

2019 Annual Report of the **Federal Select Agent Program**



Contents

- ACRONYMS 3**
- EXECUTIVE SUMMARY 5**
- FEDERAL SELECT AGENT PROGRAM: BY THE NUMBERS..... 8**
- BIOLOGICAL SELECT AGENTS AND TOXINS..... 9**
- INTRODUCTION 10**
- KEY PROGRAM STATISTICS..... 11**
 - REGISTRATION..... 11
 - AMENDMENTS TO REGISTRATION 14
 - TIER 1 BSAT 14
 - TOP BSAT REGISTERED WITH EACH AGENCY..... 15
 - LABORATORY TYPES 15
 - SECURITY RISK ASSESSMENTS 16
 - INSPECTION DATA..... 18
 - INSPECTION FINDINGS AND COMPLIANCE 19
 - REPORTS AND REFERRALS..... 20
 - RESTRICTED EXPERIMENTS 21
 - EXCLUSIONS 21
 - TRANSFERS OF BSAT..... 22
 - THEFT, LOSS, AND RELEASE OF BSAT..... 24
 - REPORT OF THE IDENTIFICATION OF BSAT 25
 - EMERGENCY MANAGEMENT 27
 - FEDERAL REGISTER NOTICES, POLICY STATEMENTS, GUIDANCE, AND REGULATORY INTERPRETATIONS 28
 - OUTREACH..... 29
- CONCLUSION 30**
- REFERENCES..... 31**

Acronyms

Acronym	Description
AgSAS	The Agriculture Select Agent Services , located within the Animal and Plant Health Inspection Service of the United States Department of Agriculture, regulates the possession, use, and transfer of biological select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products.
APHIS	The Animal and Plant Health Inspection Service , located within the United States Department of Agriculture, is a multi-faceted Agency with a broad mission area that includes protecting and promoting U.S. agricultural health, regulating genetically engineered organisms, administering the Animal Welfare Act and carrying out wildlife damage management activities.
APHIS IES	APHIS Investigative and Enforcement Services , located within the United States Department of Agriculture, provides investigative, enforcement, and regulatory support services to four APHIS programs—Animal Care, Biotechnology Regulatory Services, Plant Protection and Quarantine, and Veterinary Services. IES also provides these services for agricultural quarantine inspection activities carried out by the Department of Homeland Security’s Customs and Border Protection
ARO	An Alternate Responsible Official is an individual that is appointed and approved to assume the Responsible Official’s duties in their absence and has the authority to act on behalf of the registered entity.
BRAG	Located in the Federal Bureau of Investigation’s Criminal Justice Information Services division, the Bioterrorism Risk Assessment Group is responsible for conducting security risk assessments.
BSAT	Biological select agents and toxins are pathogens or toxins that have been determined to have the potential to pose a severe threat to human, animal, or plant health, or to animal or plant products.
BSC	A Biosafety Cabinet is an enclosed, ventilated laboratory workspace for safely working with materials contaminated with (or potentially contaminated with) pathogens requiring a defined biosafety level.
BSL	A Biosafety Level is used to identify the protective measures needed in a laboratory setting to protect workers, the environment, and the public.
CAP	A Corrective Action Plan is voluntarily developed by an entity to address serious and recurrent concerns that do not present an imminent risk to public health and safety; the plan is submitted to the Federal Select Agent Program and includes target completion dates and the specifics of how the entity will correct identified regulatory deficiencies.
CDC	The Centers for Disease Control and Prevention , located within the Department of Health and Human Services, conducts science and provides health information to protect people from health, safety, and security threats.

Acronym	Description
DSAT	The Division of Select Agents and Toxins , located within the Center for Preparedness and Response within the Centers for Disease Control and Prevention, regulates the possession, use, and transfer of biological select agents and toxins that have the potential to pose a severe threat to human health.
eFSAP	eFSAP is the Federal Select Agent Program's electronic information system which allows for registered entities to manage their registrations and directly interact with the Program.
FBI	The Federal Bureau of Investigation is an intelligence-driven and threat-focused national security organization with both intelligence and law enforcement responsibilities.
FSAP	The Federal Select Agent Program is jointly comprised of CDC/DSAT and APHIS/AgSAS. FSAP oversees the possession, use and transfer of biological select agents and toxins, which have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products.
HHS	The U.S. Department of Health and Human Services is a cabinet-level agency whose mission is to enhance the health of all Americans by providing effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.
HHS OIG	HHS Office of Inspector General is an independent office within HHS dedicated to oversight, combating fraud, waste and abuse and to improving the efficiency of HHS programs.
RO	The Responsible Official is the individual designated by a registered entity with the authority and responsibility to act on behalf of the entity to ensure compliance with the select agent regulations.
SAR	The Select Agent Regulations implement the provisions of the Public Health Security and Bioterrorism Preparedness and Response and the Agricultural Bioterrorism Protection Acts of 2002, setting forth the requirements for possession, use, and transfer of select agents and toxins.
SRA	A Security Risk Assessment is conducted by FBI/BRAG of all individuals, ROs, AROs, and non-governmental entities to identify those individuals who are prohibited from access to select agents and toxins based on the restrictions identified in the USA PATRIOT Act.
USC	The United States Code is a consolidation and codification by subject matter of the general and permanent laws of the United States. It is prepared by the Office of the Law Revision Counsel of the United States House of Representatives.
USDA	The United States Department of Agriculture provides leadership on food, agriculture, natural resources, rural development, nutrition, and related issues based on public policy, the best available science, and effective management.

Executive Summary

The Federal Select Agent Program, established in response to a Congressional mandate, regulates the possession, use, and transfer of biological select agents and toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products. The Federal Select Agent Program is jointly managed by the U.S. Department of Health and Human Services/Centers for Disease Control and Prevention/Center for Preparedness and Response/Division of Select Agents and Toxins and the U.S. Department of Agriculture/Animal and Plant Health Inspection Service/Veterinary Services/Agriculture Select Agent Services. Examples of select agents and toxins include the organisms that cause anthrax, smallpox, and Foot-and-Mouth disease, the plant pathogen *Ralstonia solanacearum*, as well as the toxin ricin.

Work with select agents and toxins provides important scientific discoveries that have led to improved detection and prevention of human, animal and plant diseases, as well as diagnostic and treatment options to address them. The Federal Select Agent Program regulates laboratories that conduct research on these potentially dangerous select agents and toxins, while ensuring this work is done as safely and securely as possible.

The Federal Select Agent Program publishes an annual report to communicate operational metrics to increase understanding of its work. This report, summarizing calendar year 2019 data, is the fifth such report. Previous reports can be found on the Federal Select Agent Program website at <https://www.selectagents.gov/publications.html>.

Registered Entities

Entities that wish to possess, use, or transfer biological select agents and toxins must register with the Federal Select Agent Program. As of December 31, 2019, 247 entities were registered with the Federal Select Agent Program: 34 entities registered with the Agriculture Select Agent Services as the lead agency and 213 entities with the Division of Select Agents and Toxins as the lead agency. The term “lead agency” indicates which agency the registered entity uses as its primary point of contact (i.e., U.S. Department of Agriculture/Agriculture Select Agent Services or U.S. Department of Health and Human Services/Division of Select Agents and Toxins).

Entities can be jointly overseen by both the Agriculture Select Agent Services and the Division of Select Agents and Toxins if the entity is registered with one lead agency but is also registered for an agent or toxin regulated solely by the other agency. In 2019, 47 of the 247 registered entities were jointly managed: The Agriculture Select Agent Services served as the lead agency for nine of those entities and the Division of Select Agents and Toxins served as the lead agency for 38 of those entities. During 2019, three entities applied to the Federal Select Agent Program for new registrations, and the approval process was still underway as of December 31, 2019. Seven entities withdrew their registrations with the Federal Select Agent Program, all with the Division of Select Agents and Toxins. Entities withdraw their registrations when they no longer need to possess, use, or transfer biological select agents or toxins.

Security Risk Assessments

The Bioterrorism Risk Assessment Group, a program of the Federal Bureau of Investigation’s Criminal Justice Information Services Division, performs a security risk assessment (an electronic records check) to identify individuals who apply for access to biological select agents and toxins that are prohibited access because they are a “restricted person.”¹ As of December 31, 2019, the Federal Select Agent Program had 8,360 individuals approved to access biological select agents and toxins. Based on security risk assessments conducted during 2019, the Federal Select Agent Program granted 3,835 new approvals for access to biological select agents and toxins (i.e., new individuals, renewals, and individuals approved for access at multiple entities). In 2019, the Bioterrorism Risk Assessment Group identified 27 individuals as “restricted persons” and the

¹ A “restricted person” is an individual who is denied access to select agents or toxins due to restrictors defined by Title 18 of the United States Code [18 USC 175b(d)(2)].

Federal Select Agent Program prohibited them from having access to biological select agents and toxins. The most common reason for restriction (18 of the 27 individuals) was due to a conviction in any court of a crime punishable by imprisonment for a term exceeding one year.

Inspections

The Federal Select Agent Program conducted 189 inspections in 2019: 21 by the Agriculture Select Agent Services, 122 by the Division of Select Agents and Toxins, and 46 jointly.

Compliance Actions

If significant departures from the select agent regulations are identified, the Federal Select Agent Program has a number of options for compliance actions, including:

- Participation in the Federal Select Agent Program Corrective Action Plan program, where an entity voluntarily develops and implements a plan of corrective actions that is closely monitored by the Federal Select Agent Program;
- Suspension (in part or in whole) of an entity's registration to possess, use, or transfer biological select agents and toxins;
- Revocation of an entity's registration;
- Referral of an entity to the Health and Human Services Office of Inspector General or the Animal and Plant Health Inspection Service Investigative and Enforcement Services (or other Offices of Inspector General if the entity is a federal entity) for further investigation and possible civil monetary penalties; and
- Notification to the Federal Bureau of Investigation of inspection findings that may involve a violation of criminal law.

Compliance actions taken in 2019 include the following:

- One entity entered into the Federal Select Agent Program Corrective Action Plan program.
- An entity that was placed on partial suspension in 2018 continued to fail to meet biosafety regulatory requirements and was placed on a full suspension in 2019. After the entity implemented corrective actions, the entity registration was restored to partial suspension in 2019.
- Two additional entities remained on partial suspensions that were initially imposed in 2018. These two entities received approval to resume their work during 2019.
- The Federal Select Agent Program referred one entity to both the Health and Human Services Office of Inspector General and the Animal and Plant Health Inspection Service Investigative and Enforcement Services. The Federal Select Agent Program also referred one entity to the Department of Defense Office of Inspector General.
- The Federal Select Agent Program notified the Federal Bureau of Investigation of 18 matters for potential investigation. This included 13 reports of losses that are discussed further in the "Theft, Loss, or Release of Biological Select Agents and Toxins" section.

Confidential Reporting Systems

The Health and Human Services Office of Inspector General and the Department of Agriculture Office of Inspector General operate confidential systems the public can use to report biosafety and security issues associated with the possession, use, and transfer of biological select agents and toxins. The Offices of Inspector General request that the Federal Select Agent Program assess each report to determine if non-compliance with the select agent regulations occurred. In 2019, the Federal Select Agent Program received one such report from the Health and Human Services Office of Inspector General. Following an inspection by the Federal Select Agent Program, no regulatory concerns related to the reported issue were discovered.

Transfers of Biological Select Agents or Toxins

Entities must request prior authorization to transfer or import biological select agents or toxins. Biological select agents and toxins may be transferred from one entity to another for purposes such as additional testing of identified biological select agents and toxins from diagnostic specimens, scientific or clinical research, and the production of therapeutics. In 2019, the Federal Select Agent Program approved 171 transfers: 136 (including 7 importations) by the Division of Select Agents and Toxins and 35 (including 19 importations) by the Agriculture Select Agent Services. During 2019, 158 transfers were completed.

Theft, Loss, or Release of Biological Select Agents and Toxins

Theft (unauthorized removal), loss (failure to account for), or release (occupational exposure or release outside of the primary barriers of the biocontainment area) of a biological select agent or toxin must be reported to the Federal Select Agent Program.

In 2019, the Federal Select Agent Program received 13 reports of loss and 219 reports of a release of a biological select agent or toxin. There were no reports of theft.

- None of the losses resulted in a risk to public or agricultural health.
- Of the 219 reports of a release, registered entities submitted 92 reports, and non-registered entities (e.g., clinical, diagnostic, or public health laboratories, which are not required to register) submitted 127 reports.
 - ◆ For 24 of the reported releases, the Federal Select Agent Program agreed with the entity that these reports presented minimal to no risk of an occupational exposure.
 - ◆ The remaining 195 reported releases did involve occupational exposure to a biological select agent or toxin.
 - 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 release reports, entities provided 1,076 individuals (166 individuals from registered entities and 910 from non-registered entities) with occupational health services, including medical assessments and, if needed, diagnostic testing and prophylaxis.
 - ◆ None of the releases resulted in illnesses, deaths, or transmissions among workers or outside of a laboratory.

The Federal Select Agent Program engages with the regulated community throughout the year to increase awareness of safe work practices in the laboratory to reduce the number of occupational exposures.

Report of the Identification of a Biological Select Agent or Toxin

Registered entities and unregistered clinical, diagnostic, or public health laboratories must notify the Federal Select Agent Program of biological select agents and toxins identified as a result of diagnosis, verification, and proficiency testing, and of the final disposition of these biological select agents and toxins. The Federal Select Agent Program received 1,304 such reports in 2019. Of these, the Agriculture Select Agent Services received 34; the Division of Select Agents and Toxins received 1,270.

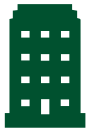
The most frequently identified biological select agents and toxins reported to the Division of Select Agents and Toxins in 2019 were Eastern equine encephalitis virus (425), Botulinum neurotoxin (219), Botulinum neurotoxin producing species of *Clostridium* (173), *Brucella melitensis* (106), and *Francisella tularensis* (83).

The most frequently identified biological select agents and toxins reported to the Agriculture Select Agent Services in 2019 were highly pathogenic avian influenza viruses (16), Newcastle disease virus (8), *Bacillus anthracis* (6) and *Ralstonia solanacearum* (2).

Conclusion

The Federal Select Agent Program was established in response to a Congressional mandate to ensure the safety and security of research involving select agents and toxins. Overall, most entities registered with the Federal Select Agent Program are compliant with the regulations as evidenced by the small number of compliance issues identified in this report. Also, of note, none of the relatively small number of reported releases or losses of select agents and toxins resulted in a risk to public or agricultural health. By providing oversight through the Federal Select Agent Program, entities are able to work with potentially dangerous biological agents and toxins in a safe and secure manner. This work is essential as it has led to important scientific discoveries that have improved detection and prevention of human, animal and plant diseases, as well as diagnostic and treatment options to address them.

FEDERAL SELECT AGENT PROGRAM: BY THE NUMBERS 2019



247

entities registered



8,360

individuals approved to access
biological select agents and
toxins



189

inspections conducted

HHS Select Agents and Toxins

Abrin
Bacillus cereus Biovar *anthracis**
Botulinum neurotoxins*
Botulinum neurotoxin producing species of
*Clostridium**
Conotoxins
Coxiella burnetii
Crimean-Congo hemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus
Ebola virus*
*Francisella tularensis**
Lassa fever virus
Lujo virus
Marburg virus*
Monkeypox virus
Reconstructed 1918 Influenza virus
Ricin
Rickettsia prowazekii
SARS-associated coronavirus
Saxitoxin
Chapare
Guanarito
Junin
Machupo
Sabia
Staphylococcal enterotoxins
T-2 toxin
Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses
 Far Eastern subtype
 Siberian subtype
Kyasanur Forest disease virus
Omsk hemorrhagic fever virus
Variola major virus*
Variola minor virus*
*Yersinia pestis**

USDA Select Agents

African horse sickness virus
African swine fever virus
Avian influenza virus
Classical swine fever virus
Coniothyrium glycines (formerly *Phoma glycinicola*
and *Pyrenochaeta glycines*)
Foot-and-mouth disease virus*
Goat pox virus
Lumpy skin disease virus
Mycoplasma capricolum
Mycoplasma mycoides
Newcastle disease virus
Peronosclerospora philippinensis
(*Peronosclerospora sacchari*)
Peste des petits ruminants virus
Ralstonia solanacearum
Rathayibacter toxicus
Rinderpest virus*
Sclerophthora rayssiae
Sheep pox virus
Swine vesicular disease virus
Synchytrium endobioticum
Xanthomonas oryzae

Overlap Select Agents⁺

*Bacillus anthracis**
Bacillus anthracis Pasteur strain
Brucella abortus
Brucella melitensis
Brucella suis
*Burkholderia mallei**
*Burkholderia pseudomallei**
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan equine encephalitis virus

* Tier 1 agents

⁺ These are regulated by both HHS and USDA due to their potential to pose a severe threat to both public health and safety and to animal health or products.

List last updated on September 24, 2018

Introduction

The Federal Select Agent Program (FSAP) was established in response to a Congressional mandate to ensure the safety and security of research with biological select agents and toxins (BSAT). While potentially dangerous if not conducted safely and securely, work with select agents and toxins has led to important scientific discoveries which have improved detection and prevention of human, animal and plant diseases, as well as diagnostic and treatment options to address them.

FSAP is jointly managed by the U.S. Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC)/Center for Preparedness and Response/Division of Select Agents and Toxins (DSAT) and the U.S. Department of Agriculture (USDA)/Animal and Plant Health Inspection Service (APHIS)/Veterinary Services/Agriculture Select Agent Services (AgSAS). FSAP oversees the possession, use, and transfer of BSAT, which have the potential to pose severe threat to human, animal, or plant health, or to animal or plant products, in accordance with the HHS and USDA select agent regulations (SAR)².

FSAP helps to ensure work with BSAT is conducted as safely and securely as possible by:

- Developing, implementing, and enforcing the SAR;
- Maintaining a national database to track who, where, and what work is being conducted with BSAT;
- Inspecting entities that possess, use, or transfer BSAT to ensure that these agents and toxins are handled safely and securely;
- Ensuring all individuals applying for access to BSAT undergo a security risk assessment (SRA), and that those deemed “restricted persons” are prohibited from accessing BSAT;
- Developing guidance documents and conducting trainings to help regulated entities maintain compliance with the SAR; and
- Reviewing incidents in which non-compliance with the SAR may have occurred.

FSAP has an active outreach program designed to provide opportunities for the program to interact with members of the regulated community. FSAP also engages with the regulated community to identify solutions that ensure compliance with the SAR, including publishing policy statements, guidance documents, and other materials. Examples of FSAP outreach include holding trainings and workshops and participating in conferences.

This annual report provides insight into the regulatory functions of FSAP, as well as compliance with the SAR at laboratories across the nation. Publication of this report reflects FSAP’s ongoing commitment to increasing transparency and understanding of the program.

² 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121

Key Program Statistics

Registration

Registered Entities

BSAT are divided into three categories based on whether an agent causes disease in humans, animals, plants, or a combination of humans and animals (see current list found on page 9). In accordance with the Public Health Service Act (42 U.S.C. 262a(a)(2)) and the Agricultural Bioterrorism Protection Act (7 U.S.C. 8401(a)(2)) of 2002, FSAP performs biennial reviews to update and revise the BSAT list as necessary. The three categories of BSAT are:

- **HHS select agents and toxins:** BSAT that have the potential to pose a severe threat to public health and safety. These are regulated by HHS.
- **USDA select agents:** BSAT that have the potential to pose a severe threat to animal health or to animal products and to plant health or to plant products. These are regulated by USDA.
- **Overlap select agents:** BSAT that have the potential to pose a severe threat to both public health and safety and to animal health or products. Overlap BSAT are regulated by both HHS and USDA.

Work with BSAT by entities may include the development of diagnostic assays that are critical to inform patient care decisions, disease surveillance and diagnostic services, basic science and clinical research, and production of biologics and therapeutics such as antibiotics and vaccines. Entities that wish to possess, use, or transfer BSAT must register with either DSAT or AgSAS by completing the Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins (i.e., [APHIS/CDC Form 1](#)).

The APHIS/CDC Form 1 requires:

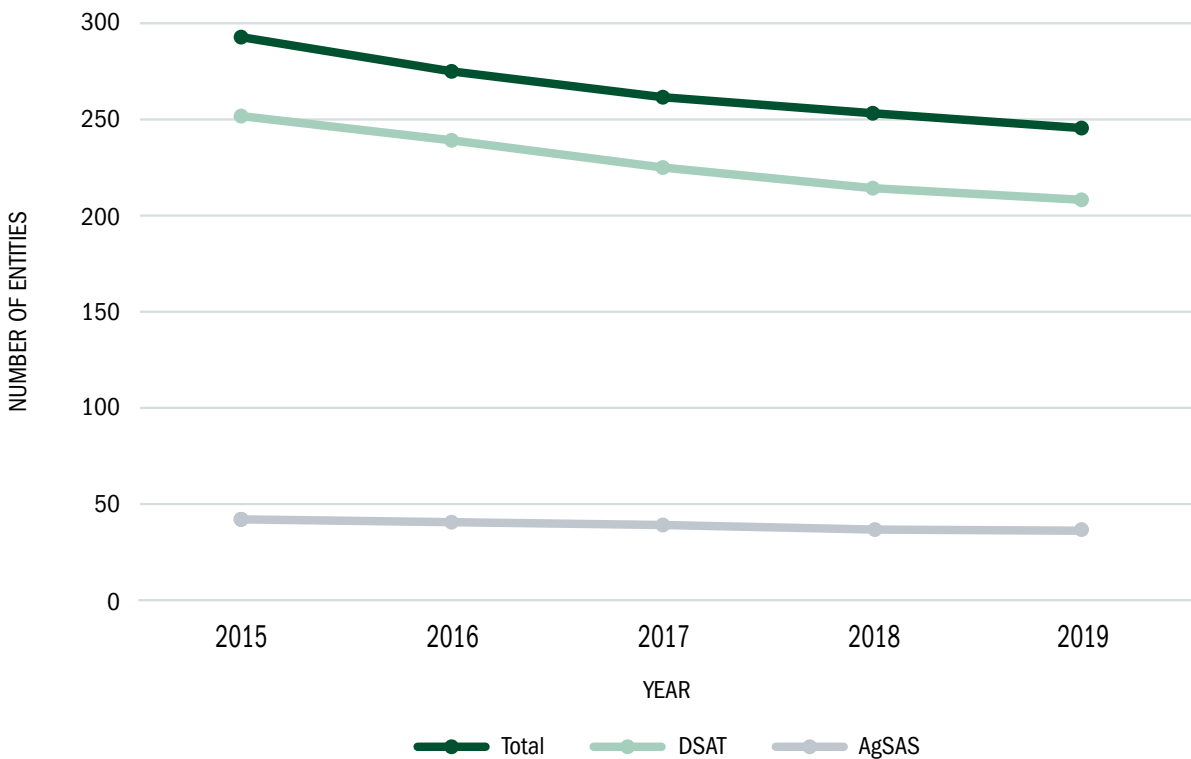
- Facility information
- A list of BSAT to be possessed, used, or transferred by the entity
- A list of individuals who will have access to BSAT
- A description of the work to be performed
- Information about where the work will be performed

Once the initial APHIS/CDC Form 1 is received and reviewed, a site inspection is scheduled to verify the submitted information and to confirm the entity can be compliant with the SAR. Once the inspection is complete and the entity addresses any issues identified during the inspection, a certificate of registration is issued allowing the entity to acquire and work with the BSAT listed in the application.

If the entity plans to register for USDA-only BSAT, it must register with AgSAS; and if it plans to register for HHS-only BSAT, it must register with DSAT. If the entity plans to register for overlap BSAT or a combination of HHS-only and USDA-only BSAT, it may choose to register with either DSAT or AgSAS. DSAT and AgSAS work closely together in the oversight of entities that have BSAT regulated by both agencies.

At the end of 2019, 247 entities were registered with FSAP: 34 with AgSAS and 213 with DSAT (Figure 1). The lead agency, either DSAT or AgSAS, is responsible for administering all activities and communications with respect to an entity's registration, including coordination with the non-lead agency. Entities are jointly overseen by both AgSAS and DSAT if the entity is registered with one lead agency but is also registered for an agent or toxin regulated solely by the other agency. In 2019, both AgSAS and DSAT jointly oversaw 47 of the 247 total entities registered with the program: AgSAS served as the lead agency for 9 of those entities and DSAT served as the lead agency for 38 of those entities. There has been a general downward trend in the number of registered entities since 2015.

Figure 1: Number of FSAP-Registered Entities by Agency and Year, 2015-2019



Entity Types

FSAP regulates a diverse community of registered entities that are sorted into five types:

- Academic – A university, college, or other institution of higher learning. Academic institutions can be either private (neither owned nor controlled by any government entity) or state supported (predominantly funded through the government).
- Commercial – A privately owned for-profit company, including partnerships and corporations either privately held or whose shares are traded on the open market.
- Federal government – An entity that is part of an agency of the federal government.
- Non-federal government – An entity that is part of an agency of a state or local government (excluding academic entities).
- Private – A privately owned non-profit company, including partnerships and corporations where no part of the income is distributed to its owners, directors, officers, members, or stockholders and whose principal purpose is for charitable or benevolent purposes.

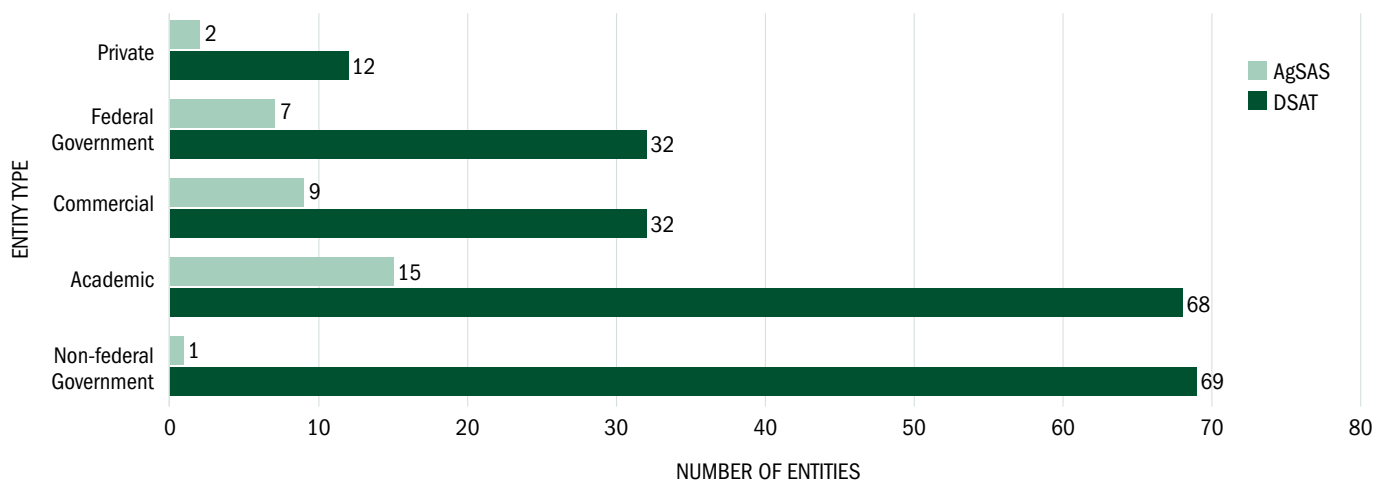
Regulated entities during calendar year 2019 consisted of³:

- 34% academic,
- 28% non-federal government,
- 17% commercial,
- 16% federal government, and
- 6% private.

³ Note that the entity type percentages do not add up to 100% due to rounding decimals to the nearest whole number.

The relative percentages of each entity type have remained consistent since 2015. Figure 2 details the number of entities registered either with DSAT or AgSAS by entity type in 2019.

Figure 2: Number of FSAP-Registered Entities by Type, 2019



New Registration Applications

A facility must register with FSAP to possess, use, or transfer BSAT. During 2019, FSAP reviewed six applications from entities that wished to newly register with FSAP. Three of the six applications were received by FSAP in 2019, and the approval process was still underway for all three of those as of December 31, 2019. The other three applications were received in 2018. Of these, one application was approved in 2019, one entity withdrew their application, and one was still underway as of the end of 2019.

Entity Withdrawals

When an entity decides that it no longer needs to possess, use, or transfer BSAT, it can request to withdraw its registration. To do so, the entity must provide documentation that all BSAT in its possession was either destroyed or transferred to another registered entity in compliance with the SAR. If the entity decides to resume BSAT work after withdrawing their registration, it must reapply to obtain a new FSAP certificate of registration.

As shown in Table 1, seven entities withdrew their registration from FSAP in 2019, all from DSAT. The reason entities cited for withdrawing were that they no longer needed to possess or work with BSAT. A total of 75 entities withdrew their registrations during 2015-2019, which contributed to a 15% reduction in the total number of registered entities.

Table 1: Number of Entity Withdrawals by Entity Type, 2019

Entity Type	Number
Academic	0
Commercial	3
Federal government	1
Non-federal government	2
Private	1
Total	7

Renewals

A registered entity must renew its registration every three years. In 2019, FSAP approved 70 renewals: 14 by AgSAS and 56 by DSAT, compared to 86 total renewals in 2016 when the same entities last renewed their registrations. While year-to-year variation in the number of registration renewals is expected, the overall decrease in the number of FSAP-registered entities also resulted in a decrease in the number of entity renewals in 2019.

Amendments to Registration

When a registered entity needs to amend their approved registration, they must submit an updated section of the APHIS/CDC Form 1 to FSAP. Inspectors review the amendments to ensure that appropriate measures are in place at each registered entity to prevent the unauthorized access, theft, loss, or release of select agents and toxins. Examples of amendments to registration include addition or removal of laboratory rooms on a registration, adding a new BSAT to a registration, or updating a principal investigator's work objective. Table 2 lists the 1,259 amendments to registration approved in 2019 that required FSAP inspector review, stratified by the approving agency and the sections of the APHIS/CDC Form 1 that were modified.

Table 2: Number of Approved Amendments to Registration that Required FSAP Inspector Review, by Amended Section of the APHIS/CDC Form 1 and Agency, 2019

Registration Amendment to APHIS/CDC Form 1	AgSAS	DSAT	Total
Section 1 - Change Entity Physical or Additional Address	5	17	22
Section 4 - Change Responsible Official	6	42	48
Section 5A - Modify Entity-Wide Security Assessment and Incident Response	8	47	55
Section 5B - Modify Entity-Wide Biosafety/Biocontainment	2	3	5
Section 5C - Modify Entry Requirements for Federal Select Agent Program Inspectors	11	50	61
Section 6 - Modify Building	0	10	10
Section 6 - Modify Room or Suite	6	61	67
Section 6 - Remove Room or Suite	2	10	12
Section 7AC - Add New Work Objective	7	69	76
Section 7AC - Modify Work Objective and/or Attachment(s)	71	723	794
Section 7AC - Remove Approved Work Objective	11	98	109
Total Approved Amendments	129	1,130	1,259

The electronic Federal Select Agent Program (eFSAP) information system, which allows for registered entities to manage their registrations and directly interact with FSAP, automates many other types of administrative amendments that do not require FSAP inspector review. Examples of these administrative amendments are removal of an individual from an entity's registration, generating a unique identifier number for an individual being added to entity's registration for the Bioterrorism Risk Assessment Group (BRAG) to use for the SRA, or updating entity contact information.

Tier 1 BSAT

Tier 1 BSAT are those that represent the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects on the economy, critical infrastructure, or public confidence. In 2019, nine entities were registered with AgSAS for Tier 1 BSAT, representing 26% of all AgSAS-led entities. An additional 117 entities were registered with DSAT for Tier 1 BSAT, representing 55% of all DSAT-led entities. Since 2015, the total percentage of FSAP-regulated entities registered for Tier 1 BSAT has averaged around 50%, including 51% of FSAP-regulated entities in 2019.

Top BSAT Registered with Each Agency

Table 3 lists the BSAT most frequently registered with each agency as of December 31, 2019. To determine the most frequently registered BSAT, FSAP counted the total number of entities registered for each BSAT, regardless of whether the entity currently possessed the select agent or toxin. The most frequently registered BSAT remained relatively consistent over the last five years. The most frequently registered BSAT with DSAT are the *Brucella* species and *Bacillus anthracis* Pasteur strain. For AgSAS, Newcastle disease virus and Avian influenza virus have consistently ranked as the most commonly registered BSAT.

Table 3: Most Frequently Registered Agents with Each Agency, 2019

Registered with DSAT	Registered with AgSAS
1. <i>Brucella melitensis</i>	1. Newcastle disease virus
2. <i>Brucella suis</i>	2. Avian influenza virus
3. <i>Brucella abortus</i>	3. <i>Ralstonia solanacearum</i>
4. <i>Bacillus anthracis</i> (Pasteur strain)	4. <i>Xanthomonas oryzae</i>
5. <i>Francisella tularensis</i> *	5. <i>Brucella abortus</i>
6. <i>Yersinia pestis</i> *	6. <i>Bacillus anthracis</i> *
7. <i>Burkholderia pseudomallei</i> *	<i>Francisella tularensis</i> *+
<i>Bacillus anthracis</i> *	<i>Brucella melitensis</i>
8. <i>Burkholderia mallei</i> *	<i>Brucella suis</i>
9. Botulinum neurotoxin producing species of <i>Clostridium</i> *	7. <i>Burkholderia mallei</i> *
Eastern Equine Encephalitis virus	<i>Burkholderia pseudomallei</i> *
	<i>Bacillus anthracis</i> (Pasteur Strain)
	<i>Rathayibacter toxicus</i>

*Indicates Tier 1 BSAT

+Some entities that are registered with AgSAS as a lead agency may also be registered for HHS-only agents

Laboratory Types

Each regulated entity has one or more laboratories or secure storage locations where BSAT work is conducted or where BSAT is stored. Laboratories that work with BSAT range from biosafety level 2 (BSL-2) to maximum containment at biosafety level 4 (BSL-4). At each containment level, there is an equivalent set of biosafety guidelines for work with animals designated as animal biosafety level 2 (ABSL-2) through maximum containment at animal biosafety level 4 (ABSL-4). Entities may register multiple types of laboratories at different biosafety levels (BSL) depending on the work performed in those laboratories.

In 2019, 30% of entities had registered BSL-2/ABSL-2 laboratories, 81% of entities had registered BSL-3/ABSL-3 laboratories, and 3% of entities had registered BSL-4/ABSL-4 laboratories. Table 4 lists the number of entities that are registered for a Tier 1 BSAT at each BSL/ABSL, and the number of entities at each BSL/ABSL by entity type. The percentages for each BSL/ABSL have remained consistent over the last three years.

Table 4: Number of Entities by Laboratory and Entity Types, 2019

Laboratory Type: Biosafety Level	Total Registered Laboratories	Registered for Tier 1 Agent	Entity Type: Commercial	Entity Type: Federal Government	Entity Type: Academic	Entity Type: Non-Federal Government	Entity Type: Private
BSL-2/ABSL-2	74	52	24	16	19	10	5
BSL-3/ABSL-3	199	100	18	27	72	69	13
BSL-4/ABSL-4	8	8	0	5	2	0	1

Note: Entities may register multiple types of laboratories at different BSL, and therefore the total number does not reflect the number of registered entities

Security Risk Assessments

One of the fundamental elements of the SAR is to prohibit access to BSAT to those who intend to use them for unlawful purposes, particularly bioterrorism. FSAP works closely with BRAG, a program of the Federal Bureau of Investigation's (FBI) Criminal Justice Information Services Division, to identify individuals who apply for access to BSAT but are prohibited because they are a "restricted person" as defined by Title 18 of the United States Code (USC) [18 USC 175b(d)(2)]. An SRA is a BRAG electronic records check to determine whether an entity or an individual is a "restricted person" as identified by one of the statutory restrictors which would either deny or limit access. The results of an SRA assist FSAP in determining whether an individual or entity can have access to BSAT. By regulation, an SRA is valid for three years, at which point access approval must be renewed.

A "restricted person" cannot be granted access to any BSAT. A "restricted person" is defined by statute⁴ as an individual who:

- is under indictment for a crime punishable by imprisonment for a term exceeding one year;
- has been convicted in any court of a crime punishable by imprisonment for a term exceeding one year;
- is a fugitive from justice;
- is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 USC 802));
- is an alien illegally or unlawfully in the United States;
- has been adjudicated as a mental defective or has been committed to any mental institution;
- (i) is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country which the Secretary of State, pursuant to section 6(j) of the Export Administration Act of 1979 (50 USC App. 2405(j)), section 620A of chapter 1 of part M of the Foreign Assistance Act of 1961 (22 USC 2371), or section 40(d) of chapter 3 of the Arms Export Control Act (22 USC 2780(d)), has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism, or (ii) acts for or on behalf of, or operates subject to the direction or control of, a government or official of a country described in this subparagraph;
- has been discharged from the Armed Services of the United States under dishonorable conditions; or
- is a member of, acts for or on behalf of, or operates subject to the direction or control of, a terrorist organization as defined in section 212(a)(3)(B)(vi) of the Immigration and Nationality Act (8 USC 1182(a)(3)(B)(vi)).

4 18 USC 175b(d)(2)

In addition, an individual’s access approval may be denied, limited, or revoked if the FBI identifies the individual as being reasonably suspected by any Federal law enforcement or intelligence agency of:

- Committing a crime as defined in Title 18 of the USC (18 USC 2332b(g)(5));
- Knowing involvement with an organization that engages in domestic or international terrorism as defined in Title 18 of the USC (18 USC 2331) or with any other organization that engages in intentional crimes of violence; or
- Being an agent of a foreign power as defined in Title 50 of the USC (50 USC 1801).

At the end of 2019, there were 8,360 individuals with current SRAs approved for access to BSAT. In 2019, FSAP granted 3,835 approvals (new and renewal applications) for access to BSAT (Table 5). The total number of individuals approved for access to BSAT per entity type (8,650 total access approvals) is greater than the number of SRAs for individuals because an individual can be approved for access to BSAT at multiple entities (e.g., as collaborator or guest researcher) based on one current SRA. Thirty-eight percent of the individuals approved for access to BSAT were those working at academic entities, followed by individuals working at federal government entities (30%). For the fifth year in a row, academic entities had the most individuals approved for access to BSAT, followed by federal government entities.

Table 5: BSAT Access Approvals by Entity Type, 2019

Entity Type	2019 Access Approvals	Total Access Approvals as of December 31, 2019
Academic	1,422	3,262
Federal Government	1,160	2,615
Non-Federal Government	455	1,065
Commercial	498	1,038
Private	300	670
Total	3,835	8,650

In 2019, 30 individuals were initially identified as being a “restricted person.” This number of individuals is more than the 10 to 17 restricted individuals per year observed for 2015-2017, but similar to 2018 (28 individuals). Of the 30 individuals initially identified as “restricted persons,” three of these decisions were reversed. Two individuals were determined to be unlawfully present in the U.S. at the time the SRA was conducted. These individuals appealed their identifications as restricted persons, and the initial determinations were overturned based on the individuals’ establishment that they were in the U.S. lawfully (change in immigration status). Another identified restricted person who was under an indictment for a crime punishable by imprisonment for a term exceeding one year also appealed. This initial determination was overturned after the individual provided documentation that the charge was dismissed.

Table 6 summarizes the reasons for restriction for the 27 individuals who maintained “restricted person” status.

Table 6: Total Number of Restricted Persons Identified by Restrictor Type, 2019

Reason for Restriction	Total
Conviction exceeds 1 year (Has been convicted in any court of a crime punishable by imprisonment for a term exceeding one year)	18
Has been adjudicated as a mental defective or has been committed to any mental institution	1
An alien illegally or unlawfully in the United States	3
Unlawful user of any controlled substance	4
Alien of country that sponsors terrorism as determined by the Secretary of State	1
Total	27

Inspection Data

Inspections

Entities regulated by FSAP are subject to announced and unannounced inspections. The type of inspection scheduled depends on the reason for the inspection, but all inspections focus on compliance with the SAR, such as biosafety and security of the work with BSAT. The different types of FSAP inspections are:

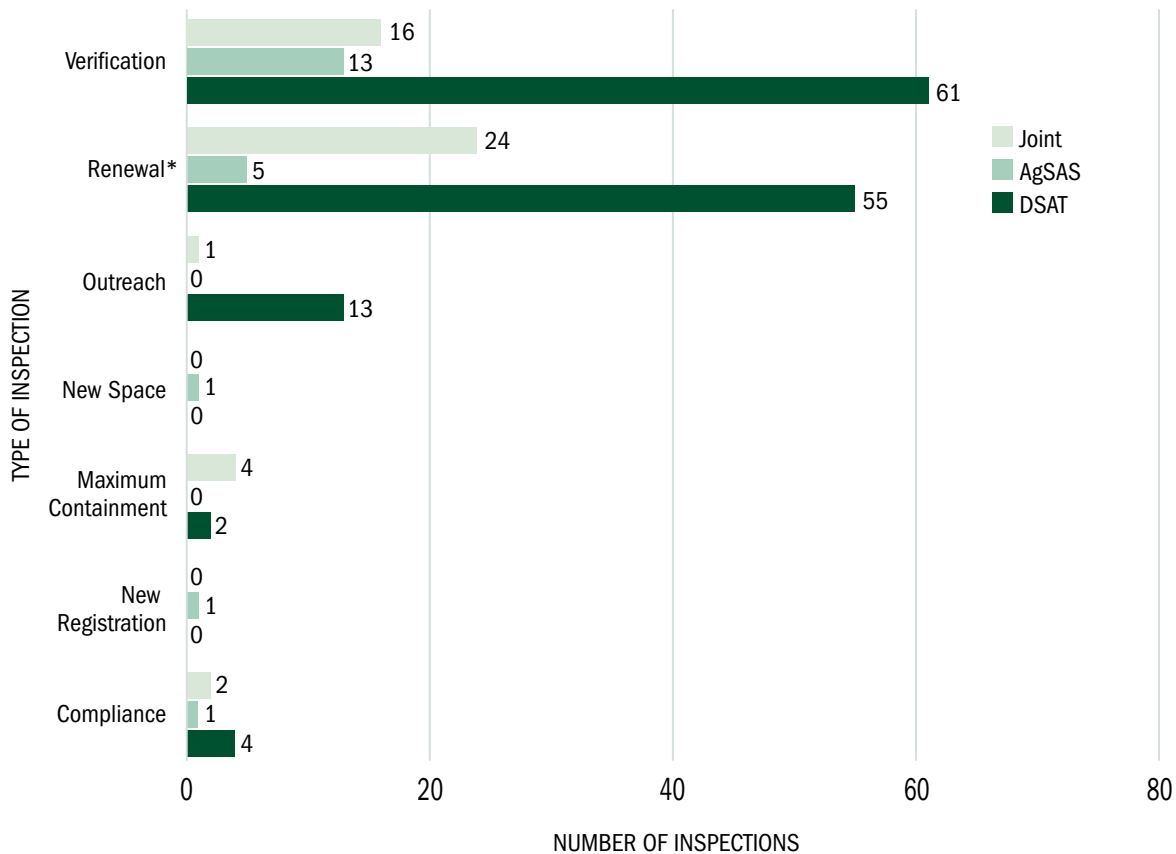
- **Compliance** – Review of entity’s registration, including laboratory spaces and documents (e.g., plans, records, facility verification documentation), with a focus on compliance issues.
- **Maximum Containment** – Review of entity’s registered maximum containment program, including laboratory spaces and documents specific to work that requires the highest levels of containment – such as Biosafety Level (BSL)-4.
- **New Entity** – Review of information provided in an entity’s application to register with FSAP, as well as all laboratory spaces and documents, to support approval or denial of a new entity registration application.
- **New Space** – Review of laboratory space and documents for adding laboratory space to an existing entity registration.
- **Renewal** – Comprehensive review of the facility to make a determination regarding renewal of an existing entity registration, including all registered laboratory spaces and documents; typically occurs every three years.
- **Verification** – Review of selected portions of an entity’s registration, including laboratory spaces and documents; often includes an assessment of responses to previous inspection findings and may be conducted prior to allowing an entity to withdraw from FSAP.

Either DSAT or AgSAS lead the inspection, depending on which is the lead agency and the BSAT for which the entity is registered. DSAT inspects entities registered for HHS-only BSAT and AgSAS inspects entities registered for USDA-only BSAT. Entities registered for both HHS BSAT and USDA BSAT are normally inspected jointly by DSAT and AgSAS.

In 2019, FSAP performed 189 inspections: 21 by AgSAS, 122 by DSAT, and 46 jointly.

Figure 3 compares the number of each type of inspection conducted in 2019 by either DSAT, AgSAS, or both jointly.

Figure 3: Number of Inspections by Lead Agency and Type, 2019



*One of the renewal inspections conducted in 2019 also included an inspection of the entity's maximum containment registered space

Length of Inspections

In 2019, inspection length ranged from 1 to 8 business days on site with an average length of 2.4 business days, which is similar to the average length of inspections for the past four years. In each year, maximum containment inspections took the longest due to the complexity of high containment facilities. For all other types of inspections (new entity, new space, verification, compliance, and renewals) over the last four years, the average length of the inspections remained consistent at 2-3 business days.

Inspection Findings and Compliance

A goal of the SAR is to ensure a registered entity has the operating conditions to minimize biosafety and security risks. FSAP works closely with all regulated entities to assist them with compliance to the SAR. Following inspections, entities address inspection findings and provide evidence of corrective action implementation. The following are the most common findings during inspections in 2019.

- Strengthening needed in entity biosafety, incident response, or security plans.
- Inaccurate records for inventory, training, or access to BSAT.
- Biosafety practices not adequate to contain BSAT.
- Facility and equipment issues that could result in occupational exposures.

Corrective Action Plan

FSAP's voluntary Corrective Action Plan (CAP) program assists entities with systemic biosafety and security deficiencies identified during an inspection in achieving compliance with the SAR. To participate, an entity submits a detailed plan, including the specifics of how the entity will correct identified regulatory deficiencies, and completion target dates. Participation in the CAP program allows FSAP to provide technical assistance as well as monitor an entity's progress in correcting deficiencies. If an entity chooses not to participate in a CAP, the entity is expected to successfully resolve the identified regulatory departures within 30 days. If the entity cannot successfully resolve these departures within 30 days, its registration would be subject to suspension or revocation.

In 2019, one entity was offered the opportunity and agreed to participate in the CAP program. This entity continued their participation in the CAP program into 2020.

Registration Suspensions

An entity's registration can be suspended when a departure from the SAR is found to represent a danger to human, animal, and/or plant health, or to public safety. An entity's registration remains suspended until the compliance issues are properly addressed. If the compliance issues are limited and not systemic, part of an entity's registration can be suspended, allowing other work to be conducted at another part of the entity.

In 2018, an entity that was placed on partial suspension continued to fail to meet biosafety regulatory requirements. The entity was placed on a full suspension in 2019. After the entity implemented corrective actions, the entity registration was restored to partial suspension in 2019. Two additional entities continued their partial suspensions that were initially imposed in 2018. These two entities received approval to resume their work during 2019.

Reports and Referrals

Confidential Reporting System

The HHS Office of Inspector General (OIG) and the USDA OIG maintain confidential reporting systems for the public to report safety, security, or other concerns associated with BSAT. FSAP received one such report from these systems in 2019. Since 2015, the HHS and USDA OIGs have received no more than five reports per year. The 2019 report involved a complaint about building security at an entity when a fire alarm sounded. FSAP conducted an inspection at the entity, and no regulatory departures were identified related to this issue.

Referrals to HHS OIG, APHIS IES, or Other Federal Oversight Offices

For serious non-compliance of the SAR, FSAP may refer entities to HHS OIG or APHIS Investigative and Enforcement Services (IES) for further investigation and possible civil monetary penalties. FSAP referred one entity to both HHS OIG and APHIS IES in 2019. Since 2015, three to seven entities have been referred to either HHS OIG or APHIS IES each year. The entity was referred to both HHS OIG and APHIS IES in 2019 due to possession of HHS and USDA select agents in areas not listed on the entity's certificate of registration. This referral is still pending.

FSAP may also refer federal entities to other relevant Offices of the Inspector General as appropriate. One entity was referred to the Department of Defense Office of Inspector General for failure to meet the biosafety requirements of the SAR. The entity was partially suspended.

FBI Notifications

FSAP notifies the FBI of any security-related issue identified by either FSAP or a registered entity (for example, allowing an unapproved individual access to BSAT, or a security breach of BSAT storage space) and any report of a loss of BSAT. This allows FSAP to leverage FBI resources to help determine whether a security issue presents a criminal threat, including whether a loss may represent a theft. FSAP also provides information in support of specific FBI investigations upon request.

In 2019, FSAP notified the FBI of 18 matters for investigation.

- Fourteen matters concerned the loss of BSAT. In six matters, there were volume amount differences between actual vial contents and what was recorded on inventory when accounting for toxins. In the

remaining eight matters, there were inventory discrepancies of BSAT due to the BSAT being used or destroyed without updating the inventory record, or were losses attributed to record keeping errors. After initial notification of the FBI, one matter was determined to not be a loss and was not counted in the Theft, Loss, and Release of BSAT section below.

- Four matters concerned the discovery of BSAT outside of registered space.

In nine matters, FBI analysis determined there was no criminal nexus requiring the opening of a case. As of December 31, 2019, the other nine matters were still pending a determination.

Restricted Experiments

An individual or entity may not conduct a restricted experiment or possess the product resulting from a restricted experiment unless the experiment is approved by and conducted in accordance with the conditions prescribed by FSAP. These restricted experiments require prior approval from FSAP due to their significant potential threat to human, animal, or plant health, or to animal or plant products.

The SAR defines two types of restricted experiments:

- The deliberate transfer of, or selection for, a drug-resistance trait to a select agent that is not known to acquire the trait naturally, if such acquisition could compromise the control of the disease agent in humans, veterinary medicine, or agriculture (HHS-only and overlap agents). The deliberate transfer of, or selection for, a drug or chemical resistance trait to a select agent that is not known to acquire the trait naturally, if such acquisition could compromise the control of a disease agent in humans, veterinary medicine, or agriculture (USDA-only agents).
- The deliberate formation of synthetic or recombinant DNA containing genes for the biosynthesis of a select toxin lethal for vertebrates at an LD50 < 100 ng/kg body weight. Currently, only one select toxin (botulinum neurotoxin) possesses an LD50 < 100 ng/kg body weight.

FSAP received two new requests from academic entities in 2019 that met the restricted experiment definition. Both requests were for the deliberate formation of recombinant DNA containing genes for the biosynthesis of botulinum neurotoxin, and both were approved. Also, FSAP received four requests in 2019 that did not meet the definition of a restricted experiment and therefore, did not require prior approval of FSAP.

Exclusions

The SAR provide criteria for the exclusion of BSAT from the regulatory requirements. An entity or individual may request to exclude an attenuated (weakened) strain of a select agent or a select toxin modified to be less potent or toxic from the SAR. As required by the SAR, if approved, FSAP will issue a written decision to the requestor and post the exclusion on the FSAP website in case others wish to work with the attenuated strain or toxin modified to be less potent or toxic. FSAP received four exclusion requests in 2019 (Table 7). Three of the requests were approved during the year, and one request was pending at the end of 2019.

Table 7: Summary of Requests for Exclusions by Entity Type, Select Agent or Toxin, and Decision Status, 2019

Entity Type	Select Agent or Toxin	Decision Status
Academic	<i>Clostridium botulinum</i> Beluga Ei strain (E213A/R348A/Y351F)	Approved
Federal Government	Catalytically inactive Botulinum neurotoxin serotype D holoprotein (ciBoNT/D)	Approved
Academic	Δ lpp Δ msbB Δ pla <i>Yersinia pestis</i> CO92 mutant strain	Approved
Academic	<i>Burkholderia pseudomallei</i> strain PBK001 (Δ tonB Δ hcp1)	Pending

Transfers of BSAT

The Request to Transfer Select Agents and Toxins ([APHIS/CDC Form 2](#)) is used by any entity (registered or not) to request authorization prior to transferring BSAT. BSAT may be transferred from one entity to another for diagnostic testing, scientific or clinical research, or production of therapeutics. In 2019, FSAP approved 171 BSAT transfers – 35 by AgSAS and 136 by DSAT. For the 35 transfers approved by AgSAS, this represented 18 recipient entities requesting a transfer, and 30 unique sender entities. For the 136 transfers approved by DSAT, this represented 38 recipient entities requesting a transfer, and 50 unique sender entities. Thirty-five (20%) of the approved transfers in 2019 involved unregistered entities transferring to registered entities. These transfers were imported BSAT (26) or occurred either after the identification of BSAT in a diagnostic specimen at an unregistered entity (8) or after discovery of an agent at an unregistered entity (1). Of those select agents or toxins that were imported from outside the U.S., AgSAS approved 19 transfers, and DSAT approved 7 transfers.

In 2019, 158 BSAT transfers occurred during the year, including six transfers that had been approved in 2018 but not shipped until 2019. Six transfers were approved towards the end of 2019 but had not yet been shipped as of December 31, 2019, and 13 approved transfers were cancelled by the entities before shipping the BSAT.

There was a decline in the number of BSAT transfer approvals in 2019 after remaining relatively stable from 2016-2018 (Figure 4). This decline was observed at both DSAT and AgSAS.

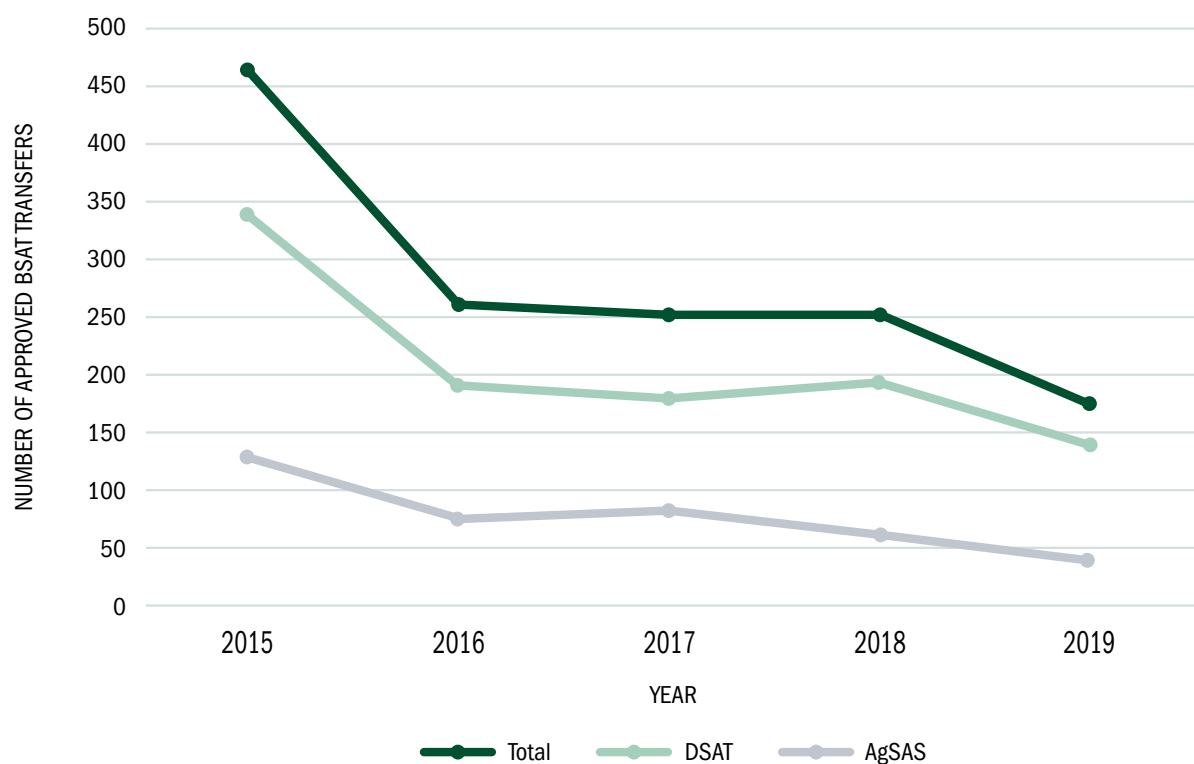


Figure 4: Total Number of Approved BSAT Transfers, 2015-2019

For AgSAS, Avian influenza virus was the most frequently transferred BSAT for 2019 (Table 8) and has been since 2015.

Table 8: Number of BSAT Transfers (Form 2) Approved by AgSAS, 2019

BSAT	Total*
Avian influenza virus	13
Foot-and-mouth disease virus	6
African swine fever virus	4
Classical Swine Fever	3
<i>Xanthomonas oryzae</i>	3
Newcastle disease virus	2
<i>Bacillus anthracis</i>	1
<i>Burkholderia pseudomallei</i>	1
<i>Ralstonia solanacearum</i>	1
Rift Valley Fever Virus	1
<i>Synchytrium endobioticum</i>	1

*This total reflects the number of instances a transfer included the BSAT, not the total number of BSAT transferred. Some shipments included multiple vials or strains of the same BSAT.

For DSAT, Botulinum neurotoxin was the most frequently transferred BSAT in 2019 (Table 9) and has been since 2016. Botulinum neurotoxin is unique in that it is used both as a drug and for research purposes.

Table 9: Number of BSAT Transfers (Form 2) Approved by DSAT, 2019

BSAT	Total*
Botulinum neurotoxin	48
<i>Burkholderia pseudomallei</i>	16
Botulinum neurotoxin producing species of <i>Clostridium</i>	15
<i>Brucella abortus</i>	8
<i>Francisella tularensis</i>	8
Ebola virus	8
<i>Bacillus anthracis</i>	7
<i>Brucella melitensis</i>	7
<i>Brucella suis</i>	7
<i>Coxiella burnetii</i>	7
Eastern equine encephalitis virus	7
<i>Yersinia pestis</i>	7
Venezuelan equine encephalitis virus	6
<i>Burkholderia mallei</i>	5
Genomic: Eastern equine encephalitis virus	5
Lassa fever virus	4
<i>Bacillus anthracis</i> (Pasteur strain)	3

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BSAT	Total*
Crimean-Congo haemorrhagic fever virus	3
Marburg virus	3
Monkeypox virus	2
Genomic: Venezuelan equine encephalitis virus	2
South American Haemorrhagic Fever virus: Junin	2
Kyasanur Forest disease virus	2
Nipah virus	1
South American Haemorrhagic Fever virus: Sabia	1
<i>Rickettsia prowazekii</i>	1
Rift Valley Fever Virus	1
Lujo virus	1
Tick-borne encephalitis virus: Far Eastern subtype	1

*This total reflects the number of instances a transfer included the BSAT, not the total number of BSAT transferred. Some shipments included multiple vials or strains of the same BSAT.

Theft, Loss, and Release of BSAT

An entity uses the Report of Theft, Loss, or Release of Select Agents and Toxins ([APHIS/CDC Form 3](#)) to report a theft (unauthorized removal of BSAT), loss (failure to account for BSAT), or release [occupational exposure or release of BSAT outside of primary containment, such as a biological safety cabinet (BSC)].

Examples of the causes of a release may include:

- Bites or scratches from an infected animal
- Equipment or mechanical failure
- Spill of BSAT outside of a BSC
- Failure or problem with personal protective equipment (PPE)
- Needlestick or other percutaneous exposures with contaminated sharp objects
- Open bench work involving diagnostic samples (later identified as BSAT) without appropriate PPE

Any individual or entity (including a non-registered entity such as clinical or diagnostic laboratories that possess BSAT contained in a specimen presented for diagnosis or verification) must immediately notify FSAP of each theft, loss, or release. Entities must also notify appropriate federal, state, or local law enforcement agencies in the case of a theft or loss. All thefts or losses must be reported, even if the BSAT is subsequently recovered and/or the responsible parties are identified.

In 2019, FSAP received 219 reports of BSAT release and 13 reports of BSAT loss. By comparison, FSAP has received between 193 and 237 reports of releases each year since 2015, and 8 to 12 reports of losses. As in 2015 through 2018, there were again no reports of theft of BSAT in 2019.

Of the 219 reports of a BSAT release, 92 were submitted by registered entities and 127 were from non-registered entities. For registered entities, the most common cause of a release was due to a failure or problem with laboratorian personal protective equipment. For non-registered laboratories, the most common cause of a release was due to manipulation of BSAT outside of a BSC or other type of equipment designed to protect laboratorians from exposure to infectious aerosols.

FSAP reviews each report of a release to determine the potential for an occupational exposure.

- For 24 of the reported releases, FSAP agreed with the entity that these reports presented minimal to no risk of occupational exposure.
- The remaining 195 reported releases did involve a 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 release reports, entities provided 1,076 individuals (166 individuals from registered entities and 910 individuals from non-registered entities) with occupational health services, including medical assessments and, if needed, diagnostic testing and prophylaxis.
 - ◆ None of the releases resulted in identified illnesses, deaths, or transmissions among workers or outside of a laboratory.

All 13 reports of a loss met the regulatory criteria for a loss. For each report, FSAP identified the cause of the failure to account for the BSAT. None of the losses resulted in a risk to human, animal, or plant health.

FSAP engages with the regulated community throughout the year to increase awareness on safe work practices in the laboratory to reduce the number of occupational exposures.

Report of the Identification of BSAT

Entities use the Report of the Identification of a Select Agent or Toxin ([APHIS/CDC Form 4](#)) to notify FSAP of the identification of BSAT that is the result of diagnosis, verification, or proficiency testing, as well as the final disposition of the identified BSAT. There are three versions of the APHIS/CDC Form 4, depending on the reporting circumstance:

- [APHIS/CDC Form 4A](#) – Reporting the Identification from a Clinical/Diagnostic Specimen
- [APHIS/CDC Form 4B](#) – Reporting the Identification from a Proficiency Test
- [APHIS/CDC Form 4C](#) – Federal Law Enforcement Reporting Seizure of Select Agent or Toxin

APHIS/CDC Forms 4A and 4B are used by institutions that need to report the identification of BSAT. APHIS/CDC Form 4C is used by law enforcement to notify FSAP of seized BSAT.

In 2019, DSAT received and processed 1,270 APHIS/CDC Form 4As to report the identification of BSAT as a result of diagnosis or verification. Eastern Equine Encephalitis virus was the most commonly identified BSAT reported to DSAT in 2019 due to an outbreak, followed by Botulinum neurotoxin and botulinum neurotoxin-producing species of *Clostridium* (Table 10). Botulinum neurotoxin was also the most commonly identified BSAT in 2018, 2017, and 2016. By comparison, *Francisella tularensis* was the most commonly identified select agent in 2015.

Clinical, diagnostic, or public health laboratories that are not registered to work with BSAT may, in the course of their work, identify BSAT within a specimen or environmental sample. For DSAT, non-registered laboratories accounted for 11% of all reports of the identification of BSAT using the APHIS/CDC Form 4A, which is a lower percentage than the past four years (19% for 2018, 17% for 2017 and 2016, and 14% for 2015). Upon identification of BSAT, the unregistered laboratory must notify FSAP and either register with FSAP to keep the sample for research purposes, transfer the sample to an entity registered to possess that BSAT, or destroy the sample by a proven method.

DSAT received 46 APHIS/CDC Form 4Bs reporting BSAT identified through proficiency testing in 2019. Proficiency testing allows entities to test their capabilities to identify BSAT in samples provided by a sponsor/entity. DSAT did not receive any reports regarding seizures by federal law enforcement (Form 4C) and has not received any of this type of report since 2015 (when DSAT received three).

Table 10: BSAT Reported to DSAT on Form 4A by Sample Type, 2019

BSAT	Animal Specimens	Environmental Samples	Food Sample	Human Specimens	Total
<i>Bacillus anthracis</i>	9	0	0	4	13
Botulinum neurotoxin producing species of <i>Clostridium</i>	30	1	14	128	173
Botulinum neurotoxins	33	1	3	182	219
<i>Brucella abortus</i>	20	0	0	23	43
<i>Brucella melitensis</i>	0	0	0	106	106
<i>Brucella suis</i>	8	0	0	44	52
<i>Burkholderia pseudomallei</i>	0	8	0	27	35
<i>Coxiella burnetii</i>	47	0	1	2	50
Eastern Equine Encephalitis virus	409	15	0	1	425
Ebola virus	0	0	0	10	10*
<i>Francisella tularensis</i>	23	2	0	58	83
Genomic material: Eastern Equine Encephalitis Virus	2	28	0	2	32
Hendra virus	1	0	0	0	1
Marburg virus	3	0	0	0	3
Monkeypox virus	1	0	0	0	1
Nipah virus	1	0	0	0	1
Ricin	0	6	0	0	6
Rift Valley fever virus	0	0	0	2	2
Saxitoxin	0	1	0	0	1
South American Haemorrhagic Fever virus: Chapare	0	0	0	2	2
T-2 toxin	0	0	7	0	7
<i>Yersinia pestis</i>	4	0	0	1	5
Total	591	62	25	592	1,270

*Eight of the ten Form 4As were for Ebola virus identified in 2019 in samples originally received during the 2015 West Africa outbreak

AgSAS received and processed 34 APHIS/CDC Form 4A reports in 2019 (Table 11). For AgSAS, non-registered laboratories accounted for 1% of all reports of the identification of BSAT using the APHIS/CDC Form 4A. Highly pathogenic avian influenza virus was also the most commonly identified BSAT for AgSAS in 2015, while Newcastle disease virus was the most commonly identified BSAT for AgSAS in 2018, 2017, and 2016.

Table 11: BSAT Reported to AgSAS on Form 4A by Sample Type, 2019

BSAT	Animal Specimens	Environmental Samples	Plant Sample	Total
Avian influenza virus	15	1	0	16
<i>Bacillus anthracis</i>	6	0	0	6
<i>Burkholderia pseudomallei</i>	0	1	0	1
Classical swine fever virus	1	0	0	1
Newcastle disease virus	8	0	0	8
<i>Ralstonia solanacearum</i>	0	0	2	2
Total	30	2	2	34

In 2019, AgSAS received two APHIS/CDC Form 4Bs reporting BSAT identified through proficiency testing, compared to two reports in 2018, and one report in both 2017 and 2016. AgSAS received no reports from federal law enforcement regarding seizure of BSAT in 2019 (APHIS/CDC Form 4C); nor did AgSAS receive any such reports in the previous four years.

Emergency Management

FSAP monitors entities that may be affected by severe weather or natural disasters for impacts to employee safety or BSAT security. FSAP contacts the entities and assists with safely transferring or securing BSAT as needed. There were 10 such events in 2019, and FSAP contacted a total of 57 affected entities. Table 12 summarizes FSAP's assistance efforts during weather or other natural disaster emergencies in 2019. FSAP successfully contacted all affected entities and none required FSAP assistance. There were no thefts, losses, or releases of BSAT as the result of any weather or natural disaster emergencies in 2019.

Table 12: FSAP Emergency Management, 2019

2019 Event	Number of Entities Contacted
Nebraska Flooding	2
Louisiana Flooding	2
Missouri Tornado	1
California Earthquake	1
Pre/Post Hurricane Barry	15
Tropical Storm Flossie	2
Pre/Post Hurricane Dorian	15
Pre- Hurricane Humberto	7
Texas Flooding	4
Alabama, Mississippi and Louisiana Tornadoes	8
Totals	57

Federal Register Notices, Policy Statements, Guidance, and Regulatory Interpretations

FSAP engages and partners with the regulated community to identify solutions that ensure compliance with the SAR. To that end, FSAP periodically publishes Federal Register Notices, policy statements, regulatory interpretations, guidance documents, and frequently asked questions (FAQs) for the benefit of the regulated community. In 2019, FSAP did not publish any Federal Register Notices. FSAP policy statements, guidance documents, and regulatory interpretations can be found on the [FSAP website](#) and are included in Table 13.

Table 13: FSAP Policy Statements, Guidance, and Regulatory Interpretations, 2019

Policy Statements	Date
Revision to Entity Annual Internal Inspections Policy	March
Draft Personal Quarantine Policy for Specific USDA Select Agents	May
Guidance	Date
Updated Responsible Official Guidance	February
Regulatory Interpretations	Date
Updated Regulatory Interpretation Regarding Requirement for Inactivation Certificates and Intra-Entity Transfers	May
Regulatory Interpretation Regarding Transferring Excluded Amounts of Toxins	June
FAQs	Date
Updated Frequently Asked Question on Extracted Nucleic Acids	February
Updated Frequently Asked Questions on Inactivation	September
New Frequently Asked Question Clarifying the Difference between Federal Regulations, Regulatory Interpretations, Policy Statements, and Guidance Documents	September
New Frequently Asked Question Regarding SAMS Accounts and eFSAP Access	November

Outreach

FSAP's outreach program provides opportunities for the program to interact with members of the regulated community. Table 14 summarizes outreach events that FSAP either organized or participated in. In 2019, these included:

Table 14: FSAP Outreach Events, 2019

Conference ¹	Date	Booth Attendees
American Society for Microbiology Biothreats	January 29-31	65
USDA Agricultural Research Service Biosafety Symposium	February 11-14	82
American Society for Microbiology Microbe	June 21-23	184
American Veterinary Medical Association	July 13-17	50
American Biological Safety Association	November 17-19	194

eFSAP Webinars ²	Date	Attendees
Release Updates	February 6*, 8, 12, 14, 21* September 19*, 20 *(two sessions)	65

FSAP-Sponsored In-Person Events ³	Date	Attendees
New Responsible Official (RO)/Alternate Responsible Official (ARO) Workshop	July 22	44
RO/ARO Workshop	July 23-25	121

Notes:

1. FSAP exhibited an informational booth at five scientific conferences to provide guidance and promote compliance with the SAR.
2. FSAP conducted 10 webinars for ROs and AROs to provide guidance on the eFSAP information system, the program's secure web-based system that is used by registered entities to communicate with FSAP. A total of 271 ROs and AROs attended the sessions.
3. FSAP conducted a multi-day in-person workshop attended by 121 ROs and AROs to provide information about maintaining regulatory compliance and to build community among those working in this area. FSAP also conducted a pre-workshop session attended by 44 new ROs and AROs to provide information about establishing a select agent program.

In addition, FSAP also conducted the following efforts to engage with the regulated community:

- FSAP invited recently inspected entities to submit feedback surveys anonymously following inspections to assist FSAP in gauging its performance during inspections and to identify ways to improve the inspection process.
- FSAP distributed important programmatic updates on topics such as new policies, guidance documents, regulatory interpretations, and training opportunities via SA (Select Agent) Grams, an electronic communication used to disseminate information to the regulated community. In 2019, FSAP issued 47 SA Grams.

Conclusion

FSAP was established in response to a Congressional mandate to ensure the safety and security of research with BSAT. Overall, most of the 247 entities registered with the Federal Select Agent Program are compliant with the regulations as evidenced by the small number of compliance issues identified in this report. Also, of note, none of the relatively small number of reported releases or losses of select agents and toxins resulted in a risk to public or agricultural health. As part of ensuring the security of BSAT, FSAP employs the SRA process, which makes sure that individuals are screened prior to allowing access to BSAT in order to keep these materials out of the hands of individuals that are identified as “restricted” persons. In 2019, 27 individuals were determined to be “restricted” and were prohibited access to BSAT based on federal statute. There were 3,835 individuals (new and renewals) granted access to BSAT. By providing oversight through the Federal Select Agent Program, entities are able to work with potentially dangerous biological agents and toxins in a safe and secure manner. This work is essential as it has led to important scientific discoveries that have improved detection and prevention of human, animal and plant diseases, as well as diagnostic and treatment options to address them.

References

Select Agents and Toxins Regulations. 7 CFR Part 331, 9 CFR Part 121, 42 CFR Part 73.

2015 Annual Report of the Federal Select Agent Program. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and US Department of Agriculture, Animal and Plant Health Inspection Service. June 2016.

2016 Annual Report of the Federal Select Agent Program. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and US Department of Agriculture, Animal and Plant Health Inspection Service. October 2017.

2017 Annual Report of the Federal Select Agent Program. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and US Department of Agriculture, Animal and Plant Health Inspection Service. December 2018.

2018 Annual Report of the Federal Select Agent Program. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and US Department of Agriculture, Animal and Plant Health Inspection Service. January 2020.

For questions, please contact DSAT at LRSAT@cdc.gov or AgSAS at AgSAS@usda.gov.