2015
Annual Report of the Federal Select Agent Program

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Please note: An erratum has been published for this report. To view the erratum, please click here.

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Executive Summary

The Federal Select Agent Program (FSAP) is managed jointly by the Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) and United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Agriculture Select Agent Services (AgSAS). FSAP oversees the possession, use and transfer of biological select agents and toxins (BSAT) so that research can be conducted as safely and securely as possible. This research provides important scientific discoveries that have led to improved detection, prevention, diagnostic, and treatment options for diseases considered to be some of the most threatening to public health.

The United States Government (USG) recently released two sets of recommendations related to the safety and security of work with BSAT, one from the Federal Experts Security Advisory Panel (FESAP) and another from the Fast Track Action Committee on Select Agent Regulations (FTAC-SAR). The implementation of these recommendations is underway and represents progress toward strengthening the government's biosafety and biosecurity practices and the oversight system. The recommendations recognize that work with BSAT has human, animal, and plant health and national security benefits. The recommendations of both groups are complementary and will help further ensure that life science efforts, which benefit the global community in countering biological threats, are carried out safely and securely. The Centers for Disease Control and Prevention (CDC) also released its own recommendations for oversight program improvement through a 90-day Internal Review of the Division of Select Agents and Toxins. All three reviews recommended that FSAP increase transparency and public engagement, as well as improve communication between it and the regulated community. To further public understanding of FSAP, this report marks the program's first annual effort towards communicating operational metrics to the American public. Over time, the program expects to gain more experience with reporting these data, improve the reporting process, and be able to share more details on other aspects of the program. FSAP will publish a similar report on an annual basis going forward.

The following report summarizes calendar year 2015 data for FSAP. The three reviews discussed above were published in October 2015, and not all recommended improvements are reflected in this summary.

Registered Entities

As of December 31, FSAP regulated 291 entities, with 40 entities registered with AgSAS as the lead agency and 251 entities registered with DSAT as the lead agency. When an entity is registered for both HHS-only and USDA-only agents, their registration is managed jointly under a lead agency. Fifty-one entities were jointly overseen by AgSAS and DSAT with AgSAS serving as the lead agency for 15 entities and DSAT serving as the lead agency for 36 entities. Registration with FSAP requires an entity to renew their registration every three years.

Regulated entities include:

- 32% academic.
- 18% commercial.
- 15% federal government.
- 29% non-federal government.
- 6% private.

Please note: An erratum has been published for the data contained in this section of the report. To view the erratum, please click here.

In 2015, FSAP renewed the registration of 106 entities (12 AgSAS and 94 DSAT). Two entities applied to AgSAS for new registrations (both registrations were approved), and 27 entities withdrew from the program.

Security Risk Assessments

A security risk assessment (SRA) is an electronic records check performed by the Federal Bureau of Investigation (FBI) to determine whether a person requesting to have access to select agents and toxins is a "restricted person" or otherwise may be prohibited from having such access. The FBI conducted 4,442 SRAs in 2015, with 4,426 individuals being approved and 16 individuals identified as meeting the definition of a "restricted person."[1]

Inspections

FSAP conducted 216 inspections in 2015. FSAP conducts inspections of registered entities for many reasons: registration renewals, lack of compliance with the select agent regulations, verification of corrective actions, addition of new space, investigation of incidents, and new registration applications. Of the 216 inspections, 33 were conducted by AgSAS, 145 were conducted by DSAT, and 38 inspections were conducted jointly by AgSAS and DSAT. Inspection length ranged from one to eight days on site with an average length of three days.

Inspection Findings and Compliance

FSAP works closely with all regulated entities to assist them with complying with the select agent regulations (SAR)[2]. Inspection findings range from minor documentation errors in plans to serious biosafety or security issues, such as failure to use personal protective equipment (PPE) appropriately or working with a select agent outside of approved registered laboratory spaces.

When an inspector finds a significant biosafety and/or security concern during an entity inspection, FSAP works with the entity to bring them into compliance with SAR. In some cases, an entity is offered the opportunity to participate in the FSAP Corrective Action Plan (CAP) program, in which the entity develops and implements a plan of corrective actions closely monitored by FSAP. If an entity chooses not to go on a CAP, they are expected to successfully resolve the corrective action requirements within 30 days. If necessary, FSAP can suspend an entity's registration when a departure from SAR is found to represent an imminent danger to human, animal, or plant health, or public safety. An entity may also be referred to the Department of Health and Human Services (HHS) Office of Inspector General (OIG) or APHIS Investigative and Enforcement Services (IES) for further investigation and possible civil penalties. FSAP may also refer a matter to the FBI for investigation.

In 2015:

- Six entities agreed to participate in the CAP program.
- Three entities had their registration suspended.

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[1] The definition of a "restricted person" may be found in 18 U.S.C. § 175b(d).
[2] The select agent regulations can be found at 7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73.

- Four entities were referred to either the HHS OIG or USDA IES including two of the entities that had their registration suspended (the third suspended entity was referred in 2016) and two entities associated with the multiple and repeated discovery of BSAT materials in unregistered locations.
- 16 entities were referred to the FBI.

HHS OIG and USDA OIG Hotlines

FSAP has established a confidential means for reporting safety and security issues associated with the possession, use, and transfer of BSAT. The HHS OIG and the USDA OIG maintain a hotline that allows individuals or entities to anonymously report safety or security issues related to BSAT or safety issues associated with infectious biological agents, infectious substances, and vectors. Each report is investigated to determine if a violation of the regulations has occurred. In 2015, three reports to FSAP were received through the hotline.

Restricted Experiments

An individual or entity may not conduct or possess products resulting from restricted experiments involving BSAT unless approved by and conducted in accordance with the conditions prescribed by FSAP. 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.
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.

In 2015, DSAT approved three of the four requests it received to conduct a restricted experiment for nucleic acids encoding for botulinum neurotoxin. DSAT did not receive any requests involving drug resistance traits that met the definition of the first restricted experiment listed above in 2015. AgSAS did not receive any requests to conduct restricted experiments.

Exclusions

An entity or individual may request to exclude from SAR an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. In 2015, there were eight requests for permission to exclude attenuated select agent strains or less potent/toxic forms of select toxins. All eight requests were approved. A detailed list of all excluded select agent strains can be found at Select Agents and Toxins Exclusions.

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 and unregistered clinical, diagnostic, or public health laboratories to notify FSAP of BSAT identified as the result of diagnosis, verification, and proficiency testing, and of the final disposition of identified BSAT. Unregistered laboratories do not deliberately work with BSAT but may occasionally encounter BSAT in the course of their diagnostic activity. When this occurs, the laboratory is required to submit a Form 4 and either register with FSAP in order to keep the sample, transfer the sample to an entity registered to possess that BSAT, or destroy the sample.

The top 10 most identified BSAT as reported to DSAT in 2015 were: *Francisella tularensis* (219 identified), Botulinum neurotoxin (202)[3], Botulinum producing species of Clostridium (144), *Brucella melitensis* (89), *Yersinia pestis* (75), Eastern equine encephalitis virus (71), *Coxiella burnetii* (30), *Brucella abortus* (29), *Brucella suis* (25), and *Burkholderia pseudomallei* (22).

Identified BSAT reported to AgSAS in 2015 were: Highly pathogenic avian influenza virus (304), Newcastle disease virus (26), African swine fever virus (2), and *Ralstonia solanacearum* (13).

Transfers of Select Agents or Toxins

The APHIS/CDC Form 2 Request to Transfer Select Agents and Toxins is used by entities to request prior authorization to transfer BSAT. BSAT may be transferred from one entity to another for many reasons, including diagnostic testing, scientific or clinical research, and production of therapeutics. In 2015, DSAT approved 337 BSAT transfers. AgSAS approved 126 BSAT transfers. There were two transfer violations in 2015 involving entities not registered with FSAP. These entities identified BSAT in an unknown diagnostic sample but did not properly initiate the BSAT transfer process. In both cases, the samples were received unexpectedly by a registered federal government entity which immediately notified FSAP. It was determined that there was not any evidence of theft, loss, or release of BSAT.

Theft, Loss, and Release of Select Agents and Toxins

An entity registered with FSAP is required by SAR (7 CFR § 331.19, 9 CFR § 121.19, and 42 CFR § 73.19) to notify either AgSAS or DSAT immediately upon discovery of a 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) of BSAT.

In 2015, there were 12 potential losses and 233 potential releases reported to FSAP.

- 12 reports of potential losses of BSAT were investigated by the FBI, and all were determined to be records management errors or were samples mistakenly autoclaved as waste.
    - Of the 233 potential releases, 199 reports were determined to represent potential occupational exposure to laboratory workers.
        - Of these 199, two were reports of seroconversions involving three laboratory staff with no known incident, and were identified by routine annual screening of laboratory staff.
    - Two reports were determined to represent potential releases of *Xanthomonas oryzae*. Because this BSAT infects plants and is not a danger to humans, these events were not classified as potential occupational exposures but as releases outside primary containment (like a biosafety cabinet (BSC)).
    - 32 reports did not meet the regulatory criteria for a release.

None of the potential releases resulted in illnesses, deaths, or transmissions outside of laboratories into the surrounding environment. No thefts of BSAT were reported.

[3] Infant Botulism cases represent ~80% of botulism cases every year. http://www.cdc.gov/nationalsurveillance/botulism-surveillance.html

Emergency Response

FSAP reaches out to assist entities with transferring or securing BSAT that may be impacted by adverse weather events that could affect the safety and security of BSAT. FSAP assistance includes arranging transfers and/or destruction of BSAT. There were 13 adverse weather events tracked by FSAP in 2015. FSAP successfully contacted a total of 121 affected entities that did not require assistance. There were no reported releases of BSAT associated with these weather events.

Federal Register Notices, Policy Statements, and Guidance

There were five issuances of information in 2015:

- Policy statement regarding when APHIS and CDC Import Permits are not required for the importation or interstate transportation of BSAT (February).
- Updated guidance on the criteria reviewed and considered by FSAP in determining if certain experiments meet the definition of a restricted experiment (March).
- Federal Register/Advance Notice of Proposed Rulemaking regarding the biennial review and republication of the list of select agents and toxins (March)
- Notice of Proposed Rulemaking seeking comment for a proposal to add certain influenza viruses to the list of HHS BSAT (July).
- Policy statement regarding inactivated *B. anthracis* and new requirements necessary to protect human and animal health (November).

Outreach

FSAP has an active outreach program designed to provide opportunities for interaction of the program with members of the regulated community. Outreach initiatives in 2015 included conducting a national webcast and exhibiting an informational booth at scientific conferences to provide guidance and promote compliance with SAR.

Acronyms

Acronym	Meaning
AgSAS	Agriculture Select Agent Services
Ag-ISATTAC	Agricultural-Intragovernmental Select Agents and Toxins Technical Advisory Committee
ASIS	American Society for Industrial Security
APHIS	Animal and Plant Health Inspection Service
APHL	Association of Public Health Laboratories
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
DSAT	Division of Select Agents and Toxins
FAQ	Frequently Asked Questions
FBI	Federal Bureau of Investigation
FESAP	Federal Experts Security Advisory Panel
FSAP	Federal Select Agent Program
FTAC-SAR	Fast Track Action Committee on Select Agent Regulations
HHS	Department of Health and Human Services
IES	Investigative and Enforcement Services
ISATTAC	Intragovernmental Select Agents and Toxins Technical Advisory Committee
HHS OIG	HHS Office of Inspector General
RO	Responsible Official
PPE	Personal Protective Equipment

Acronym	Meaning
PPQ	Plant Protection and Quarantine
SAR	Select Agents and Toxins Regulations
SRA	Security Risk Assessment
TLR	Theft, Loss or Release
USDA	United States Department of Agriculture
USG	United States Government
VS	Veterinary Services

Introduction

The Federal Select Agent Program (FSAP) is jointly managed by the Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC)/Division of Select Agents and Toxins (DSAT) and the Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS)/Agriculture Select Agent Services (AgSAS). 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 HHS and USDA Select Agents and Toxins 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 the select agents and toxins regulations (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 efforts are conducted safely and securely.
- Ensuring that all individuals who have access to BSAT undergo a security risk assessment performed by the Federal Bureau of Investigation (FBI)/Criminal Justice Information Services Division.
- Developing guidance documents and conducting informational workshops and webinars to help regulated entities maintain SAR compliance.
- Investigating incidents in which human, animal, or plant health is put at risk and in which non-compliance with SAR may have occurred.

The United States Government (USG) recently released two sets of recommendations, one from the Federal Experts Security Advisory Panel (FESAP) and another from the Fast Track Action Committee on Select Agent Regulations (FTAC-SAR). The implementation of these recommendations is underway and represents progress toward strengthening the government's biosafety and biosecurity practices and the oversight system. The recommendations recognize that work with BSAT has human, animal, and plant health and national security benefits. The recommendations of both groups are complementary and will help to further ensure that life science efforts, which benefit the global community in countering biological threats, are carried out safely and securely. CDC also released its own recommendations for oversight program improvement through a 90-day Internal Review of the Division of Select Agents and Toxins.

All three reviews recommended that FSAP increase transparency and public engagement, as well as improve communication between FSAP and the regulated community. This report marks the program's first annual effort towards communicating operational metrics to the American public to further public understanding of FSAP. Over time, the program expects to gain more

HHS Only Select Agents and Toxins

Abrin
Botulinum neurotoxins*
Botulinum neurotoxin producing species of *Clostridium**
Conotoxins
Coxiella burnetii
Crimean-Congo hemorrhagic fever
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
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 Only 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

Plant Protection and Quarantine Select Agents and Toxins

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

* Tier 1 agents

experience with reporting these data, improve the reporting process, and be able to share more details on other aspects of the program. FSAP will publish a similar report on an annual basis going forward.

The following report summarizes calendar year 2015 data for FSAP.

Key Program Statistics

Registered Entities

BSAT are divided into four categories based on whether the agent causes disease in humans, animals, or plants. 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 and are regulated by HHS.
- USDA Select Agents and Toxins: BSAT that have the potential to pose a severe threat to animal health or to animal products and are regulated by USDA.
- USDA Select Agents and Toxins: BSAT that have the potential to pose a severe threat to plant health or to plant products and are regulated by USDA.
- Overlap Select Agents and Toxins: 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 by both USDA and HHS.

Entities that wish to possess, use, or transfer BSAT must register with either DSAT or AgSAS by completing the APHIS/CDC Form 1 (Form 1). An entity that plans to register for HHS-only BSAT must submit their Form 1 to DSAT. If it registers for USDA-only BSAT, it must register with AgSAS. If it plans to register for overlap BSAT, it may choose with which agency to register. DSAT and AgSAS work together to assist each other if one of their regulated entities has BSAT under the other's authority.

Form 1 provides:

- 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.
- Information about the work to be performed.

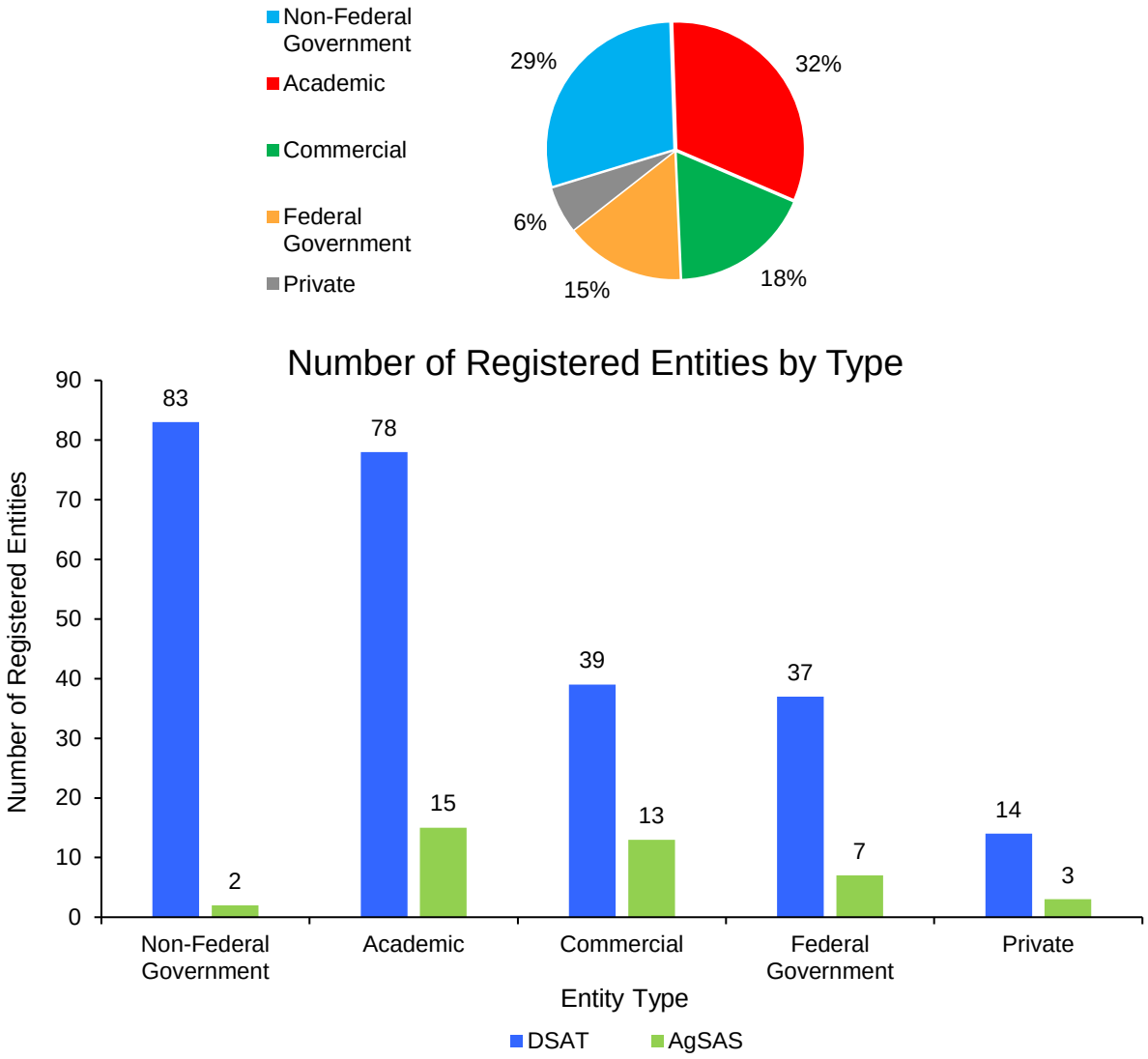
Once the initial Form 1 is received, it is reviewed and a file manager is assigned to the entity. A site inspection is then scheduled to verify information submitted on the Form 1 and to review the site-specific biosafety and security measures in place. Once the inspection is completed and any issues have been addressed, the entity receives a certificate of registration, can acquire BSAT, and begin work.

FSAP regulates a diverse community of entities ranging from government facilities at the federal, state, and local levels, to academic institutions and commercial and other private entities. The work of these entities with BSAT includes: 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.

The five entity types are:

- 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 public (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.

Figure 1: The number of entity types by regulatory agency. Percent breakdown in pie chart.



At the end of 2015, 291 entities were registered with FSAP, including 251 with DSAT and 40 with AgSAS. Figure 1 gives the total number of each entity type, grouped by lead agency (i.e., DSAT or AgSAS). When an entity is registered for both HHS-only and USDA-only agents, their registration is managed jointly under a lead agency. Fifty-one entities were jointly overseen by AgSAS and DSAT with AgSAS serving as the lead agency for 15 entities and DSAT serving as the lead agency for 36 entities (data not shown). The lead agency 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.

New Registrations

Please note: An erratum has been published for the data contained in this section of the report. To view the erratum, please click here.

A facility must register with FSAP if it would like to possess, use, or transfer BSAT. In 2015, AgSAS approved two new applications from entities requesting to register for permission to possess, use, or transfer BSAT. DSAT received none.

Renewals

Please note: An erratum has been published for the data contained in this section of the report. To view the erratum, please click here.

Registration with FSAP requires an entity to renew their registration every three years. This is accomplished by submitting an updated Form 1 and completing the renewal inspection process. In 2015, all registration renewals were approved: AgSAS approved 12 and DSAT approved 94, for a total of 106 renewals processed.

Entity Withdrawals

When an entity decides that it no longer needs to possess, use, or transfer BSAT, it can request to withdraw its registration. As part of this process, the entity must destroy its BSAT or transfer its BSAT inventory to another registered entity. An inspection of the entity may be needed. If the entity's needs change, and it wishes to begin BSAT work again, it must reapply. In 2015, 27 entities withdrew their registration with FSAP. The one entity that withdrew from AgSAS was a non-federal government entity. The 26 entities that withdrew from DSAT included four academic, four commercial, three federal government, fourteen non-federal government, and one private entity. Table 1 provides information on the entities that withdrew.

Entity Withdrawals from FSAP 2015

Agency	Entity Type	Number of Withdrawals	Reason
AgSAS	Non-federal Government	1	No longer need to store the agent
DSAT	Academic	4	2 did not provide a reason 1 possessed only an excluded amount of toxin –registration not required. 1 has had a change in research direction
	Commercial	4	1 validated non-select agents to serve as positive controls in place of select agents 1 the facility shut down 1 decommissioned the laboratory and the work was transferred to different facility 1 possessed only an excluded amount of toxin-registration not required. and wanted to reduce the administrative burden
	Federal Government	3	1 did not provide a reason 1 has not possessed agent in the last 6 years 1 changed research focus to non-select agents
	Non-federal Government	14	5 did not provide a reason 7 no longer need to register due to only performing diagnostic work 2 chose not to renew for undisclosed reasons
	Private	1	No longer possesses the agent

Table 1: The entities that withdrew from FSAP in 2015 and their reason for withdrawal.

Tier 1 BSAT

Please note: An erratum has been published for the data contained in this section of the report. To view the erratum, please click here.

81% of all FSAP-regulated entities have Tier 1 BSAT.

Tier 1 BSAT are those biological agents and toxins 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. Thirteen entities possess Tier 1 BSAT and are registered with AgSAS as their lead agency, representing 32.5% of all AgSAS-led entities. Two hundred twenty-three entities possess Tier 1 BSAT and are registered with DSAT as their lead agency, representing 88.8% of all DSAT-led entities.

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Top 10 Agents Registered by Entities

Registered with DSAT

1. *Francisella tularensis**
2. *Yersinia pestis**
3. *Bacillus anthracis**
4. *Burkholderia pseudomallei**
5. *Brucella abortus*
6. *Brucella melitensis*
7. *Burkholderia mallei**
8. *Brucella suis*
9. Botulinum producing species of *Clostridium**
10. *Coxiella burnetii*

**Indicates a tier 1 select agent*

Registered with AgSAS

1. Avian influenza virus
2. Newcastle disease virus
3. *Brucella abortus*
4. *Bacillus anthracis**
5. *Ralstonia solanacearum*
6. *Xanthomonas oryzae*
7. *Brucella melitensis*
8. *Brucella suis*
9. *Burkholderia pseudomallei**
10. *Burkholderia mallei**

Laboratory Types

Biosafety level 3 laboratories are the most common type of laboratory space approved to work with BSAT regulated by FSAP.

Each regulated entity has one or more laboratories or secure storage location(s) where BSAT work is conducted or stored. Laboratories that work with BSAT range from biosafety level 2 (BSL2) to maximum containment at biosafety level 4 (BSL4). At each containment level, there is an equivalent set of biosafety guidelines for work with animals designated as animal biosafety level 2 (ABSL2) through maximum containment at animal biosafety level 4 (ABSL4). There is also a BSL3Ag 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. The most important example of primary containment is a biosafety cabinet (BSC). Federal government, academic, and private entities have registered laboratories at all biosafety levels. Non-federal government or commercial entities have all biosafety levels except BSL4 and ABSL4.

Security Risk Assessments

One of the fundamental elements of the SAR is to keep select agents and toxins out of the possession of individuals who might intend to misuse them, such as a bioterrorist. FSAP works closely with the FBI's

Criminal Justice Information Services Division (CJIS) to identify those individuals who are prohibited from access to the biological agents and toxins regulated by FSAP based on the restrictions identified in the USA PATRIOT Act (Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001; Public Law 107-56). A security risk assessment (SRA) is the electronic records check performed by the FBI, CJIS to determine whether an entity (including the owner and/or controller of an entity) or an individual who wishes to register to possess, use, or transfer BSAT, or an individual who has been identified by a registered entity as having a legitimate need to access BSAT, is a "restricted person" or meets one of the statutory restrictors which would either prohibit registration/access or restrict access, respectively. The results of an SRA assists FSAP in determining that an individual or entity may possess, use, or transfer BSAT, or that an individual may be granted access to BSAT. An SRA is valid for a period not to exceed three years and can be renewed. Table 2 provides the total number of SRAs for individuals that the FBI processed in 2015, including the total number of individuals approved for access and not approved for access by entity type. In 2015, the majority of SRAs were performed on individuals from academia.

Security Risk Assessment by Entity Type for 2015

Entity Type	Individuals Newly Approved in 2015	Individuals NOT approved in 2015
Federal Government	1,248	6
Non-federal Government	533	2
Commercial	571	5
Private	374	1
Academic	1,700	2
Total	4426	16

Table 2: The total security risk assessments conducted in 2015 by entity type and approval status. An individual may have more than one prohibitor.

A "restricted person" may not be granted access to BSAT. A "restricted person" is 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 U.S.C. 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 U.S.C. App. 2405(j)), section 620A of chapter 1 of part M of the Foreign Assistance Act of 1961 (22 U.S.C. 2371), or section 40(d) of chapter 3 of the Arms Export Control Act (22

Restricted Persons by Prohibitor for 2015

Prohibitor	Total
Adjudicated mental defective	1
Conviction exceeds 1 year	14
Felony	6
Misdemeanor	8
Fugitive from justice	2
Under indictment	1
Felony	1
Misdemeanor	0
Unlawful user of any controlled substance	1
Total	19

Table 3: Number of restricted persons by prohibitor type for 2015. An individual may have more than one prohibitor. 16 individuals are represented above.

U.S.C. 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 U.S.C. 1182(a)(3)(B)(vi)).

In addition, the FBI will notify FSAP when they identify an individual who is reasonably suspected by any Federal law enforcement or intelligence agency of the following:
- Committing a crime set forth in section 2332b (g) (5) of title 18, United States Code.
- Knowing involvement with an organization that engages in domestic or international terrorism (as defined in section 2331 of such title 18) or with any other organization that engages in intentional crimes of violence.
- Being an agent of a foreign power (as defined in section 1801 of title 50, United States Code).

From inception of FSAP through December 31, 2015, the FBI has conducted 58,734 SRAs and identified 345 Restricted Persons.

FSAP must deny access approval to any "restricted person." Table 3 provides data on the number of restricted persons by prohibitor type and shows that "conviction that exceeds 1 year" was the most common prohibitor type for 2015. An individual may have more than one prohibitor, which is why the total number of restricted persons by prohibitors in Table 2 differs from the number of restricted persons in Table 3.

Inspections

Entities regulated by FSAP are subject to announced and unannounced inspections. The type of inspection scheduled depends on the event that triggers it, but all inspections focus on the biosafety and security of the work with BSAT. The following are the types of inspections conducted by FSAP and their definitions:

- 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 ABSL4 and BSL4 laboratories.
- New Entity – Review of all laboratory spaces and documents for entity that is submitting a new application.
- New Space – Review of 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 which are typically conducted every three years.
- Verification – Review of selected portions of the entity program, including assessment of responses to previous inspection departures which are conducted within 12 to 18 months of a renewal inspection.

Inspections can be led by DSAT or AgSAS depending on the agents the entity is registered to possess, use, or transfer. DSAT inspects entities registered for HHS-only agents. Entities registered for both HHS

and USDA agents are normally inspected jointly by DSAT and AgSAS. When joint inspection is not possible, each agency has agreed to recognize the other's findings. AgSAS inspects entities with USDA-only agents. In 2015, AgSAS conducted 33 inspections. DSAT conducted 145 inspections. AgSAS and DSAT jointly conducted 38 inspections. In total, FSAP conducted 216 inspections in 2015.

Length of Inspections

Inspection length ranged from one to eight days onsite with an average length of three days. Figure 2 shows the average length of an FSAP inspection by inspection type. Maximum containment inspections were the longest inspections, likely due to the complexity of facilities that achieve the highest containment.

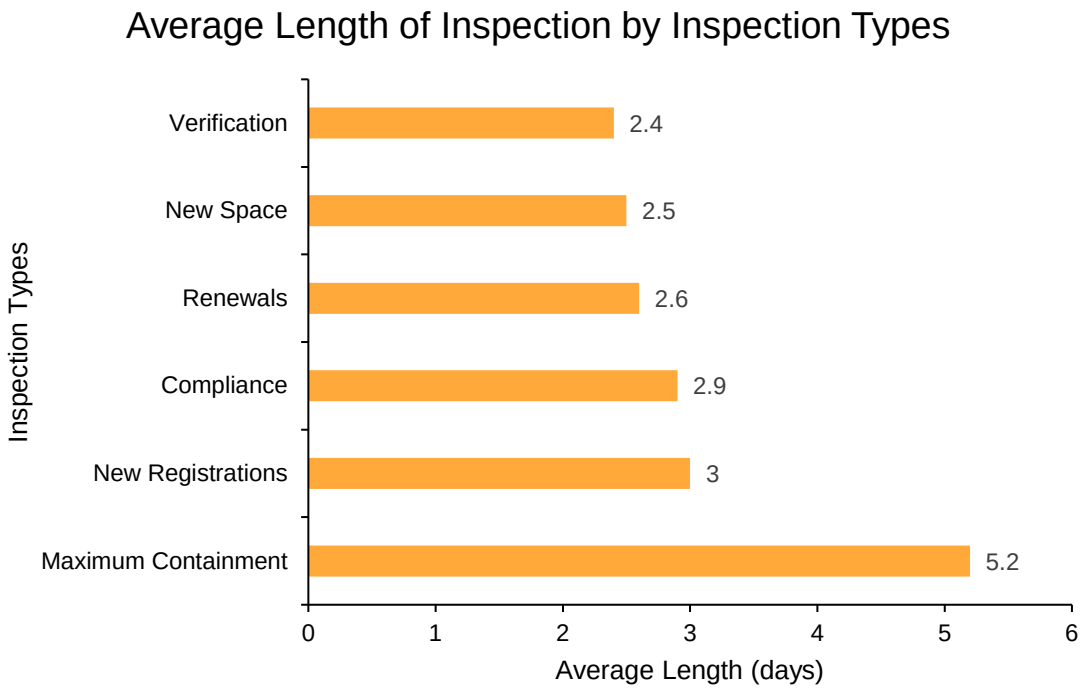

Figure 2: Average length of inspection by inspection type.

Inspection Findings and Compliance

The goal of 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 made by inspectors during inspections:

- Omission or clarification needed in biosafety, incident response, or security plans.
- Inaccurate records for inventory, training, or access to BSAT.
- Biosafety practices not adequate to contain BSAT.
- Failure of Responsible Official (RO) to ensure adequate oversight of BSAT activities.
- Failure to properly implement all regulatory requirements for possession of Tier 1 agents.
- Failure to wear or use appropriate PPE in BSAT laboratories.
- Failure to properly secure BSAT materials from unapproved access.
- Work with BSAT materials outside of registered laboratories.

- Work with BSAT outside of BSC.

When there are significant findings during an entity inspection, FSAP can suspend BSAT work, or suspend or revoke an entity's registration. Additionally, FSAP can offer an entity the opportunity to participate in an FSAP Corrective Action Plan (CAP) program to address serious and recurrent findings that do not present an imminent risk to public health and safety. The CAP program was formerly known as the Performance Improvement Plan (PIP) program.

Corrective Action Plan

In March 2008, FSAP established the CAP program to assist entities identified as having systemic biosafety and security deficiencies in achieving compliance with SAR. To participate, an entity submits a detailed plan, including target completion dates and the specifics of how the entity will correct identified regulatory deficiencies. An entity's participation in the CAP program allows FSAP to both provide technical assistance as well as monitor an entity's progress in correcting security or biosafety shortcomings. Although often seen as an alternative to the initiation of suspension or revocation proceedings, participation in the CAP program is voluntary. If an entity chooses not to go on a CAP, it is expected to successfully resolve the corrective action requirements of the normal inspection report process within 30 days. In 2015, AgSAS did not have any entities participate in a CAP. Six entities participated in the CAP program with DSAT: one private, two commercial, two federal government, and one non-federal government. No further action was taken since entities on a CAP in 2015 were successful at meeting milestones established during the onset of the CAP. Each entity offered a CAP was found to have one or more of the following types of systemic biosafety and security deficiencies:

- Worked with BSAT in laboratories not listed on the entity's registration.
- Failed to follow safe work practices and work in a safe environment with BSAT that could have resulted in an occupational exposure to the BSAT.
- Responsible Official (RO) failed to ensure compliance of the SAR for work with BSAT.
- Inaccurate inventory records.
- Failed to secure BSAT properly which made the inventory vulnerable to theft.

In 2015, six entities were placed on CAPs, representing 2% of all entities.

Registration Suspensions

Entities receive suspensions when FSAP has significant concerns for imminent danger to the health and safety of humans, animals, or plants because of the entity's failure to comply with SAR. Their registrations remain suspended until such time as the compliance issues are properly addressed. In 2015, three entities were suspended (two academic and one federal government) for the following reasons:

- Failure to properly inactivate BSAT, and subsequently shipping live agent to numerous unsuspecting locations throughout the United States and the world. Referred to HHS OIG for further investigation.
- Failure to properly contain BSAT resulting in the unintentional infection of laboratory animals. Referred to APHIS IES for further investigation.
- Failure to maintain compliance with SAR by implementing requirements to secure BSAT, inventory accountability, and failing to train staff that led to an imminent threat to worker safety. Referred to HHS OIG for further investigation.

No suspensions were appealed in 2015.

HHS OIG and USDA OIG Hotlines

HHS OIG and USDA OIG maintain a confidential hotline and email reporting system that allows anyone to report safety, security, or other concerns associated with BSAT. In addition, AgSAS and DSAT each maintain a general email account that receives concerns about BSAT issues. FSAP received three reports for potential investigation in 2015:

- A report from an academic entity about a potential restricted experiment. After investigation, the agent was determined to not be BSAT. The issue was referred to National Institutes of Health (NIH) under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.
- A report from an academic entity in regard to problems with the intrusion detection system (IDS) and whether the entity would be able to respond appropriately to an alarm. DSAT conducted an inspection and found that the IDS system was functioning properly.
- A complaint from a private entity in regards to laboratory conditions. After inspection, this was determined not to be a BSAT issue.

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 regulations. FSAP referrals to the HHS OIG or the APHIS IES reflect a serious departure from SAR.

- In 2015, there were a total of four entities referred to HHS OIG or APHIS IES.
    - Two referrals were associated with two of the three entities suspended in 2015 (one was referred in 2016).
    - Two referrals were associated with the multiple and repeated discovery of BSAT materials in unregistered locations.

The 2015 referrals are still under investigation by HHS OIG or APHIS IES.

Referrals to FBI

Based on its Memorandum of Understanding with the FBI, FSAP refers any security-related issue identified by a registered entity and any report of a loss of a select agent or toxin. The FSAP also provides requested information in support of a specific FBI investigation. In 2015, FSAP referred a total of 16 entities to the FBI for investigation.

- 12 entities were referred to the FBI for potential losses of BSAT. After investigation, all were determined to be records management errors or were samples mistakenly autoclaved as waste.
- Three entities were referred to FBI for findings during inspections: two referrals were for inventory discrepancies, and one was for a "restricted person" who accessed a registered area. In all three incidents, the FBI determined that there was no criminal intent.
- One referral was as a result of information received by email from an anonymous individual alleging that an entity was providing falsified documents to the USG in regards to an entity's personnel suitability program. The FBI conducted interviews and determined there was no criminal intent.

Restricted Experiments

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

- The first type involves 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.
- The second type involves 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.

These experiments are considered restricted experiments due to their potential threat to public health. DSAT must review them before they can be conducted.

FSAP has published a Restricted Experiment Guidance Document detailing instructions on how to apply for approval or appeal a decision made by FSAP.

The Intragovernmental Select Agents and Toxins Technical Advisory Committee (ISATTAC) and Ag-ISATTAC are tasked with reviewing the biosafety measures associated with proposed restricted experiments. They also provide recommendations to the DSAT Director (for HHS and Overlap BSAT) and the AgSAS Director (for Overlap and USDA-only BSAT) on whether an experiment should be approved. Restricted experiments involving the deliberate introduction of a drug-resistant trait are reviewed to determine if the trait involves a drug used therapeutically for treatment. If the drug resistance trait could compromise the control of disease, other considerations are taken into account, (e.g., are there other drugs available to treat the select agent infection, whether the drug is used for treatment within or outside of the U.S.). Experiments with specific select agent strains that have naturally acquired resistance to drugs used to treat the disease are not considered restricted experiments.

Both restricted experiment types are assessed to ensure that they can be conducted safely under biosafety conditions that meet the biosafety guidelines prescribed in the CDC/National Institutes of Health publication Biosafety in Microbiological and Biomedical Laboratories 5th edition.

Request for Approval of Restricted Experiments for 2015

Entity Type	Select Agent	Decision Status
Academic	Botulinum Neurotoxin Nucleic Acids	Approved
	Botulinum Neurotoxin Nucleic Acids	Approved
	Botulinum Neurotoxin Nucleic Acids	Denied
Commercial	Botulinum Neurotoxin Nucleic Acids	Approved

Table 4: Summary of restricted experiments by entity type, agent, and decision status.

Restricted experiment approval decisions are the result of careful consideration of the unique situation at the entity, the work proposed by the principal investigator, biosafety factors, and the fact that BSAT cannot be transferred to another entity or principal investigator planning similar work without prior permission.

Table 4 lists the restricted experiment requests submitted in 2015 by entity type, agent, and decision status. In 2015, DSAT received four restricted experiment requests for nucleic acids encoding for Botulinum neurotoxin, of which three were approved. One was denied because the entity requested blanket approval for such experiments. FSAP is unable to give blanket approval without specific details of each experiment in order to ensure safety and security. In addition, the FSAP received 19 requests that were deemed not to meet the definition of a restricted experiment.

Restricted experiments require written approval by FSAP before any work can begin.

Exclusions

SAR provides criteria for the exclusion of BSAT (See 42 CFR §§ 73.3 and 73.4, 9 CFR §§ 121.3 and 121.4, 7 CFR § 331.3). This guidance can be found in the Exclusion Guidance Document published on the FSAP website. An entity or individual may request to exclude from SAR an attenuated (weakened) strain of a select agent or a select toxin modified to be less potent or toxic. Similar to restricted experiments, ISATTAC or Ag-ISATTAC reviews requests for exclusion and provides a recommendation to FSAP. As required by SAR, FSAP renders a written decision to the requestor and posts the exclusion on FSAP website so that others can benefit from this knowledge in case they also wish to work with the attenuated strain.
In 2015, there were eight requests for permission to exclude attenuated select agent strains or less potent/toxic forms of select toxins all of which were approved, which are detailed in Table 5 below.

Exclusion Requests Received in 2015

Entity Type	Select Agent	Decision Status
Academic	*Brucella melitensis* strain ΔnorD Δznu *Brucella melitensis*-lacZ	Approved
	Burkholderia mallei strain CHL001 (ΔtonB Δhcp1)	
Commercial	Anhydrotetrodotoxin	
	Recombinant Newcastle disease virus*	
Federal Government	Recombinant Avian influenza virus*	
	Recombinant Avian influenza virus*	
	Recombinant Avian influenza virus*	
Private	Recombinant Avian influenza virus*	

Table 5: Summary of requests for exclusions by entity type, select agent, and approval status. *Specific candidate vaccine strains have not been listed for proprietary reasons.

The attenuated strains and modified toxin listed in Table 5 were excluded based on results demonstrating they no longer pose a threat to public health and safety, animal health or animal products, and plant health or plant products. Recombinant candidate vaccine strains of Newcastle disease virus and avian influenza virus have been excluded based on results from *in vitro* and *in vivo* studies indicating that these strains do not pose a severe threat to animal health or animal products.

An entity or individual may request to exclude from SAR an attenuated strain of a select agent or toxin modified to be less potent.

Report of the Identification of a Select Agent or Toxin

Unregistered clinical, diagnostic, or public health laboratories may identify BSAT within a specimen or environmental sample. These laboratories do not deliberately work with BSAT but may occasionally encounter BSAT in the course of their diagnostic activity. When this occurs, the laboratory is required to either register with FSAP in order to keep the sample, transfer the sample to an entity registered to possess that BSAT, or destroy the sample.

APHIS/CDC Form 4 - Report of the Identification of a Select Agent or Toxin (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. FSAP has published a Guidance Document for the Completion of APHIS/CDC Form 4 on the website. 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

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

Top 10 BSAT Identified from Unknown Samples Reported to DSAT in 2015

Agent/Toxin	Animal Specimens	Environmental	Food Sample	Human Specimens	Total
Francisella tularensis	89	0	0	130	219
Botulinum neurotoxins	44	0	10	148*	202
Botulinum producing species of *Clostridium*	18	2	15	109	144
Brucella melitensis	0	0	1	88	89
Yersinia pestis	44	0	0	31	75
Eastern Equine Encephalitis virus	51	16	0	4	71
Coxiella burnetii	24	0	0	6	30
Brucella abortus	21	0	0	8	29
Brucella Suis	8	0	1	16	25
Burkholderia pseudomallei	3	0	0	19	22
Total	302	18	27	559	906

Table 6: Top 10 select agents and toxins identified on Form 4A data by isolate type. * Infant Botulism cases represent ~80% of botulism cases every year. For more information, please visit http://www.cdc.gov/nationalsurveillance/botulism-surveillance.html.

Table 6 summarizes data on the 10 agents most frequently identified in 2015 and submitted to DSAT on a Form 4A for HHS or Overlap BSAT. In 2015, unregistered laboratories accounted for 14% of all reports of the identification of BSAT via APHIS/CDC Form 4A. In addition to the 4A reports, DSAT only received 17 4B reports (14 for Abrin, 2 for *B. anthracis*, 1 for *F. tularensis*). The reason for the small number of 4B reports is likely that the laboratories sponsoring proficiency testing typically use excluded strains of select agents which obviates the Form 4B reporting requirement. DSAT only received three 4C reports (one for Abrin and two for Ricin) in 2015.

In 2015, AgSAS received 345 APHIS/CDC Form 4s for USDA BSAT. The agents identified from these unknown animal specimens included 304 reports of Highly Pathogenic Avian Influenza virus, 26 reports of Newcastle disease virus, 2 reports of African swine fever virus, and 13 reports of *Ralstonia solanacearum* (plant bacterial agent). Of the 304 reports of identification of HPAI received, 263 were due to a HPAI outbreak during the spring and summer of 2015. This outbreak was the largest animal health emergency in the country's history. AgSAS did not receive any form 4B or 4C reports in 2015.

Transfers of Select Agents or Toxins

The APHIS/CDC Form 2, Request to Transfer Select Agents and Toxins (Form 2), is used by entities to request authorization prior to shipping BSAT. BSAT may be transferred from one entity to another for many reasons, including diagnostic testing, scientific or clinical research, and production of therapeutics. FSAP has published an APHIS/CDC Form 2 Guidance Document and a FAQ to assist entities in requesting permission to transfer BSAT.

In 2015, AgSAS approved 126 transfers. DSAT approved 337 transfers. Unregistered entities initiated 32% of all transfers, mostly as a result of identification of BSAT in a diagnostic specimen.

Figure 3 shows the total number of transfers by agent approved by AgSAS in 2015. Figure 4 shows the number of transfers by agent approved by DSAT in 2015. The most frequent transfer approved by DSAT was for *B. anthracis*. The most frequent transfer approved by AgSAS was for avian influenza virus. A

transfer request submitted to FSAP may include the transfer of more than one BSAT, which is why the total number of transfers by BSAT differs from the total number of Form 2s submitted.

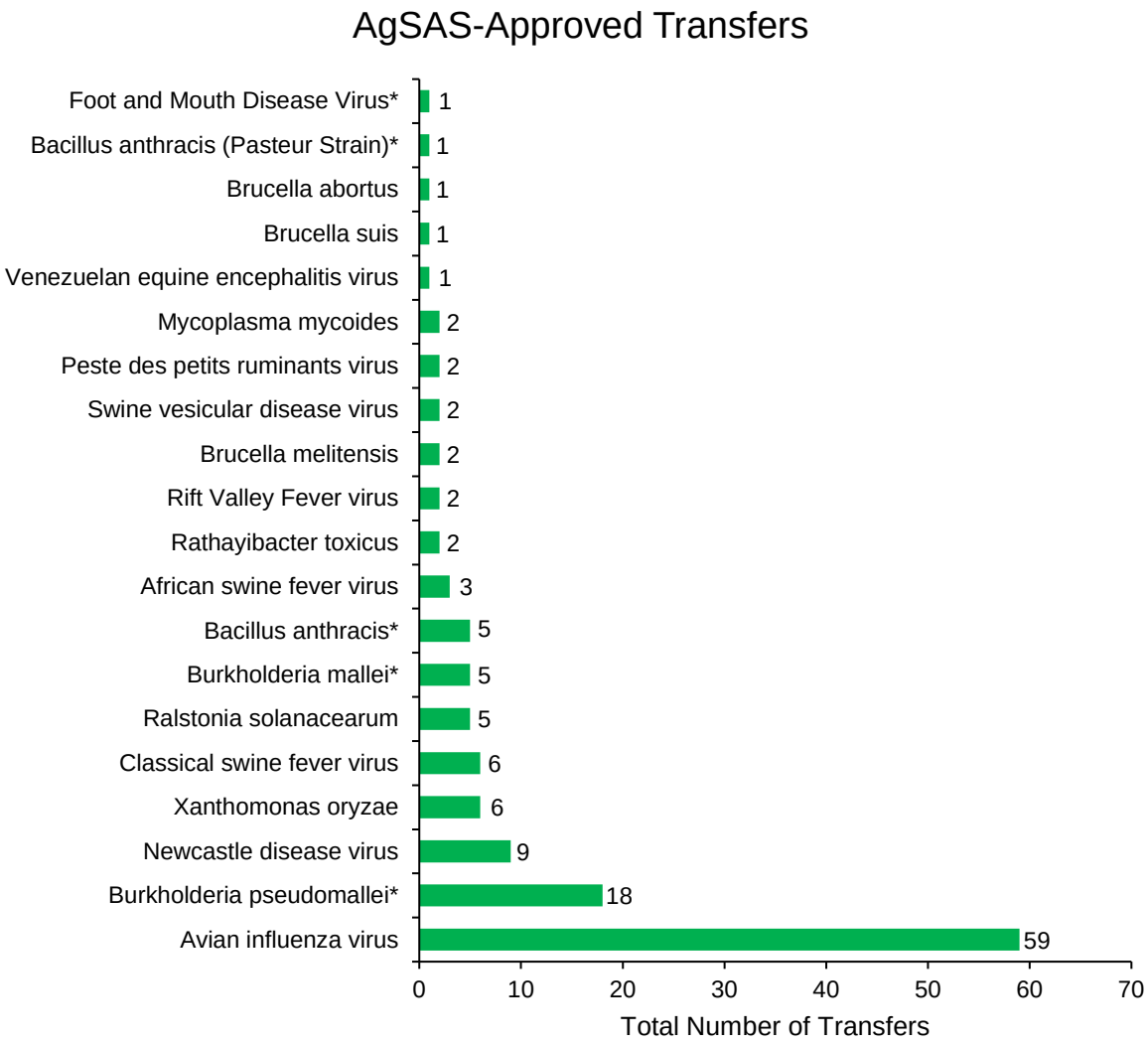

Figure 3: Total approved transfers by AgSAS in 2015 by select agent. *Tier 1 BSAT.

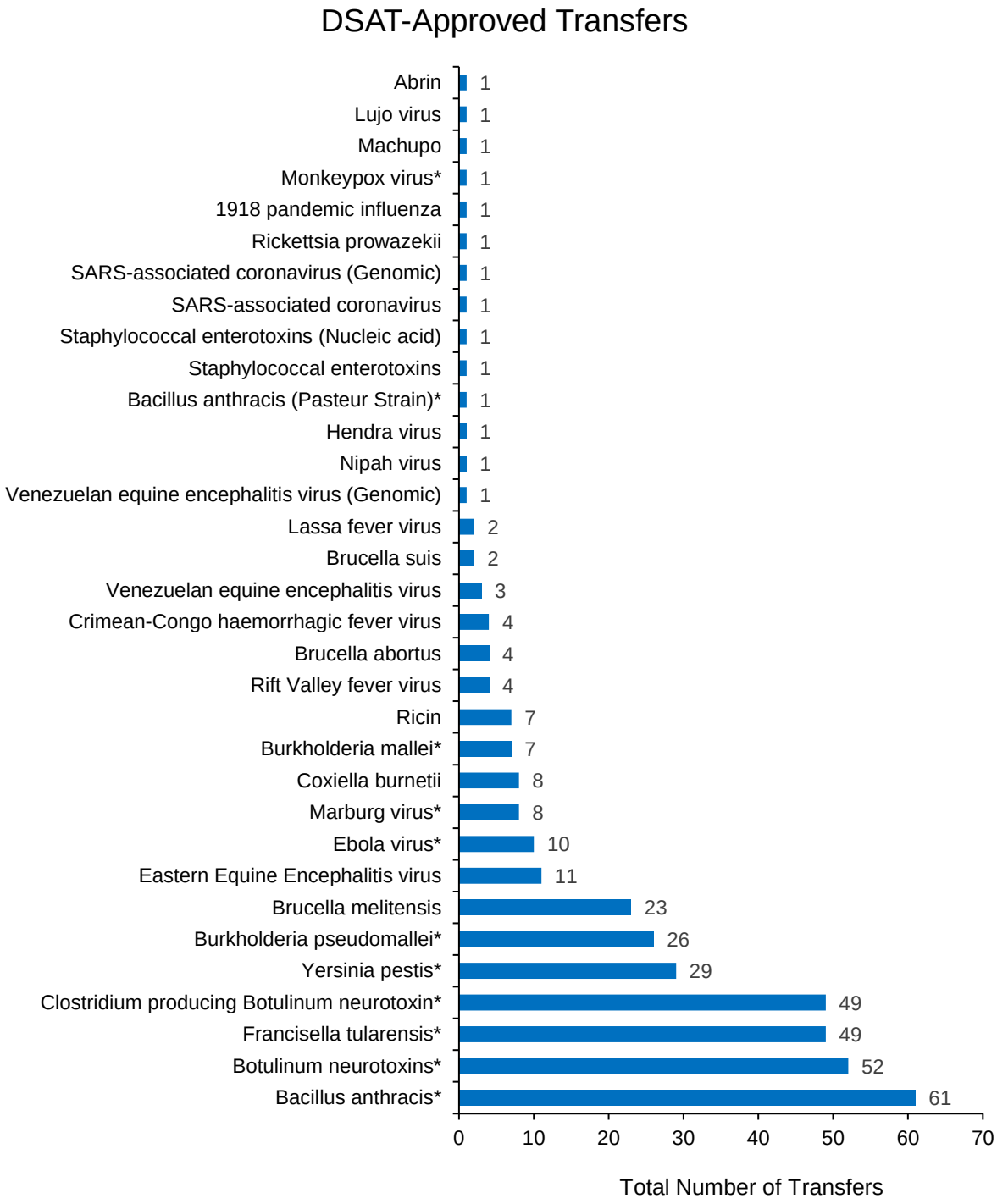

Figure 4: Total approved transfers by DSAT in 2015 by select agent. *Tier 1 BSAT.

Figure 5 shows the number of approved transfers by agency and receiving entity type. Federal government entities received the most BSAT, likely due to their large size and amount of BSAT work. Transfers from non-registered entities are included in this analysis.

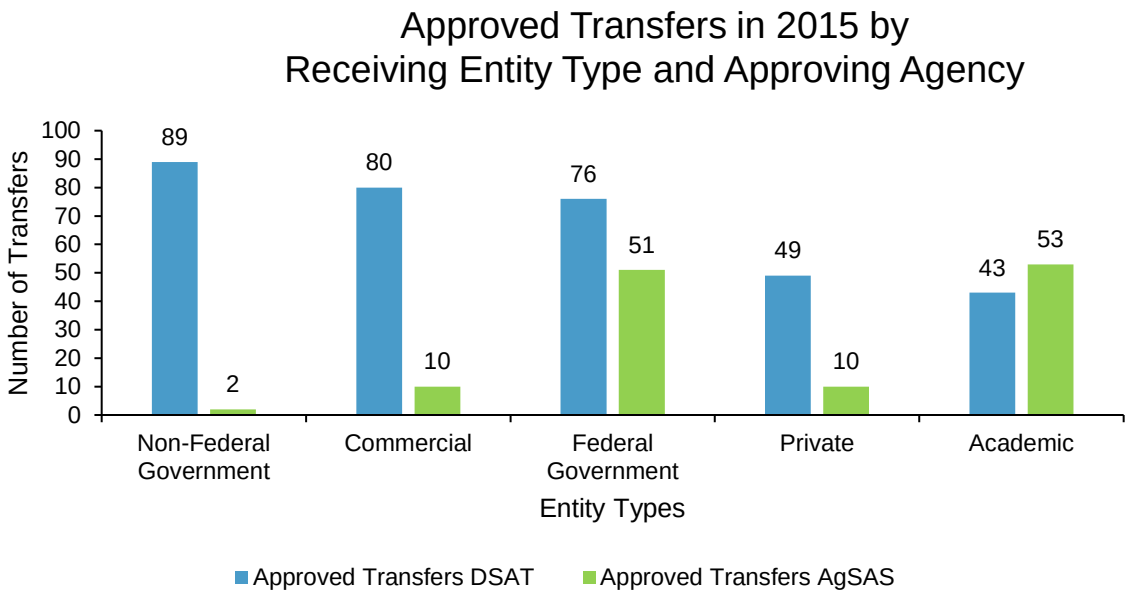

Figure 5: Total approved transfers by agency and entity type.

Figure 6 shows the total number of received transfers by approving agency and month in 2015. Spikes in transfers were observed in May, June, and July of 2015.

- In May and June of 2015, there were 45 *B. anthracis* transfers. During this time, the inadvertent shipment of viable *B. anthracis* was discovered. Entities that were unable to properly destroy the agent were instructed to transfer their *B. anthracis* samples to registered entities for testing or destruction, causing a spike of *B. anthracis* transfers.
- In July of 2015, 17 *Francisella tularensis* samples (14 associated with a Form 4), and 9 *Yersinia pestis* samples (4 associated with a Form 4) were transferred. DSAT has noted similar seasonal spikes for these agents in past years.
- In July of 2015, a shipping company that routinely accepted shipments of BSAT stopped handling these types of shipments. This likely contributed to the decline in the number of shipments for the rest of the year.

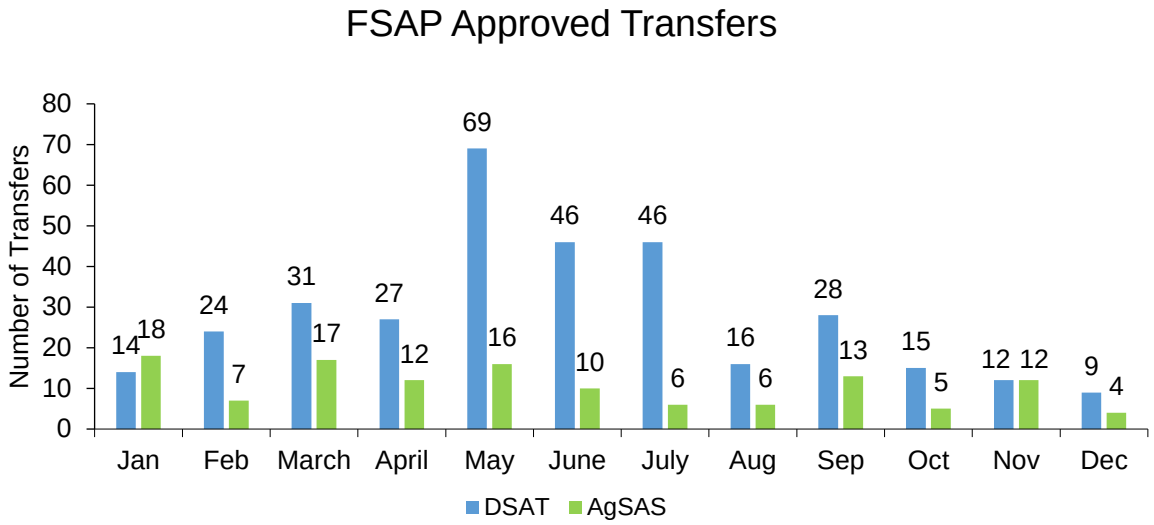

Figure 6: Transfers of BSAT by approving agency by month.

Table 7 describes the two transfer violations in 2015 that involved entities not registered with FSAP that identified BSAT in a diagnostic sample and did not properly initiate the BSAT transfer process. In both cases, the samples were received by a registered federal government entity without forewarning or an APHIS/CDC Form 2, and immediately notified FSAP.

Transfer Violations in 2015

Sending Entity Type	Receiving Entity Type	Self-Report /Inspection discovery	Agent	Resolution
Non-registered international entity	Federal government	Self-report	*Burkholderia pseudomallei*	International entity counseled
Non-registered domestic entity	Federal government	Self-report	*Bacillus anthracis*	Domestic Entity counseled

Table 7: Transfer violations in 2015.

Theft, Loss, and Release of Select Agents and Toxins

APHIS/CDC Form 3 - Report of Theft, Loss, or Release (TLR) of Select Agents and Toxins (Form 3), is used by entities to report a theft, loss, or release of BSAT. An entity is required by regulation (7 CFR § 331.19, 9 CFR § 121.19, and 42 CFR § 73.19) to notify AgSAS or DSAT immediately upon discovery of a theft (unauthorized removal of BSAT), loss (failure to account for BSAT), or release (occupational exposure or release of BSAT outside of primary containment, like a BSC) of BSAT. Clinical or diagnostic laboratories and other non-registered entities that possess, use, or transfer BSAT within a specimen presented for diagnosis, verification, or proficiency testing must immediately report this information if there has been a theft, loss, or release of BSAT. Any incident that results in the activation of a post-exposure medical surveillance/prophylaxis protocol is expected to be reported as a release. The most recent version of the Form 3 became effective on 12/31/2015. Examples of a release can include:

- Bites or scratches from infected animals.
- Accidental needle sticks or other sharps.
- Spills of BSAT materials outside of a BSC.

- Failure or problem with PPE that results in a potential occupational exposure.
- Work outside of BSC with unknown samples later determined to be BSAT.

As in many work places, accidents and incidents occur in laboratory work. Laboratory staff work hard to minimize these events but unfortunately they still occur. Bites and scratches occur through PPE while laboratory staff handle infected animals. Needle sticks occur while handling animals or preparing syringes and represent some of the most risky laboratory manipulations of BSAT for the worker. Laboratory staff are trained to minimize use of glass and to avoid sharp edges but these items still cause injuries. Failure or problems with PPE reported to the FSAP included tears in gloves or gowns and failure to wear appropriate PPE properly. Laboratory standard operating procedures are in place to ensure safety and security of BSAT. Failure to follow standard operating procedures can result in potential releases of BSAT. Work outside of containment (e.g. outside of a BSC) with BSAT or an unknown sample that is later identified to contain BSAT, is considered a potential release because many standard procedures used on an open laboratory bench have the potential to generate infectious aerosols. In many of these circumstances, respiratory PPE has not been worn by laboratory staff. The risk in these situations is difficult to quantify, and out of an abundance of caution, FSAP considers these incidents as potential exposures.

In 2015, there were 12 potential losses and 233 potential releases reported to FSAP.

- 12 reports of losses of BSAT were investigated by the FBI, and all were determined to be records management errors or were samples mistakenly autoclaved as waste.
- Of the 233 potential releases:
    - 199 reports were determined to represent potential occupational exposure to laboratory workers.
        - Of the 199, two reports of seroconversions involving three laboratory staff with no known incident which were identified by routine annual screening of laboratory staff.
    - Two were potential releases of *Xanthomonas oryzae*. Because this BSAT infects plants and is not a danger to humans, these events were not classified as potential exposures but as releases outside primary containment (like a BSC).
    - 32 reports did not meet the regulatory criteria for a release.

In response to these 201 potential occupational exposure events (90 from registered entities and 111 from unregistered entities), 908 laboratory workers (196 at registered entities, 712 at non-registered entities) were provided occupational health services, including medical assessments, diagnostic testing, and prophylaxis as necessary. Six hundred seventy-one of the potentially exposed laboratorians worked with the unknown diagnostic samples outside of a BSC prior to their identification as BSAT, causing a large number of individuals potentially exposed at non-registered entities. Similarly, regulated entities had 25 individuals potentially exposed to BSAT while working on unknown diagnostic samples outside of a BSC. The FSAP considers all laboratory staff that entered the laboratory while these samples were being worked on as potentially exposed. No potential releases resulted in transmissions outside of the laboratories, illnesses in any of the potentially exposed individuals, or deaths.

FSAP received two reports involving three individuals that seroconverted (e.g., 4-fold rise in antibodies associated with infection from an agent) to BSAT they worked with. These events are detailed in the following list:

- Two workers at a federal government entity were exposed to *Coxiella burnetii*. This was discovered as part of the entity's routine serological testing of laboratory staff. No laboratory incident or event was

linked to the seroconversion. Both workers have remained asymptomatic and continue to perform their work without restrictions. There was no evidence of transmission to other workers.

- One worker at an academic entity tested positive for *Brucella* by serological testing during an annual screening process. There was no known laboratory incident or event linked with this seroconversion. Occupational health professionals monitored the worker for an extended period of time. The worker never demonstrated symptoms and has remained asymptomatic. There was no evidence of transmission to other workers.

In 2015, there were no reported thefts of BSAT. While 12 losses of BSAT were reported, the FBI investigations determined these were the result of administrative errors and no actual losses occurred. The reported losses break down as follows:

- Three were samples mistakenly autoclaved as waste.
- Nine were determined to be human error in inventory record keeping.

Emergency Response

FSAP reaches out to assist entities with transferring or securing BSAT that may be affected by adverse weather events that could affect the safety and security of BSAT. There were 13 adverse weather events in 2015, and FSAP contacted a total of 121 affected entities. Table 9 summarizes FSAP's assistance efforts during weather emergencies. All affected entities were successfully contacted and did not require assistance. There were no releases of BSAT as the result of any weather emergencies in 2015.

Emergency Response Events of 2015

2015 Event	# of Entities Contacted
Tropical Storm Ana	2
Tropical Depression Hawaii	1
Tropical Storm Erika	8
Hurricane Ignacio	1
Hurricane Danny	1
Tropical Storm Joaquin/Flooding	2
January Winter Storm	27
February Winter Storm	25
March Winter Storm	15
Tropical Storm Bill/Flooding	4
Kentucky Storm	3
South Carolina Flooding	1
December Winter Storm	31
Total	121

Table 9: Number of entities contacted during emergency response.

Federal Register Notices, Policy Statements and Guidance

There were five issuances of information in 2015 that fell into three categories: policy, regulatory and guidance. More information can be found in Table 10 below.

Federal Register Notices, Policy Statements, and Guidance Issued in 2015

Federal Register Notices	Policy	Guidance
Federal Register/Advance Notice of Proposed Rulemaking regarding the biennial review and republication of the list of select agents and toxins (March)	Policy statement regarding when APHIS and CDC Import Permits are not required for the importation or interstate transportation of select agents (February).	Updated guidance on the criteria reviewed and considered by the FSAP in determining if certain experiments meet the definition of a restricted experiment (March).
Notice of Proposed Rulemaking seeking comment for a proposal to add certain influenza viruses to the list of HHS select agents and toxins (July).	Policy statement regarding inactivated *B. anthracis* and new requirements necessary to protect human and animal health (November).	

Table 10: Federal Register Notices, policy statements, and guidance issued by FSAP in 2015.

Outreach

FSAP has an active outreach program designed to provide opportunities for the program to interact with members of the regulated community. Outreach initiatives in 2015 included conducting a national webcast and exhibiting an informational booth at scientific conferences to provide guidance and promote compliance with SAR.

Table 11 summarizes FSAP outreach efforts for 2015.

Outreach Efforts for 2015

Conference	Date
USDA Agriculture Research Service 3rd International Biosafety and Biocontainment Symposium	February 2-4, 2015
American Society for Microbiology (ASM) Biodefense and Emerging Diseases Research Meeting	February 9-11, 2015
National Biocontainment Laboratories (NBL)-Regional Biocontainment Laboratories (RBL) Network Meeting	April 12-14, 2015
2015 Association of Public Health laboratories (APHL) Annual Meeting & Ninth Government Environmental Laboratory Conference	May 18-21, 2015
115TH ASM General Meeting	May 30-June 2, 2015
Joint Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) and the International Society of Chemotherapy (ISC) Meeting	September 17-21, 2015
American Society for Industrial Security (ASIS) International 61st Annual Seminar and Exhibits	September 28 - October 1, 2015
American Biological Safety Association Annual Conference	October 10-14, 2015
Webcasts	**Date**
Select Agent webcast addressing questions on forms, referrals, and thefts, loss and releases	November 19, 2015

Table 11: A listing of FSAP outreach to the regulated community in 2015.

References

Select Agents and Toxins Regulations. 7 CFR Part 331, 9 CFR Part 121, 42 CFR Part 73. Last accessed on 5/11/2016.

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NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) U.S. Department of Health and Human Services, National Institutes of Health. April 2016.

Review of Restricted Experiment Requests, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 2006-2013. Smith J, Gangadharan D, and Weyant R. Health Security. September 2015, Vol. 13, No. 5: 307-316

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

Send requests for additional information to FSAP at LRSAT@cdc.gov or AgSAS@aphis.usda.gov.