



**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, or Releases  
of Biological Select Agents and Toxins**

**Calendar Year 2020**

**June 2021**

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Notifications of Thefts, Losses, or Releases of Biological Select Agents and Toxins  
January 1, 2020 – December 31, 2020**

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. § 262a) and the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. § 8401) require the Secretaries of Health and Human Services and Agriculture, respectively, to annually report to Congress on the number and nature of notifications received concerning the reports of a theft, loss, or release of a biological select agent and toxin (BSAT).

**I. 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/Division of Agricultural Select Agents and Toxins.<sup>1</sup> HHS regulates the biological agents and toxins that have the potential to pose a severe threat to public health and safety. USDA regulates the 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, and to animal health or animal products. These types of biological agents and toxins are also known as overlap select agents and toxins.

The select agent and toxin regulations require immediate notification to FSAP upon discovery of a BSAT theft (unlawful taking), loss (failure to account for), or release (causing an occupational exposure or release outside of the primary barriers of the biocontainment area).<sup>2</sup> FSAP separates these notifications into two categories based on the FSAP registration status of the entity: *registered entity* and *non-registered entity*. A registered entity is authorized by FSAP to possess, use, or transfer BSAT. The non-registered entity includes those that are not registered for possession of BSAT, but have identified BSAT in specimens for diagnosis, verification, or proficiency testing. Non-registered entities are exempt from the requirements of the select agent and toxin regulations, provided that they meet the exemption requirements, including reporting to FSAP of any identification of BSAT from a clinical or diagnostic sample (including environmental).<sup>3</sup>

In calendar year 2020 (CY20), FSAP received 13 reports of losses, 158 reports of releases, and no reports of thefts. None of the reported losses or releases resulted in a risk to public, animal, or plant health, or animal or plant products. Only one reported release resulted in an occupational illness. None of the releases resulted in illnesses among the general public, nor did they result in death of or transmission among workers or transmission to the outside of a laboratory into the surrounding environment or community. Below are the findings from each reporting category.

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<sup>1</sup> Name change effective January 12, 2021.

<sup>2</sup> 7 CFR § 331.19, 9 CFR § 121.19, and 42 CFR § 73.19 outline the reporting of theft, loss or release provisions.

<sup>3</sup> 7 CFR § 331.5, 9 CFR § 121.5, and 9 CFR § 121.6 (Overlap-USDA), and 42 CFR § 73.5, and 42 CFR § 73.6 (Overlap-HHS) outline the exemption provisions.

## II. Reports of Loss

FSAP refers reports of BSAT loss to the Federal Bureau of Investigation (FBI) for further investigation. In CY20, the FBI investigated and determined there was no criminal nexus for any of the 13 losses reported. Table 1 provides the type of reported loss.

*Table 1. CY20 Reports of BSAT Loss by Incident Type*

<b>Incident Type</b>	<b>Number of Reports</b>
Human error in accounting for materials	4
Sample mistakenly destroyed; appropriate biosafety procedures were used for destruction	9

## III. Reports of Release

In CY20, FSAP received 158 reports of releases: 69 from registered entities and 89 from non-registered entities.

FSAP reviews each report of a release to determine the potential for occupational exposure.<sup>4</sup> FSAP agreed with the reporting entities that 24 releases presented minimal to no risk of occupational exposure. The remaining 134 releases involved occupational exposure to BSAT. In 12 of the 134 releases, the reporting entity determined no occupational health services were necessary based on the circumstances of the release. In the remaining 122 releases, the reporting entities provided occupational health services, (including medical assessments, diagnostic testing and/or pharmaceutical prophylaxis) to a total of 483 individuals (68 individuals from 25 registered entities and 415 individuals from 77 non-registered entities). None of the releases resulted in illnesses among the general public, nor did they result in death or transmission among workers or transmission to the outside of a laboratory into the surrounding environment or community. Table 2 includes the cause for each reported release.

*Table 2. CY20 Reports of BSAT Release by Incident Type and Source<sup>5</sup>*

<b>Incident Type</b>	<b>Reports from Registered Entities</b>	<b>Reports from Non-registered Entities</b>
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*	8	84
Decontamination failure	1	0

<sup>4</sup> “Occupational exposure” is defined by the select agent and toxin 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.” 9 C.F.R. § 121.1 (USDA); 42 C.F.R. § 73.1 (HHS).

<sup>5</sup> Registered entities indicated multiple (two) incident types (denoted by an \*) in six reports of release. Therefore, the total number of reports categorized by incident type does not reflect the number of reports received from registered entities.



Incident Type	Reports from Registered Entities	Reports from Non-registered Entities
Deviation from standard laboratory operating procedures, policy, or training, such as not wearing appropriate personal protective equipment prior to entering the laboratory	2	3
Equipment or mechanical failure*	19	0
Failure or problem with personal protective equipment	13	0
Failure in performing a validated inactivation or BSAT removal method*	2	0
Needle stick or other percutaneous exposure with possibly contaminated sharp objects	12	1
Spills of select agents*	16	1
Loss of containment (escaped animal) <sup>6</sup>	1	0

#### *Incident Resulting in Occupational Illness*

One release reported by a non-registered entity resulted in illness of one worker after exposure to *Coxiella burnetii*. The source of the infection was attributed to contact with infected animals in the performance of the worker's duties. The worker received medical treatment and fully recovered from the illness. The entity notified all workers potentially exposed to the infected worker and found no evidence of disease transmission to others.

#### **IV. Summary**

During CY20, FSAP received 13 reports of losses, 158 reports of releases, and no reports of theft of BSAT. None of the reported releases resulted in death or transmission among workers nor transmission to the outside of a laboratory into the surrounding environment or community. FSAP received one report from a non-registered entity of a release that resulted in an occupational illness in one worker that made a full recovery after receiving medical treatment. The FBI investigated all 13 reports of losses and, in all cases, determined there was no criminal nexus.

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<sup>6</sup> All escaped animals were found, secured, and returned to containment.