



The United States Department of Agriculture (USDA)

and

**The United States Department of Health and Human Services
(HHS)**

**Report to Congress
on the
Notifications of Thefts, Losses, or Releases
of Select Agents and Toxins**

for Calendar Year 2014

February 2016

Report to Congress
on the Notifications of Thefts, Losses, or Releases of Select Agents and Toxins
January 1, 2014 - December 31, 2014

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) requires the Secretaries of Agriculture and Health and Human Services to report to Congress annually on the number and nature of notifications received concerning the theft, loss, or release of biological select agents and toxins (BSAT) regulated pursuant to section 351A (k) of the Public Health Service Act and section 212(k) of the Agricultural Bioterrorism Protection Act of 2002, respectively.

I. Overview

To meet the requirement of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188), the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (HHS) promulgated regulations (7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73) to require reporting of theft (unauthorized removal of BSAT), loss (failure to account for BSAT), or release (occupational exposure or release of BSAT outside of the primary barriers of the biocontainment area) of a BSAT. Given that the evidence of release of a biological incident may not be identified until a later date, USDA and HHS encourage regulated entities to report all laboratory incidents involving a BSAT as soon as possible.

Between January 1, 2014, and December 31, 2014, the select agent regulatory programs at USDA and HHS received 195 reports of a loss or release of a BSAT and zero reports of a theft of a BSAT in Calendar Year (CY) 2014. Follow-up investigations on the 195 reports identified:

- 10 reports of losses that met the regulatory criteria for a loss. USDA and HHS identified the cause of the failure of accountability for each loss. None of the losses resulted in a risk to public health; and
- 185 reports of release incidents, of which 168 incidents met the regulatory criteria for a release. Three of these incidents resulted in laboratory-acquired infections:
 - Two incidents involved three workers exposed; however, there was no evidence of transmission to other workers; and
 - One incident involved three non-human primates, and to date, no staff that worked with the animals has reported any symptoms or illness.

At the time of submittal of this report, there are no reports remaining under review by USDA and HHS for CY 2014. Of the 195 reports received, 103 reports were received from entities registered with USDA or HHS to possess, use, or transfer BSAT. The remaining 92 reports were received from clinical or diagnostic laboratories that were not required to be registered with USDA or HHS, but met conditions specified in the select agent regulations (exempt entities).¹

¹ Clinical or diagnostic laboratories and other entities that have identified select agents contained in a specimen presented for diagnosis, verification, or proficiency testing are required by the Select Agent Regulations to report this identification to USDA or HHS by completing APHIS/CDC Form 4 - Report of the Identification of a Select Agent or Toxin. In addition to the reporting requirement, the identified select agent must be secured against theft, loss, or release during the period between identification and final disposition. In the event that a release has occurred, the laboratories must report this release using APHIS/CDC Form 3 - Report of Theft, Loss, or Release of a Select Agent or Toxin.

It is important to note that USDA and HHS are looking into ways to improve transparency by releasing aggregate information associated with regulated entities in the Federal Select Agent Program. We believe the biosafety and security of research with select agents and toxins will be enhanced by greater information sharing and increased understanding by the public about why this work is done, what is done to ensure biosafety and security, and what violations and incidents mean in terms of risk to workers or the general public.

II. Reports of Losses (10 reports)

Of the 195 reports that USDA and HHS received, 10 reports stated the loss of (i.e., a failure to account for) a BSAT. USDA and HHS investigated each report and determined that each one met the regulatory criteria for a loss. USDA and HHS investigations also identified the cause of the failure of accountability for each loss. None of the losses resulted in a risk to public health. Please see below for a breakdown and description of the 10 reports based on the cause of the failure of accountability.

Cause	Number of Reports
Sample mistakenly discarded following appropriate biosafety procedures	6
Human error in accounting for materials	4
Total	10

Given that USDA and HHS identified the cause of the failure of accountability for each of the 10 losses, it was not necessary to refer any reports to the Federal Bureau of Investigation to determine whether deliberate theft or other criminal activity may have occurred.

III. Reports of Releases (185 reports)

USDA and HHS encourage regulated entities to take a proactive and vigorous response to any incident that has the potential to meet the regulatory criteria for a release (i.e., an occupational exposure or release of a BSAT outside of the primary barriers of the biocontainment area).

For CY 2014, USDA and HHS received 185 reports of releases. Of these, USDA and HHS found that 168 reports met the regulatory criteria for a release, and 17 reports did not meet the regulatory criteria for a release. These 17 reports involved spills of a BSAT inside of biocontainment laboratories; none of the spills resulted in the release of a BSAT outside of the primary barriers of the biocontainment area nor an occupational exposure. Therefore, the incidents did not meet the regulatory criteria for a release.

Please see below for a breakdown and description of the 168 reports that met the regulatory criteria for a release based on the cause of the release.

Cause	Number of Reports
Bite or scratch from an animal infected with a BSAT	7
Equipment or mechanical failure	3
Needle stick or other percutaneous exposure with possibly contaminated sharp objects	14
Failure or problem with personal protective equipment	14
Deviating from standard laboratory operating procedures, such as not checking personal protective equipment prior to entering the laboratory, not using secondary containers for transporting specimens from one point to another, and deviation from policy and training	6
Manipulating a BSAT outside of a biological safety cabinet or other type of equipment designed to protect laboratory workers from exposures to infectious aerosols	124
Total	168

Incidents Resulting in Laboratory-acquired Infection

Of the 168 reports of releases that met the regulatory criteria for a release, USDA and HHS confirmed that occupational exposure resulted in laboratory-acquired infection in three of them. Please see below for a description of each incident.

- 1) Two workers at a veterinary medical teaching hospital (exempt entity) were exposed to *Coxiella burnetii* and became ill with Q fever. USDA and HHS confirmed the release with serological testing.² Both workers were treated, made a full recovery, and returned to work with no restrictions. All potentially exposed individuals were notified of the potential exposure. There was no evidence of transmission to other workers.
- 2) A worker at a veterinary diagnostic hospital (registered entity) tested positive for *Coxiella burnetii* by serological testing during the annual screening process. Occupational health professionals monitored the worker for an extended period of time. The worker never demonstrated symptoms for Q fever and continues to perform daily work with no restrictions. All potentially exposed individuals were notified of the potential exposure. There was no evidence of transmission to other workers.

² Testing for presence of detectable, specific antibodies to microorganisms in the blood as a result of infection or immunization.



MAR 03 2016

The Honorable Kevin McCarthy
Majority Leader
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative McCarthy:

We are pleased to transmit to Congress the Report on Thefts, Losses, or Releases of Select Agents or Toxins as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). The Secretaries of the Departments of Health and Human Services (HHS) and Agriculture (USDA) must report to Congress annually on the number and nature of notifications received concerning the theft, loss, or release of biological agents or toxins regulated pursuant to that Act.

The regulations require all persons to notify either the HHS Secretary or USDA Secretary in the event of a theft, loss, or release of a listed select agent or toxin. USDA, HHS, and/or the Federal Bureau of Investigation investigate all notifications. The enclosed report includes notifications received of a theft, loss, or release of a select agent or toxin between January 1, 2014, and December 31, 2014.

Similar letters and copies of the report are being sent to Senators McConnell and Reid, Representatives Ryan and Pelosi, and Vice President Biden. We appreciate your continued support in this critical area of public, animal, and plant health and national security.

Sincerely,

A handwritten signature in cursive script that reads "Thomas J. Vilsack".

Thomas J. Vilsack
Secretary
Department of Agriculture

A handwritten signature in cursive script that reads "Sylvia M. Burwell".

Sylvia M. Burwell
Secretary
Department of Health and
Human Services

Enclosure



MAR 03 2016

The Honorable Joseph R. Biden, Jr.
President of the Senate
United States Senate
Washington, D.C. 20510

Dear President Biden:

We are pleased to transmit to Congress the Report on Thefts, Losses, or Releases of Select Agents or Toxins as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). The Secretaries of the Departments of Health and Human Services (HHS) and Agriculture (USDA) must report to Congress annually on the number and nature of notifications received concerning the theft, loss, or release of biological agents or toxins regulated pursuant to that Act.

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Sincerely,

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Thomas J. Vilsack
Secretary
Department of Agriculture

A handwritten signature in cursive script, appearing to read "Sylvia M. Burwell".

Sylvia M. Burwell
Secretary
Department of Health and
Human Services

Enclosure



MAR 03 2016



The Honorable Nancy Pelosi
Minority Leader
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Pelosi:

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Department of Health and
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MAR 03 2016



The Honorable Paul D. Ryan
Speaker of the House of Representatives
U.S. House of Representatives
Washington, D.C. 20515

Dear Speaker Ryan:

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Department of Health and
Human Services

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MAR 03 2016



The Honorable Harry Reid
Minority Leader
United States Senate
Washington, D.C. 20510

Dear Senator Reid:

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Similar letters and copies of the report are being sent to Senator McConnell; Representatives Ryan, McCarthy, and Pelosi; and Vice President Biden. We appreciate your continued support in this critical area of public, animal, and plant health and national security.

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MAR 03 2016



The Honorable Mitch McConnell
Majority Leader
United States Senate
Washington, D.C. 20510

Dear Senator McConnell:

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