2017 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

Contents

Executive Summary

This report summarizes calendar year 2017 data for the Federal Select Agent Program (FSAP) and marks the program's third annual effort towards communicating operational metrics to further public understanding of FSAP. FSAP will continue to publish a similar report annually.

Registered Entities

As of December 31, 2017, 263 entities were registered with the FSAP: 37 entities registered with Agriculture Select Agent Services (AgSAS) as the lead agency and 226 entities registered with the Division of Select Agents and Toxins (DSAT) as the lead agency. Lead agency is a term used by FSAP to indicate which agency the entity uses as its primary contact (i.e., AgSAS or DSAT). In 2017, no entities applied to FSAP for new registrations. FSAP approved two new entity applications (one AgSAS and one DSAT) in 2017 which had been submitted in 2016. No applications were pending at the beginning of 2018. Fifteen entities withdrew from FSAP: 13 from DSAT and 2 from AgSAS. This represents the second consecutive year in which there has been a 5% reduction in registered entities from the previous year.

Security Risk Assessments

The Federal Bureau of Investigation's (FBI) Criminal Justice Information Services Division (CJIS) conducted 3,714 Security Risk Assessments (SRA) in 2017. Based on these SRA, 17 individuals were identified as meeting the definition of a "restricted person" and were thus prohibited from having access to select agents and toxins. For the third consecutive year, the majority of newly approved individuals for access were individuals working at academic entities, followed by individuals working at federal government entities.

Inspections

FSAP conducted 169 inspections in 2017: 31 were conducted by AgSAS alone, 106 were conducted by DSAT alone, and 32 inspections were conducted jointly. FSAP has seen a continued decrease in inspections over the past three years.

Compliance Actions

Based upon findings of departures from the Select Agent Regulations (SAR), FSAP performs compliance actions through multiple mechanisms. These mechanisms include:

- Participation in the FSAP Corrective Action Plan (CAP) program, where an entity voluntarily develops and implements a plan of corrective actions that is closely monitored by FSAP
- Suspension (in part or in whole)
- Revocation of an entity's registration, for departures from the SAR that represent a danger to human, animal, or plant health, or to public safety.

FSAP can also refer entities to the United States Department of Health and Human Services (HHS) Office of Inspector General (OIG) or Animal and Plant Health Inspection Service (APHIS) Investigative and Enforcement Services (IES) for further investigation and possible civil monetary penalties, or notify the FBI of inspection findings that may involve a violation of criminal law.

In 2017:

- There were a total of eight entities in the CAP program, including one new entity and seven that continued in the program from 2016. An entity typically takes six to nine months to successfully complete a CAP. In rare cases, it may take an entity a year to successfully complete a CAP. All entities but two successfully completed a CAP in 2017.

- Two entities had their registration suspended, and two additional entities remained suspended from 2016.
- Seven entities were referred to either the HHS OIG or APHIS IES.
- FSAP notified the FBI of 18 matters for potential investigation.

Confidential Reporting Systems

HHS OIG, USDA OIG, and FSAP operate confidential systems for individuals to report biosafety and security issues associated with the possession, use, and transfer of biological select agent and toxin (BSAT). Each report received is investigated to determine if a violation of SAR has occurred. FSAP received five reports in 2017. All were investigated. Four reports were not substantiated in the resulting investigation; the fifth report was substantiated, and the entity withdrew its registration from FSAP. FSAP saw an increase in reports for 2017.

Transfers of 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 BSAT. BSAT may be transferred from one entity to another for purposes including additional testing of identified BSAT from diagnostic specimens, scientific or clinical research, and production of therapeutics. In 2017, FSAP approved 256 transfers: 177 were approved by DSAT and 79 were approved by AgSAS, including 15 importations approved by DSAT and 54 importations approved by AgSAS (four fewer than 2016).

Approving Agency	Number of Transfers
AgSAS Transfers	79
DSAT Transfers	177
FSAP Transfer Total	256

Theft, Loss, and Release of Select Agents and Toxins

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

In 2017, FSAP received 237 reports of releases and 9 reports of a loss of BSAT.

- No reports of thefts.
- None of the losses resulted in a risk to public or agricultural health.
- Of the 237 reports of a release, 108 reports were from entities registered with FSAP, and 129 reports of a release were from clinical or diagnostic laboratories not registered with FSAP. The 237 reports of a release involved:
  - 199 reports that documented a potential for an occupational exposure to 1,152 individuals (181 individuals from 73 registered entities and 971 from 126 exempt entities). The individuals were provided occupational health services, including medical assessments, diagnostic testing, and prophylaxis as the entity determined was necessary.
  - 38 reports (36 reports from registered entities and 2 reports from exempt entities) that documented a release outside of primary containment took place, but no occupational exposure occurred (e.g., spill outside BSC but laboratory workers were wearing PPE).

- None of the releases resulted in illnesses, deaths, or transmissions among workers or outside of laboratories into the surrounding environment.

Report of the Identification of a 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 FSAP of BSAT identified as a result of diagnosis, verification, and proficiency testing, and of the final disposition of identified BSAT. FSAP received 918 APHIS/CDC Form 4s in 2017: AgSAS received 62; DSAT received 856.

The most frequently identified BSAT reported to DSAT in 2017 were: Botulinum neurotoxin (169), *Francisella tularensis* (143), Botulinum neurotoxin producing species of *Clostridium* (120), *Brucella melitensis* (89), and Eastern equine encephalitis virus (76).

The most frequently identified BSAT reported to AgSAS in 2017 were: Newcastle disease virus (36), highly pathogenic avian influenza viruses (16), *Ralstonia solanacearum* (8), African swine fever virus (1), and *Bacillus anthracis* (1).

Acronyms

Acronym	Meaning
AgSAS	Agriculture Select Agent Services
Ag-ISATTAC	Agricultural-Intragovernmental Select Agents and Toxins Technical Advisory Committee
APHIS	Animal and Plant Health Inspection Service
ARO	Alternate Responsible Official
ASM	American Society for Microbiology
BSAT	Biological Select Agents and Toxins
BSC	Biosafety Cabinet
BSL	Biosafety Level
CAP	Corrective Action Plan
CDC	Centers for Disease Control and Prevention
CJIS	Criminal Justice Information Services Division
DAIG	DAIG Department of the Army Inspector General
DSAT	Division of Select Agents and Toxins
FAQ	Frequently Asked Questions
FBI	Federal Bureau of Investigation
FSAP	Federal Select Agent Program
HHS	United States Department of Health and Human Services
IES	Investigative and Enforcement Services
ISATTAC	Intragovernmental Select Agents and Toxins Technical Advisory Committee
NIH	National Institutes of Health
OIG	Office of Inspector General
RO	Responsible Official
PPE	Personal Protective Equipment
PPQ	Plant Protection and Quarantine
SAR	Select Agent Regulations
SRA	Security Risk Assessment
USC	United States Code
USDA	United States Department of Agriculture
VS	Veterinary Services

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) 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). Together, FSAP oversees the possession, use and transfer of biological select agents and toxins (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 (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121) (SAR). FSAP helps to ensure work with BSAT is conducted as safely and securely as possible by:

- Developing, implementing, and enforcing SAR.
- Maintaining a national database to track where and what work is being conducted with BSAT.
- Inspecting entities that possess, use, or transfer BSAT to ensure that legitimate use with these agents and toxins are conducted safely and securely.
- Ensuring that all individuals who have access to BSAT undergo a security risk assessment (SRA) performed by the Federal Bureau of Investigation (FBI)/Criminal Justice Information Services Division (CJIS).
- Developing guidance documents and conducting informational workshops and webinars to help regulated entities maintain SAR compliance.
- Investigating incidents in which non-compliance with the SAR may have occurred.

In 2015, the United States Government published three reports that included recommendations to strengthen the government's safety and security practices and the oversight system, both through FSAP and at a broader national level. One of the reports was developed by a federal advisory panel, the Federal Experts Security Advisory Panel. A second report which included external stakeholder input was developed by the Fast Track Action Committee on Select Agent Regulations. CDC published a third report containing recommendations to improve the CDC select agent and toxin regulatory program, the 90-day Internal Review of the Division of Select Agents and Toxins. There were many recommendations included in the three reports that complemented one another. FSAP either has completed or is continuing to address all of the recommendations, several of which require our ongoing monitoring to ensure continual program improvements.

Key Program Statistics

Registration

Registered Entities

BSAT are divided into four categories based on whether the agent causes disease in humans, animals, plants, or a combination of humans and animals. In accordance with section 351A(a)(2) of the Public Health Service Act (42 USC 262a(a)(2)) and section 212(a)(2) of the Agricultural Bioterrorism Protection Act of 2002 (7 USC 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** (42 CFR Part 73): BSAT that have the potential to pose a severe threat to public health and safety are regulated by HHS.
- **Overlap select agents and toxins** (42 CFR Part 73 and 9 CFR Part 121): BSAT that have the potential to pose a severe threat to public health and safety and to animal health, or to animal products. Overlap BSAT are regulated jointly by USDA and HHS.
- **USDA Veterinary Services (VS) select agents and toxins** (9 CFR Part 121): BSAT that have the potential to pose a severe threat to animal health or to animal products are regulated by USDA.
- **USDA Plant Protection and Quarantine (PPQ) select agents and toxins** (7 CFR Part 331): BSAT that have the potential to pose a severe threat to plant health or to plant products are regulated by USDA.

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). An entity that plans to register for HHS-only BSAT must submit their APHIS/CDC Form 1 to DSAT. If the entity registers for USDA-only BSAT, it must register with AgSAS. 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 DSAT or AgSAS. DSAT and AgSAS work together to jointly oversee entities that have BSAT under the other's authority.

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.

Entities must renew their registration every three years.

Once the initial APHIS/CDC Form 1 is received, it is reviewed and a Select Agent Program Officer is assigned to the entity. A site inspection is then scheduled to verify information submitted on the APHIS/CDC Form 1 and to ensure the entity is compliant with SAR. Once the inspection is completed and any identified issues have been addressed, the entity receives a certificate of registration, which allows it to acquire and work with BSAT.

FSAP regulates a diverse community of entities including government facilities at the federal, state, and local levels, academic institutions, commercial, and other private entities in the United States. Work with BSAT may include: clinical diagnostics that are critical to inform patient care decisions, disease surveillance

and confirmation services, basic science and clinical research, and production of biologics and therapeutics such as antibiotics and vaccines.

Registered entities can be sorted into five types:

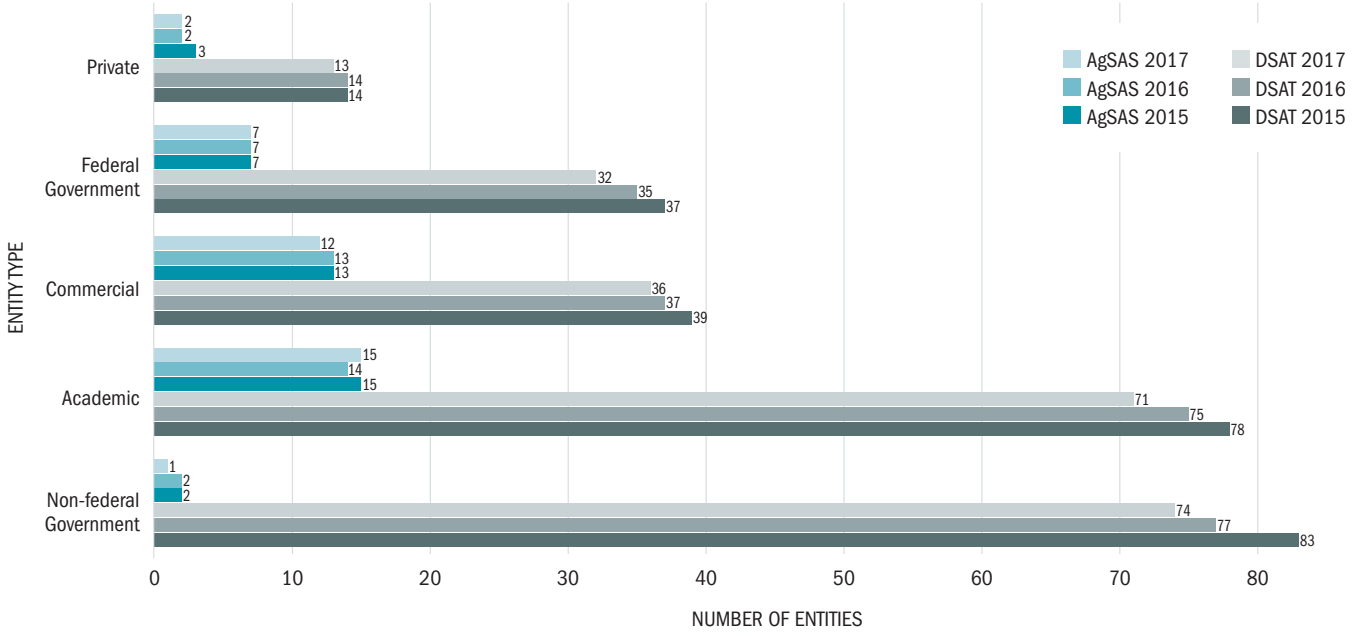
- **Academic—**A university, college, or other institution of higher learning. Academic institutions can be either private (neither owned nor controlled by any government entity) or state (predominantly funded through the government).
- **Commercial—**A privately owned for-profit company including partnerships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

At the end of 2017, 263 entities were registered with FSAP: 37 with AgSAS and 226 with DSAT (Figure 1). This represents the second consecutive year in which there has been a 5% reduction in registered entities from the previous year.

Regulated entities during calendar year 2017 consisted of:[1]

- 33% academic,
- 29% non-federal government,
- 18% commercial,
- 15% federal government, and
- 6% private.

Figure 1: Number of FSAP-Registered Entities by Type



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

The lead agency, DSAT or AgSAS, is responsible for coordinating all activities and communications with respect to an entity's registration, including coordination with the non-lead agency for entities with overlap agents. In 2017, 51 entities were jointly overseen by AgSAS and DSAT: AgSAS served as the lead agency for 13 of those entities and DSAT served as the lead agency for 38 of those entities. Compared to 2016, the number of jointly overseen entities led by DSAT increased by one entity in 2017 while the number led by AgSAS reduced by one entity. In 2015, there were also 51 entities jointly overseen by the two agencies (15 with AgSAS and 36 with DSAT).

New Registration Applications

A facility must register with FSAP to possess, use, or transfer BSAT. In 2017, FSAP received no new applications requesting to register to possess, use, or transfer BSAT. AgSAS and DSAT each received one new application in 2016 that was completed and approved in 2017, adding one new entity to each agency. Both were new academic entities. By comparison, AgSAS and DSAT each approved two new applications in 2015, and AgSAS approved one new application in 2016.

Renewals

Registered entities must renew their registration at least every 3 years. To renew a registration, an entity must undergo a renewal inspection. In 2017, AgSAS approved six registration renewals and DSAT approved 95, for a total of 101 renewals approved by FSAP. By comparison, FSAP approved 86 registration renewals in 2016 (19 approved by AgSAS and 67 approved by DSAT), and FSAP approved 104 registration renewals in 2015 (12 approved by AgSAS and 92 approved by DSAT).

Entity Withdrawals

When an entity decides that it no longer needs to possess, use, or transfer BSAT, it can request to withdraw its registration from FSAP. To do so, the entity must provide documentation that all of the BSAT in its possession was either destroyed or transferred to another registered entity via an approved APHIS/CDC Form 2. 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, 15 entities withdrew their registration from FSAP in 2017: 13 entities from DSAT and 2 entities from AgSAS. One fewer entity withdrew their registration from FSAP in 2017 than in 2016 (16) and 12 fewer withdrew compared to 2015 (27). The reasons entities cited for withdrawing were similar in 2015, 2016, and 2017: they no longer needed to work with BSAT and therefore did not need to be registered with FSAP.

Table 1. Number of entity withdrawals by agency and entity type, 2017

Entity Type	AgSAS	DSAT
Academic	0	5
Commercial	1	1
Federal government	0	3
Non-federal government	1	3
Private	0	1

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 2017, 11 entities had registered with AgSAS are registered for Tier 1 BSAT, representing 30% of all AgSAS-led entities, compared with 12 entities (32%) in 2016, and 13 entities (33%) in 2015. DSAT had 122 entities registered for Tier 1 BSAT, representing 54% of all DSAT-led entities, compared with 130 entities (55%) reported for 2016, and 135 entities (54%) in 2015. The total percentage of FSAP-regulated entities registered for Tier 1 BSAT changed to 50%, down from 51% in 2015 and 2016.

50% of all FSAP-regulated entities are registered for Tier 1 BSAT.

Top Agents Registered With Each Agency

Tables 2a and 2b list the top agents registered by each agency as of December 31, 2017. To determine the top agents registered by each agency, FSAP counted the total number of entities registered for each BSAT regardless of whether the entity possessed the agent.

Tables 2a and 2b. Top agents registered with each agency, 2017

	Registered with DSAT
1.	*Brucella melitensis*
2.	*Brucella suis*
3.	*Brucella abortus*
4.	*Bacillus anthracis* (Pasteur strain)
5.	*Francisella tularensis**
6.	*Yersinia pestis**
7.	*Burkholderia pseudomallei**
8.	*Bacillus anthracis**
9.	*Burkholderia mallei**
10.	Botulinum neurotoxin producing species of *Clostridium**

	Registered with AgSAS
1.	Newcastle disease virus
2.	Avian influenza virus
3.	*Brucella abortus* *Bacillus anthracis** *Ralstonia solanacearum*
4.	*Francisella tularensis** *Xanthomonas oryzae*
5.	*Brucella melitensis* *Yersinia pestis** *Burkholderia pseudomallei** *Brucella suis* *Burkholderia mallei**

**Indicates Tier 1 agent or toxin*

Laboratory Types

Each regulated entity has one or more laboratories or secure storage location(s) 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). There is also a BSL-3Ag containment level which is generally used for work with agricultural animals in which the laboratory itself serves as primary containment. Primary containment refers to devices that protect the worker, product, and environment from exposure to microbiological agents, such as a biosafety cabinet (BSC). Entities may register multiple types of laboratories at different biosafety levels (BSL) depending on the work required in those laboratories.

In 2017, 31% 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. Over the last 2 years, the types of laboratories registered with FSAP have remained relatively consistent. Table 3 lists the number of entities that are registered for a Tier 1 agent at each BSL, and the number of entities at each BSL by entity type.

Table 3: Number of Entities by Laboratory and Entity Types, 2017

Laboratory Type: Biosafety Level	Total*	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	82	49	28	17	19	10	8
BSL-3/ABSL-3	207	104	18	26	75	73	15
BSL-4/ABSL-4	8	8	0	5	2	0	1

**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 keep BSAT out of the possession of individuals who might intend to misuse them, such as bioterrorists. FSAP works closely with the FBI's CJIS to identify those individuals who are prohibited from access to BSAT because they are a "restricted person" as defined by section 175b of title 18, United States Code (USC). A security risk assessment (SRA) is a CJIS electronic records check to determine whether: an entity or individual seeking to access BSAT within the entity is not a "restricted person" or does not meet one of the statutory restrictors which would either deny registration/access or limit access. The results of an SRA assist FSAP in determining whether an individual or entity may possess, use, or transfer BSAT; or if an individual may be granted approval to access BSAT. An SRA is valid for a period not to exceed 3 years.

As of December 31, 2017, FSAP managed a total of 9,916 active SRAs for unique individuals, an increase of 253 over the 9,663 SRAs in 2016 (FSAP did not report these data in 2015). In 2017, the FBI conducted new SRAs on 3,714 individuals and FSAP approved 3,672 of those individuals to have access to BSAT. There were 17 individuals identified as "restricted persons" and were denied access to BSAT. The remaining 25 individuals not approved for access to BSAT did not complete the application process.

Because an individual may be approved for access to BSAT at more than one entity, the total number of BSAT access approvals is greater than the number of SRAs conducted. FSAP granted 3,771 approvals for access in 2017 (Table 4), which represents a 5% decrease in the number of approvals in 2017 as compared to 2016. The decrease from 2016 to 2017 was smaller than the 10% decrease observed from 2015 to 2016 (data not shown). For the third consecutive year, the majority of newly approved individuals for access were for individuals working at academic entities, followed by individuals working at federal government entities. With the exception of federal and non-federal government entities, the number of approved individuals decreased for all other entity types from 2016.

Table 4: Total security risk assessments by entity type and approval status, 2017

Entity Type	Newly Approved SRAs in 2017	Individuals Identified as Restricted in 2017	Total Currently Active SRA as of 12/31/2017
Federal government	1,192	7	3,064
Non-federal government	527	1	1,312
Commercial	383	0	1,090
Private	327	1	826
Academic	1,342	8	3,624
Total	**3,771***	**17**	**9,916**

**The total number of individuals approved for access to BSAT per entity type is greater than the number of SRAs conducted because individuals can be approved at multiple entities based on one SRA.*

A "restricted person" cannot be granted access to select agents or toxins. Section 175b(d)(2) of Title 18 United States Code (18 USC 175b(d)(2)) defines a "restricted person" as a person 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.
- Is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to 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.
- Has been discharged from the Armed Services of the United States under dishonorable conditions.
- 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 forth in 18 USC 2332b(g)(5);
- Knowing involvement with an organization that engages in domestic or international terrorism (as defined in 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 50 USC § 1801).

In 2017, 17 individuals were identified as being a "restricted person," compared to 10 in 2016 and 16 in 2015. The reasons are summarized in Table 5.

Table 5. Number of "restricted person" categories by restrictor type identified, 2017

Prohibitor	Total
Conviction exceeds 1 year (Has been convicted in any court of a crime punishable by imprisonment for a term exceeding one year)	11
Has been adjudicated as a mental defective or has been committed to any mental institution	1
Is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism	1
An alien illegally or unlawfully in the United States	1
Fugitive from justice	1
Under indictment (Is under indictment for a crime punishable by imprisonment for a term exceeding one year)	1
Unlawful user of any controlled substance	1
Total	**17**

Inspection Data

Inspections

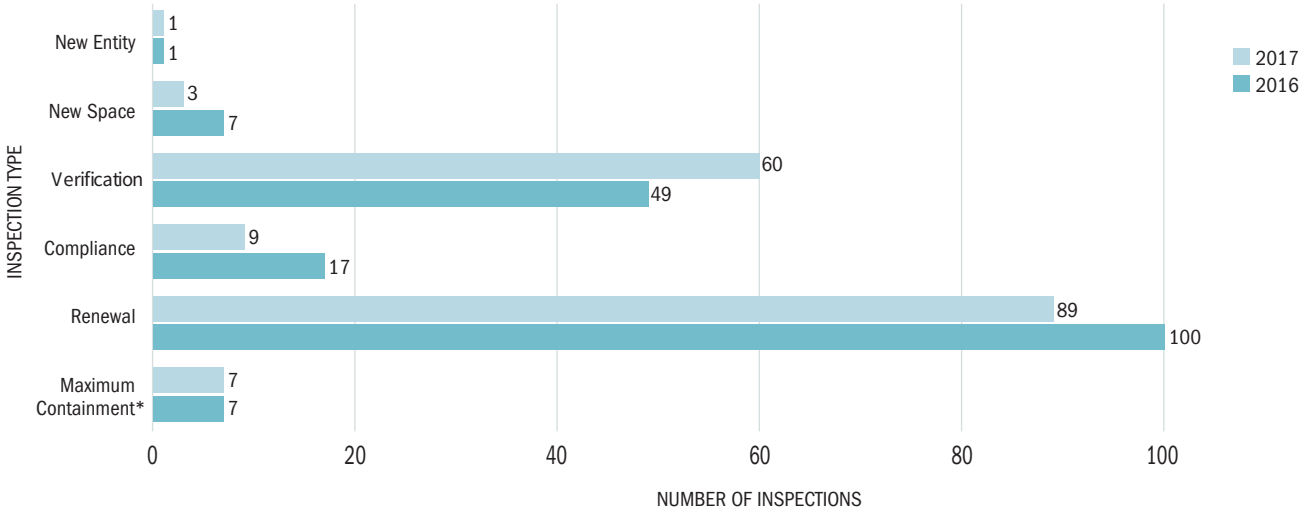
Entities regulated by FSAP are subject to announced and unannounced inspections. Some events that trigger an inspection are: a registration renewal, an incident or report that indicates a possible lack of compliance with SAR, periodic verifications that an entity has made corrective actions identified during previous inspections, the addition of new space, and a new registration application. The type of inspection scheduled depends on the triggering event, but all inspections focus on compliance with SAR, as well 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 program for compliance issues, including inspections to investigate whistleblower reports.
- **Maximum containment—**Review of entity program, including laboratory spaces and documents, for ABSL-4 and BSL-4 laboratories.
- **New entity—**Review of all laboratory spaces and documents for an entity that is submitting a new application for registration.
- **New space—**Review of new laboratory space and documents for adding new laboratory space to an existing registration.
- **Renewals—**Review of entire entity program, including all registered spaces and documents, to renew existing registration. Renewal inspections are typically conducted every 3 years.
- **Verification—**Review of selected portions of the entity program, including assessment of responses to previous inspection departures. Verification inspections are conducted within 12 to 18 months of a renewal inspection.

Inspections can be led by either DSAT or AgSAS depending on the BSAT the entity is registered to possess, use, or transfer. DSAT inspects entities registered for HHS-only BSAT and AgSAS inspects entities with USDA-only BSAT. Entities registered for both HHS and USDA BSAT are normally inspected jointly by DSAT and AgSAS.

In 2017, FSAP performed 169 inspections: 31 by AgSAS, 106 by DSAT, and 32 jointly. By comparison, FSAP performed 181 inspections in 2016: 29 by AgSAS, 103 by DSAT, and 49 jointly, representing a 7% decrease in the number of FSAP inspections from 2016 to 2017. In 2015, FSAP performed 216 inspections, 33 by AgSAS, 145 by DSAT, and 38 jointly. FSAP has seen a continued decrease in inspections over the past three years. One factor for the decreased number of inspections in 2017 is the withdrawal of 15 entities from FSAP registration. Figure 2 compares the number of each type of inspection conducted by FSAP in 2016 and 2017.

Figure 2: Number of Each Type of Inspection

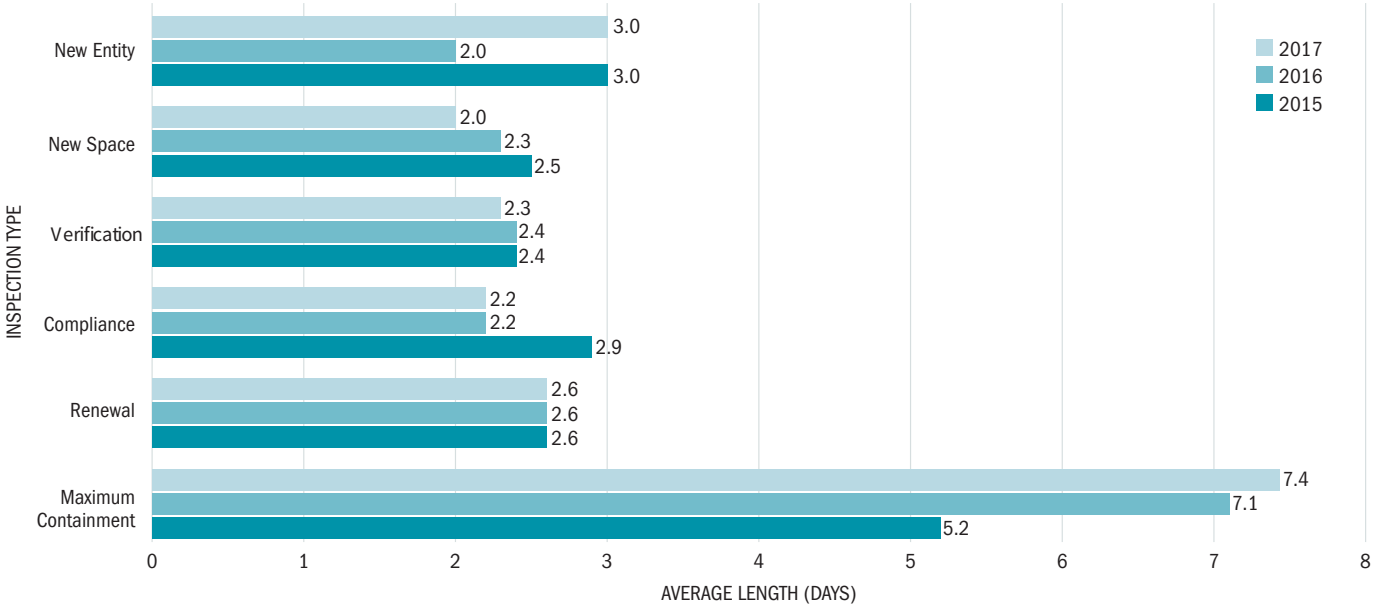


**Two of the seven maximum containment inspections in 2017 were conducted as part of their entity's renewal inspection.*

Length of Inspections

In 2017, inspection length ranged from 1 to 9 federal government business days on-site with an average length of 2.6 days. For 2015 and 2016, the range was 1 to 8 days, with an average length of 3 days. Figure 3 compares the average length of an FSAP inspection by inspection type for 2015–2017. In all 3 years, maximum containment inspections were the longest inspections, likely due to the complexity of high containment facilities. During 2017, additional DSAT inspectors were trained to conduct maximum containment inspections. The addition of these inspectors should help to shorten the length of maximum containment inspections in the future.

Figure 3: Average Length of Inspection by Inspection Type



Inspection Findings and Compliance

The 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. The following is a representative listing of the types of observations during inspections in 2017. These observations are not listed in any particular order.

- Omission or 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 or facility and equipment issues that could result in exposure.
- Failure to properly secure BSAT materials from unapproved access.
- Work with BSAT materials outside of registered laboratories.

Corrective Action Plan

FSAP's Corrective Action Plan (CAP) program assists entities identified, during an inspection, as having systemic biosafety and security deficiencies 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 the target completion dates. An entity's participation in the CAP program allows FSAP to provide technical assistance as well as monitor an entity's progress in correcting security or biosafety shortcomings. Participation in the CAP program is voluntary. If an entity chooses not to participate in a CAP, the entity is expected to successfully resolve the regulatory departures identified in their inspection report within 30 days. If the entity cannot successfully resolve these departures within 30 days, they may have their registration suspended.

In 2017, one entity agreed to participate in the CAP program, and seven entities continued in the program from the previous year. Eight entities participated in the CAP program in 2017 with six completing the program as of December 31, 2017. Of the eight, a total of three AgSAS entities participated in the CAP program—with one new entity being added in 2017. The other two entities continued participation in CAP program from the previous year. One of the three AgSAS entities successfully completed the CAP program in 2017. In 2017, five DSAT entities participated in the CAP program (all continuations from the previous year), with no new additions in 2017. All five DSAT entities successfully completed the CAP program in 2017.

Participants in the CAP program were each found to have one or more of the following types of systemic biosafety and security deficiencies:

- Responsible Official (RO) failure to ensure compliance with the SAR for work with BSAT.
- Multiple incidents involving an entity's effluent decontamination system.
- Inadequate inactivation protocols.
- Work with BSAT in laboratories not listed on the entity's registration or failure to secure BSAT making it vulnerable to theft.
- Failure to follow safe work practices and work safely in an environment with BSAT that could have resulted in an occupational exposure to the BSAT.
- Failure to submit required FSAP forms, such as Form 2, Form 3, and Form 4.
- Inaccurate BSAT inventory records.

In 2017, eight entities participated in the CAP program, with six completing the program by the end of the year.

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. A total of four entities were under suspension during 2017. Two of these entities (both registered with DSAT) were previously suspended (one in 2015 and one in 2016) and were still under suspension at the beginning of 2017. During 2017, one entity had their suspension lifted, while the other entity withdrew their registration. No AgSAS entities were suspended in 2017. At the end of 2017, the two remaining entities (both registered with DSAT) were suspended for the following reasons:

- One entity failed to ensure that biosafety and containment procedures were sufficient to properly contain select agents in possession.
- The other entity failed to comply with the regulatory requirements of having a knowledgeable RO, implementing Tier 1 requirements for security and occupational health, training of individuals on the registration, and maintaining an accurate inventory. The entity also failed to maintain the corrective actions specified in the entity's CAP.

By comparison, three entities were newly suspended in both 2016 and 2015. None of the suspensions in 2017 were appealed.

Reports and Referrals

Confidential Reporting System

The HHS Office of Inspector General (OIG), USDA OIG, and FSAP maintain confidential reporting systems that allow anyone to report safety, security, or other concerns associated with BSAT. FSAP received five such reports in 2017, compared to two reports in 2016 and three reports in 2015. Below is a summary of the reports for 2017:

- Allegedly an academic entity had biosafety concerns associated with their registered BSL-3 laboratory. An inspection of the entity did not substantiate the allegations.
- Allegedly a federal government entity was missing vials of a select agent, and work outside of proper containment. An inspection revealed no evidence of missing vials or inventory issues. There was also no evidence of work outside of containment.
- Allegedly a federal government entity may have allowed unauthorized access to a select toxin. An inspection of the entity determined that no work had occurred with the select toxin in recent years. The allegations could not be substantiated.
- Allegedly a federal government entity was allowing work with select agents to occur with animals after this type of work had been suspended. An inspection found no evidence to substantiate this claim.
- A federal government entity was reported for general biosafety concerns. These concerns were referred to other appropriate federal inspectors who also had oversight of the facility. The allegations were substantiated. This entity withdrew from FSAP.

Referrals to HHS OIG or APHIS IES

Entities may be referred to HHS OIG or APHIS IES for further investigation and for civil monetary penalties for serious violations of the SAR. FSAP referred seven entities to HHS OIG or APHIS IES in 2017, compared with three entities in 2016 and four entities in 2015. Three of the seven referrals in 2017 are still pending. In addition to being referred to HHS OIG or APHIS IES, an entity can also be referred to other applicable investigatory groups such as the FBI or the Department of the Army Inspector General (DAIG). One of the

2016 referrals is still under investigation, and all of the 2015 referrals are closed. Below is a summary of the referrals in 2017:

- A non-federal government entity stored and manipulated regulated genomic material in unregistered space, and the regulated genomic material was accessed by unapproved individuals.
- A private entity failed to ensure that biosafety and containment procedures were sufficient to properly contain BSAT in its possession.
- An academic entity failed to maintain the corrective actions specified in their CAP.
- Two unregistered entities possessed regulated BSAT in unregistered space.
- A non-federal government entity discovered BSAT in unregistered space.
- A federal entity within the Department of Defense failed to have a RO or an Alternate Responsible Official (ARO). This entity was also referred to the DAIG.

FBI Notifications

Based on an agreement with the FBI, 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 FSAP partnership with the FBI allows FSAP to leverage FBI resources to determine whether a security issue presents a criminal threat, including whether a loss may have actually represented a theft. FSAP also provides information in support of specific FBI investigations upon request. In 2017, the FBI was informed of 18 matters for investigation. In 16 of the 18 investigated matters, FBI analysis determined there was no criminal nexus requiring the opening of a case. For one matter, the FBI decided not to follow-up because it determined that the issue was not directly related to the entity's select agent program. The remaining investigation was ongoing as of December 31, 2017.

- Nine matters concerned losses of BSAT. All losses were determined to be records management errors.
- Two matters concerned lost shipments of toxins below the regulated amount. Each shipment was ultimately delivered to the entity within 48 hours after discovery of potential loss.
- One matter concerned the criminal investigation of an individual approved for access.
- One matter concerned a whistleblower complaint. The matter was addressed by APHIS IES.
- One matter concerned possible work with a select agent in unregistered space by non-approved individuals. The matter was also referred to HHS OIG.
- One matter concerned a cyber-attack on an entity. The entity determined that information systems used to manage security for the registered space was not compromised. FBI did not open an investigation into this matter.
- One matter concerned the discovery of BSAT outside of registered space. The BSAT was secured. The FBI closed the investigation.
- One matter concerned a hotline call of possible nefarious use of a biological weapon. Investigation by the FBI determined no criminal nexus.
- One matter involved the theft of a select toxin below the regulated amount. The matter is still under investigation.

Restricted Experiments

An individual or entity may not conduct or possess products resulting from restricted experiments unless approved by FSAP and conducted in accordance with the conditions prescribed. SAR defines two types of restricted experiments:

1. The deliberate transfer of, or selection for, drug-resistance traits to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents 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 select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents 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 select toxins lethal for vertebrates at an LD_{50} < 100 ng/kg body weight. Currently, only one select toxin (botulinum neurotoxin) possesses an LD_{50} < 100 ng/kg body weight.

These experiments require prior approval from FSAP due to their significant potential threat to human, animal, or plant health, or to animal or plant products.

Experiments that meet the restricted experiment definition require written approval by FSAP before any work can begin.

As shown in Table 6, FSAP received seven requests in 2017 that met the restricted experiment definition. Six restricted experiment requests were for the transfer of drug resistance traits into agents, including *B. mallei, B. pseudomallei, F. tularensis* (2 requests), and *Y. pestis* (2 requests). All six requests were denied. Another request was for approval of an experiment with recombinant Botulinum neurotoxin nucleic acids. This request remained pending as of December 31, 2017. FSAP received six requests that met the restricted experiment definition in 2016, and four requests in 2015. In 2017, FSAP received nine requests (compared to 38 requests in 2016 and 19 requests in 2015) that did not meet the definition of a restricted experiment and therefore did not require prior approval of FSAP.

Table 6: Summary of restricted experiments by entity type, select agent, and decision status, 2017

Entity Type	Agent	Decision Status
Academic	*Burkholderia mallei*	Denied
Academic	*Burkholderia pseudomallei*	Denied
Academic	*Francisella tularensis (2)*	Denied
Academic	*Yersinia pestis (2)*	Denied
Academic	Recombinant Botulinum neurotoxin nucleic acids	Pending

Exclusions

The SAR provide criteria for the exclusion of BSAT from the requirements of the SAR. (See 42 CFR §§ 73.3 and 73.4, 9 CFR §§ 121.3 and 121.4, 7 CFR § 331.3). 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 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.

In 2017, FSAP received 12 requests to exclude attenuated select agent strains or less potent/toxic forms of select toxins. Ten of the twelve requests were approved and excluded based on results demonstrating they no longer had a potential to pose a threat to public health and safety, animal health or animal products, and plant health or plant products (Table 7). The two exclusion requests that were denied were due to insufficient data to demonstrate attenuation. A detailed list of all excluded select agent strains can be found at Select Agents and Toxins Exclusions.

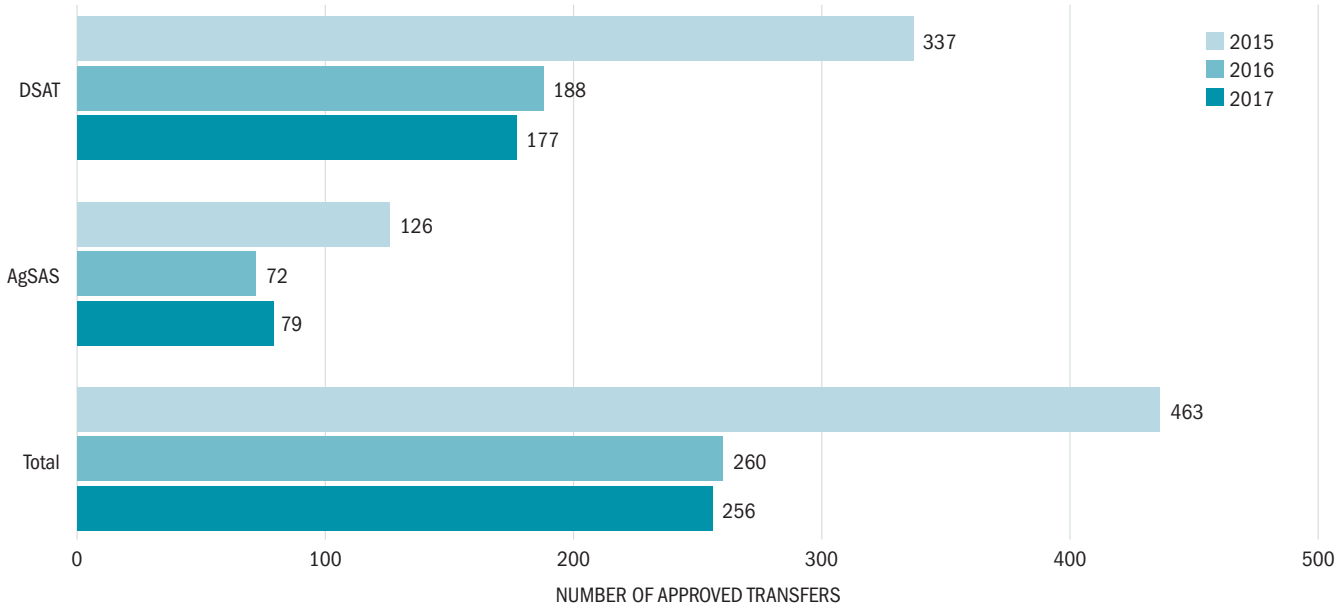
Table 7. Summary of requests for exclusions by entity type, select agent, and approval status, 2017.

Entity Type	Select Agent	Decision Status
Academic	Δasd mutants—4 *B. mallei* and 9 *B. pseudomallei* mutants	Approved
Academic	*B. pseudomallei* 576a strain (Δasd mutant)	Approved
Academic	Genetically modified, non-toxic BoNT/B (E231Q/R370A/Y373F)	Denied due to insufficient data to demonstrate attenuation
Private	Avian Influenza Reassortant 608468 [derived from A/chicken/Netherlands/EMC-3/2014 (H5N8)]	Approved
Private	Avian Influenza Reassortant 611645 [derived from A/snow goose/MO/CC15-84A/2015 (H5N2)]	Approved
Academic	Avian Influenza Reassortant rg A/chicken/Vietnam/NCVD-15A59/2015 (DHA, NA) x PR8 virus (H5N6)	Approved
Academic	A/chicken/Pennsylvania/7659/1985 Avian Influenza isolate	Approved
Commercial	Avian Influenza Reassortant H5 Hu Cobra 2 (derived from H5N1; A/Whooper swan/Mongolia/244/2005; A/Puerto Rico/8/34)	Approved
Private	A/Hong Kong/61/2016 (H7N9) and A/Hong Kong/125/2017 (H7N9) Avian Influenza isolates	Denied due to insufficient data to demonstrate attenuation
Academic	*B. pseudomallei* strain 576mn	Approved
Private	Avian Influenza Reassortant derived from A/duck/Vietnam/NCVD-1584/2012 (NIBRG-301)	Approved
Private	Avian Influenza Reassortant derived from A/Egypt/N04915/2014 (NIBRG-306)	Approved

Transfers of Select Agents or Toxins

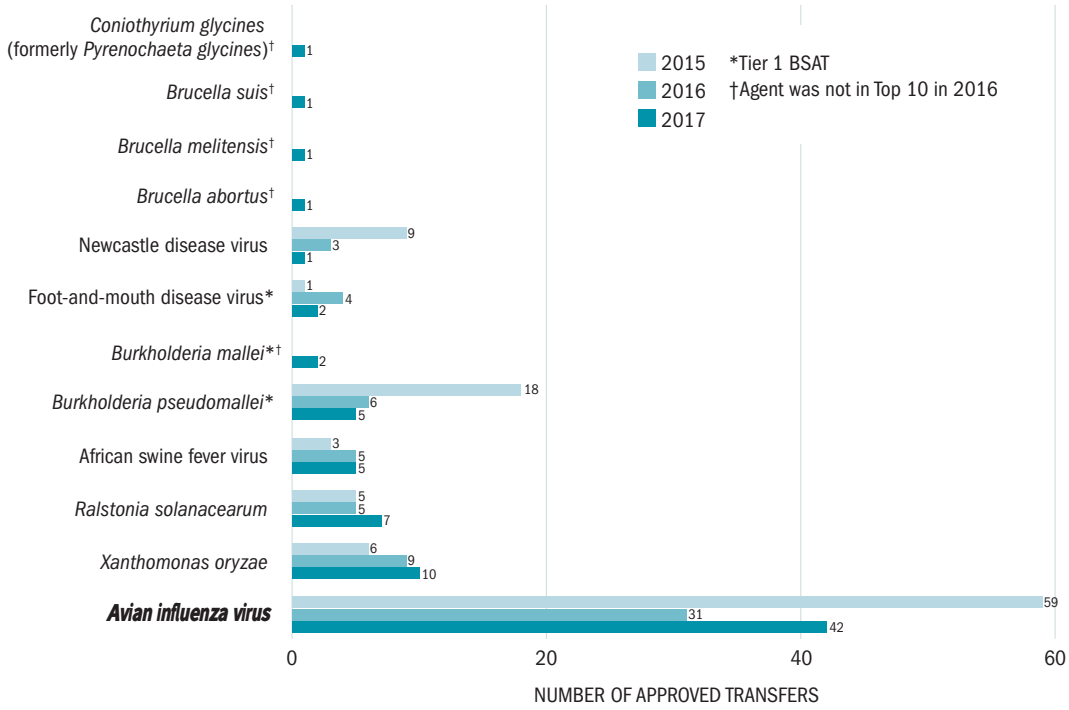
The Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2) is used by entities to request authorization prior to transferring BSAT. BSAT may be transferred from one entity to another for diagnostic testing, scientific or clinical research, and production of therapeutics. In 2017, FSAP approved 256 BSAT transfers, 79 by AgSAS and 177 by DSAT, four fewer than transfers approved (260) in 2016. In 2015, there were 463 approved transfers (Figure 4). Overall from 2015 to 2016, there was a 56% reduction in the number of transfers approved by FSAP (i.e., 463 in 2015 and 260 in 2016). The increase in transfers in 2015 resulted from the investigation involving Department of Defense shipment of presumed inactivated *Bacillus anthracis* and shipments of unknown diagnostic samples shipped as "suspected" select agents and toxins using APHIS/CDC Form 2. Twenty-nine percent of those transfers involved unregistered exempted entities transferring to registered entities, mostly as a result of the identification of a select agent in a diagnostic specimen. This transfer from unregistered exempt entities to registered entities represented a decrease of 24% from 2016.

Figure 4: Summary of Approved Transfers



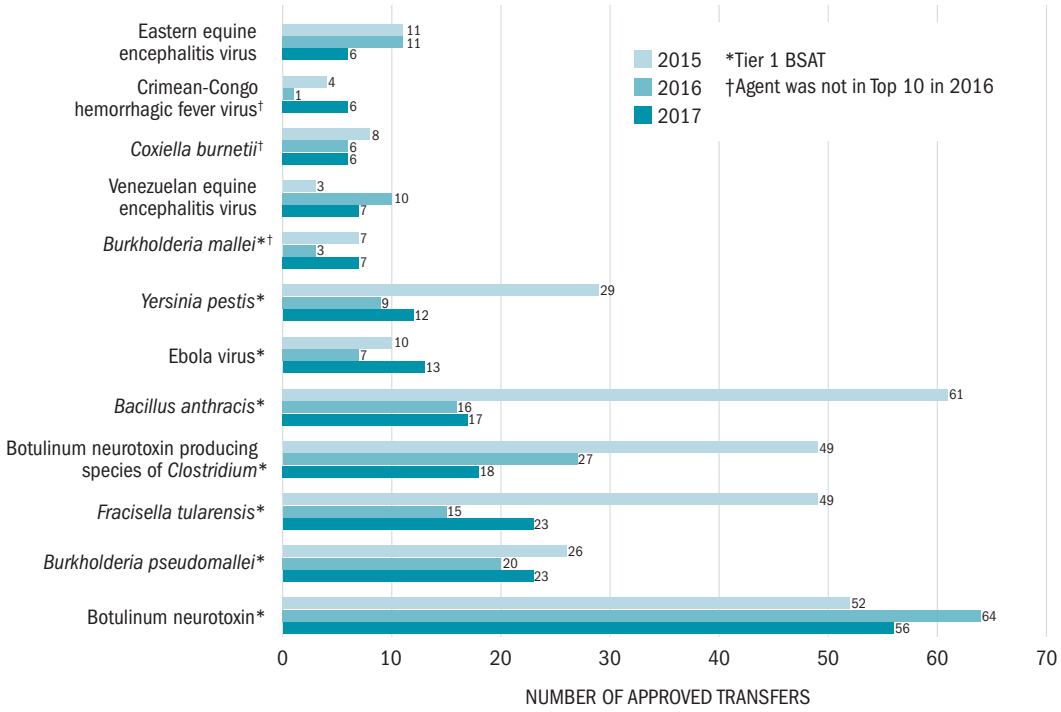
AgSAS approved 7 more transfers in 2017 as compared to 2016. Avian influenza virus was the most frequent AgSAS-approved transfer in 2015, 2016, and 2017, followed in 2017 by *Xanthamonas oryzae, R. solanacearum,* African swine fever virus, and *B. pseudomallei* (Figure 5). Of the 79 AgSAS-approved transfers, 54 transfers were imported from outside the U.S.

Figure 5: Top Agents Approved for Transfer by AgSAS, 2017



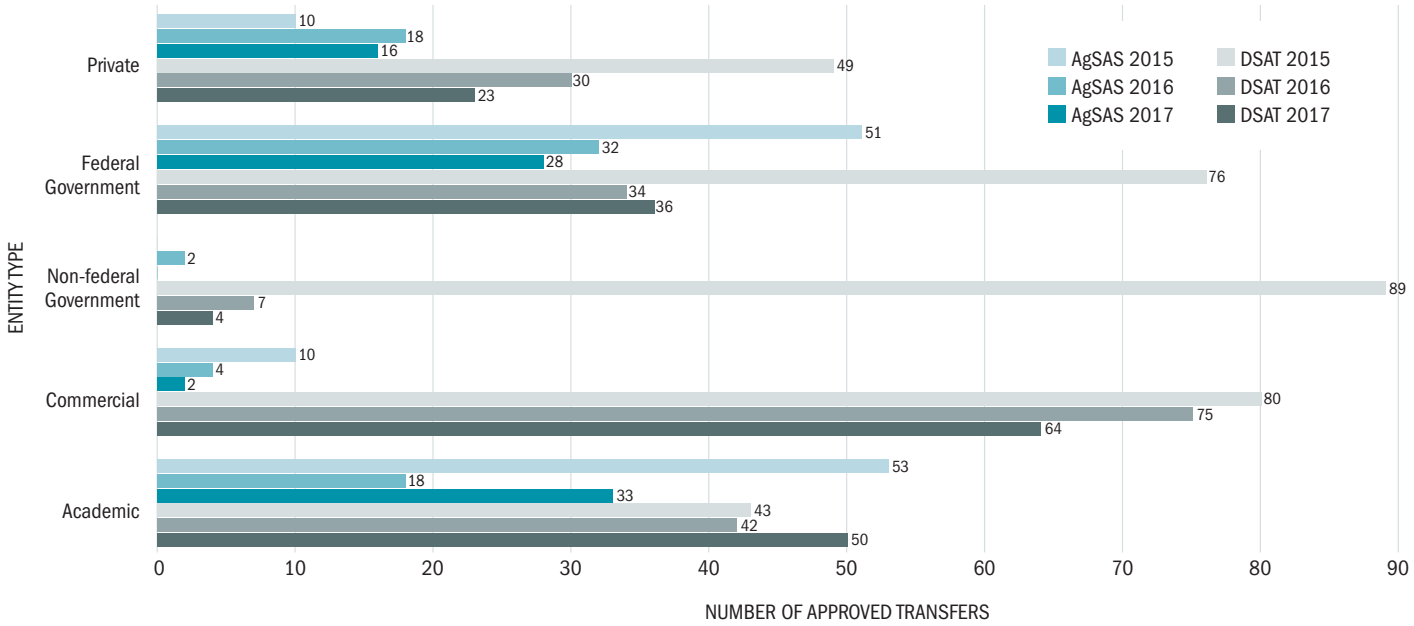
DSAT approved 11 fewer BSAT transfers in 2017 compared to 2016. Botulinum neurotoxin was the most frequently approved BSAT transfer in 2017, followed by *B. pseudomallei* and *F. tularensis* (Figure 6). Of the 177 DSAT-approved transfers in 2017, 15 transfers were for imported BSAT from outside the U.S.

Figure 6: Top Agents Approved for Transfer by DSAT, 2017



In 2017, 64 BSAT transfers were approved by DSAT for commercial entities, which was the most transfers approved for any entity type (Figure 7). For DSAT, both federal government and academic entities slightly increased in number of approved transfers in 2017 as compared to 2016, while private, non-federal government, and commercial entities decreased in 2017. For AgSAS, academic entities had the most approved transfers by entity type at 33. Academic entities were also the only entity type that did not have a decrease in AgSAS-approved transfers as compared to 2016.

Figure 7: Approved Transfers by Receiving Entity Type and Approving Agency



Theft, Loss, and Release of Select Agents and Toxins

The Report of Theft, Loss, or Release of Select Agents and Toxins (APHIS/CDC Form 3), is used by entities 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 BSC) of BSAT.

Examples of the causes of a release can include:

- Bites or scratches from infected animals.
- Equipment or mechanical failure.
- Spills of materials outside of a BSC.
- Failure or problem with PPE.
- Needle stick or other percutaneous exposure with contaminated sharp objects.

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

In 2017, FSAP received 237 APHIS/CDC Form 3 reports of releases and 9 APHIS/CDC Form 3 reports of a loss of BSAT. By comparison, in 2016 FSAP received APHIS/CDC Form 3 reports of 196 releases and 9 losses in 2016, and 233 releases and 12 losses in 2015. There were no reports of a theft of BSAT in 2017.[2] This is the same as in 2016 and 2015.

- All 9 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 public or agricultural health.

2 The program received two additional reports concerning select toxins in amounts lower than the threshold which would have required reporting, thus excluding them from select agent and toxin regulatory requirements. One report involved material believed to be lost during transit, but which was recovered and delivered to the recipient intact; the other report involved a suspected forced entry and theft of excluded amount of toxin. Both incidents were referred to the FBI for investigation. FBI determined there was no criminal nexus for the material believed to be lost during transit. The other incident is still under investigation by the FBI.

- Of the 237 reports of a release:
  - 108 reports were from entities registered with FSAP for the possession, use, or transfer of BSAT.
  - The remaining 129 reports of a release were from clinical or diagnostic laboratories not registered with FSAP because those laboratories were exempted from the select agent and toxin regulatory requirements.
- The 237 reports of a release involved:
  - 199 reports that documented a potential for an occupational exposure to 1,152 individuals (181 individuals from 73 registered entities and 971 from 126 exempt entities). The individuals were provided occupational health services, including medical assessments, diagnostic testing, and prophylaxis as the entity determined was necessary.
  - 38 reports (36 reports from registered entities and 2 reports from exempt entities) that documented a release outside of primary containment took place, but no occupational exposure occurred (e.g., spill outside BSC but laboratory workers were wearing PPE).
- None of the releases resulted in illnesses, deaths, or transmissions among workers or outside of laboratories into the surrounding environment.

Report of the Identification of a Select Agent or Toxin

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. Upon identification of BSAT, the 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.

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.

DSAT received and processed 856 APHIS/CDC Form 4As in 2017 to report the identification of BSAT as a result of diagnosis or verification. In 2017, Botulinum neurotoxin was the most common identified HHS or overlap BSAT, followed by botulinum neurotoxin-producing species of *Clostridium* and *F. tularensis* (Table 8). Botulinum neurotoxin was also the most commonly identified agent in 2016. By comparison, *F. tularensis* was the most commonly identified in 2015. For DSAT, non-registered laboratories accounted for 17% of all reports of the identification of BSAT using the APHIS/CDC Form 4A, which was the same percentage in 2016. In 2015, non-registered laboratories accounted for 14% of the APHIS/CDC Form 4As reported.

DSAT did not receive any APHIS/CDC Form 4Bs reporting BSAT identified through proficiency testing in 2017, compared to 15 in 2016 and 17 in 2015. DSAT did not receive any reports regarding seizures by federal law enforcement (Form 4C) in 2017 or 2016, compared with three reports in 2015.

Table 8. Top BSAT Reported to DSAT on Form 4A by Isolate Type, 2017

Agent/Toxin	Animal Specimens	Environmental Samples	Food Sample	Human Specimens	Total
Botulinum neurotoxins	44	0	2	123	169
Francisella tularensis	53	0	0	90	143
Botulinum producing species of *Clostridium*	23	0	1	96	120
Brucella melitensis	1	0	0	88	89
Eastern Equine Encephalitis virus (Including genomic material)	46	29	0	1	76
Brucella abortus	52	0	0	12	64
Brucella suis	24	0	0	32	56
Coxiella burnetii	41	0	0	3	44
Yersinia pestis	19	2	0	6	27
Burkholderia pseudomallei	4	2	0	20	26
Newcastle Disease Virus	26	0	0	0	26
Total	**333**	**33**	**3**	**471**	**840**

AgSAS received and processed 61 APHIS/CDC Form 4A reports for USDA BSAT in 2017, including 36 reports of Newcastle disease virus, 8 reports of *R. solanacearum,* 16 reports of Avian influenza virus, and 1 report of *B. anthracis*. For AgSAS, non-registered laboratories accounted for 5% of all reports of the identification of BSAT using the APHIS/CDC Form 4A. Also in 2017, AgSAS received one report of African Swine Fever virus identified in a proficiency test (Form 4B). By comparison, AgSAS received one report of Foot and Mouth Disease virus identified in a proficiency test (APHIS/CDC Form 4B) in 2016. AgSAS received no reports from the FBI regarding seizure (APHIS/CDC Form 4C) of USDA BSAT in 2017. AgSAS did not receive any reports in 2015 involving an identified USDA BSAT in proficiency test or seized by FBI.

Emergency Management

FSAP reaches out to assist entities with transferring or securing BSAT that may be affected by adverse weather events that could affect the safety of employees and security of BSAT. There were seven adverse weather events in 2017 during which FSAP contacted a total of 94 affected entities. By comparison, FSAP responded to 14 adverse weather events affecting 86 entities in 2016 and 13 adverse weather events affecting 121 entities in 2015. Table 9 summarizes FSAP's assistance efforts during weather emergencies in 2017. All affected entities were successfully contacted and none required FSAP assistance. There were no thefts, losses, or releases of BSAT as the result of any weather emergencies in 2017.

Table 9. FSAP Emergency Response Events, 2017

2017 Event	Number of Entities Contacted
LA/MS Tornadoes	3
Midwest Flooding IL/WI	2
Kansas City, MO Flooding	1
Pre/Post Hurricane Harvey	28
Pre/Post Hurricane Irma	48
Pre/Post Hurricane Marie	2
Pre/Post Hurricane Nate	10
Total	**94**

Federal Register Notices, Policy Statements, and Guidance

Throughout the year, FSAP publishes regulations, policies, regulatory interpretations, and guidance documents for the benefit of the regulated community. In 2017, FSAP issued a total of 39 such materials, compared with 19 FSAP issuances in 2016 and five in 2015. The increase in FSAP issuances in 2017 is due to a concerted effort by FSAP to engage and partner with the regulated community to identify solutions that improve compliance with the SAR. FSAP policies and guidance documents can be found on the FSAP website. Some examples of FSAP issuances are included in Tables 10a–10d.

Tables 10a–10d. Examples of FSAP Federal Register Notices, Regulatory Interpretations, Policy Statements, and Guidance, 2017

Federal Register Notices	Date
Final Rule for amendments to the HHS and USDA select agent regulations	January
Final Rule for *Bacillus cereus* Biovar *anthracis*	April
Revised APHIS/CDC Form 3 (Report of Theft, Loss, or Release of Select Agents and Toxins) Available for Public Comment	August

Regulatory Interpretations	Date
Synthetically created DNA sequence	February
Signature by "Principal Investigator" on inactivation certificates	April
Surrogate strains which can be used to validate inactivation procedures	April
Requirement for inactivation certificates and intra-entity transfers	June
Gram stained slides containing select agents	June
Waste disposal of select agents and toxins	June

Policy Statements	Date
Specific circumstances in which a registered entity may allow a "restricted person" into an area containing a select agent or toxin	January
Application of the phrases "conclusion of patient care" or "delivery of patient care by health care professionals has concluded" as used in the SAR	April
Application of the requirement for a "validated inactivation procedure" as used in the SAR	April
Approval of a person to be a Responsible Official at only one entity	August
Revised "Inactivated *Bacillus anthracis*" policy to include *B. cereus* Biovar *anthracis*	April, August
Non-exclusion of study-related activities involving naturally infected animals	August

Continued on next page

Guidance	Date
New and/or updated guidance documents related to amended select agent regulations-11 total	March
Access control systems	April
Permits for Asian lineage H7N9 strains	June
Information Requirement for HHS/USDA Office of Inspector General Hotlines	August
Transfers and Security Plan Development	October
Clarification regarding regulatory requirements on inactivation certificates and intra-entity transfers	November

Outreach

FSAP has an active outreach program designed to provide opportunities for the program to interact with members of the regulated community. Tables 11a–11d and the bullets below summarize the 2017 FSAP outreach initiatives and events. These activities included:

- 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 101 ROs to provide information about maintaining regulatory compliance and to build community among those working in this area.
- Conducted a webcast to provide guidance and information about the amended SAR.
- Conducted 17 webinars for ROs and AROs to provide guidance on the electronic Federal Select Agent Program Portal (eFSAP), the program's new secure web-based information system. A total of 540 ROs and AROs attended at least one of the 17 sessions.
- Distributed updates regarding changes to FSAP leadership, policies, regulatory interpretations, and workshop information via SA (Select Agent) Grams, an electronic communication used to disseminate information to the regulated community. In 2017, FSAP issued 68 SA Grams.
- Exhibited an informational booth at four scientific conferences to provide guidance and promote compliance with the SAR.

Tables 11a-11d. FSAP Outreach Events, 2017

Conference	Date
American Society for Microbiology (ASM) Biothreats Conference–105*	February 6–8
USDA ARS 4th International Biosafety and Biocontainment Symposium–73*	February 6-8
2017 ASM Microbe Annual Meeting–116*	June 1–5
American Biological Safety Association (ABSA) International Annual Conference–266*	October 13–18

Workshop	Date
FSAP RO Workshop–101*	November 28–30

Continued on next page

Webcast	Date
FSAP Webcast–1,236*	April 28

Webinars	Date
Secure Asset Management System (SAMS) Training (for eFSAP pilot entities)–42*	April 21 and 24
APHIS/CDC Form 1 Data Entry Training (for eFSAP pilot entities)–40*	May 19 and 22
SAMS Training (for all RO/AROs)–222*	July 11–13 (Two sessions per day)
APHIS/CDC Forms 1 and 3 Data Entry Training (for all RO/AROs)–236*	August 23, 29, 30 September 6, 7, 13, and 14

**Number of visitors to booth or event attendees*

For comparison, FSAP participated in seven conferences in 2016 and eight conferences in 2015, and organized one workshop in 2016. FSAP also increased the number of webinars in 2017 due to training provided for the new eFSAP system.

References

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

Transfer of Select Agents and Toxins, 2003–2013. Division of Select Agents and Toxins, Centers for Disease Control and Prevention. Shelby BD, Cartagena D, McClee V, Gangadharan D, Weyant R. Health Security. August 2015 Vol. 13, No. 4 256-66.

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 Services. 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 Services. October 2017.

Please send requests for additional information to FSAP at LRSAT@cdc.gov or AgSAS@usda.gov.