2020 Annual Report of the
Federal Select Agent Program

CS326113-A

Note for accessibility: Explanations for Figures 1–4 are located in Appendix for Accessibility Descriptions, page 30.

Contents

Acronyms

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

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

Executive Summary

The Federal Select Agent Program, established in response to a U.S. Congressional mandate, regulates the possession, use, and transfer of biological select agents and toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products. The Federal Select Agent Program is jointly managed by the U.S. Department of Health and Human Services/Centers for Disease Control and Prevention/Center for Preparedness and Response/Division of Select Agents and Toxins and the U.S. Department of Agriculture/Animal and Plant Health Inspection Service/Emergency and Regulatory Compliance Services/Division of Agricultural Select Agents and Toxins.[1] Examples of select agents and toxins include the organisms that cause anthrax, smallpox, and Foot-and-Mouth disease, the plant pathogen *Ralstonia solanacearum*, as well as the toxin ricin.

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

The Federal Select Agent Program publishes an annual report to communicate operational metrics to increase understanding of its work. This is the sixth annual report that summarizes data for calendar year 2020. Previous annual reports can be found on the Federal Select Agent Program website at https://www.selectagents.gov/resources/publications/index.htm.

Registered Entities

Entities that wish to possess, use, or transfer biological select agents and toxins must register with the Federal Select Agent Program. As of December 31, 2020, 244 entities were registered with the Federal Select Agent Program: 35 entities registered with the Division of Agricultural Select Agents and Toxins as the lead agency and 209 entities with the Division of Select Agents and Toxins as the lead agency. The term "lead agency" indicates which agency the registered entity uses as its primary point of contact.

Entities can be jointly overseen by both the Division of Agricultural Select Agents and Toxins and the Division of Select Agents and Toxins if the entity is registered with one lead agency but is also registered for an agent or toxin regulated solely by the other agency. In 2020, 49 of the 244 registered entities were jointly managed: The Division of Agricultural Select Agents and Toxins served as the lead agency for 10 entities and the Division of Select Agents and Toxins served as the lead agency for 39 entities. During 2020, four entities applied to the Federal Select Agent Program for new registrations, and four additional applications were pending from previous years (one in 2018 and three in 2019). The application from 2018 was approved in 2020, while the approval process was still underway for the other seven entities as of December 31, 2020. Four entities withdrew their registrations with the Federal Select Agent Program. Entities withdraw their registrations when they no longer need to possess, use, or transfer biological select agents or toxins.

Security Risk Assessments

The Bioterrorism Risk Assessment Group, a program of the Federal Bureau of Investigation's Criminal Justice Information Services Division, performs a security risk assessment (an electronic records check) on individuals who apply for access to biological select agents and toxins. As of December 31, 2020, the Federal Select Agent Program had 8,121 individuals approved to access biological select agents and toxins. Based on security risk assessments conducted during 2020, the Federal Select Agent Program granted 2,577 new approvals for access to biological select agents and toxins (i.e., new individuals, renewals, and individuals approved for access at multiple entities). In 2020, the Bioterrorism Risk Assessment Group identified 12 individuals as "restricted persons"[2] and the Federal Select Agent Program prohibited them from having access to biological select agents and toxins. The most common reason for restriction (9 of the 12 individuals) was due to a conviction in any court of a crime punishable by imprisonment for a term exceeding one year.

---

1 Formally known as the Agricultural Select Agent Services (AgSAS), name change effective January 12, 2021.

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

Inspections

The Federal Select Agent Program conducted 149 inspections in 2020: 20 by the Division of Agricultural Select Agents and Toxins, 93 by the Division of Select Agents and Toxins, and 36 jointly. The Federal Select Agent Program developed and implemented processes for remote and hybrid (i.e., a combination of remote and on-site) inspections due to travel restrictions related to the Coronavirus Disease 2019 pandemic. Of the 149 inspections, 43 were on-site inspections, 103 were remote inspections, and three were hybrid inspections.

Compliance Actions

If significant departures from the select agent regulations are identified, the Federal Select Agent Program has several options to address noncompliance, including:

- Participation of the entity in the voluntary Corrective Action Plan program. An entity voluntarily develops and implements a plan of corrective actions to address significant departures from the select agent regulations. The entity is closely monitored by the Federal Select Agent Program.
- Suspension of (in part or in whole) the entity's registration to possess, use, or transfer biological select agents and toxins.
- Revocation of the entity's registration.
- Referral of the entity to the Health and Human Services Office of Inspector General, the Animal and Plant Health Inspection Service Investigative and Enforcement Services, other Offices of Inspector General (if the entity is a federal entity), or other federal agencies if within their jurisdiction (e.g., Food and Drug Administration, Department of Transportation), for further investigation and possible civil monetary penalties.
- Notification to the Federal Bureau of Investigation of inspection findings that identify potential violation of criminal law.

A summary of compliance actions taken in 2020 is as follows:

- Three entities entered the Federal Select Agent Program Corrective Action Plan program.
- One entity that had been placed on a partial suspension in 2019 had their suspension lifted in 2020. No new entities were suspended.
- The Division of Select Agents and Toxins referred one entity to the Health and Human Services Office of Inspector General. The Federal Select Agent Program also referred one entity to the Food and Drug Administration.
- The Federal Select Agent Program notified the Federal Bureau of Investigation of 18 matters for potential investigation.

Confidential Reporting Systems

The Health and Human Services Office of Inspector General and the Department of Agriculture Office of Inspector General operate confidential systems the public can use to report biosafety and security issues associated with the possession, use, and transfer of biological select agents and toxins. The Offices of Inspector General request that the Federal Select Agent Program assess each report to determine if non-compliance with the select agent regulations occurred. In 2020, the Federal Select Agent Program received one such report from the Health and Human Services Office of Inspector General. The report was referred to the Department of Transportation and the Food and Drug Administration for concerns not pertaining to the select agent regulations.

Transfers of Biological Select Agents or Toxins

Entities must request prior authorization to transfer or import biological select agents or toxins. Biological select agents and toxins may be transferred from one entity to another for purposes such as additional testing of identified biological select agents and toxins from diagnostic specimens, scientific or clinical research, and the production of therapeutics. In 2020, the Federal Select Agent Program approved 183 transfers: 157 (including nine importations) by the Division of Select Agents and Toxins and 26 (including eight importations) by the Division of Agricultural Select Agents and Toxins. During 2020, 168 transfers were completed.

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

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

In 2020, the Federal Select Agent Program received 13 reports of losses, 158 reports of releases, and no reports of theft. The Federal Bureau of Investigation assessed all 13 losses and found no criminal intent for 12 of those losses, with one report still under investigation as of the end of 2020. None of the releases resulted in illnesses among the general public, nor did they result in any deaths or transmission among workers or to the outside of a laboratory into the surrounding environment or community. However, one report of a release from a non-registered entity resulted in illness of one worker after exposure to *Coxiella burnetii*. The source of the infection was attributed to contact with infected animals in the performance of the worker's duties. The worker received medical treatment and fully recovered from the illness. The entity notified all workers potentially exposed to the infected worker and found no evidence of disease transmission to others.

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

Report of the Identification of a Biological Select Agent or Toxin

Registered entities and unregistered clinical, diagnostic, or public health laboratories must notify the Federal Select Agent Program of biological select agents and toxins identified as a result of diagnosis, verification, and proficiency testing. The final disposition of the identified biological select agents and toxins must be included as part of the notification. The Federal Select Agent Program received 865 such notifications in 2020, 52 to the Division of Agricultural Select Agents and Toxins and 813 to the Division of Select Agents and Toxins.

The biological select agents and toxins most frequently identified as a result of diagnostic testing and verification that were reported to the Division of Select Agents and Toxins in 2020 were Botulinum neurotoxin (219), Botulinum neurotoxin producing species of *Clostridium* (191), Eastern equine encephalitis virus (120), *Francisella tularensis* (67), and *Brucella melitensis* (56). The biological select agents and toxins most frequently identified as a result of diagnostic testing and verification that were reported to the Division of Agricultural Select Agents and Toxins in 2020 were *Bacillus anthracis* (19), *Ralstonia solanacearum* (17), and highly pathogenic avian influenza viruses (10).

Conclusion

The Federal Select Agent Program was established in response to a U.S. Congressional mandate to ensure the safety and security of select agents and toxins. Overall, most entities registered with the Federal Select Agent Program are compliant with the regulations as evidenced by the small number of compliance issues identified in this report. Also, of note, none of the reported releases resulted in illnesses among the general public, nor did they result in death of or transmission among workers or transmission to the outside of a laboratory into the surrounding environment or community. With oversight from the Federal Select Agent Program, entities are able to work with select agents and toxins as safely and securely as possible. This has led to important scientific discoveries that have improved diagnostics and detection, treatment and prevention of human, animal and plant diseases.

FEDERAL SELECT AGENT PROGRAM:
BY THE NUMBERS
2020

244

entities registered

8,121

individuals approved to access biological select agents and toxins

149

inspections conducted

HHS Select Agents and Toxins

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

Overlap Select Agents+

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

USDA Select Agents

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

* Tier 1 agents
+ These are regulated by both HHS and USDA due to their potential to pose a severe threat to both public health and safety and to animal health or products.

For information on exclusions from the regulations, please refer to the list on the Federal Select Agent Program website:

https://www.selectagents.gov/sat/list.htm

List last updated on September 24, 2018

Introduction

The Federal Select Agent Program (FSAP) was established in response to a U.S. Congressional mandate to ensure the safety and security of research with biological select agents and toxins (BSAT). With oversight from FSAP, entities are able to work as safely and securely as possible with select agents and toxins. This has led to important scientific discoveries that have improved diagnostics and detection, treatment and prevention of human, animal and plant diseases.

FSAP is jointly managed by the U.S. Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC)/Center for Preparedness and Response (CPR)/Division of Select Agents and Toxins (DSAT) and the U.S. Department of Agriculture (USDA)/Animal and Plant Health Inspection Service (APHIS)/ Emergency and Regulatory Compliance Services (ERCS)/Division of Agricultural Select Agents and Toxins (DASAT). FSAP oversees the possession, use, and transfer of BSAT, which have the potential to pose a severe threat to human, animal, or plant health, or to animal or plant products, in accordance with the HHS and USDA select agent regulations (SAR).[3]

FSAP regulates work with BSAT to help ensure that it is conducted as safely and securely as possible by:

- Developing, implementing, and enforcing the SAR;
- Maintaining a national database to track possession and work conducted with BSAT;
- Inspecting entities that possess, use, or transfer BSAT to ensure adherence to the select agent regulations;
- Ensuring all individuals applying for access to BSAT undergo a security risk assessment (SRA), and that those deemed "restricted persons" are prohibited from accessing BSAT;
- Developing guidance documents and conducting trainings to help regulated entities maintain compliance with the SAR; and
- Reviewing incidents in which non-compliance with the SAR may have occurred.

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

This annual report provides insight into the regulatory functions of FSAP, as well as compliance with the SAR at registered entities. It also reflects FSAP's commitment to program transparency.

Electronic Federal Select Agent Program (eFSAP) Information System

FSAP uses the electronic Federal Select Agent Program (eFSAP) Information System to maintain a national database that includes the names and locations of registered entities, the BSAT each is registered for, as well as the names of individuals with access to BSAT. eFSAP is a highly secure platform allowing real-time bi-directional communication between FSAP and the regulated community. It allows entities to directly update information such as work objectives, addition and removal of personnel working with BSAT, strains/serotypes of BSAT in their possession; as well as request approvals for transfers, report identification of BSAT, and report a theft, loss or release. Entities have full transparency regarding the status of any requests sent to FSAP, such as amendments to their program registration. In addition, eFSAP is used for inspection processes including inspection scheduling, a preview of items that will be assessed during the inspection, and notification of when inspection findings are released, as well as provides the ability for entities to directly respond to the inspection findings by uploading documentation of their corrective actions.

The use of the eFSAP information system has resulted in substantial increases in program effectiveness. With the eFSAP information system, FSAP has seen a reduction in the time required for entities to resolve inspection observations, as well as the time required for review and approval of registration amendment requests.

---

3 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121

Key Program Statistics

Registration

Registered Entities

BSAT are divided into three categories based on whether an agent causes disease in humans, animals, plants, or a combination of humans and animals (see current list found on page 9). The three categories of BSAT are:

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

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

The APHIS/CDC Form 1 requires:

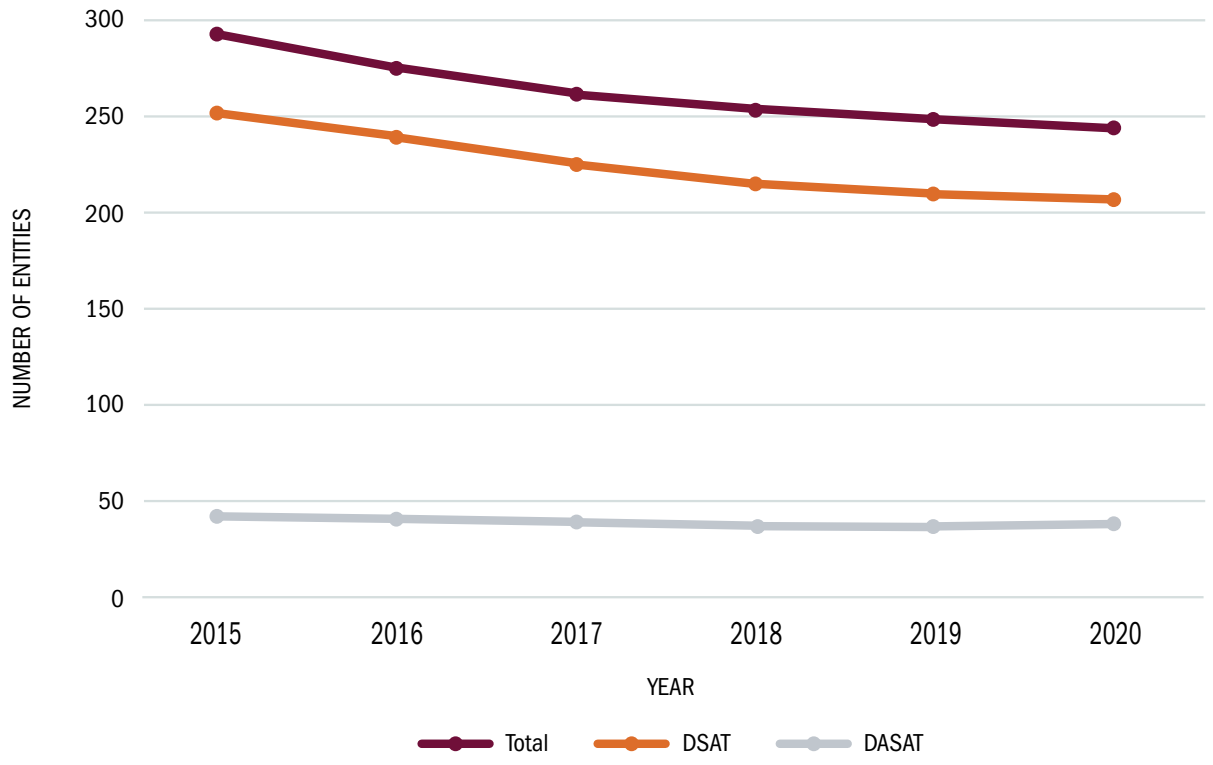
- Facility information
- A list of BSAT to be possessed, used, or transferred by the entity
- A list of individuals who will have access to BSAT
- A description of the work to be performed
- Information about where the work will be performed

After submission of the APHIS/CDC Form 1, FSAP will review and schedule a site inspection to verify the submitted information and to confirm that the entity is compliant with the SAR. Once the inspection is complete and the entity fulfills all regulatory requirements, FSAP will issue a certificate of registration allowing the entity to acquire and work with the BSAT.

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

At the end of 2020, 244 entities were registered with FSAP: 35 with DASAT and 209 with DSAT (Figure 1). The lead agency, either DSAT or DASAT, is responsible for administering all activities and communications with respect to an entity's registration, including coordination with the non-lead agency. Entities are jointly overseen by both DASAT and DSAT if the entity is registered with one lead agency but is also registered for an agent or toxin regulated solely by the other agency. In 2020, DASAT and DSAT jointly oversaw 49 of the 244 total entities registered with the program: DASAT served as the lead agency for 10 of those entities and DSAT served as the lead agency for 39 of those entities. There has been a general downward trend in the number of registered entities since 2015.

Figure 1: Number of FSAP-Registered Entities by Agency and Year, 2015-2020



Entity Types

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

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

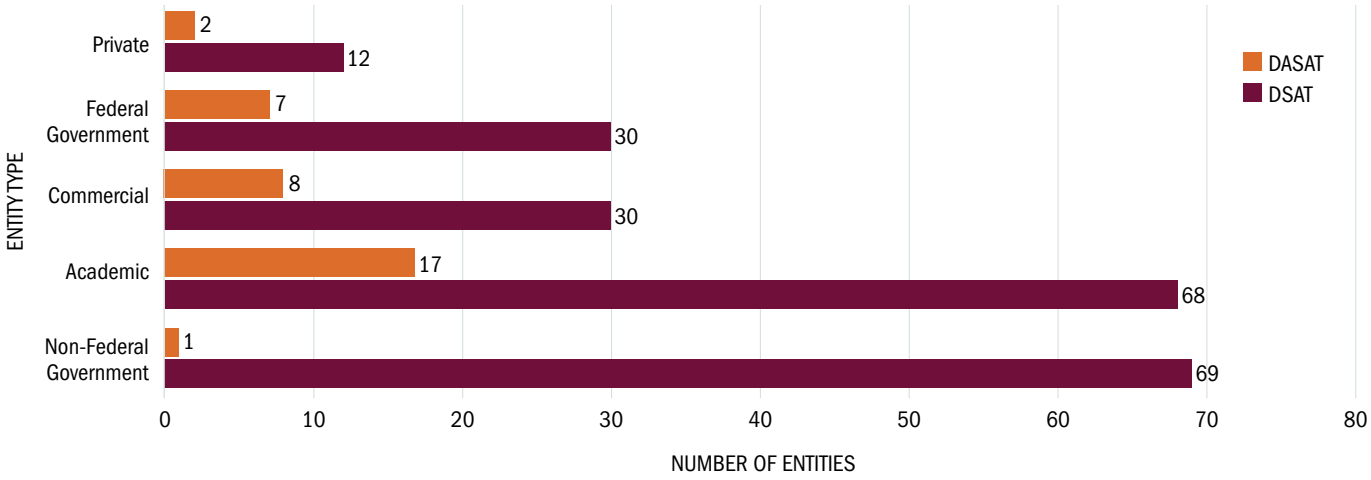
Regulated entities during calendar year 2020 consisted of:[4]

- 35% academic,
- 29% non-federal government,
- 16% commercial,
- 15% federal government, and
- 6% private.

The relative percentages of each entity type have remained consistent since 2015. Figure 2 details the number of entities registered either with DSAT or DASAT by entity type in 2020.

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

Figure 2: Number of FSAP-Registered Entities by Type, 2020



New Registration Applications

During 2020, FSAP reviewed eight new applications from entities that wished to register. FSAP received four of the eight applications in 2020, and the approval process was still underway for all four of those as of December 31, 2020. The other four applications were received in previous years: one in 2018 and three in 2019. Of these, the one application from 2018 was approved in 2020, and the other three applications from 2019 were still under review as of the end of 2020.

Entity Withdrawals

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

As shown in Table 1, four entities withdrew their registration from FSAP in 2020, all from DSAT. The reason entities cited for withdrawing were that they no longer needed to possess or work with BSAT. A total of 79 entities withdrew their registrations during 2015-2020, which contributed to a 16% reduction in the total number of registered entities.

Table 1: Number of Entity Withdrawals by Entity Type, 2020

Entity Type	Number
Academic	1
Commercial	1
Federal Government	2
Total	**4**

Renewals

Typically, a registered entity must renew its registration at least every three years. However, due to the Coronavirus Disease 2019 (COVID-19) pandemic, entity registrations that were about to expire were conditionally renewed for 6 months to maintain registration certification and then extended for two years following a remote renewal inspection. In 2020, FSAP approved a total of 108 renewals: 11 by DASAT and 97 by DSAT.

Amendments to Registration

When a registered entity needs to amend their approved registration, they must submit an updated APHIS/CDC Form 1 to FSAP via the eFSAP information system. After review of the request, FSAP staff will approve or deny the amendment. Examples of amendments to registration include addition or removal of laboratory rooms, adding a new BSAT or updating a principal investigator's work objective(s). Table 2 lists the 689 amendments to registration approved in 2020 that required FSAP staff review, stratified by the approving agency and the sections of the APHIS/CDC Form 1 that were modified.

Table 2: Number of Approved Amendments to Registration that Required FSAP Inspector Review, by Amended Section of the APHIS/CDC Form 1 and Agency, 2020

Registration Amendment to APHIS/CDC Form 1	DASAT	DSAT	Total
Section 1 - Change Entity Physical or Additional Address	0	3	3
Section 4 - Change Responsible Official	7	32	39
Section 5A - Modify Entity-Wide Security Assessment and Incident Response	3	3	6
Section 5B - Modify Entity-Wide Biosafety/Biocontainment	2	1	3
Section 5C - Modify Entry Requirements for Federal Select Agent Program Inspectors	3	14	17
Section 6 - Modify Building	1	5	6
Section 6 - Modify Room or Suite	31	36	67
Section 7AC - Add New Work Objective	10	71	81
Section 7AC - Modify Work Objective and/or Attachment(s)	36	332	368
Section 7AC - Remove Approved Work Objective	3	93	96
Other Amendments (Including Registration Withdrawals)	0	3	3
Total Approved Amendments	**96**	**593**	**689**

The eFSAP information system allows for registered entities to manage their registrations and directly interact with FSAP staff. The eFSAP information system also automates many other types of administrative amendments including removal of an individual from an entity's registration, generating a unique identifier number for an individual being added to the entity's registration for the Bioterrorism Risk Assessment Group (BRAG) to use for the SRA, or updating entity contact information.

Tier 1 BSAT

Tier 1 BSAT represent the greatest risk of deliberate misuse with the most significant potential for mass casualties, devastating effects on the economy, critical infrastructure, or public confidence. In 2020, 127 entities were registered with FSAP for Tier 1 BSAT: nine with DASAT (representing 26% of all DASAT-led entities) and 118 entities with DSAT (representing 56% of all DSAT-led entities). Since 2015, the total percentage of entities registered for Tier 1 BSAT has averaged around 50%, including 52% of FSAP-regulated entities in 2020 (127 total entities).

Top BSAT Registered with Each Agency

Table 3 lists the BSAT most frequently registered with each agency as of December 31, 2020. The most frequently registered BSAT with DSAT are the *Brucella* species and *Bacillus anthracis* Pasteur strain. For DASAT, Newcastle disease and Avian influenza viruses have consistently ranked as the most commonly registered BSAT. The most frequently registered BSAT remained consistent over the last six years.

Table 3: Most Frequently Registered Agents with Each Agency, 2020

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

**Indicates Tier 1 BSAT*

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

Laboratory Types

Laboratories that work with BSAT range from biosafety level 2 (BSL-2) to maximum containment at biosafety level 4 (BSL-4). At each containment level, there is an equivalent set of biosafety guidelines for work with animals designated as animal biosafety level 2 (ABSL-2) through maximum containment at animal biosafety level 4 (ABSL-4). Entities may register multiple types of laboratories at different biosafety levels (BSL) depending on the work performed in those laboratories.

In 2020, 29% of entities were approved to work in a BSL-2/ABSL-2 laboratory, 78% of entities were approved to work in a BSL-3/ABSL-3 laboratory, and 3% of entities were approved to work in a BSL-4/ABSL-4 laboratory. Table 4 lists the number of entities that are approved to work with Tier 1 BSAT at each BSL/ABSL, and the number of entities approved to work at each BSL/ABSL by entity type.

Table 4: Number of Entities by Laboratory and Entity Type, 2020

Laboratory Type: Biosafety Level	Total Registered Laboratories	Registered for Tier 1 Agent	Entity Type: Commercial	Entity Type: Federal Government	Entity Type: Academic	Entity Type: Non-Federal Government	Entity Type: Private
BSL-2/ABSL-2	70	50	21	14	20	10	5
BSL-3/ABSL-3	190	97	16	26	67	68	13
BSL-4/ABSL-4	8	8	0	5	2	0	1

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

Security Risk Assessments

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

At the end of 2020, there were 8,121 unique individuals with current SRAs approved for access to BSAT. In 2020, FSAP granted 2,577 approvals (new and renewal applications) for access to BSAT (Table 5). The total number of individuals approved for access to BSAT per entity type (8,432 total access approvals) is greater than the number of SRAs for individuals because an individual can be approved for access to BSAT at multiple entities (e.g., as collaborator or guest researcher) based on one current SRA. Thirty-eight percent of the individuals approved for access to BSAT were those working at academic entities, followed by individuals working at federal government entities (30%). For the sixth year in a row, academic entities had the most individuals approved for access to BSAT, followed by federal government entities.

Table 5: BSAT Access Approvals by Entity Type, 2020

Entity Type	2020 Access Approvals	Total Access Approvals as of December 31, 2020
Academic	1,033	3,240
Federal Government	704	2,497
Non-Federal Government	299	976
Commercial	257	971
Private	284	748
Total	**2,577**	**8,432**

In 2020, 12 individuals were identified as a "restricted person." This number is similar to the 10 to 17 per year observed for 2015-2017, contrasting with the higher number in 2018 and 2019 (28 and 30, respectively). Two individuals appealed their restriction but were not successful in overturning the decision.

Table 6 summarizes the reasons for restriction for the 12 individuals.

Table 6: Total Number of Restricted Persons Identified by Restrictor Type, 2020

Reason for Restriction	Total
Conviction exceeds 1 year (Has been convicted in any court of a crime punishable by imprisonment for a term exceeding one year)	9
An alien illegally or unlawfully in the United States	1
Unlawful user of any controlled substance	1
Total	**12**

Inspection Data

Inspections

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

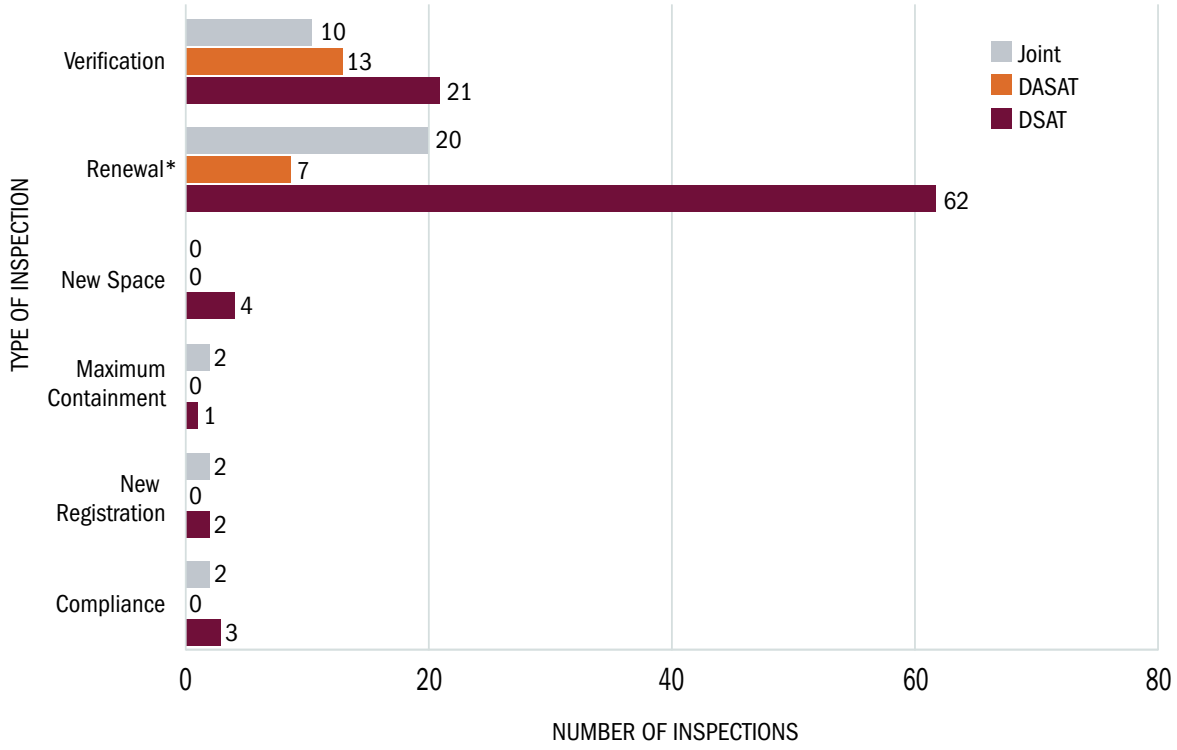
- **Compliance** – Review of entity's registration, including laboratory spaces and documents (e.g., plans, records, facility verification documentation), with a focus on compliance issues.
- **Maximum Containment** – Review of entity's registered maximum containment program, including laboratory spaces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

Either DSAT or DASAT lead the inspection, depending on which is the lead agency and the BSAT for which the entity is registered. DSAT inspects entities registered for HHS-only BSAT and DASAT inspects entities registered for USDA-only BSAT. Entities registered for both HHS and USDA BSAT are normally inspected jointly by DSAT and DASAT. In 2020, FSAP performed 149 inspections: 20 by DASAT, 93 by DSAT, and 36 jointly.

In April 2020, due to the COVID-19 pandemic travel restrictions and to protect the safety of inspectors and entity staff, FSAP developed the capability to conduct remote inspections of entities. Remote inspections focused primarily on review of the documentation aspects of the regulations and employee interviews, as well as plans and training requirements. FSAP also conducted a small number of hybrid inspections, which included both on-site and remote inspections of the registered entity. FSAP performed hybrid inspections when there was a need for on-site inspection (such as previous compliance problems or complex facility issues), while conducting document review remotely to minimize time at the entity. When on-site inspections fully resume, FSAP will further refine the hybrid inspection process. Of the 149 inspections conducted by FSAP in 2020, 43 were on-site inspections, 103 were remote inspections, and three were hybrid inspections.

Figure 3 compares the number of each type of inspection conducted in 2020 by either DSAT, DASAT, or both jointly.

Figure 3: Number of Inspections by Lead Agency and Type, 2020



**One of the renewal inspections conducted in 2020 also included an inspection of the entity's maximum containment registered space.*

Length of Inspections

In 2020, inspection length ranged from 1 to 5 business days on site with an average length of 2.3 business days, which is similar to the average length of inspections for the past 5 years. Starting in April 2020, due to the COVID-19 pandemic, on-site inspections were minimized in favor of remote or hybrid inspections. This change impacted the 2020 inspection length range as compared to previous years. The longest inspection lasted 5 days in 2020 versus 8-10 business days in previous years.

Inspection Findings and Compliance

A goal of the SAR is to ensure a registered entity has the operating conditions to minimize biosafety and security risks. FSAP works closely with all regulated entities to assist them with compliance to the SAR. The following are the most common findings during inspections in 2020:

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

Corrective Action Plan

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

One entity agreed to participate in the CAP program in 2019, and successfully resolved the deficiencies and was removed from the CAP program in 2020. In 2020, three entities agreed to participate in the CAP program. All three entities continued their participation in the CAP program into 2021.

Registration Suspensions

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

One entity that was placed on partial suspension for failing to meet biosafety regulatory requirements in 2019 had the suspension lifted in 2020. No entities were suspended (either partially or entirely) in 2020.

Reports and Referrals

Confidential Reporting System

The HHS Office of Inspector General (OIG) and the USDA OIG maintain confidential reporting systems for the public to report safety, security, or other concerns associated with BSAT. In 2020, FSAP received one report from these systems. The 2020 report involved a complaint about transportation issues that were unrelated to the SAR. FSAP referred this complaint to the Food and Drug Administration and the Department of Transportation. Since 2015, the HHS and USDA OIGs have received no more than five reports per year.

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

For serious non-compliance of the SAR, FSAP may refer entities to HHS OIG or APHIS Investigative and Enforcement Services (IES) for further investigation and possible civil monetary penalties. In 2020, one entity was referred to the HHS OIG for failure to have an approved Responsible Official (RO) as required by the regulations, and for allowing unauthorized access to select agents and toxins. Since 2015, three to seven entities have been referred to either HHS OIG or APHIS IES each year, except for 2019 and 2020 when only one entity was referred.

FSAP may also refer entities to other relevant federal agencies as appropriate. In 2020, one entity was referred to the Food and Drug Administration for issues related to vaccine development.

FBI Notifications

FSAP notifies the FBI of any security-related issue identified by either FSAP or a registered entity (e.g., an unapproved individual having access to BSAT or a security breach of BSAT storage space) and any report of a loss of BSAT. The FBI investigates the incident to determine whether there was a criminal threat. FSAP also supports FBI investigations upon request.

In 2020, FSAP notified the FBI of 18 matters for investigation.

- Twelve notifications concerned the loss of BSAT. For nine of the notifications, there were volume amount differences between actual vial contents and the inventory record. For the other three notifications, these were inventory record discrepancies of BSAT due to the BSAT being used or destroyed without updating the inventory record, or were losses attributed to record keeping errors.
- Four notifications concerned the discovery of BSAT outside of registered space.
- Two notifications concerned an unsecured incubator or key box, allowing for unauthorized access to BSAT.

One loss discussed in the Theft, Loss, and Release section below was not referred to the FBI due to the material being found by the entity before referral. In 17 of the notifications, FBI analysis determined there was no criminal nexus requiring the opening of a case. As of December 31, 2020, the one remaining notification was still pending a determination.

Restricted Experiments

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

The SAR defines two types of restricted experiments:

- The deliberate transfer of, or selection for, a drug-resistance trait to a select agent that is not known to acquire the trait naturally, if such acquisition could compromise the control of the disease agent in humans, veterinary medicine, or agriculture (HHS-only and overlap agents).

  The deliberate transfer of, or selection for, a drug or chemical resistance trait to a select agent that is not known to acquire the trait naturally, if such acquisition could compromise the control of a disease agent in humans, veterinary medicine, or agriculture (USDA-only agents).

- The deliberate formation of synthetic or recombinant DNA containing genes for the biosynthesis of a select toxin lethal for vertebrates at an LD50 < 100 ng/kg body weight. Currently, only one select toxin (botulinum neurotoxin) possesses an LD50 < 100 ng/kg body weight.

In 2020, FSAP received no requests that met the restricted experiment definition. However, in 2020, FSAP received three requests that did not meet the definition of a restricted experiment and did not require prior approval of FSAP.

Exclusions

The SAR provide criteria for the exclusion of BSAT from the regulatory requirements. An entity or individual may request to exclude from the SAR an attenuated (weakened) strain of a select agent or a select toxin modified to be less potent or toxic. If approved, FSAP will issue a written decision to the requestor and post the exclusion on the FSAP website in case others wish to work with the attenuated strain or toxin modified to be less potent or toxic. FSAP received ten exclusion requests for evaluation in 2020 and made a decision on a request received at the end of 2019 (Table 7). Ten of the requests were approved during the year and one request was denied.

Table 7: Summary of Requests for Exclusions by Entity Type, Select Agent or Toxin, and Decision Status, 2020

Entity Type	Select Agent	Decision Status
Academic	*Burkholderia pseudomallei* Strain PBK001 (*ΔtonB Δhcp1*)	Received in 2019 Approved
Commercial	African Swine Fever Virus strain ASFV-G-Δ9GL/ΔUK	Approved
Commercial	African Swine Fever Virus strain ASFV-G-ΔMGF	Approved
Private	Avian Influenza virus IDCDC-RG64A (sublot A and B) reassortant viruses (derived from A/Gansu/23277/2019 (H7N9); A/Puerto Rico/8/34)	Approved
Private	Avian Influenza virus 692250 reassortant virus (derived from A/Chicken/Viet Nam/15A59/2015 (H5N6); A/Puerto Rico/8/34)	Approved
Private	Avian Influenza virus IDCDC-RG63A (Lot C) reassortant viruses (derived from A/Duck/Bangladesh/17D1012/2018 (H5N1); A/Puerto Rico/8/34)	Approved
Government	African Swine Fever Virus strain ASFV-G-ΔI177L	Approved
Private	Avian Influenza virus IDCDC-RG65A (Lot A) reassortant virus (derived from A/Guangdong/18SF020/2018 (H5N6); A/Puerto Rico/8/34)	Approved
Government	African Swine Fever Virus strain ASFV-G-ΔI177L	Approved
Academic	ciBoNT/B, C, D, E, F, X	Denied
Government	*Brucella abortus* strain S1119-3	Approved

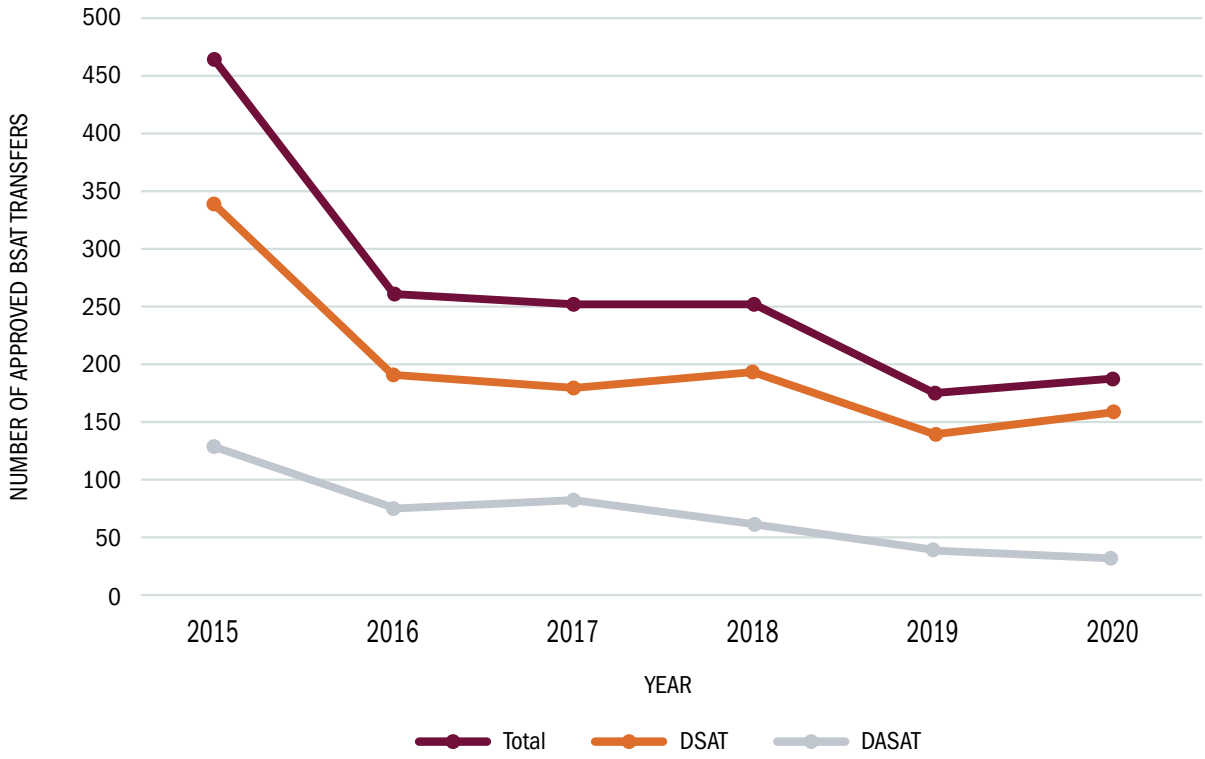
Transfers of BSAT

Entities (registered or not) use the Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2) to request authorization from FSAP prior to transferring BSAT. BSAT may be transferred from one entity to another registered entity for diagnostic testing, scientific or clinical research, or production of therapeutics. In 2020, FSAP approved 183 BSAT transfers – 26 by DASAT and 157 by DSAT. For the 26 transfers approved by DASAT, this represented 10 recipient entities requesting a transfer, and 17 sender entities. For the 157 transfers approved by DSAT, this represented 43 recipient entities requesting a transfer, and 45 sender entities. Twenty-nine (16%) of the approved transfers in 2020 involved unregistered entities transferring to registered entities. These transfers were either imported BSAT (17) or occurred after the identification of BSAT in a diagnostic specimen (12). Of the 17 imported BSAT, DASAT approved 8 transfers, and DSAT approved 9. For the 12 BSAT identified in diagnostic specimens by unregistered entities, DASAT approved 7 transfers, and DSAT approved 5.

In 2020, 168 BSAT transfers occurred during the year, including six transfers that had been approved in 2019 but were not shipped until 2020. Four transfers were approved towards the end of 2020 but had not yet been shipped as of December 31, 2020, and 17 approved transfers were cancelled by the entities before shipping the BSAT.

There was a slight increase in the number of BSAT transfer approvals by DSAT in 2020 from 2019, while BSAT transfer approvals by DASAT continued to decrease in 2020 (Figure 4).

Figure 4: Total Number of Approved BSAT Transfers, 2015-2020



For DASAT, Avian influenza virus was the most frequently transferred BSAT for 2020 (Table 8) and has been since 2015.

Table 8: Number of BSAT Transfers (Form 2) Approved by DASAT, 2020

BSAT	Total*
Avian influenza virus	9
African swine fever virus	6
Burkholderia pseudomallei	2
Ralstonia solanacearum	8
Rift Valley Fever Virus	1

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

For DSAT, Botulinum neurotoxin was the most frequently transferred BSAT in 2020 (Table 9) and has been since 2016. Botulinum neurotoxin is unique in that it is used both as a drug and for research purposes.

Table 9: Number of BSAT Transfers (Form 2) Approved by DSAT, 2020

BSAT	Total*
Botulinum neurotoxin	48
Brucella abortus	32
Bacillus anthracis	17
Botulinum neurotoxin producing species of *Clostridium*	13
Francisella tularensis	13
Yersinia pestis	13
Eastern Equine Encephalitis virus	10
Burkholderia pseudomallei	9
Burkholderia mallei	6
Ebola virus	6
Brucella suis	5
Venezuelan equine encephalitis virus	5
Brucella melitensis	4
Rickettsia prowazekii	4
Coxiella burnetii	3
SARS-associated coronavirus (SARS-CoV)	3
Bacillus anthracis Pasteur strain	2
Lassa fever virus	2
Marburg virus	2
Crimean-Congo haemorrhagic fever virus	1
Genomic material: Eastern Equine Encephalitis Virus	1
Rift Valley fever virus	1

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

Theft, Loss, and Release of BSAT

An entity uses the Report of Theft, Loss, or Release of Select Agents and Toxins (APHIS/CDC Form 3) to report a theft (unlawful taking), loss (failure to account for), or release (causing an occupational exposure or release outside of the primary barriers of the biocontainment area).

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

In 2020, FSAP received 13 reports of losses, 158 reports of releases, and no reports of thefts.

For the 158 reports of releases, 69 were submitted by registered entities and 89 by non-registered entities.

Examples of the causes of a release may include:

- Bites or scratches from an infected animal
- Equipment or mechanical failure

- Spill of BSAT outside of a BSC
- Failure or problem with personal protective equipment (PPE)
- Needlestick or other percutaneous exposures with contaminated sharp objects
- Open bench work involving diagnostic samples (later identified as BSAT) without appropriate PPE

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

- FSAP agreed with the reporting entities that 24 releases presented minimal to no risk of occupational exposure.
- The remaining 134 releases involved occupational exposure to BSAT.
  - In 12 of the 134 releases, the reporting entity determined no occupational health services were necessary based on the circumstances of the release.
  - In the remaining 122 releases, the reporting entities provided occupational health services (including medical assessments, diagnostic testing and/or pharmaceutical prophylaxis) to a total of 483 individuals (68 individuals from 25 registered entities and 415 individuals from 77 non-registered entities).

None of the releases resulted in illnesses among the general public, nor did they result in any deaths or transmission among workers or to the outside of a laboratory into the surrounding environment or community.

However, one release reported by a non-registered entity resulted in the illness of one worker after exposure to *Coxiella burnetii*. The source of the infection was attributed to contact with infected animals in the performance of the worker's duties. The worker received medical treatment and fully recovered from the illness. The entity notified all workers potentially exposed to the infected worker and found no evidence of disease transmission to others.

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

Report of the Identification of BSAT

Entities use the Report of the Identification of a Select Agent or Toxin (APHIS/CDC Form 4) to notify FSAP of the identification of BSAT that is the result of diagnosis, verification, or proficiency testing. The final disposition of the identified BSAT must be included as part of the notification. 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 Form 4A is used by institutions that need to report the identification of BSAT. APHIS/CDC Form 4B is used by an institution that needs to report the identification of BSAT while performing proficiency testing. Proficiency testing allows entities to test their capabilities to identify BSAT in samples provided by a sponsor/entity. APHIS/CDC Form 4C is used by law enforcement to notify FSAP of seized BSAT.

In 2020, DSAT received and processed 813 APHIS/CDC Form 4As to report the identification of BSAT as a result of diagnosis or verification. Botulinum neurotoxin was the most commonly identified BSAT reported to DSAT, followed by Botulinum neurotoxin producing species of *Clostridium* and Eastern Equine Encephalitis virus (Table 10). Botulinum neurotoxin was also the most commonly identified BSAT in 2018, 2017, and 2016. Eastern Equine Encephalitis virus was the most commonly identified BSAT in 2019, and *Francisella tularensis* was the most commonly identified BSAT in 2015.

Clinical, diagnostic, or public health laboratories that are not registered to work with BSAT may, in the course of their work, identify BSAT. For DSAT, unregistered laboratories accounted for 21% of all reports of the identification of BSAT using the APHIS/CDC Form 4A. Upon identification of BSAT, the unregistered laboratory must notify FSAP and either register with FSAP to keep the samples, transfer the sample to an entity registered to possess that BSAT, or destroy the sample.

In 2020, DSAT received 38 APHIS/CDC Form 4Bs reporting BSAT identified through proficiency testing, compared to an annual range of zero through 63 reports over the previous five years. DSAT did not receive any reports regarding seizures by federal law enforcement (APHIS/CDC Form 4C) and has not received any of this type of report since 2015 (when DSAT received three).

Table 10: BSAT Reported to DSAT on Form 4A by Sample Type, 2020

BSAT	Animal Specimens	Environmental Samples	Food Samples	Human Specimens	Total
Bacillus anthracis	6	0	0	0	6
Botulinum neurotoxin producing species of *Clostridium*	23	1	3	164	191
Botulinum neurotoxins	29	1	1	188	219
Brucella abortus	11	0	0	6	17
Brucella melitensis	0	0	0	56	56
Brucella suis	4	0	0	28	32
Burkholderia pseudomallei	1	5	0	16	22
Coxiella burnetii	33	0	0	5	38
Eastern Equine Encephalitis virus	110	9	0	1	120
Francisella tularensis	31	0	0	36	67
Genomic material: Eastern Equine Encephalitis Virus	7	3	0	0	10
Lassa fever virus	0	0	0	2	2
Ricin	0	4	1	0	5
Rickettsia prowazekii	0	0	0	1	1
Rift Valley fever virus	0	0	0	2	2
South American Haemorrhagic Fever virus: Chapare	0	0	0	1	1
Staphylococcal enterotoxins A, B, C, D, E subtypes	1	0	1	0	2
Yersinia pestis	8	2	0	12	22
Total	**264**	**25**	**6**	**518**	**813**

DASAT received and processed 52 APHIS/CDC Form 4A reports in 2020 (Table 11). For DASAT, non-registered laboratories accounted for 35% of all reports of the identification of BSAT using the APHIS/CDC Form 4A. In 2020, *Bacillus anthracis* was the most identified BSAT for DASAT. Highly pathogenic avian influenza virus was the most identified BSAT for DASAT in 2019 and 2015, while Newcastle disease virus was the most identified in 2018, 2017, and 2016.

Table 11: BSAT Reported to DASAT on Form 4A by Sample Type, 2020

BSAT	Animal Specimens	Environmental Samples	Plant Samples	Human Specimens	Total
Brucella suis	0	0	0	1	1
Avian influenza virus	10	0	0	0	10
Ralstonia solanacearum	0	0	17	0	17
Bacillus anthracis	13	6	0	0	19
Newcastle disease virus	4	0	0	0	4
African swine fever virus	1	0	0	0	1
Total	**28**	**6**	**17**	**1**	**52**

In 2020, DASAT received no APHIS/CDC Form 4Bs reporting BSAT identified through proficiency testing, compared to two reports in 2019 and 2018, and one report in both 2017 and 2016. DASAT received no reports from federal law enforcement regarding seizure of BSAT in 2020 (APHIS/CDC Form 4C); nor did DASAT receive any such reports in the previous five years.

Emergency Management

FSAP monitors registered entities that may be affected by external threats to their operations, such as severe weather or natural disasters, for impacts to employee safety or BSAT security. FSAP contacts the registered entities and assists with safely transferring or securing BSAT as needed. There were 17 events in 2020, and FSAP contacted 140 affected entities. Table 12 summarizes FSAP's assistance efforts during weather, natural disasters, or other emergencies in 2020. FSAP successfully contacted all affected entities and none required FSAP assistance. There were no thefts, losses, or releases of BSAT as the result of any external threats in 2020.

Table 12: FSAP Emergency Management, 2020

2019 Event	Number of Entities Contacted
Earthquake in Puerto Rico	1
Flooding in Mississippi	1
Tornadoes in Tennessee	2
Earthquake in Utah	1
Tornadoes in Southeast	5
Civil Unrest in the U.S.	14
Tropical Storm Cristibol	8
Hurricane Hanna	13
Hurricane Douglas	4
Hurricane Isaias	9
Hurricane Laura/Marco	13
California Wildfires	29
Oregon Wildfires	1
Hurricane Sally	8
Hurricane Delta	12
Colorado Wildfires	3
Tropical Storm Zeta	16
Total	**140**

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

FSAP engages and partners with the regulated community to identify solutions that ensure compliance with the SAR. For the benefit of the regulated community, FSAP periodically publishes Federal Register Notices, policy statements, regulatory interpretations, guidance documents, and frequently asked questions (FAQs). In 2020, FSAP did not publish any regulatory interpretations. Federal Register Notices, policy statements, and guidance documents issued by FSAP in 2020 are located on the FSAP website and are summarized in Table 13.

Table 13: FSAP Federal Register Notices, Policy Statements, and Guidance

Federal Register Notices	Month
Advanced Notice of Proposed Rulemaking for HHS Select Agent Regulations	March
Advanced Notice of Proposed Rulemaking for USDA Select Agent Regulations	March
Select Agent Forms Available for Public Comment	April

Policy Statements	Month
Revised Policy Statement Regarding Laboratory Work with Genomes Capable of Producing Infectious Virus of Regulated Risk Group 3 and 4 Select Agents and Veterinary Services Select Agents at One Containment Level Lower than the Infectious Virus without RNA Inactivation	February
Preview of Draft FSAP Policy Statement: Biosafety for Large Animal Study-Related Activities with *Brucella abortus* and *Brucella suis* Using Outdoor Containment Spaces	October

Guidance	Month
Revised Security Plan Guidance	February
Updated FAQs Regarding Security Risk Assessments	April
Updated Guidance on the Transfer of Select Agents and Toxins	June
New FAQs Regarding SAMS Accounts	September
Updated Responsible Official Manual and Inventory Guidance	December

Outreach

FSAP's outreach provides opportunities for program staff to interact with members of the regulated community. Table 14 summarizes outreach events that FSAP either organized or participated in during 2020.

Table 14: FSAP Outreach Events, 2020

Conference[1]	Date	Booth Attendees
16th CDC International Biosafety Symposium	March 2-3	48
ABSA Virtual Conference	November 4-6	167

eFSAP Information System Webinars[2]	Date	Attendees
eFSAP New Entity Release	March 23, 25, 26	105
eFSAP Updates	July 7, 8, 9	148
eFSAP Updates	September 18, 19	100

RO Webinar Series[3]	Date	Attendees
Directors' Updates and Question and Answer Session	May 27	170
FSAP Operations Updates	June 24	179
Site-Specific Risk Assessment	August 5	205
Inactivation	September 30	177

Other Outreach Events[4]	Date	Attendees
FSAP Multi-Agency Informational Meeting to Discuss Reporting Requirements for Entities	September 23	404

Notes:

1. FSAP exhibited an informational booth at two scientific conferences to provide guidance and promote compliance with the SAR. Due to the COVID-19 pandemic, one of the conferences was held virtually, and FSAP exhibited a virtual booth to interact with conference attendees.
2. FSAP conducted eight webinars for ROs and AROs to provide guidance on the eFSAP information system, the program's secure web-based system that is used by registered entities to engage in bi-directional communication with FSAP. A total of 353 ROs and AROs attended the sessions.
3. Due to the COVID-19 pandemic, FSAP conducted a series of four webinars for ROs and AROs to replace its usual annual multi-day in-person workshop for the regulated community. Attendance ranged from 170 to 205 ROs/AROs for each webinar. This seminar series allowed FSAP the opportunity to interact with the regulated community when it was not possible to meet in person due to travel and mass gathering restrictions related to the COVID-19 pandemic.
4. FSAP held a multi-agency meeting to provide guidance and information regarding the submission of APHIS/CDC Form 2, APHIS/CDC Form 3, and APHIS/CDC Form 4. In addition to FSAP, representatives from the U.S. Department of Transportation and the Minnesota Department of Health also presented during the meeting. A total of 404 attendees participated in this meeting.

In addition to the above, in 2020, FSAP also conducted the following efforts to engage with the regulated community:

- FSAP invited recently inspected entities to submit feedback surveys anonymously following inspections to assist FSAP in gauging its performance during inspections and to identify ways to improve the inspection process.
- FSAP distributes Select Agent (SA) Grams (an electronic communication used to disseminate information to the regulated community) on important programmatic updates on topics such as new policies, guidance documents, regulatory interpretations, and training opportunities. In 2020, FSAP issued 52 SA Grams.

Conclusion

FSAP was established in response to a Congressional mandate to ensure the safety and security of research with BSAT. Overall, most of the 244 entities registered with FSAP are compliant with the regulations as evidenced by the small number of compliance issues identified in this report. Also, of note, none of the releases resulted in illnesses among the general public, nor did they result in death of or transmission among workers or transmission to the outside of a laboratory into the surrounding environment or community. As part of ensuring the security of BSAT, FSAP employs the SRA process, which makes sure that individuals are screened prior to allowing access to BSAT in order to keep these materials out of the hands of individuals that are identified as "restricted" persons. In 2020, 12 individuals were determined to be "restricted" and were prohibited access to BSAT based on federal statute. There were 2,577 individuals (new and renewals) granted access to BSAT. With oversight from the Federal Select Agent Program, entities are able to work as safely and securely as possible with select agents and toxins. This has led to important scientific discoveries that have improved diagnostics and detection, treatment and prevention of human, animal and plant diseases.

Appendix for Accessibility Descriptions

Figure 1. The number of entities registered with FSAP is displayed in this line graph. The vertical y-axis is the number of entities ranging from 0 to 300, by increments of 50, and the horizontal x-axis lists the year ranging from 2015 to 2020. There are three decreasing lines: one for the total number of entities registered with FSAP, one for the number of entities registered with DSAT, and one for the number of entities registered with DASAT. The total number of entities registered with FSAP in 2015 was 291, and this decreased to 244 in 2020. For DSAT, the number of registered entities in 2015 was 251, and this decreased to 209 in 2020. For DASAT, the number of registered entities in 2015 was 40, and this decreased to 35 in 2020 (page 12).

Figure 2. The number of entities registered with FSAP is displayed in this horizontal bar graph. The vertical y-axis lists the five entity types (private, federal government, commercial, academic, non-federal government), and the horizontal x-axis lists the number of entities ranging from 0 to 80 in increments of 20. For each entity type, there are two bars representing the number of entities registered with either DASAT or DSAT. From top to bottom, the numbers of entities are: private (2 for DASAT, 12 for DSAT), federal government (7 for DASAT, 30 for DSAT), commercial (8 for DASAT, 30 for DSAT), academic (17 for DASAT, 68 for DSAT), and non-federal government (1 for DASAT, 69 for DSAT) (page 13).

Figure 3. The number of FSAP inspections conducted by inspection type is displayed in this horizontal bar graph. The vertical y-axis lists the six inspection types (verification, renewal, new space, maximum containment, new registration, compliance), and the horizontal x-axis lists the number of inspections ranging from 0 to 80 in increments of 20. For each inspection type, there are three bars representing the number of inspections conducted by either DASAT or DSAT, or as a joint inspection. From top to bottom, the numbers of inspections are: verification (10 for joint, 13 for DASAT, 21 for DSAT), renewal (20 for joint, 7 for DASAT, 62 for DSAT), new space (0 for joint, 0 for DASAT, 4 for DSAT), maximum containment (2 for joint, 0 for DASAT, 1 for DSAT), new registration (2 for joint, 0 for DASAT, 2 for DSAT), and compliance (2 for joint, 0 for DASAT, and 3 for DSAT) (page 18).

Figure 4. The number of approved BSAT transfers is displayed in this line graph. The vertical y-axis is the number of approved BSAT transfers ranging from 0 to 500, by increments of 50, and the horizontal x-axis lists the year ranging from 2015 to 2020. There are three decreasing lines: one for the total number of approved BSAT transfers for FSAP, one for the number of approved BSAT transfers for DSAT, and one for the number of approved BSAT transfers for DASAT. The total number of approved BSAT transfers for FSAP in 2015 was 463, and this decreased to 183 in 2020. For DSAT, the number of registered entities in 2015 was 337, and this decreased to 157 in 2020. For DASAT, the number of registered entities in 2015 was 126, and this decreased to 26 in 2020 (page 22).

References

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

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

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

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

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

2019 Annual Report of the Federal Select Agent Program. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and US Department of Agriculture, Animal and Plant Health Inspection Service. September 2020.

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