



**U.S. Department of Agriculture (USDA)**

**and**

**U.S. Department of Health and Human Services (HHS)**

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

**Calendar Year 2019**

**July 6, 2020**

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Notifications of Thefts, Losses, or Releases of Biological Select Agents and Toxins  
January 1, 2019 – December 31, 2019**

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 Agriculture 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/Agriculture Select Agent Services. 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.

Select agent regulations<sup>1</sup> require immediate notification to 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 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 agents and toxins 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) in accordance with the regulations.<sup>2</sup>

In calendar year 2019 (CY19), FSAP received 13 reports of losses, 219 reports of releases, and no reports of thefts. 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.

**II. Reports of Loss**

FSAP refers reports of BSAT loss to the Federal Bureau of Investigation (FBI) for further investigation. In CY19, the FBI investigated and determined there was no criminal nexus for any of the 13 losses reported. Table 1 provides the cause of the failure for the losses.

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<sup>1</sup> 7 C.F.R. §331.19 and 9 C.F.R. §121.19 (USDA), and 42 C.F.R. §73.19 (HHS)

<sup>2</sup> 7 CFR §331.5, 9 CFR §121.5, 9 CFR §121.6, 42 CFR §73.5, and 42 CFR §73.6 outline the exemption provisions.

*Table 1. CY19 Reports of BSAT Loss by Cause*

<b>Cause</b>	<b>Number of Reports</b>
Human error in accounting for materials	8
Sample mistakenly destroyed; appropriate biosafety procedures were used for destruction	5
<b>Total</b>	<b>13</b>

**III. Reports of Release**

In CY19, FSAP received 219 reports of releases. Of these reports, 92 were from registered entities, and 127 were from non-registered entities.

FSAP reviews each report of a release to determine the potential for occupational exposure.<sup>3</sup> For 24 of the reported releases, FSAP agreed with the entities that these releases presented minimal to no risk of occupational exposure. The remaining 195 reported releases involved BSAT occupational exposure. In 18 of the 195 reports, the entity determined no occupational health services were necessary based on the circumstances of the release. In the remaining 177 instances, entities provided a total of 1076 individuals (166 individuals from 55 registered entities and 910 from 122 non-registered entities) with occupational health services, including medical assessments, and diagnostic testing and/or pharmaceutical prophylaxis as needed. None of the releases resulted in illness, death, or secondary transmission to/or among workers, nor were there any BSAT transmissions outside of a laboratory. Table 2 includes the causes of releases for all reported instances.

*Table 2. CY19 Reports of BSAT Release by Cause and Source*

<b>Cause</b>	<b>Reports from Registered Entities</b>	<b>Reports from Non-registered Entities</b>
Bite or scratch from an animal infected with BSAT	4	0
BSAT manipulation outside of a biological safety cabinet or other type of equipment designed to protect laboratorians from exposure to infectious aerosols	13	127 <sup>4</sup>
Decontamination failure	1	0
Deviation from standard laboratory operating procedures, policy, or training, such as not wearing appropriate personal protective equipment prior to entering the laboratory	10	0
Equipment or mechanical failure	16	0
Failure or problem with personal protective equipment	21	0
Failure in performing a validated inactivation or BSAT removal method	2	0

<sup>3</sup> 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.”

<sup>4</sup>Primarily clinical or diagnostic laboratories working with diagnostic samples that were later identified as containing BSAT.

<b>Cause</b>	<b>Reports from Registered Entities</b>	<b>Reports from Non-registered Entities</b>
Needle stick or other percutaneous exposure with possibly contaminated sharp objects	13	0
Spills of select agents	10	0
Loss of containment (escaped animal)	2	0
<b>Total</b>	<b>92</b>	<b>127</b>

#### **IV. Summary**

During CY19, FSAP received 13 reports of losses, 219 reports of releases, and zero reports of thefts. None of the releases resulted in illnesses, deaths, or transmissions to/or among workers, nor was there a BSAT transmission to the outside of a laboratory into the surrounding environment or community. The FBI investigated all 13 reports of losses and, in all cases, determined there was no criminal nexus.