DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

April 12, 2017

Mr. John Greenewald, Jr.
The Black Vault
[redacted]
Via email: john@greenewald.com

Dear Mr. Greenewald:

This letter is in response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of March 16, 2017, for copies of the Report to Congress on Thefts, Losses, or Releases of a Select Agent or Toxin E (2002 to present).

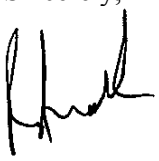
We located 38 pages of responsive records (38 pages released in full or in part). Please note that the 2006 report within the enclosed responsive record starts the reporting period of 2003. The 2006 report is from the earliest reporting period of February 7, 2003 to December 31, 2006. All other reports provided are for their individual respective calendar years. There is no current record yet for the 2016 Annual Report to Congress. Finally, we redacted information under 5 U.S.C. §552 (b)(3).

Exemption (b)(3) protects information that has been specifically exempted from disclosure by statute. We redacted information under 42 U.S.C. §262a(h).

You may contact our FOIA Public Liaison at 770-488-6277 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal by writing to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, 5600 Fishers Lane, Room 19-01, Rockville, Maryland 20857. Please mark both your appeal letter and envelope "FOIA Appeal." Your appeal must be postmarked or electronically transmitted by June 30, 2017.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Information Officer
(770) 488-6399
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Enclosures

17-00418-FOIA

The Department of Agriculture

and

The Department of Health and Human Services

Report to Congress

on

Thefts, Losses, or Releases of Select Agents or Toxins

February 7, 2003, to December 31, 2006

November 2007

The Department of Agriculture and the Department of Health and Human Services
Report to Congress on Thefts, Losses, or Releases of Select Agents or Toxins
February 7, 2003, to December 31, 2006

The Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188) requires the Secretaries of Health and Human Services and Agriculture to report to the Congress annually on the number and nature of notifications received concerning the theft, loss, or release of biological agents or toxins (select agents) regulated pursuant to that Act.

Overview

The Select Agent Programs at the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) received 83 reports[1] of Theft, Loss[2], or Release[3] of a select agent or toxin between February 7, 2003, (the effective date of the interim final rule) and December 31, 2006. As a result of the follow-up investigations conducted by HHS, USDA, and the Federal Bureau of Investigation (FBI) regarding these reports, it was determined that there were:

- No confirmed thefts of a select agent;
- No confirmed losses of a select agent; and
- Five confirmed releases of a select agent.

Nine reports involved an apparent non-compliance with the Select Agent Regulations. Of the 9 reports, 6 reports were referred to the HHS Office of Inspector General (OIG) and 3 reports were referred to the USDA, Animal and Plant Health Inspection Service, Investigative and Enforcement Services (IES) for further investigation and enforcement.

Nine reports did not involve a select agent. For the remaining 74 of the initial 83 reports received by HHS and USDA, there were 28 reports of a possible loss of a select agent and 46 reports of a possible release of a select agent.

Reports of Possible Losses

Of the 74 reports involving select agents, there were 28 reports of a possible loss of a select agent. Of the 28 reports:

- Twelve reports involved a transfer in which the entire shipment of select agents did not occur.

(b)(3):42 U.S.C. § 262a(h)

[1] This report does not include reports from the [redacted] investigation. The reports will be included in the annual report for 2007.
[2] A loss is defined as a failure to account for a select agent or toxin.
[3] A release is defined as an occupational exposure or release of a select agent or toxin outside of the primary barriers of the biocontainment area.

- Ten reports involved an inventory discrepancy where the entity could not account for vials containing a select agent. Based on the investigations conducted by HHS, FBI, USDA IES, or USDA OIG, the accounting discrepancies were determined to be a result of poor recordkeeping by the entities. Five of the 10 reports involved an apparent non-compliance with the Select Agent Regulations. Two reports were referred to HHS OIG and the other 3 reports were referred to USDA IES for further investigation and enforcement.

- Three reports involved a possible loss where the entity could not account for mice infected with a select agent. Based on the investigation conducted by HHS and the FBI, the mice were believed to have been cannibalized by other mice in the cage or buried under the bedding and autoclaved by mistake by the animal care staff. Two of the 3 reports involved an apparent non-compliance of the Select Agent Regulations and were referred to HHS OIG for further investigation and enforcement.

- Two reports involved a delay in transfer of a select agent. For one report, the delay was due to a hurricane. For the other report, the delay was due to high volume of shipments related to the holiday season.

- One report identified a loss during transit. After the entity reported the loss of select agents in transit during importation into the United States, the FBI tracked the packages to Belgium where the select agents were incinerated.

Reports of Possible Releases

Of the 74 reports involving select agents, there were 46 reports regarding a possible release of a select agent. It is important to note that none of the reported releases were considered by HHS or USDA to be a threat to public, animal, or plant health. Of the 46 reports:

- There were 5 confirmed reports of releases of a select agent. These releases were identified by illnesses in 7 laboratorians that had occurred as a result of working with these materials.

    - Two of these reports involved exposure to Newcastle disease virus (velogenic) and resulted in conjunctivitis.

    - One of these reports involved exposure of 3 laboratorians to a virulent strain of *Francisella tularensis*. This resulted from an error in the identification of the strain, which led the laboratorians to manipulate the strain under Biosafety Level 2 conditions, which in turn failed to protect the workers from possible aerosol exposure.

- Two of the reports involved exposure to *Brucella* that resulted in illness. One of these two reports involved an exposure to a virulent *Brucella melitensis* strain in a diagnostic laboratory. As with the *Francisella tularensis* incident, a significant factor in this release was the incorrect identification of the organism. In this case, prior to its identification as *Brucella*, this strain was handled in conditions that did not protect the worker from potential aerosol exposure. The second report involved the exposure of a laboratorian to *Brucella* in a research laboratory in which the exact incident involving the exposure was not determined.

- In all cases, the individuals involved have recovered from their illnesses.

- Twenty-three reports involved incidents where a possible exposure of the select agent may have occurred and medical treatment was provided as a precaution, but no illnesses or other evidence of infection occurred. Two of the 23 reports involved an apparent non-compliance of the Select Agent Regulations and were referred to HHS OIG for further investigation and enforcement.

- Fourteen reports involved a release outside the primary barrier of containment. However, after the investigation was conducted by HHS and USDA Select Agent Programs, it was determined that an occupational exposure was unlikely.

- Four reports were determined to not be occupational exposures or releases outside the primary barrier of containment after investigations were conducted by the HHS Select Agent Program.

Summary

In summary, the Select Agent Program received 83 reports of Theft, Loss, or Release of a select agent or toxin between February 7, 2003, and December 31, 2006. As a result of the follow-up investigations conducted by HHS, USDA, and the FBI regarding these reports, it was determined that there were:

- No confirmed thefts of a select agent;
- No confirmed losses of a select agent; and
- Five confirmed releases of a select agent.

The United States Department of Agriculture

and

The United States Department of Health and Human Services

Report to Congress on Thefts, Losses, or Releases of Select Agents or Toxins For Calendar Year 2007

September 2008

Report to Congress on Thefts, Losses, or Releases of Select Agents or Toxins
January 1, 2007 to December 31, 2007

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

Overview

The Select Agent Programs at the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) received seventy-one (71) reports of theft, loss (failure to account for a select agent or toxin), or release (occupational exposure or release of a select agent or toxin outside of the primary barriers[1] of the biocontainment area) of a select agent between January 1, 2007 and December 31, 2007. As a result of the follow-up investigations conducted by HHS, USDA, and the Federal Bureau of Investigation (FBI) regarding these reports, it was determined that there were:

- No confirmed thefts of a select agent;
- One (1) confirmed loss of a select agent; and,
- One (1) confirmed release of a select agent.

Thirteen (13) of the seventy-one (71) reports involved apparent non-compliance with the Select Agent Regulations (7 CFR part 331, 9 CFR part 121, 42 CFR part 73). Of these thirteen (13) reports, six (6) reports involving one (1) entity were referred to the HHS Office of Inspector General (OIG) and seven (7) reports[2] involving five (5) entities were referred to the USDA, Animal and Plant Health Inspection Service, Investigative and Enforcement Services (IES).

Four (4) of the seventy-one (71) reports did not involve a select agent. However, one of the reports was referred to USDA IES for further investigation.

For the remaining sixty-seven (67) of the seventy-one (71) reports received by HHS and USDA, there were nine (9) reports of a possible loss of a select agent and fifty-eight (58) reports of a possible release of a select agent.

Reports of Possible Losses

It is important to note that none of the reported losses were considered by HHS or USDA to be a threat to public, animal, or plant health or safety. Of the nine (9) reports of a possible loss of a select agent:

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[1] In interpreting its regulations, the Select Agent Programs use the concept of "primary barrier of containment" found in the 5th edition of *Biosafety in Microbiological and Biomedical Laboratories*. The term "containment" is used in describing safe methods, facilities and equipment for managing infectious materials in the laboratory environment where they are being handled or maintained. Primary containment, the protection of personnel and the immediate laboratory environment from exposure to infectious agents, is provided by both good microbiological technique and the use of appropriate safety equipment. Safety Equipment (Primary Barriers) includes biological safety cabinets (BSCs), enclosed containers, and other engineering controls designed to remove or minimize exposures to hazardous biological materials.

[2] Three (3) of the seven (7) reports involved one entity.

- There was one (1) confirmed report of a loss of a select agent. This loss involved a package that contained a select agent lost during shipment. After the entity reported the loss of the select agent in transit, the FBI conducted an investigation. The FBI determined that there was no criminal intent because the FBI believed that the package containing the select agent was damaged by the courier and discarded as refuse. This report was referred to the Department of Transportation for further investigation and enforcement.
- One (1) report involved an inventory discrepancy where the entity was able to determine that the vials had been inadvertently autoclaved.
- Two (2) reports involved an inventory discrepancy due to poor recordkeeping. Each of these reports involved apparent non-compliance with the Select Agent Regulations and were referred to USDA IES for further investigation and enforcement.
- Five (5) reports are currently under investigation by USDA, HHS and FBI. Three (3) of the five (5) reports involved apparent non-compliance with the Select Agent Regulations and were referred to USDA IES for further investigation and enforcement.

Reports of Possible Releases

It is important to note that none of the reported releases were considered by HHS or USDA to be a threat to public, animal, or plant health or safety. Of the fifty-eight (58) reports of a possible release of a select agent:

- There was one (1) confirmed report of a release of a select agent. This release was identified by an illness in a laboratorian that occurred as a result her working with *Brucella melitensis* under conditions that failed to protect her from an aerosol exposure. This report involved an apparent non-compliance with the Select Agent Regulations and was referred to HHS OIG for further investigation and enforcement.
- Thirty-nine (39) reports involved incidents of possible exposure to a select agent and medical treatment was provided as a precaution, but where there was no illness or other evidence of an actual exposure. Five (5) of these thirty-nine (39) reports that were received from one entity involved an apparent non-compliance with the Select Agent Regulations and were referred to HHS OIG for further investigation and enforcement.
- Four (4) reports involved a possible release outside the primary barrier of containment. However, an investigation conducted by the HHS and USDA Select Agent Programs concluded that an occupational exposure was unlikely.
- Two (2) reports were determined to not be occupational exposures or releases outside the primary barrier of containment after investigations were conducted by the HHS and USDA Select Agent Programs.
- Twelve (12) reports are currently under investigation by HHS and USDA. One (1) of these twelve (12) reports involved apparent non-compliance with the Select Agent Regulations and was referred to USDA IES for further investigation and enforcement.

Summary

In summary, the APHIS and CDC Select Agent Programs received seventy-one (71) reports of theft, loss, or release of a select agent or toxin between January 1, 2007 and December 31, 2007. As a

result of the follow-up investigations conducted by HHS, USDA, and the FBI regarding these reports, it was determined that there were:

- No confirmed thefts of a select agent;
- One (1) confirmed loss of a select agent; and,
- One (1) confirmed release of a select agent.

The United States Department of Agriculture (USDA)

and

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

Report to Congress on Thefts, Losses, or Releases of Select Agents or Toxins For Calendar Year 2008

June 2009

Report to Congress on Thefts, Losses, or Releases of Select Agents or Toxins
January 1, 2008 to December 31, 2008

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

Overview

In 2008, the Select Agent Programs at the Department of Agriculture (USDA) and the Department of Health and Human Services (HHS) received one-hundred sixteen (116) reports[1] of theft, loss (failure to account for a select agent or toxin), or release (occupational exposure or release of a select agent outside of the primary barriers[2] of the biocontainment area) of a select agent between January 1, 2008 and December 31, 2008. As a result of the follow-up investigations conducted by USDA, HHS, and the Federal Bureau of Investigation (FBI) regarding these reports, it was determined there were:

- No reported thefts of a select agent;
- No confirmed losses of a select agent; and,
- Two (2) validated releases of a select agent.

Four (4) of the one-hundred sixteen reports received in 2008 involved apparent non-compliance with the Select Agent Regulations (7 CFR part 331, 9 CFR part 121, 42 CFR part 73).

Thirteen (13) of the one-hundred sixteen (116) reports received by HHS and USDA, involved the possible loss of a select agent and one-hundred three (103) reports involved the possible release of a select agent. In 2008, there were no reports of a possible theft of a select agent.

For calendar year 2008, there are a total of 22 reports of possible loss or release that remain under investigation by HHS, USDA, or the FBI.

Of the twenty-four (24) reports from calendar year 2007 that were under investigation at the time of the March 2008 report, HHS and USDA have determined that there were no confirmed thefts, losses, or releases of a select agent and none of the reported incidents posed a threat to public, animal, or plant health or safety.

Reports of Possible Losses (13 reports)

USDA and HHS determined that none of the reported possible losses were considered to be a threat to public, animal, or plant health or safety. Of the thirteen (13) reports of a possible loss of a select agent:

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[1] HHS and USDA received one-hundred fifty four (154) APHIS-CDC Form 3s (Report of Theft, Loss, or Release Select Agents and Toxins). After review, it was determined that thirty-eight (38) of these submitted reports did not meet the definition of a reportable loss or release.

[2] In interpreting its regulations, the Select Agent Program's use the concept of "primary barrier of containment" found in the 5th edition of *Biosafety in Microbiological and Biomedical Laboratories*. The term "containment" is used in describing safe methods, facilities and equipment for managing infectious materials in the laboratory environment where they are being handled or maintained. Primary containment, the protection of personnel and the immediate laboratory environment from exposure to infectious agents, is provided by both good microbiological technique and the use of appropriate safety equipment. Safety Equipment (Primary Barriers) includes biological safety cabinets (BSCs), enclosed containers, and other engineering controls designed to remove or minimize exposures to hazardous biological materials.

- There were no confirmed reports of a loss of a select agent.
- Seven (7) reports involved an inventory discrepancy. Based on our investigations, these reports were found to be most likely inventory errors that involved poor recordkeeping or counting of materials. Three (3) reports involved apparent non-compliance with the Select Agent Regulations and were referred to HHS Office of Inspector General (OIG) and the USDA/APHIS Investigative and Enforcement Services (IES) for further investigation and are now closed. The remaining four (4) reports are still under investigation.
- Two (2) reports involved possible loss in transit. After the entities reported the loss of select agents in transit, the FBI recovered one package within three days and IES recovered the other package within five hours.
- Three (3) reports involved the apparent loss of animals infected with select agents. One (1) of these involved the loss of a mouse that had been injected with select agent. This incident is currently under investigation by the FBI. The remaining two (2) reports involved the loss of an animal carcass. In one (1) case our investigation indicates that the carcass was most likely autoclaved and discarded without proper recordkeeping. The other case is currently under investigation.
- One (1) report involved the receipt of an empty vial. Based on the receipt of an empty vial that may have contained a select agent, the report was referred to FBI and still under investigation.

Reports of Possible Releases (103 reports)

USDA and HHS determined that none of the reported possible releases were considered to be a threat to public, animal, or plant health or safety. Of the one-hundred three (103) reports of a possible release of a select agent:

- There were two (2) validated reports of a release of a select agent. One (1) release was identified as a result of a routine annual laboratory test of cattle for brucellosis. One (1) cow in an adjacent brucellosis-free herd at a facility with ongoing brucellosis research tested positive for brucellosis and was destroyed. The report was referred to IES for apparent non-compliance with the Select Agent Regulations and resulted in USDA and HHS suspending the entity's research. In addition, IES imposed a civil money penalty of $425,000. The other report was identified by an illness in a laboratory worker that occurred as a result of her working with *Brucella melitensis*. This report is still under investigation to confirm the cause of the laboratory worker's illness. No additional cases have been identified in association with this incident.

- Thirty-five (35) reports involved possible exposures while working with samples potentially containing select agents or toxins (e.g., clinical isolates or diagnostic samples). Twenty-eight (28) reports indicated that medical treatment was provided as a precaution. Three (3) of these reports are still under investigation by HHS and USDA.

- Nine (9) reports described incidents involving laboratory animals (e.g., animal bites or scrapes). All reports indicated that medical treatment was provided as a precaution. Two (2) of these reports are still under investigation by HHS and USDA.

- Fifty-seven (57) reports involved laboratory incidents (e.g., needle sticks, scalpel cuts, spills, or mechanical failure of personal protective or facility equipment) where an individual may have been exposed to a select agent or toxin. Thirty (30) reports indicated medical treatment was

provided as a precaution. Nine (9) of these reports are still under investigation by HHS and USDA.

Summary

In summary, HHS and USDA received one-hundred sixteen (116) reports of potential theft, loss, or release of a select agent between January 1, 2008 and December 31, 2008. As a result of the follow-up investigations conducted by USDA, HHS and the FBI regarding these reports, it was determined that there were:

- No reported thefts of a select agent;
- No confirmed losses of a select agent; and,
- Two (2) validated releases of a select agent.

For calendar year 2008, there are a total of 22 reports of possible loss or release that remain under investigation by HHS, USDA, or the FBI.

The United States Department of Health and Human Services (DHHS)

and

The United States Department of Agriculture (USDA)

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

For Calendar Year 2009

September 2010

Report to Congress on Thefts, Losses, or Releases of Select Agents and Toxins
January 1, 2009 to December 31, 2009

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

Overview

In 2009, the Select Agent Programs at the United States Department of Agriculture (USDA) and the Department of Health and Human Services (DHHS), received two hundred forty three (243) reports of potential theft, loss (failure to account for a select agent or toxin), or release (occupational exposure or release of a select agent outside of the primary barriers of the biocontainment area) between January 1, 2009 and December 31, 2009.

As a result of the follow-up investigations conducted by the USDA, DHHS and Federal Bureau of Investigation (FBI), it was determined there were:

- No (0) reports of thefts of a select agent or toxin
- No (0) confirmed losses of a select agent or toxin
- One (1) confirmed[1] release of a select agent or toxin

Of the two hundred forty three (243) reports received by USDA and DHHS in 2009, there were thirty (30) reports that described incidents that after evaluation did not meet the regulatory definition for a reportable loss or release of a select agent. Of the remaining two hundred thirteen (213) reports received, seventeen (17) reports involved the potential loss of a select agent and one-hundred ninety six (196) reports involved the potential release of a select agent.

For calendar year 2009, there are no (0) reports that remain under investigative review by USDA and DHHS.

Reports of Potential Losses (17 reports)

The seventeen (17) reports of a potential loss of a select agent included:

- Fourteen (14) reports of discrepancies in the inventory records of registered entities. Based on investigations by DHHS and the FBI, these reports were determined to be a result from errors in recordkeeping or accounting of materials.
- Three (3) reports were determined to involve samples that were discarded without adequate documentation of the disposition of these materials. Investigations into these three reports have been completed.
- There were no (0) confirmed reports of a loss of a select agent.

Reports of Potential Releases (196 reports)

The one-hundred ninety six (196) reports describing the potential release of a select agent included:

- Two (2) reports of a potential exposure that resulted from a bite/scratch from an animal infected with a select agent.

- Nine (9) reports described incidents involving equipment or mechanical failures.

- Twelve (12) reports involved needle stick or other percutaneous exposures with other potentially contaminated sharp objects.

- Four (4) reports described incidents in which a failure or problem with personal protective equipment occurred.

- Eleven (11) reports involved potential exposures resulting from non-adherence to safety procedures.

- Thirty-four (34) reports involved spills of select agents inside of biocontainment laboratories. None of these spills resulted in the release of a select agent outside of the redundant safety barriers of the laboratory.

- The remaining one hundred and twenty four (124) reports involved events in which select agents were either manipulated outside of a biological safety cabinet or other type of equipment designed to protect laboratory workers from exposures to infectious aerosols. One hundred two (102) reports of this type of potential exposure occurred in unregistered laboratories. These laboratories were primarily clinical or diagnostic laboratories working with specimens from patients with previously undetected infections with select agents.

- Persons involved in one hundred nineteen (119) reports of potential releases received some type of medical evaluation and/or treatment.

- There was one (1) confirmed[1] report of a release of a select agent. This release resulted in the infection of a laboratory worker with *Francisella tularensis*. The laboratory worker received medical treatment and has recovered from this infection.

- For calendar year 2009, and all calendar years prior to 2009, there are no reports that remain under investigative review by USDA and DHHS.

Summary

In summary, USDA and DHHS received two hundred and forty three (243) reports of potential theft, loss, or release between January 1, 2009 and December 31, 2009.

As a result of the follow-up investigations conducted by USDA, DHHS, and the FBI regarding these reports, it was determined that there were:

- No (0) reports of thefts of a select agent;
- No (0) confirmed losses of a select agent; and,
- One (1) confirmed[1] release of a select agent.

[1]For human select agents, in this context, confirmed means that an exposure occurred that resulted in occupational illness.

Report to Congress on Thefts, Losses, or Releases of Select Agents and Toxins
January 1, 2010 to December 31, 2010

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

Overview

In 2010, the Select Agent Programs at the United States Department of Agriculture (USDA) and the Department of Health and Human Services (HHS), received two hundred seventy five (275) reports of potential loss (failure to account for a select agent or toxin), or release (occupational exposure or release of a select agent outside of the primary barriers of the biocontainment area) between January 1, 2010 and December 31, 2010.

As a result of the follow-up investigations conducted by the USDA, HHS and Federal Bureau of Investigation (FBI), it was determined there were:

- No (0) reports of thefts of a select agent or toxin
- No (0) confirmed losses of a select agent or toxin
- Three (3) confirmed[1] releases of a select agent or toxin

Of the two hundred seventy five (275) reports received, twenty five (25) reports involved the potential loss of a select agent and two hundred fifty (250) reports involved the potential release of a select agent. There were five (5) reports that described incidents that after evaluation did not meet the regulatory definition for a reportable loss or release of a select agent.

At the time of report submission, there are eight (8) reports that remain under review by USDA and HHS for calendar year 2010.

Reports of Potential Losses (25 reports)

The twenty five (25) reports of a potential loss of a select agent included:

- Twenty three (23) of these reports have been determined to be a result from errors in recordkeeping or accounting of materials based on investigations by USDA, HHS and the FBI.
- One (1) report was determined to involve shipping and transport issues where the materials were later recovered.
- One (1) report at this writing is still under the investigation of the FBI.
- There were no (0) confirmed reports of a loss of a select agent.

[1] For human select agents, in this context, confirmed means that an exposure occurred that resulted in occupational illness. For select agents involving animals, confirmed means that an exposure occurred that resulted in clinical illness.

Reports of Potential Releases (250 reports)

The two hundred fifty (250) reports describing the potential release of a select agent included:

- Three (3) reports of potential exposures that resulted from a bite/scratch from an animal infected with a select agent.

- Six (6) reports described incidents involving equipment or mechanical failures.

- Eighteen (18) reports involved needle stick or other percutaneous exposures with other potentially contaminated sharp objects.

- Five (5) reports described incidents in which a failure or problem with personal protective equipment occurred.

- Four (4) reports involved potential exposures resulting from non-adherence to safety procedures.

- Eleven (11) reports involved spills of select agents inside of biocontaiment laboratories. None of these spills resulted in the release of a select agent outside of the redundant safety barriers of the laboratory.

- The remaining two hundred three (203) reports involved events in which select agents were either manipulated outside of a biological safety cabinet or other type of equipment designed to protect laboratory workers from exposures to infectious aerosols. One hundred fifty three (153) reports of this type of potential exposure occurred in exempted laboratories[2]. These laboratories were primarily clinical or diagnostic laboratories working with specimens from patients with previously undetected infections with select agents.

- Persons involved in one hundred twenty seven (127) reports of potential releases received some type of medical evaluation and/or treatment.

- There were three (3) confirmed[1] reports of a release of a select agent. These releases resulted in two laboratory workers who were infected with *Brucella suis* in two separate states. Both laboratory workers received medical treatment and both recovered from their illness. There was one confirmed release of a select agent involving, Classical Swine Fever virus which resulted in clinical illness in two (2) animals. Both animals were euthanized.

- For all calendar years prior to 2009, there are no reports that remain under review by USDA and HHS.

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[2] Clinical or diagnostic laboratories and other entities (exempted laboratories) that have identified select agents and toxins contained in a specimen presented for diagnosis, verification, or proficiency testing are required by the select agent regulations to report this identification to APHIS or CDC Select Agent Program 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 or toxin 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.

Summary

In summary, USDA and HHS received two hundred seventy five (275) reports of potential loss, or release between January 1, 2010 and December 31, 2010.

As a result of the follow-up investigations conducted by USDA, HHS, and the FBI regarding these reports, it was determined that there were:

- No (0) reports of thefts of a select agent;
- No (0) confirmed losses of a select agent; and,
- Three (3) confirmed[3] releases of a select agent.

[3] For human select agents, in this context, confirmed means that an exposure occurred that resulted in occupational illness. For select agents involving animals, confirmed means that an exposure occurred that resulted in clinical illness.

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

and

The United States Department of Agriculture (USDA)

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

For Calendar Year 2011

April 2012

Report to Congress on Thefts, Losses, or Releases of Select Agents and Toxins January 1, 2011 to December 31, 2011

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

Overview

In 2011, the Select Agent Programs at the United States Department of Agriculture (USDA) and the Department of Health and Human Services (HHS), received two hundred forty seven (247), reports of potential release (occupational exposure or release of a select agent outside of the primary barriers of the biocontainment area) or reports of potential loss (failure to account for a select agent or toxin) between January 1, 2011 and December 31, 2011.

As a result of the follow-up investigations conducted by the USDA, HHS and Federal Bureau of Investigation (FBI), it was determined there were:

- No (0) reports of thefts of a select agent or toxin
- No (0) confirmed losses of a select agent or toxin
- One (1) confirmed release[1] of a select agent or toxin

Of the two hundred forty seven (247) reports received, twelve (12) reports involved the potential loss of a select agent and two hundred thirty five (235) reports involved the potential release of a select agent. At the time of report submission, there are two (2) reports that remain under review by USDA and HHS for calendar year 2011.

Of the two hundred forty seven (247) reports received, one hundred twenty three (123) reports were received from entities registered with APHIS or CDC Select Agent Program to possess, use or transfer select agents and toxins. One hundred twenty four reports were received from exempted laboratories.[2]

Reports of Potential Losses (12 reports)

The twelve (12) reports of a potential loss of a select agent received from entities registered with APHIS or CDC Select Agent Program to possess, use or transfer select agents and toxins included:

- Twelve (12) of these reports have been determined to be a result from errors in recordkeeping or accounting of materials based on investigations by USDA, HHS and the FBI.
- There were no (0) confirmed reports of a loss of a select agent.

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[1] For human select agents, in this context, confirmed release means that an exposure occurred that resulted in occupational illness.

[2] Clinical or diagnostic laboratories and other entities (exempted laboratories) that have identified select agents and toxins contained in a specimen presented for diagnosis, verification, or proficiency testing are required by the select agent regulations to report this identification to the Federal Select Agent Program 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 or toxin 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.

Reports of Potential Releases (235 reports)

Out of two hundred thirty five (235) reports, one hundred twenty four (124) reports were received from exempted laboratories[3] describing the potential release of a select agent included:

- Eight (8) reports (2 reports received from exempted laboratories) of potential exposures that resulted from a bite or scratch from an animal infected with a select agent.
- Thirteen (13) reports described incidents involving equipment or mechanical failures.
- Seventeen (17) reports involved needle stick or other percutaneous exposures with other potentially contaminated sharp objects.
- Sixteen (16) reports described incidents in which a failure or problem with personal protective equipment occurred.
- Twelve (12) reports (3 reports received from exempted laboratories) involved potential exposures resulting from deviations from laboratory standard operating procedures.
- Thirty three (33) reports (2 reports received from exempted laboratories) involved spills of select agents inside of biocontaiment laboratories. None of these spills resulted in the release of a select agent outside of the redundant safety barriers of the laboratory.
- The remaining one hundred thirty six (136) reports (117 reports received from exempted laboratories) involved events in which select agents were either manipulated outside of a biological safety cabinet or other type of equipment designed to protect laboratory workers from exposures to infectious aerosols.
- Persons involved in one hundred forty nine (149) reports of the 235 potential releases received some type of medical evaluation and/or treatment.
- There was one (1) confirmed report of a release of a select agent. The release involved a confirmed occupational illness with *Francisella tularensis* that occurred within a privately owned veterinary clinic, which is an exempted laboratory. The worker in this case made a full recovery and returned to work and there was no evidence of spread beyond this one worker.
- There are no reports that remain under review by USDA and HHS for calendar years prior to 2010.

Summary

In summary, USDA and HHS received two hundred forty seven (247) reports of potential loss, or release between January 1, 2011 and December 31, 2011. As a result of the follow-up investigations conducted by USDA, HHS, and the FBI regarding these reports, it was determined that there were:

- No (0) reports of thefts of a select agent;
- No (0) confirmed losses of a select agent; and,
- One (1) confirmed release[4] of a select agent.

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[3] Clinical or diagnostic laboratories and other entities (exempted laboratories) that have identified select agents and toxins contained in a specimen presented for diagnosis, verification, or proficiency testing are required by the select agent regulations to report this identification to the Federal Select Agent Program 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 or toxin 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.

[4] For human select agents, in this context, confirmed release means that an exposure occurred that resulted in occupational illness.

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

and

The United States Department of Agriculture (USDA)

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

For Calendar Year 2012

August 2013

Report to Congress on Thefts, Losses, or Releases of Select Agents and Toxins
January 1, 2012 - December 31, 2012

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188), requires the Secretaries of Health and Human Services and Agriculture to report to Congress annually on the number and nature of notifications received concerning the theft, loss, or release of biological agents and toxins (select agents) 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.

Overview

Between January 1, 2012, and December 31, 2012, the Select Agent Programs at the United States Department of Agriculture (USDA) and the Department of Health and Human Services (HHS) received 247 reports of potential releases (occupational exposure or release of a select agent outside of the primary barriers of the biocontainment area) or reports of potential loss (failure to account for a select agent or toxin).

As a result of the follow-up investigations conducted by USDA, HHS, and the Federal Bureau of Investigation (FBI), it was determined there were:

- Zero reports of thefts of a select agent or toxin;
- Zero confirmed losses of a select agent or toxin[1]; and,
- Zero confirmed releases of a select agent or toxin.

Of the 247 reports received, nine reports involved the potential loss of a select agent and 238 reports involved the potential release of a select agent. At the time of submission of this report, there are two reports that remain under review by USDA and HHS for calendar year 2012.

Of the 247 reports received, 119 reports were received from entities registered with APHIS or CDC to possess, use or transfer select agents and toxins. The remaining 128 reports were received from clinical or diagnostic laboratories not required to be registered with APHIS or CDC.[2]

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[1] Two potential losses are still undergoing investigation.

[2] Clinical or diagnostic laboratories and other entities that have identified select agents and toxins contained in a specimen presented for diagnosis, verification, or proficiency testing are required by the select agent regulations to report this identification to APHIS or CDC 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 or toxin 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 Select Agents and Toxins.

Reports of Potential Losses (nine reports)

The nine reports of a potential loss of a select agent included:

- Six reports that were determined to result from errors in recordkeeping or accounting of materials based on investigations by HHS and the FBI.
- One report that involved an entity that is not required to be registered which could not account for the select agent that had been in its custody. The loss was reported to the FBI. The FBI concluded that the most plausible explanation was that the entity inadvertenty disposed of the select agent into the biomedical waste stream.
- Two reports are still undergoing investigation.
- There were zero confirmed reports of a loss of a select agent.

Reports of Potential Releases (238 reports)

USDA and HHS received 238 reports of potential releases. Of these, 128 were reported from laboratories not required to be registered.[3] Below is a breakdown of the potential releases reported based on their category:

- Eight reports of potential exposures that resulted from a bite/scratch from an animal infected with a select agent.
- Three reports described incidents involving equipment or mechanical failures.
- Fourteen reports involved needle stick or other percutaneous exposures with other potentially contaminated sharp objects.
- Sixteen reports described incidents in which a failure or problem with personal protective equipment occurred.
- Eleven reports (including two reports received from laboratories not required to be registered) involved potential exposures resulting from deviations from laboratory standard operating procedures.
- Thirty nine reports (including two reports received from laboratories not required to be registered) involved spills of select agents inside of biocontaiment laboratories. None of these spills resulted in the release of a select agent outside of the redundant safety barriers of the laboratory.

[3] Clinical or diagnostic laboratories and other entities that have identified select agents and toxins contained in a specimen presented for diagnosis, verification, or proficiency testing are required by the select agent regulations to report this identification to APHIS or CDC 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 or toxin 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 Select Agents and Toxins.

- The remaining 147 reports involved events in which select agents were either manipulated outside of a biological safety cabinet or other type of equipment designed to protect laboratory workers from exposures to infectious aerosols.

- Persons involved in 187 reports of the 238 potential releases received some type of medical evaluation and/or treatment.

- Two reports of seroconversions[4] to *Coxiella burnetii* occurred among select agent laboratory workers in 2012. These incidents occurred at different facilities and at different times. In one case, no symptoms were reported and medical prophylaxis was not initiated. In the other case, symptoms and illness were reported and treatment was initiated. Both individuals have returned to full work status. Since neither case yielded a *C. burnetii* isolate for analysis, and both case investigations uncovered alternative possibilities for exposure outside select agent laboratories (one individual worked with *C. burnetti* vaccine strains and the other individual served as a large animal veterinarian outside of work), we have not considered them confirmed select agent laboratory acquired infections.

- There are zero reports still under review by USDA and HHS for calendar years prior to 2011.

- There were zero confirmed releases.

Summary

In summary, USDA and HHS received 247 reports of potential loss, or release between January 1, 2012, and December 31, 2012.

As a result of the follow-up investigations conducted by USDA, HHS, and the FBI regarding these reports, it was determined that there were:

- Zero reports of thefts of a select agent;
- Zero confirmed losses of a select agent[5]; and,
- Zero confirmed releases of a select agent.

At the time of report submission, there are two reports that remain under review by USDA and HHS for calendar year 2012.

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[4] Seroconversion is the development of detectable specific antibodies to microorganisms in the blood serum as a result of infection or immunization.

[5] Two potential losses are still undergoing investigation.

USDA

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

and

The United States Department of Agriculture (USDA)

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

For Calendar Year 2013

2014

Report to Congress on Thefts, Losses, or Releases of Select Agents and Toxins
January 1, 2013 - December 31, 2013

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) requires the Secretaries of Health and Human Services and Agriculture to report to Congress annually on the number and nature of notifications received concerning the theft, loss, or release of biological agents and toxins (select agents) 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.

Overview

Between January 1, 2013, and December 31, 2013, the Select Agent Programs at the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (HHS) received 219 reports of potential releases (occupational exposure or release of a select agent outside of the primary barriers of the biocontainment area) or reports of potential loss (failure to account for a select agent).

As a result of the follow-up investigations conducted by USDA, HHS, and the Federal Bureau of Investigation (FBI), it was determined there were:

- Zero reports of thefts of a select agent;
- Two confirmed losses of a select agent; and,
- Two confirmed releases of a select agent.

Of the 219 reports received by HHS and USDA, 20 reports involved the potential loss of a select agent. After investigation by CDC and the FBI, only two of these reports were confirmed as losses. One hundred ninety-nine reports involved potential releases of select agents. Only two of these reports were determined to be confirmed releases of select agents. At the time of submission of this report, there are no reports that remain under review by USDA and HHS for calendar year 2013.

Of the 219 reports received, 127 reports were received from entities registered with USDA or HHS to possess, use, or transfer select agents. The remaining 92 reports were received from clinical or diagnostic laboratories, which are not required to be registered with USDA or HHS so long as they meet certain conditions specified in the select agent regulations.[1]

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[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 Select Agents and Toxins.

Reports of Potential Losses (18 reports)

Eighteen reports of potential loss were determined to result from errors in recordkeeping or accounting of materials based on investigations by USDA, HHS, and the FBI.

Reports of Confirmed Losses (two reports)

- One loss involved one vial of Guanarito virus.

- After an extensive investigation was conducted by the entity's police department and the FBI, no criminal intent was found.

- One loss involved a clinical diagnostic isolate shipped to a diagnostic laboratory to rule out *Francisella tularensis*. The isolate did not arrive at the clinical laboratory and was not located by the FBI. A second clinical isolate from the same laboratory and source was shipped to the reference laboratory and later identified as *Francisella tularensis*. Although an extensive investigation was conducted by the FBI, no criminal intent was found.

Reports of Potential Releases (197 reports)

USDA and HHS received 197 reports of potential releases. Of these, 92 were reported from laboratories not required to be registered.[2] Below is a breakdown of the potential releases reported based on the type of activity associated with the release event:

- Four reports of potential exposures that resulted from a bite or scratch from an animal infected with a select agent.

- Ten reports described incidents involving equipment or mechanical failures.

- Eleven reports involved needle sticks or other percutaneous exposures with other potentially contaminated sharp objects.

- Seventeen reports involved incidents in which a failure or problem occurred with personal protective equipment.

- Two reports involved potential exposures resulting from deviations from standard laboratory operating procedures.

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[2]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 Select Agents and Toxins.

- Thirty-one reports involved spills of select agents inside of the biocontainment laboratories. None of these spills resulted in the release of a select agent outside of the safety barriers of the laboratory.

- The remaining 122 reports involved events in which select agents were either manipulated outside of a biological safety cabinet or other type of equipment designed to protect laboratory workers from exposures to infectious aerosols.

- Persons involved in 156 reports of the 197 potential releases received some type of medical evaluation and/or treatment.

Report of Confirmed Releases (2 Reports)

- There were two confirmed releases identified by serological testing in 2013.[3] These incidents occurred at two different facilities at different times during the year.

- One case involved an exposure to *Burkholderia pseudomallei*. Exposure to this microorganism was detected prior to the onset of symptoms. This worker was given prophylactic antibiotics to prevent the onset of illness and has returned to work.

- The second case involved exposure to *Brucella mellitensis*. While under medical observation after a suspected release event, serological testing detected the presence of antibodies against *B. mellitensis*. Shortly thereafter, symptoms consistent with brucellosis were reported by the worker, and the infection was confirmed by isolation of the microorganism from the patient's blood. Antibiotic therapy was quickly initiated and resulted in the successful recovery of the worker, who has also returned to work.

- There was no secondary transmission of these infections to other persons identified for either incident.

Summary

In summary, USDA and HHS received 219 reports of potential losses or releases of select agents between January 1, 2013, and December 31, 2013.

As a result of the follow-up investigations conducted by USDA, HHS, and the FBI regarding these reports, it was determined that there were:

- Zero reports of thefts of a select agent;

- Two confirmed losses of a select agent; and,

- Two confirmed releases of a select agent.

There are no reports that remain under review by USDA and HHS for calendar year 2013.

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[3] Seroconversion is the development of detectable specific antibodies to microorganisms in the blood serum as a result of infection or immunization.

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.

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 2015

December 2016

Report to Congress
on the Notifications of Thefts, Losses, or Releases of Select Agents and Toxins
January 1, 2015 - December 31, 2015

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) 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

This report is in response to the annual reporting 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 §331.19, 9 C.F.R. §121.19, and 42 C.F.R. §73.19) to require notification 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 BSAT.

Between January 1, 2015, and December 31, 2015, the select agent regulatory programs at USDA and HHS received 245 reports of a loss or release of BSAT and zero reports of a theft of BSAT in calendar year (CY) 2015. Follow-up investigations on the 245 reports identified the following:

- All 12 reports of losses met the regulatory criteria to be classified as a loss. USDA and HHS identified the cause of the failure to account for each loss. None of the losses resulted in a risk to public or agricultural health.
- All 201 out of 233 reports of release incidents met the regulatory criteria for a release. Of the 201 releases reported, 90 reports were received from entities registered with USDA or HHS to possess, use, or transfer BSAT. The remaining 111 reports were received from clinical or diagnostic laboratories that were not required to be registered with USDA or HHS, meeting the conditions specified in the select agent regulations as exempt entities.[1]
- Thirty-two reports of a release did not meet the regulatory criteria for a release and were excluded from further analysis. These 32 reports involved spills of BSAT within biocontainment; none of the spills resulted in the release of BSAT outside of the primary barriers of the biocontainment area or an occupational exposure. Therefore, the incidents did not meet the regulatory criteria for a release.

[1] Clinical or diagnostic laboratories and other entities that have identified as 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.

II. Reports of Losses (12 reports)

The Federal Select Agent Program (FSAP) refers security-related issues and reports of losses of BSAT to the Federal Bureau of Investigation (FBI) for further investigation. In 2015, the FSAP referred a total of 12 reports of losses meeting the regulatory criteria to the FBI. In all 12 loss reports, the FBI determined there was no criminal nexus. Table 1 provides the cause of the failure of accountability and number of associated reports.

Table 1. Reports of Loss of BSAT in 2015 by Cause

Cause	Number of Reports
Sample mistakenly discarded following appropriate biosafety procedures	3
Human error in accounting for materials	9
Total	**12**

III. Reports of Releases (201 reports)

In CY 2015, there were 201 reports of releases identifying a total of 908 persons who may have been at risk of exposure and infection. 196 of those individuals were from registered entities, and 712 were from exempt entities. Of the 201 reports of releases, two reports were of releases of a plant agent *(Xanthomonas oryzae)*, which is not a danger to humans, leaving 199 reports determined to represent an occupational exposure to laboratory workers. A conservative and cautious approach is used by FSAP to include reports from the entities of exposures, and as such, some of these individuals may not have had actual exposures to a live BSAT.

Table 2 provides the cause for the 201 reports that met the regulatory criteria for a release according to the regulated status of the reporting entity.

Table 2. Reports of BSAT Release Meeting the Regulatory Definition by Cause and Source

Cause	Reports from Registered Entities	Reports from Exempt Entities
Bite or scratch from an animal infected with BSAT	4	1
Equipment or mechanical failure	13	1
Needle stick or other percutaneous exposure with possibly contaminated sharp objects	11	0
Failure or problem with personal protective equipment	26	0
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	7	0
Manipulating BSAT outside of a biological safety cabinet or other type of equipment designed to protect laboratory workers from exposures to infectious aerosols	29	109
Total	**90**	**111**

Incidents Resulting in Seroconversion

Annual screening of worker serology is not required by the select agent regulations and is not performed by all regulated entities. When serologic testing is conducted for screening purposes, regulated entities are asked to report seroconversion to BSAT even when medical assessment onsite does not identify a compatible illness or exposure. Seroconversion itself meets the regulatory criteria for release when the exposure source is uncertain, in order to ensure that proper follow-up has been conducted. Therefore, a seroconversion to a select agent (e.g., a four-fold rise in antibodies associated with infection from an agent) is considered a worker exposure (i.e., release) unless proven otherwise.

In CY 2015, two entities submitted reports of seroconversion identified through annual screening in a total of three workers:

1) Two workers at a federal government laboratory demonstrated seroconversion to *Coxiella burnetii* during an annual screening. No laboratory incident or event was identified to explain the seroconversion. These workers conducted other duties outside the laboratory that included working with sheep. It was determined by the occupational health professional working for the facility that there was no evidence of laboratory-acquired illness. Neither worker received therapy for a presumed infection, and both workers remained asymptomatic during the 3-month monitoring period and continue to perform their work without restrictions.
2) One worker at a university research laboratory demonstrated seroconversion to *Brucella abortus* during an annual screening. No laboratory incident or event was identified to explain the seroconversion. Occupational health professionals monitored the worker for an additional 4 months. It was determined by the occupational health professional working for the facility that there was no evidence of laboratory-acquired illness. The worker received no therapy for presumed infection and remained asymptomatic during the monitoring period.

IV. Summary

During CY 2015, USDA and HHS received 12 reports of losses of BSAT, 201 reports of releases of BSAT, and no reports of theft of BSAT. None of the incidents associated with the reports indicated a release outside of the laboratory. Two individuals were identified to have seroconverted on annual screening to *Coxiella burnetii,* and one individual seroconverted to *Brucella.* All workers who seroconverted remained asymptomatic and have continued to perform their work without any restrictions. No laboratory incident or event was identified to explain the seroconversions. Twelve reports of losses were investigated by the FBI, and in all 12 cases, the FBI determined there was no criminal nexus.