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Description of document: Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR)
Report to Congress on Thefts, Losses, or Releases of a Select Agent or Toxin, 2007-2010

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Note: Reports cover the period 2003-2010

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U.S. Nuclear Regulatory Commission
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Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

April 12, 2017

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 15, 2017, for a copy of each CDC document entitled *Report to Congress on Thefts, Losses, or Releases of a Select Agent or Toxin* for the years 2002 to 2010.

We located 19 pages of responsive records (19 pages released in full or in part). Note that the 2006 Report to Congress within the attached responsive record begins the reporting period of 2003. The 2006 report is from the earliest reporting period of February 7, 2003 to December 31, 2006. All other requested annual reports are for their respective individual calendar years. 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) that involves Select Agents.

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
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Enclosures

17-00416-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 reports¹ of Theft, Loss², or Release³ 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 barriers¹ 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) reports² 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:

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.

²Three (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) reports¹ 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 barriers² 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:

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

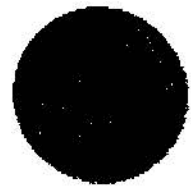
provided as a precaution. Nine (9) of these reports are still under investigation by HHS and USDA.

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) confirmed¹ 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) confirmed¹ 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) confirmed¹ release of a select agent.

¹For 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) confirmed¹ 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 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 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 laboratories². 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) confirmed¹ 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.

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) confirmed³ 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.