2018 Annual Report of the
Federal Select Agent Program

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

U.S. Department of Agriculture
Animal and Plant Health Inspection Service

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Acronyms

Acronym	Description
AgSAS	The **Agriculture Select Agent Services** 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** 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.
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.
ASM	The **American Society for Microbiology** is a professional organization of life scientists whose membership includes researchers, educators, and health professionals.
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** addresses serious and recurrent concerns at the entity 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** is a federal agency within the Department of Health and Human Services that conducts science and provides health information to protect people from health, safety, and security threats.
CJIS	The Federal Bureau of Investigation's **Criminal Justice Information Services** division provides a range of state of-the-art tools and services to law enforcement, national security and intelligence community partners, and the general public.
DSAT	The **Division of Select Agents and Toxins** regulates the possession, use, and transfer of biological select agents and toxins that have the potential to pose a severe threat to human health.
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 it 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.
IES	**Investigative and Enforcement Services** is a program housed within the United States Department of Agriculture that 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.
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 the registered entity with the authority and responsibility to act on behalf of the entity to ensure compliance with the select agent regulations.
PPQ	APHIS' **Plant Protection and Quarantine** program safeguards U.S. agriculture and natural resources against the entry, establishment, and spread of economically and environmentally significant pests, and facilitates the safe trade of agricultural products.
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.
VS	USDA's **Veterinary Services** provide responsive and quality information technology services, delivery, and training to VS and its stakeholders, which protects and improves the health, quality, and marketability of our nation's animals, animal products and veterinary biologics.

Executive Summary

The Federal Select Agent Program 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/Division of Select Agents and Toxins and the U.S. Department of Agriculture, Animal and Plant Health Inspection Service/Agriculture Select Agent Services. Common examples of select agents and toxins include the organisms that cause anthrax, smallpox, Foot-and-Mouth disease, and *Ralstonia solanacearum,* as well as the toxin ricin.

While potentially dangerous if not conducted safely and securely, work with select agents and toxins provides important scientific discoveries that have led to improved detection, prevention, diagnostic and treatment options. The Federal Select Agent Program regulates laboratories that conduct research on these pathogens and toxins that are potentially dangerous to public, animal, and plant health, or to animal and plant products, while making sure it is done as safely and securely as possible.

This report summarizes calendar year 2018 data for the Federal Select Agent Program and marks the fourth annual report for the purpose of communicating operational metrics to further public understanding of the Program. A similar report will continue to be published annually.

Registered Entities

As of December 31, 2018, 253 entities were registered with the Federal Select Agent Program: 34 entities are registered with the Agriculture Select Agent Services as the lead agency and 219 entities with the Division of Select Agents and Toxins as the lead agency. Lead agency is a term used by the Federal Select Agent Program to indicate which agency the entity uses as its primary contact (i.e., Agriculture Select Agent Services or 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 2018, 46 of the 253 total entities registered with the program were jointly managed: the Agriculture Select Agent Services served as the lead agency for 9 of those entities and the Division of Select Agents and Toxins served as the lead agency for 37 of those entities. During 2018, three entities applied to the Federal Select Agent Program for new registrations, and the approval process was still underway as of December 31, 2018. Ten entities withdrew their registrations with the Federal Select Agent Program: six that were registered with the Division of Select Agents and Toxins and four that were registered with the Agriculture Select Agent Services.

Security Risk Assessments

Based on security risk assessments conducted by the Bioterrorism Risk Assessment Group, a division of the Federal Bureau of Investigation's Criminal Justice Information Services, at the end of 2018, the Federal Select Agent Program had a total of 8,434 individuals approved to access biological select agents and toxins. During 2018, the Federal Select Agent Program granted 3,572 new approvals for access to biological select agents and toxins (i.e., new individuals, renewals, and individuals approved for access at multiple entities). Based on these security risk assessments, 24 individuals were determined to be a "restricted person" and were thus prohibited from having access to biological select agents and toxins.

Inspections

The Federal Select Agent Program conducted 206 inspections in 2018: 18 by the Agriculture Select Agent Services, 149 by the Division of Select Agents and Toxins, and 39 jointly.

Compliance Actions

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

- 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 for departures from the select agent regulations that represent a threat to human, animal, or plant health, or to public safety;
- 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 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.

In 2018:

- No entities had their registrations entirely suspended. However, FSAP partially suspended five entity registrations (three registered with DSAT, two registered with AgSAS). A total of eight entities were partially suspended, including three partial entity registration suspensions that were initially imposed in 2017. Five of the eight partially suspended entities, including the three entities originally suspended in 2017, received approval to resume their work during the year. Three entities remained partially suspended at the end of 2018.
- One entity started and completed the Federal Select Agent Program Corrective Action Plan program. Two entities, participating in the program from previous years, successfully completed their plans of corrective actions.
- The Federal Select Agent Program referred four entities to either the U. S. Health and Human Services Office of Inspector General or the Animal and Plant Health Inspection Service Investigative and Enforcement Services.
- The Federal Select Agent Program notified the Federal Bureau of Investigation of nine matters for potential investigation.

Confidential Reporting Systems

The U.S. Health and Human Services Office of Inspector General and the U.S. Department of Agriculture Office of Inspector General operate confidential systems for the public to report biosafety and security issues associated with the possession, use, and transfer of biological select agents and toxins. Each report received is investigated to determine if non-compliance with the select agent regulations has occurred. The Federal Select Agent Program received one report in 2018, and it was not substantiated in the resulting investigation.

Transfers of Biological Select Agents or Toxins

The Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2) is used by entities to request prior authorization to transfer or import biological select agents and 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 production of therapeutics. In 2018, the Federal Select Agent Program approved 253 transfers: 192 (including 19 importations) by the Division of Select Agents and Toxins and 61 (including 34 importations) by the Agriculture Select Agent Services. Of the 253 approved transfers, 218 transfers were completed.

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

The Incident Notification and Reporting APHIS/CDC Form 3 (Theft, Loss, Release) is used to report a biological select agent's or toxin's theft (unauthorized removal of biological select agents and toxins), loss (failure to account for biological select agents and toxins), or release (occupational exposure or release of biological select agents and toxins outside of the primary barriers of the biocontainment area).

In 2018, the Federal Select Agent Program received eight reports of loss and 193 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 193 reports of a release, registered entities submitted 66 reports and non-registered entities (e.g., clinical, diagnostic, or public health laboratories, which are not required to register) submitted 127 reports.
  - For eight 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 185 reported releases did involve occupational exposure to a biological select agent or toxin.
    - 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.

The Federal Select Agent Program conducts outreach, among other efforts, to increase awareness on safe work practices in the laboratory to reduce the number of occupational exposures.

Report of the Identification of a Biological Select Agent or Toxin

The Report of the Identification of a Select Agent or Toxin (APHIS/CDC Form 4) is used by registered entities and unregistered clinical, diagnostic, or public health laboratories to 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 identified biological select agents and toxins. The Federal Select Agent Program received 1,181 APHIS/CDC Form 4As (Reporting the Identification from a Clinical/Diagnostic Specimen) in 2018: the Agriculture Select Agent Services received 175; the Division of Select Agents and Toxins received 1,006.

The most frequently identified biological select agents and toxins reported to Division of Select Agents and Toxins in 2018 were: Botulinum neurotoxin (223), Botulinum neurotoxin producing species of *Clostridium* (161), Eastern equine encephalitis virus (128), *Francisella tularensis* (123), and *Coxiella burnetii* (95).

The identified biological select agents and toxins reported to the Agriculture Select Agent Services in 2018 were: Newcastle disease virus (155), highly pathogenic avian influenza viruses (14), *Ralstonia solanacearum* (5), and *Mycoplasma mycoides* (1).

FEDERAL SELECT AGENT PROGRAM:

BY THE NUMBERS

2018

253

entities registered with FSAP

8,434

active individual security risk assessments

206

inspections conducted

HHS Only 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**

Overlap Select Agents and Toxins

*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

USDA Veterinary Services (VS) Select Agents and Toxins

African horse sickness virus
African swine fever virus
Avian influenza virus
Classical swine fever virus
Foot-and-mouth disease virus*
Goat pox virus
Lumpy skin disease virus
Mycoplasma capricolum
Mycoplasma mycoides
Newcastle disease virus
Peste des petits ruminants virus
Rinderpest virus*
Sheep pox virus
Swine vesicular disease virus

USDA Plant Protection and Quarantine (PPQ) Select Agents and Toxins

Coniothyrium glycines (formerly *Phoma glycinicola* and *Pyrenochaeta glycines)*
Peronosclerospora philippinensis (Peronosclerospora sacchari)
Ralstonia solanacearum
Rathayibacter toxicus
Sclerophthora rayssiae
Synchytrium endobioticum
Xanthomonas oryzae

* Tier 1 agents

Introduction

The Federal Select Agent Program (FSAP) was established in response to a mandate by Congress 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 provides important scientific discoveries that have led to improved detection, prevention, diagnostic and treatment options.

FSAP is jointly managed by the U.S. Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC)/Division of Select Agents and Toxins (DSAT) and the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS)/Agriculture Select Agent Services (AgSAS). FSAP oversees the possession, use, and transfer of BSAT, which have the potential to pose a 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)[1].

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 that all individuals who have access to BSAT have undergone a security risk assessment (SRA) performed by the Bioterrorism Risk Assessment Group (BRAG), a division of the Federal Bureau of Investigation's (FBI) Criminal Justice Information Services (CJIS)
- Developing guidance documents and conducting trainings to help regulated entities maintain compliance with the SAR
- Investigating incidents in which non-compliance with the SAR may have occurred

FSAP makes a concerted effort to engage and partner with the regulated community to identify solutions that ensure compliance with the SAR, including publishing policy statements, guidance documents, and other materials. FSAP also has an active outreach program designed to provide opportunities for the program to interact with members of the regulated community. Examples of FSAP outreach include holding trainings, 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.

[1] 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121

Key Program Statistics

Registration

Registered Entities

BSAT are divided into four categories based on whether an agent causes disease in humans, animals, plants, or a combination of humans and animals. In accordance with the Public Health Service Act (42 U.S.C. 262a(a)(2)) and the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401(a)(2)), FSAP performs biennial reviews to update and revise the BSAT list as necessary. The four 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.
- **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.
- **USDA Veterinary Services (VS) select agents:** BSAT that have the potential to pose a severe threat to animal health or to animal products. These are regulated by USDA.
- **USDA Plant Protection and Quarantine (PPQ) select agents**: BSAT that have the potential to pose a severe threat to plant health or to plant products. These are regulated by USDA.

Work with BSAT may include clinical diagnostics 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 (APHIS/CDC Form 1).

The APHIS/CDC Form 1 requires:

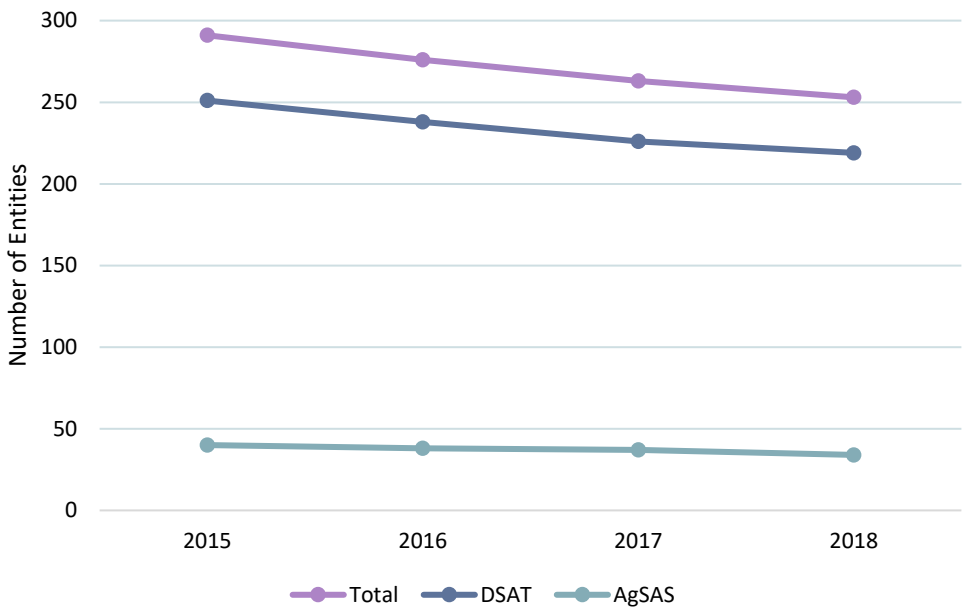
- Facility information
- A list of BSAT to be possessed, used, or transferred by the entity
- A list of individuals who will have access to BSAT
- A description of the work to be performed
- Information about where the work will be performed

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 2018, 253 entities were registered with FSAP: 34 with AgSAS and 219 with DSAT (Figure 1). The lead agency, either DSAT or AgSAS, is responsible for administration of all activities and communications with respect to an entity's registration, including coordination with the non-lead agency. 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 2018, both AgSAS and DSAT jointly oversaw 46 of the 253 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 37 of those entities.

Figure 1: Number of FSAP-Registered Entities by Agency and Year, 2015-2018



Entity Types

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

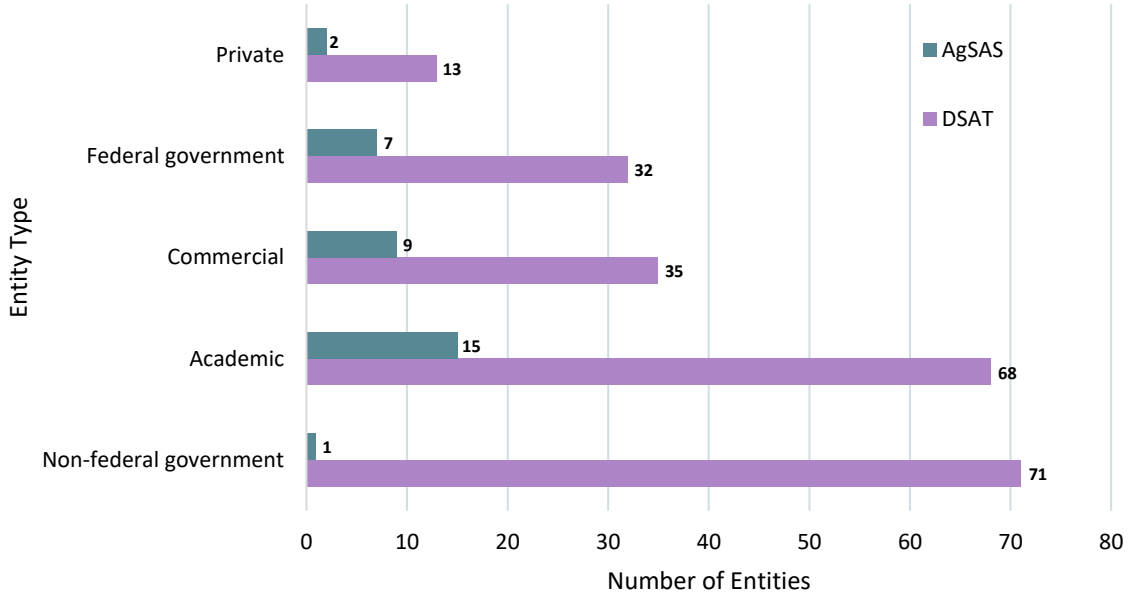
- Academic – A university, college, or other institution of higher learning. Academic institutions can be either private (neither owned nor controlled by any government entity) or state (predominantly funded through the government).
- Commercial – A privately owned for-profit company, including partnerships 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 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 2018 were:

- 33% academic,
- 29% non-federal government,
- 17% commercial,
- 15% federal government, and
- 6% private.

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 2018.

Figure 2: Number of FSAP-Registered Entities by Type, 2018



New Registration Applications

A facility must register with FSAP to possess, use, or transfer BSAT. In 2018, FSAP received three new applications, and the approval process was still underway as of December 31, 2018. During 2015-2018, only seven new entities applied for registrations.

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, ten entities withdrew their registration in 2018. The reasons entities cited for withdrawing were that they no longer needed to work with BSAT, or they could perform identification of select agents in diagnostic samples without being registered with FSAP. A total of 68 entities withdrew their registrations during 2015-2018, representing a 13% reduction in the total number of registered entities.

Table 1. Number of Entity Withdrawals by Agency and Entity Type, 2018

Entity Type	AgSAS	DSAT
Academic	1	2
Commercial	3	1
Federal government	0	0
Non-federal government	0	3
Private	0	0
Total	4	6

Renewals

A registered entity must renew its registration every three years. In 2018, FSAP approved 80 renewals: 10 by AgSAS and 70 by DSAT compared to 104 renewals in 2015. While year-to-year variation in the number of registration renewals (influenced by when the entity registered with FSAP for the first time) is expected, the decrease in the number of registered entities resulted in a decrease in the number of entity renewals.

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 2018, 10 entities registered with AgSAS for Tier 1 BSAT, representing 29% of all AgSAS-led entities. An additional 120 entities 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 averaged around 50%, including 51% of FSAP-regulated entities in 2018.

Top BSAT Registered with Each Agency

Table 2 lists the top BSAT registered with each agency as of December 31, 2018. To determine the top BSAT registered by each agency, FSAP counted the total number of entities registered for each BSAT regardless of whether the entity possessed the select agent or toxin. The top BSAT remained relatively consistent over the last four years, even with the decrease in the number of entities. The most frequently registered BSAT with DSAT are the *Brucella* species and *Bacillus anthracis* Pasteur strain. AgSAS had more fluctuations in the top BSAT due to the lower number of registered entities with that agency, but Newcastle disease virus and Avian influenza virus have consistently ranked as the most commonly registered BSAT with AgSAS.

Table 2. Top Agents Registered with Each Agency, 2018

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

*Indicates Tier 1 BSAT

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 required in those laboratories.

In 2018, 30% of entities had registered ABSL-2/BSL-2 laboratories, 79% of entities had registered ABSL-3/BSL-3 laboratories, and 3% of entities had registered ABSL-4/BSL-4 laboratories. Table 3 lists the number of entities that are registered for a Tier 1 BSAT at each BSL, and the number of entities at each BSL by entity type. The percentages for each BSL have remained consistent over the last three years, indicating no effect due to entity withdrawals.

Table 3: Number of Entities by Laboratory and Entity Types, 2018

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

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	75	54	24	16	19	10	6
BSL-3/ABSL-3	200	101	17	25	72	71	15
BSL-4/ABSL-4	8	8	0	5	2	0	1

Security Risk Assessments

One of the fundamental elements of the SAR is to keep BSAT out of the possession of those who intend to use them for unlawful purposes, particularly bioterrorism. FSAP works closely with the FBI's CJIS/BRAG to identify those individuals who applied for access to BSAT but are then 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" or meets 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[2] as an individual who:

A) is under indictment for a crime punishable by imprisonment for a term exceeding one year;
B) has been convicted in any court of a crime punishable by imprisonment for a term exceeding one year;
C) is a fugitive from justice;
D) is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 USC 802);
E) is an alien illegally or unlawfully in the United States;
F) has been adjudicated as a mental defective or has been committed to any mental institution;
G) (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

[2] 18 USC 175b(d)(2)

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;

H) has been discharged from the Armed Services of the United States under dishonorable conditions; or

I) 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)).

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 for:

- Committing a crime set 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 2018, there were a total of 8,434 individuals with current SRAs approved for access to BSAT. In 2018, FSAP granted a total of 3,572 approvals (new and renewal applications) for access (Table 4). The total number of individuals approved for access to BSAT per entity type (8,721 total access approvals) is greater than the number of SRAs for individuals because an individual can be approved for access at multiple entities (e.g. as collaborator; guest researcher) based on one current SRA. Forty percent of the individuals approved for access were those working at academic entities, followed by individuals working at federal government entities (30%). For the fourth year, academic entities had the most individuals approved for access to BSAT followed by federal government entities.

Table 4: Access Approvals by Entity Type, 2018

Entity Type	2018 Access Approvals	Total Access Approvals as of December 31, 2018
Academic	1,419	3,224
Federal government	1,061	2,690
Non-federal	440	1,154
Commercial	391	1,019
Private	261	634
Total	3,572	8,721

In 2018, 28 individuals were initially identified as being a “restricted person”. This number of individuals is more than the 10 to 17 restricted individuals per year for the last three years. Of the 28 individuals identified as a “restricted person,” four individuals were determined to be unlawfully present in the U.S. at the time the SRA was conducted. These four individuals appealed their denial for access approval and were able to have the determination that they were a “restricted person” reversed once it was established that they were in the U.S. lawfully (change in immigration status).

Table 5 summarizes the reasons for restriction for the 24 individuals who maintained "restricted person" status.

Table 5. Total Number of Restricted Persons Identified by Restrictor Type, 2018

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)	5
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	11
Under indictment (Is under indictment for a crime punishable by imprisonment for a term exceeding one year)	4
Unlawful user of any controlled substance	3
Total	24

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 following describe the scope of the different types of FSAP inspections:

- **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's registration.
- **Renewal** – Review to make a determination regarding renewal of an existing entity's 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 and USDA BSAT are normally inspected jointly by DSAT and AgSAS.

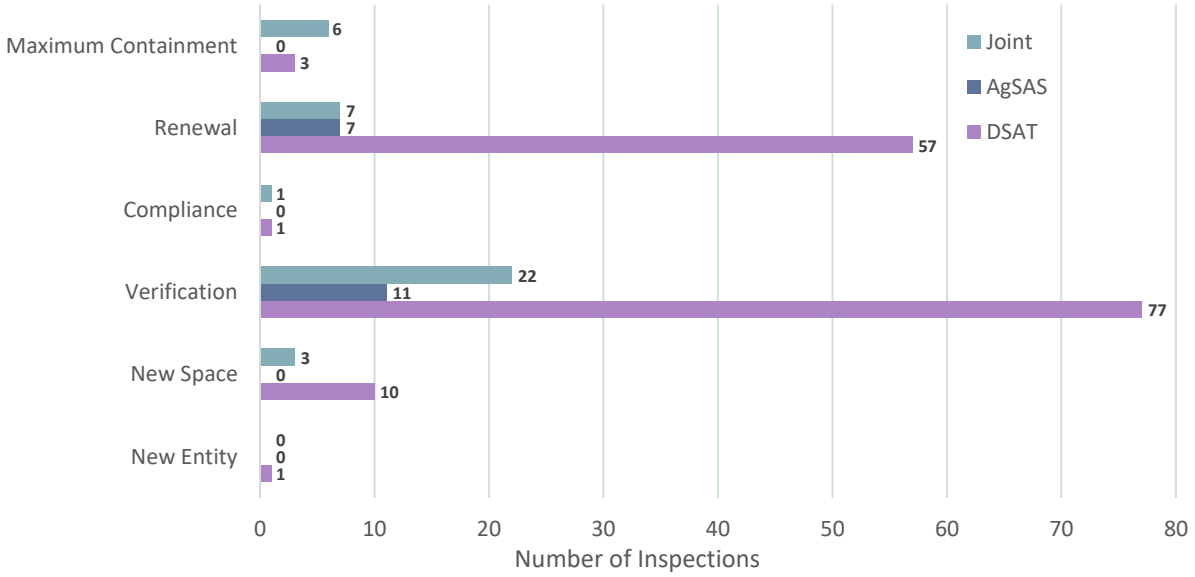
In 2018, FSAP performed 206 inspections: 18 by AgSAS, 149 by DSAT, and 39 jointly. The total number of inspections in 2018 increased compared to the last two years (169 in 2017, and 181 in 2016), but is below the total number of inspections in 2015 (216). The decrease in inspections from 2015 is most likely due to the overall decrease in the number of registered entities, and the number of entities renewing their registrations in 2015 (104 in 2015 versus 80 in 2018).

Figure 3 compares the number of each type of inspection conducted in 2018 by either DSAT, AgSAS, or both

jointly. Of note, FSAP increased the number of verification inspections over the last three years, from 49 in 2016 to 110 in 2018. This is due to a concerted effort by the program to perform more unannounced verification inspections of entities, as well as the addition of verification inspections targeting entities with effluent decontamination systems. This effort was undertaken after observing issues at some facilities with aging effluent decontamination systems, to proactively find and address potential concerns at other facilities before they become larger issues (see Registration Suspensions section below).

Figure 3: Number of Inspections by Agency and Type, 2018

Note: FSAP performed 206 inspections in 2018: 18 by AgSAS, 149 by DSAT, and 39 jointly.



Length of Inspections

In 2018, inspection length ranged from 1 to 10 business days on site with an average length of 2.5 days, which is similar to the average length of inspections for the past three years. In each of the last four years, 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 relatively 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 SAR compliance. Following the inspection, entities address the inspection findings and provide evidence of implementation of the corrections. The following are the most common inspector observations during inspections in 2018.

- 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 to achieve 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 2018, one entity agreed to participate in the CAP program, and two entities continued in the CAP program from the previous years (one from 2016 and one from 2017). All three entities successfully completed the CAP program in 2018.

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. This Annual Report is the first to include data on partially suspended entity registrations.

In 2018, no entities had their registrations entirely suspended. However, FSAP partially suspended five entity registrations (three registered with DSAT, two registered with AgSAS). In 2018, a total of eight entities were partially suspended, including three partial entity registration suspensions that were initially imposed in 2017. Five of the eight partially suspended entities, including the three entities originally suspended in 2017, received approval to resume their work during the year. Three entities remained partially suspended at the end of 2018. The 2018 partial suspensions ranged from a few days to over a year depending on the compliance issue.

The five partial entity registration suspensions imposed in 2018 were for the following reasons:

- Failure of the effluent decontamination system that treated waste from their high-containment laboratory. The suspension was lifted once measures were implemented to effectively treat the laboratory waste.
- Failure to implement procedures/equipment for decontamination of effluent originating from the containment laboratories. The suspension was lifted once measures were implemented to effectively treat the laboratory waste.
- Airflow reversal from the animal containment laboratories. The suspension was lifted once the entity corrected the heating, ventilation, and air conditioning system.
- Removal of BSAT that had not been subjected to a validated inactivation procedure from the registered space. Once the inactivation failure was identified, the material was returned to the registered space. The suspension was lifted after the entity validated the inactivation procedures.
- Failures with the decontamination systems. The suspension was lifted after the entity fixed the decontamination systems.

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 in 2018, compared to five reports in 2017, two reports in 2016, and three reports in 2015. The 2018 report involved a complaint about an unregistered entity possessing select toxin. The report was referred to the FBI, who found that it was unsubstantiated.

Referrals to HHS OIG or APHIS IES

For serious non-compliance of the SAR, FSAP may refer entities to HHS OIG or APHIS IES for further investigation and possible civil monetary penalties. FSAP referred four entities to HHS OIG or APHIS IES in 2018, compared with seven entities in 2017, three entities in 2016, and four entities in 2015. One of the four referrals in 2018 is still pending. Below is a summary of the referrals in 2018:

- An entity had repeated reports of losses of BSAT.
- An entity allowed unauthorized individuals to have access to BSAT storage space.
- Two entities discovered BSAT in unregistered space.

As in any instance that inspections reveal non-compliance of the SAR, FSAP monitors referred entities and ensures implementation of the corrective actions.

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 a 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 2018, FSAP notified the FBI of nine matters for investigation. In all nine matters, FBI analysis determined there was no criminal nexus requiring the opening of a case.

- Eight matters concerned the loss of BSAT. Inventory accounting errors caused three of the matters, and inadvertent destruction of BSAT accounted for the remaining five matters.
- One matter concerned an unsubstantiated complaint about an unregistered entity possessing a select toxin.

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:

1. The deliberate transfer of, or selection for, drug-resistance traits 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, APHIS/VS-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. (APHIS/PPQ-only agents)

2. 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 one new request in 2018 that met the restricted experiment definition, which was approved. The request was for approval of an experiment with Botulinum neurotoxin type X. In addition, a 2017 restricted experiment request for proposed research with nucleic acids encoding botulinum neurotoxin was approved in 2018. Also in 2018, FSAP received six requests that did not meet the definition of a restricted experiment and

therefore did not require prior approval of FSAP. The two restricted experiment requests received by the program in 2018 represented the lowest number of requests over the last four years.

Exclusions

The SAR provide criteria for the exclusion of BSAT from the requirements of the SAR. An entity or individual may request to exclude from the SAR an attenuated (weakened) strain of a select agent or a select toxin modified to be less potent or toxic. As required by the SAR, 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 did not receive any exclusion requests in 2018.

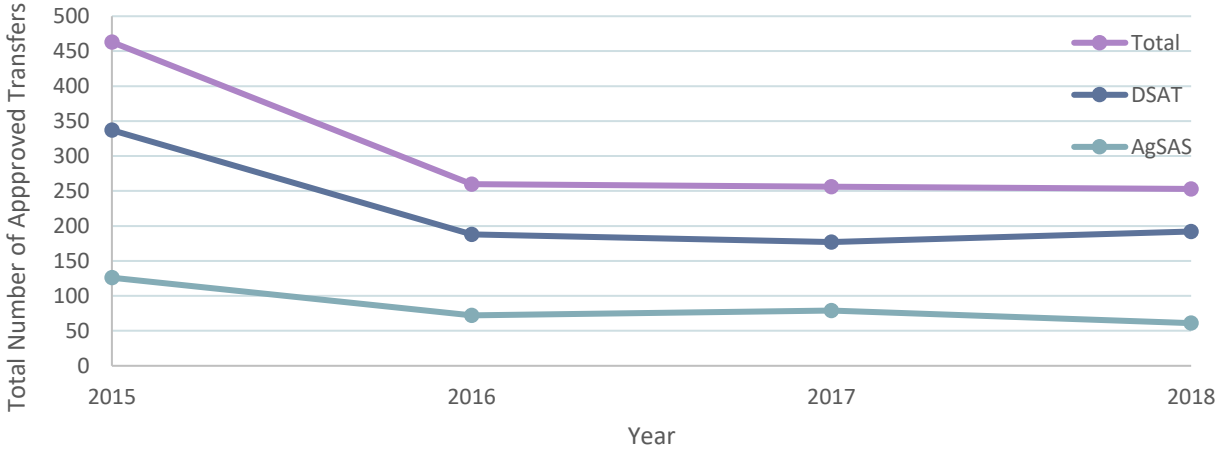
Transfers of BSAT

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 2018, FSAP approved 253 BSAT transfers – 61 by AgSAS and 192 by DSAT. Sixty-five (26%) of the approved transfers in 2018 involved unregistered entities transferring to registered entities. These transfers occurred either after the identification of BSAT in a diagnostic specimen at an unregistered entity (12) or were imported BSAT (53). Of those select agents or toxins that were imported from outside the U.S., AgSAS approved 34 transfers, and DSAT approved 19 transfers.

Of the 253 transfers approved by FSAP in 2018, 218 of the transfers occurred during the year. Six transfers approved towards the end of 2018 were not shipped until 2019. Entities cancelled 29 of the approved transfers before shipping the BSAT.

With the exception of 2015, the number of transfers during 2016-2018 remained stable at 253-260 per year (Figure 4). In 2015, due to an inadvertent shipment of viable *Bacillus anthracis* by an entity, FSAP instructed unregistered recipient entities to transfer the samples to registered entities for testing or destruction, causing an unusually high transfer rate for that select agent during that year.

Figure 4: Total Number of Approved BSAT Transfers, 2015-2018



For AgSAS, Avian influenza virus was the most frequently transferred BSAT for 2018 (Table 6) and has been since 2015.

Table 6. Number of BSAT Transfers Approved by AgSAS, 2018

BSAT	Total*
Avian influenza virus	**14**
Foot-and-mouth disease virus	**7**
Ralstonia solanacearum	**7**
African swine fever virus	**4**
Classical Swine Fever	**4**
Xanthomonas oryzae	**4**
Newcastle disease virus	**3**
Rathayibacter toxicus	**3**
Bacillus anthracis	**2**
Brucella abortus	**2**
Brucella melitensis	**2**
Brucella suis	**2**
Goat pox virus	**1**
Lumpy Skin Disease virus	**1**
Sheep pox virus	**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 2018 (Table 7) and has been since 2016. Botulinum neurotoxin is unique in that it is used both as a drug and for research purposes.

Table 7. Number of BSAT Transfers Approved by DSAT, 2018

BSAT	Total*
Botulinum neurotoxin	58
Botulinum neurotoxin producing species of *Clostridium*	18
Francisella tularensis	17
Burkholderia pseudomallei	13
Bacillus anthracis	12
Brucella suis	12
Brucella melitensis	11
Yersinia pestis	10
Ebola virus	9
Brucella abortus	6
Venezuelan equine encephalitis virus	5
Coxiella burnetii	4
Eastern equine encephalitis virus	4
Burkholderia mallei	3
Crimean-Congo haemorrhagic fever virus	3
Nipah virus	3
Bacillus anthracis (Pasteur strain)	2
Monkeypox virus	2
Rickettsia prowazekii	2
South American Haemorrhagic Fever virus: Sabia	2
Bacillus cereus Biovar *anthracis*	1
Hendra	1
Lassa fever virus	1
Marburg virus	1
SARS-associated coronavirus (SARS-CoV)	1
South American Haemorrhagic Fever virus: Guanarito	1
South American Haemorrhagic Fever virus: Junin	1
South American Haemorrhagic Fever virus: Lujo	1
South American Haemorrhagic Fever virus: Machupo	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)
- Needle stick or other percutaneous exposure 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 2018, FSAP received 193 reports of BSAT release and 8 reports of a BSAT loss. By comparison, FSAP received 237 reports of releases and 9 losses in 2017, 196 reports of releases and 9 losses in 2016, and 233 reports of releases and 12 losses in 2015. As in 2015, 2016, and 2017, there were again no reports of theft of BSAT in 2018.

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

Of the 193 reports of a BSAT release, 66 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. This also was the second most common cause of a release for registered entities.

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

- For eight of the reported releases, FSAP agreed with the entity that these reports presented a minimal to no risk of 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 identified illnesses, deaths, or transmissions among workers or outside of a laboratory into the surrounding environment or community.

FSAP conducts outreach, among other efforts, to increase awareness on safe work practices in the laboratory to reduce the number of occupational exposures.

Report of the Identification of BSAT

The Report of the Identification of a Select Agent or Toxin (APHIS/CDC Form 4) is used 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 2018, DSAT received and processed 1,006 APHIS/CDC Form 4As to report the identification of BSAT as a result of diagnosis or verification. In 2018, Botulinum neurotoxin was the most commonly identified BSAT reported to DSAT, followed by botulinum neurotoxin-producing species of *Clostridium* and Eastern Equine Encephalitis virus

(Table 8). Botulinum neurotoxin was also the most commonly identified BSAT in 2017 and 2016. By comparison, *F. tularensis* was the most commonly identified 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 19% of all reports of the identification of BSAT using the APHIS/CDC Form 4A, which is a slightly higher percentage than the past three years (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.

DSAT received 63 APHIS/CDC Form 4Bs reporting BSAT identified through proficiency testing in 2018, which represents a significant increase over the last four years. This was due to increased proficiency testing by laboratories that must routinely test their capabilities to identify BSAT and does not represent a real-world increase in diagnostic identifications. 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 8. BSAT Reported to DSAT on Form 4A by Sample Type, 2018

BSAT	Animal Specimens	Environmental Samples	Food Sample	Human Specimens	Total
Botulinum neurotoxins	**27**	**0**	**5**	**191**	**223**
Botulinum neurotoxin producing species of *Clostridium*	**30**	**2**	**4**	**125**	**161**
Eastern Equine Encephalitis virus	**103**	**24**	**0**	**1**	**128**
Francisella tularensis	**50**	**1**	**0**	**72**	**123**
Coxiella burnetii	**81**	**0**	**0**	**14**	**95**
Brucella melitensis	**0**	**0**	**0**	**85**	**85**
Brucella suis	**22**	**0**	**0**	**36**	**58**
Brucella abortus	**45**	**0**	**0**	**11**	**56**
Burkholderia pseudomallei	**0**	**2**	**0**	**23**	**25**
Bacillus anthracis	**12**	**1**	**0**	**1**	**14**
Ricin	**0**	**8**	**0**	**0**	**8**
Yersinia pestis	**7**	**0**	**0**	**1**	**8**
Ebola virus	**0**	**0**	**0**	**5**	**5***
Genomic material: Eastern Equine Encephalitis Virus	**3**	**1**	**0**	**0**	**4**
Bacillus cereus* Biovar *anthracis	**3**	**0**	**0**	**0**	**3**
Abrin	**0**	**2**	**0**	**0**	**2**
Rift Valley fever virus	**0**	**0**	**0**	**2**	**2**
Staphylococcal enterotoxins A, B, C, D, E subtypes	**0**	**0**	**1**	**1**	**2**
Crimean-Congo haemorrhagic fever virus	**0**	**0**	**0**	**1**	**1**
Monkeypox virus	**1**	**0**	**0**	**0**	**1**
Nipah virus	**0**	**0**	**0**	**1**	**1**
Tetrodotoxin	**1**	**0**	**0**	**0**	**1**
Total	**385**	**41**	**10**	**570**	**1006**

**The five Form 4As for Ebola virus batched together many identifications from the West Africa outbreak in 2015 to simplify reporting.*

AgSAS received and processed 175 APHIS/CDC Form 4A reports in 2018, including 155 reports of Newcastle disease virus, five reports of *R. solanacearum*, 14 reports of avian influenza virus, and one report of *Mycoplasma mycoides*. For AgSAS, non-registered laboratories accounted for 1% of all reports of the identification of BSAT using the APHIS/CDC Form 4A. The higher number of identifications of Newcastle disease virus in 2018 was due to an ongoing outbreak within domestic flocks in California. In July 2018 an exemption was provided to two entities responsible for the identification and reporting of Newcastle disease virus, which allowed the entities to group multiple identified samples onto one form every two weeks instead of submitting individual Form 4As for every sample. This limited the number of submitted Form 4A reports for Newcastle disease virus to 155.

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

Emergency Management

FSAP reaches out to assist entities with transferring or securing BSAT that may be affected by severe weather or natural disasters that could have an impact on the safety of employees and security of BSAT. There were nine such events in 2018, and FSAP contacted a total of 144 affected entities. Table 9 summarizes FSAP's assistance efforts during weather or natural disaster emergencies in 2018. 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 2018.

Table 9. FSAP Emergency Management, 2018

2018 Events	Number of Entities Contacted
Pre/Post Hurricane Michael	44
Pre/Post Nor'easter	34
Pre/Post Hurricane Florence	33
Pre/Post Tropical Storm Gordon	8
Virginia Flooding	7
Post Nor'easter #2	7
Pre/Post Hurricane Lane	5
Pre/Post Hurricane Olivia	5
Alaska 7.0 Earthquake	1
Totals	144

Federal Register Notices, Policy Statements, and Guidance

FSAP makes a concerted effort to engage and partner 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, and guidance documents for the benefit of the regulated community. In 2018, FSAP did not publish any regulatory interpretations, and only one Federal Register Notice on a technical amendment to the USDA SAR. Some examples of other FSAP issuances are included in Table 10. FSAP policy statements and guidance documents can be found on the FSAP website.

Table 10. Examples of FSAP Policy Statements and Guidance, 2018

Policy Statements	Date
Live bird lethality testing requirements for pathogenicity testing of reverse genetically derived viruses for avian influenza virus	February
Chemical inactivation of whole tissue or homogenized tissue	February
Inactivation Certificate	August
Registration and Inspection of Effluent Decontamination Systems	August
Revision to Validated Inactivation Procedure	August
Select agent contained in formalin-fixed paraffin-embedded tissue	October
Guidance	**Date**
Updated Avian Influenza Virus Guidance	February
Updated Incident Response Plan Guidance and Template	February
Updated Biosafety Guidance	July
Entity Annual Internal Inspections Guidance	August
Updated Guidance on the Inactivation or Removal of Select Agents and Toxins for Future Use	September

Outreach

FSAP has an active outreach program designed to provide opportunities for the program to interact with members of the regulated community. Table 11 and the bullets below summarize the 2018 FSAP outreach initiatives and events.

- Invited recently inspected entities to submit feedback surveys anonymously to assist FSAP in gauging its performance during inspections and to identify areas to improve the inspection process
- Conducted a multi-day in-person workshop for 137 Responsible Officials (ROs) and Alternate Responsible Officials (AROs) to provide information about maintaining regulatory compliance and to build community among those working in this area
- Conducted six webinars for ROs and AROs to provide guidance on the electronic Federal Select Agent Program (eFSAP) information system, the program's new secure web-based system that is used by registered entities to communicate with FSAP. A total of 214 ROs and AROs attended at least one of the six sessions
- Conducted six in-person eFSAP workshops. A total of 98 ROs and AROs attended at least one session
- Conducted 11 eFSAP pilot training sessions, which 32 ROs and AROs attended
- 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 2018, FSAP issued 76 SA Grams
- Exhibited an informational booth at five scientific conferences to provide guidance and promote compliance with the SAR

Table 11. FSAP Outreach Events, 2018

Conference	Date	Booth Attendees
15th CDC International Symposium on Biosafety	February 10-14	66
American Society for Microbiology (ASM) Biothreats	February 12-14	170
Association of Public Health Laboratories	June 2-5	122
ASM Microbe	June 7-11	200
American Veterinary Medical Association	July 13-17	50
RO Workshop	August 15-17	278
American Biological Safety Association	October 15-17	137
eFSAP Webinars	**Date**	**Attendees**
Release Update	May 8, 10, 11, 14, 16, 17	214
Pilot Entity Training	September 13 October 19 November 14, 16 December 4, 6, 7, 11, 17	32
eFSAP Workshop	**Date**	**Attendees**
Irvine, California	July 9	9
Madison, Wisconsin	July 31	11
Austin, Texas	August 30	16
Riverdale, Maryland	September 12	20
Riverdale, Maryland	September 13	29
Hartford, Connecticut	September 18	13

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.

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