility. In accordance with standing protocol, the FSAP shared information about the select agent material that was identified during the Safety Stand-Down period with the Federal Bureau of Investigation (FBI), and none of the reported violations resulted in an FBI investigation.

Each report received by the FSAP is summarized in Table 1 below. As noted below, reports were received from agencies in the Department of Health and Human Services (HHS) including CDC, the National Institutes of Health (NIH), and Food and Drug Administration (FDA); the Department of Agriculture (USDA) Animal and Plant Health Inspection Services (APHIS); the Department of Veterans Affairs (VA); and the Interior Department's United States Geological Survey (USGS). No reports of discovery were received from any other federal department or agency.

Table 1. Confirmed Select Agents and Toxins* reported to the Federal Select Agent Program during the September 2014 Federal Safety Stand Down period.

*Sweeps were conducted at over 4,000 facilities, which included examining inventory and documentation for over 40 million samples.

Entity	Discovery Date	Discovered Agent or Toxin	Quantity (out of over 40 million samples examined)	Resolution of Sample	Indication of human exposure prior to or during BSAT discovery
CDC	9/17/2014	*Clostridium botulinum*	8 vials	Destroyed	No
CDC	9/17/2014	*Burkholderia pseudomallei*	1 vial	Transferred to registered laboratory	No
CDC	9/17/2014	*Brucella abortus, B. melitensis & B. suis*	6 vials	Destroyed	No

CDC	9/18/2014	*Francisella tularensis*	3 vials	Destroyed	No
CDC	9/25/2014	*Clostridium botulinum, Francisella tularensis, Bacillus anthracis, Yersinia, pestis, Burkholderia pseudomallei, B. mallei, Brucella abortus, B. melitensis & B. suis*	27 vials	Transferred to registered laboratory	No
CDC	9/26/2014	*Burkholderia pseudomallei, Clostridium botulinum, Brucella melitensis & B. suis*	14 vials	Transferred to registered laboratory	No
CDC	9/30/2014	*Bacillus anthracis, Burkholderia pseudomallei, Brucella abortus, and B. melitensis*	5 vials	Transferred to registered laboratory	No
CDC	9/30/2014	*Clostridium botulinum, Francisella tularensis, Bacillus anthracis, Burkholderia pseudomallei, B. mallei, Brucella abortus, B. melitensis & B. suis*	36 vials	Transferred to registered laboratory	No
FDA	7/15/2014	Staphylococcal enterotoxin	8 mg	Destroyed	No
FDA	9/7/2014	*Clostridium botulinum*	3 vials	Destroyed	No
VA Medical Center	9/3/2014	*Brucella melitensis*	1 vial	Destroyed	No
VA Medical Center	9/8/2014	*Brucella abortus*	1 vial	Destroyed	No
NIH	7/29/2014 8/11/2014	Botulinum neurotoxin	2 vials, 0.9 mg total	Destroyed*	No
NIH	8/14/2014	*Burkholderia pseudomallei*	2 vials	Destroyed*	No
NIH	8/27/2014	Ricin	5g	Destroyed*	No
USDA APHIS	9/11/2014	Botulinum neurotoxin	2 vials	Destroyed	No

USDA APHIS	9/17/2014	Avian influenza virus and Newcastle disease virus	2 vials	Destroyed	No
USDA APHIS	9/24/2014	Classical swine fever virus	13 vials	Destroyed	No
USDA APHIS	9/15/2014	*Brucella abortus*	10 vials	Destroyed	No
USDA APHIS	9/26/2014	Newcastle disease virus	1 vials	Transferred to registered laboratory	No
USGS	10/1/2014	Eastern Equine Encephalitis virus	1 bird	Destroyed	No
USGS	9/22/2014	Newcastle disease virus	Tissue from infected bird	Destroyed	No
USDA ARS	9/11/14	Avian influenza virus	1 vial	Destroyed	No
USDA ARS	9/11/14	Newcastle disease virus (Pigeon Paramyxovirus)	55	Transferred to registered laboratory	No
USDA ARS	9/15/2014	Ricin	13-20 g	Destroyed material to possess excluded amounts	No
USDA ARS	10/7/2014	T-2 Toxin	3766 mg	Destroyed material to possess excluded amounts	No
USDA ARS	10/3/2014	T-2 Toxin	1161 mg	Destroyed material to possess excluded amounts	No

* Previously publicly disclosed in 9/5/2014 midterm report

There were 11 reports of material that, upon investigation by the FSAP, were determined to not be a select agent or toxin. These materials included attenuated strains (previously rendered less pathogenic) that are excluded from the select agent and toxin regulations; strains that were contained in USDA or FDA licensed products; samples, such as antiserum, that were found to contain no agent or toxin; or toxins in amounts below the threshold for regulation. These reports are summarized in Table 2 below.

Table 2. Reports from federal agencies to the Federal Select Agent Program during the 2014 Federal Safety Stand Down period that were found upon subsequent investigation not to be select agents or toxins.

Entity	Discovery Date	Discovered Agent or Toxin	Quantity	Resolution of Sample
National Institutes of Health	8/19/2014	*Francisella tularensis & Yersinia pestis*	5 vials	Not select agent: excluded strain*
National Institutes of Health	8/26/2014	*Yersinia pestis*	1 vial	Not select agent: excluded strain*
USDA APHIS	9/9/2014	Foot-and-mouth disease virus & Classical swine fever virus	20 vials	Not select agent sample, does not contain agent

USDA APHIS	9/12/2014	Classical swine fever virus	16 vials	Not select agent sample, does not contain agent
USDA APHIS	9/24/2014	Classical swine fever virus	2 Vials	Not a select agent; USDA licensed vaccine
USDA ARS	9/9/2014	Ricin	0.9 mg	Not a select toxin: less than regulated amount (<100mg)
USDA ARS	9/9/2014	Diacetoxyscirpenol	3.2 mg	Not a select toxin: less than regulated amount (<1000mg)
USDA ARS	9/9/2014	Ricin	3.2 mg	Not a select toxin: less than regulated amount (<100mg)
USDA ARS	9/4/2014	*Ralstonia solanaceaurm*	1 vial	Not a select agent: excluded strain
USDA ARS	9/10/2014	*Ralstonia solanaceaurm*	10 vials	Not a select agent; excluded strains
USDA ARS	9/10/2014	*Ralstonia solanaceaurm*	10 vials	Not a select agent: excluded strains

* Publicly disclosed in 9/5/2014 midterm report, determined later to not be a select agent violation

In addition to reports received from federal agencies, the FSAP also received reports from proactive entities outside of the federal government who did their own inventory reviews during the 2014 Federal Safety Stand Down period. The FSAP received 15 of these reports from 13 different organizations. In all cases, the FSAP worked with these organizations to ensure that all select agents and toxins discovered were either destroyed on site or transferred to an organization registered to possess select agents and toxins. As with the federal entity discovery reports, these non-federal entity reports were referred to the FBI's Weapons of Mass Destruction Directorate per the standard protocol in order to assess whether there was any criminal or malicious activity associated with the finding; the FBI did not find any criminal activity.