



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

TO: The Secretary
Through: DS _____
COS _____
ES _____

FROM: Director, Centers for Disease Control and Prevention

DATE: May 22, 2019

SUBJECT: *Report to Congress on the Notifications of Thefts, Losses, or Releases of Select Agents and Toxins for Calendar Year 2018 – DECISION*

ISSUE

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) requires the Secretaries of the U.S. Departments of Agriculture (USDA) and Health and Human Services (HHS) 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.

BACKGROUND

Between January 1, 2018 and December 31, 2018, the select agent regulatory programs at USDA and HHS received eight reports of BSAT loss, 193 reports of BSAT release, and zero reports of a theft of a BSAT for calendar year (CY) 2018. Follow-up investigations on the 201 reports identified:

- There were eight reports of a loss (failure to account for BSAT), all from registered entities. FSAP refers all reports of a BSAT loss to the Federal Bureau of Investigation (FBI). In CY 2018, the FBI determined that there was no criminal nexus for any of the eight reported losses. None of the reported losses resulted in a risk to public or agricultural health; and
- There were 193 reports of a release (occupational exposure or release of BSAT outside of the primary barriers of the biocontainment area). Of these reports, 66 reports were submitted by registered entities and 127 reports were from non-registered entities. None of the reported releases resulted in illnesses, deaths, or transmissions among workers or outside of a laboratory into the surrounding environment or community.

Page 2 – The Secretary of Health and Human Services

RECOMMENDATION

I recommend that you approve and transmit the *Report to Congress on the Notifications of Thefts, Losses, or Releases of Select Agents and Toxins*.


Robert R. Redfield, MD

DECISION

Approved

Disapproved

Need More Information


Alex M. Azar II

JUL 19 2019
Date

Attachments:

- Tab A – *Report to Congress on Thefts, Losses, or Releases of Select Agents and Toxins*
- Tab B – Letters to Congress



U.S. Department of Agriculture



U.S. Department of Health & Human Services

JUL 19 2019

The Honorable Nancy Pelosi
Speaker of the U.S. House of Representatives
Washington, D.C. 20515

Dear Madam Speaker:

We are pleased to transmit to Congress the Report on Notifications of Thefts, Losses, and Releases of Select Agents and Toxins for calendar year 2018, as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). The Secretaries of the U.S. Department of Agriculture (USDA) and Health and Human Services (HHS) must report to Congress annually on the number and nature of notifications received concerning the theft, loss, and release of a biological agent or toxin regulated pursuant to that act.

These regulations require all persons to notify either USDA's Animal and Plant Health Inspection Service (APHIS) or HHS' Centers for Disease Control and Prevention (CDC) in the event of a theft, loss, or release of a biological agent or toxin listed as a "select agent or toxin." APHIS and/or CDC review all notifications. The enclosed report includes notifications received regarding a loss or release of a select agent or toxin between January 1, 2018, and December 31, 2018. There were no reported thefts of a select agent or toxin during calendar year 2018.

We appreciate your continued support in these critical areas of public, animal, and plant health, as well as national security. This letter is also being sent to the President of the Senate, and the Majority and Minority Leaders in the House and Senate.

Sincerely,

A handwritten signature in blue ink that reads "Sonny Perdue".

Sonny Perdue
Secretary
U.S. Department of Agriculture

A handwritten signature in blue ink that reads "Alex M. Azar II".

Alex M. Azar II
Secretary
U.S. Department of Health & Human Services

Enclosure



U.S. Department of Agriculture



U.S. Department of Health & Human Services

JUL 19 2019

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

Dear Representative McCarthy:

We are pleased to transmit to Congress the Report on Notifications of Thefts, Losses, and Releases of Select Agents and Toxins for calendar year 2018, as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). The Secretaries of the U.S. Department of Agriculture (USDA) and Health and Human Services (HHS) must report to Congress annually on the number and nature of notifications received concerning the theft, loss, and release of a biological agent or toxin regulated pursuant to that act.

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We appreciate your continued support in these critical areas of public, animal, and plant health, as well as national security. This letter is also being sent to the Speaker of the House of Representatives, the President of the Senate, the Majority Leader in the House, and the Majority and Minority Leaders in the Senate.

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Enclosure



U.S. Department of Agriculture



U.S. Department of Health & Human Services

JUL 19 2019

The Honorable Michael R. Pence
President of the United States Senate
Washington, D.C. 20510

Dear Mr. President:

We are pleased to transmit to Congress the Report on Notifications of Thefts, Losses, and Releases of Select Agents and Toxins for calendar year 2018, as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). The Secretaries of the U.S. Department of Agriculture (USDA) and Health and Human Services (HHS) must report to Congress annually on the number and nature of notifications received concerning the theft, loss, and release of a biological agent or toxin regulated pursuant to that act.

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U.S. Department of Health & Human Services

Enclosure



U.S. Department of Agriculture



U.S. Department of Health & Human Services

JUL 19 2019

The Honorable Steny Hoyer
Majority Leader
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Hoyer:

We are pleased to transmit to Congress the Report on Notifications of Thefts, Losses, and Releases of Select Agents and Toxins for calendar year 2018, as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). The Secretaries of the U.S. Department of Agriculture (USDA) and Health and Human Services (HHS) must report to Congress annually on the number and nature of notifications received concerning the theft, loss, and release of a biological agent or toxin regulated pursuant to that act.

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Alex M. Azar II
Secretary
U.S. Department of Health & Human Services

Enclosure



U.S. Department of Agriculture



U.S. Department of Health & Human Services

JUL 19 2019

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

Dear Senator McConnell:

We are pleased to transmit to Congress the Report on Notifications of Thefts, Losses, and Releases of Select Agents and Toxins for calendar year 2018, as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). The Secretaries of the U.S. Department of Agriculture (USDA) and Health and Human Services (HHS) must report to Congress annually on the number and nature of notifications received concerning the theft, loss, and release of a biological agent or toxin regulated pursuant to that act.

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Secretary
U.S. Department of Health & Human Services

Enclosure



U.S. Department of Agriculture



U.S. Department of Health & Human Services

JUL 19 2019

The Honorable Chuck Schumer
Minority Leader
United States Senate
Washington, D.C. 20510

Dear Senator Schumer:

We are pleased to transmit to Congress the Report on Notifications of Thefts, Losses, and Releases of Select Agents and Toxins for calendar year 2018, as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). The Secretaries of the U.S. Department of Agriculture (USDA) and Health and Human Services (HHS) must report to Congress annually on the number and nature of notifications received concerning the theft, loss, and release of a biological agent or toxin regulated pursuant to that act.

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Alex M. Azar II
Secretary
U.S. Department of Health & Human Services

Enclosure



The United States Department of Agriculture (USDA)

and

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

**Report to Congress:
Notifications of Thefts, Losses, and Releases
of Biological Select Agents and Toxins**

July 2019

**Report to Congress:
Notifications of Thefts, Losses, and Releases of Biological Select Agents and Toxins
January 1, 2018 – December 31, 2018**

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) requires the Secretaries of Health and Human Services and the U.S. Department of Agriculture to annually report to Congress on the number and nature of notifications received concerning the thefts, losses, and releases of biological select agents and toxins (BSAT).

Overview

The Federal Select Agent Program (FSAP) is managed jointly by the U.S. Department of Health and Human Services (HHS)/Centers for Disease Control and Prevention/Division of Select Agents and Toxins and the U.S. Department of Agriculture (USDA)/Animal and Plant Health Inspection Service/Agriculture Select Agent Services. HHS provides oversight for biological agents and toxins that have the potential to pose a severe threat to public health and safety. USDA provides oversight for biological agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products. HHS and USDA jointly oversee biological agents and toxins that have the potential to pose a severe threat to public health and safety, to animal health, or to animal products. These types of biological agents and toxins are also known as overlap select agents and toxins.

Federal Select Agent Program (FSAP) regulations¹ require the immediate notification to the FSAP upon discovery of a BSAT theft (unauthorized removal), loss (failure to account for), or release (causing an occupational exposure or release outside of the primary barriers of the biocontainment area). FSAP separates these notifications into two categories: *registered entity* and *non-registered entity*. A registered entity is authorized by FSAP to possess, use, or transfer BSAT, based on their having met the requirements for registration. The non-registered entity category includes such entities as clinical or diagnostic laboratories and other entities that identify BSAT contained in specimens that come to them for diagnosis, verification, or proficiency testing. These non-registered entities are exempt from the requirements of the select agents and toxins regulations, provided that they meet the exemption requirements, including that they report any identification of a select agent or toxin from a clinical or diagnostic sample in accordance with the regulations.²

In calendar year 2018 (CY 2018), FSAP received eight reports of a BSAT loss, 193 reports of a BSAT release, and no reports of a BSAT theft. None of the reported losses or releases resulted in a risk to public or agricultural health. None of the reported releases were identified as leading to a laboratory-acquired infection. Below are the findings from each reporting category.

Reports of Loss

In CY 2018, FSAP received eight reports of a BSAT loss, all from registered entities. FSAP refers all reports of a BSAT loss to the Federal Bureau of Investigation (FBI). In CY 2018, the FBI determined that there was no criminal nexus for any of the eight reported losses. Table 1 provides the cause of the loss and number of associated reports.

¹ Found in 7 C.F.R. §331.19 (USDA), 9 C.F.R. §121.19 (USDA), and 42 C.F.R. §73.19 (HHS)

² See 7 CFR §331.5, 9 CFR §121.5, 9 CFR §121.6, 42 CFR §73.5, and 42 CFR §73.6.

Table 1. CY 2018 Reports of BSAT Loss by Cause by Registered Entities

Cause	Number of Reports
Inventory accounting error	3
Sample mistakenly discarded and appropriate biosafety procedures were followed	5
Total	8

Reports of Release

In CY 2018, FSAP received 193 reports of a BSAT release. Of these reports, 66 reports were submitted by registered entities, and 127 reports were from non-registered entities.

FSAP reviews each report of a release to determine the potential for an occupational exposure.³ For eight of the reported releases, FSAP agreed with the entity that these reports presented minimal to no risk of an occupational exposure. The remaining 185 reported releases did involve a BSAT occupational exposure. In 12 of the 185 reports, the entity determined no occupational health services were necessary, based on the circumstances of the release. In the remaining 173 release reports, entities provided 895 individuals (121 individuals from registered entities and 774 from non-registered entities) with occupational health services, including medical assessments, and if needed, diagnostic testing and prophylaxis. None of the reported releases resulted in illnesses, deaths, or transmissions among workers or outside of a laboratory into the surrounding environment or community. Table 2 includes the cause for each reported release.

Table 2. CY 2018 Reports of BSAT Release by Cause and Source

Cause	Reports from Registered Entities	Reports from Non-registered Entities
Bite or scratch from an animal infected with BSAT	1	0
BSAT manipulation outside of a biological safety cabinet or other type of equipment designed to protect laboratorians from exposure to infectious aerosols	11	127
Equipment or mechanical failure	9	0
Failure or problem with personal protective equipment	22	0
Needle stick or other percutaneous exposure with possibly contaminated sharp objects	10	0
Spill of select agent	9	0
Loss of containment (escaped animal) ⁴	4	0
Total	66	127

³ Occupational exposure is defined by the select agents and toxins regulations as "any reasonably anticipated skin, eye, mucous membrane, parenteral contact, or respiratory aerosol exposure to select agents or toxins that may result from the performance of an employee's duties."

⁴ All escaped animals were found, secured, and returned to containment.

Summary

During CY 2018, FSAP received eight reports of BSAT loss, 193 reports of BSAT release, and zero reports of BSAT theft. None of the reported releases resulted in illness, death, or transmission among workers or outside of a laboratory into the surrounding environment or community. The FBI investigated all eight reports of BSAT loss and, in all cases, determined there was no criminal nexus.