2022 Annual Report of the
Federal Select Agent Program

CDC USDA

CS343392-A

Contents

Acronyms

Table: List of Acronyms with descriptions

Acronym	Description
APHIS	The **Animal and Plant Health Inspection Service**, located within the United States Department of Agriculture, is a multi-faceted agency with work centered around animal and plant health, but programs also address animal welfare, biotechnology, wildlife damage management, and global trade.
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.
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.
BSL	A **Biosafety Level** is an enclosed, ventilated laboratory workspace for safely working with materials contaminated with (or potentially contaminated with) pathogens requiring a defined biosafety level.
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, animal and plant health, and/or animal and plant products. 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 United States 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.
DSAT	The **Division of Select Agents and Toxins**, located within the Office of Readiness 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.

Acronym	Description
eFSAP	The **electronic Federal Select Agent Program information system** allows registered entities to manage their registrations and directly interact with the Federal Select Agent 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 **United States 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.
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, Responsible Officials, Alternate Responsible Officials, 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 Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act.
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/Office of Readiness 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. 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 helping to ensure 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 eighth annual report and summarizes data for calendar year 2022. 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, 2022, 234 entities were registered with the Federal Select Agent Program: 36 entities registered with the Division of Agricultural Select Agents and Toxins as the lead agency and 198 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 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 2022, 51 of the 234 registered entities were jointly managed: The Division of Agricultural Select Agents and Toxins served as the lead agency for 11 entities and the Division of Select Agents and Toxins served as the lead agency for 40 entities.

In 2022, seven entities applied to the Federal Select Agent Program for new registrations, and eight additional applications were pending from previous years. Three new entity registration applications were approved in 2022. Two entities withdrew their registrations from the Federal Select Agent Program, both from the Division of Select Agents and Toxins. Entities withdraw their registrations when they no longer need to possess, use, or transfer biological select agents or toxins.

Security Risk Assessments

The Bioterrorism Risk Assessment Group, a program within 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, 2022, the Federal Select Agent Program had 8,516 individuals approved to access biological select agents and toxins. Based on security risk assessments conducted during 2022, the Federal Select Agent Program granted 3,861 new approvals for access to biological select agents and toxins (i.e., new individuals, renewals, and individuals approved for access at multiple entities). In 2022, the Bioterrorism Risk Assessment Group identified 16 individuals as "restricted persons"[1] and the Federal Select Agent Program prohibited them from having access to biological select agents and toxins. The most common reason for restriction (11 of the 16 individuals) was due to a conviction in any court of a crime punishable by imprisonment for a term exceeding one year.

*As of October 1, 2023, the Division of Select Agents and Toxins has been renamed to the Division of Regulatory Science and Compliance. Because this report pertains to information about the Federal Select Agent Program from 2022, the previous name (Division of Select Agents and Toxins, or DSAT) is used throughout.

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

Inspections

The Federal Select Agent Program conducted 197 inspections in 2022: 18 by the Division of Agricultural Select Agents and Toxins, 133 by the Division of Select Agents and Toxins, and 46 jointly.

Compliance Actions

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

- Participation by 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 and toxin 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 2022 is as follows:

- No new entities entered the Federal Select Agent Program Corrective Action Plan program.
- No entities had their registrations suspended.
- No entities were referred to the Health and Human Services Office of Inspector General or the Animal and Plant Health Inspection Service Investigative and Enforcement Services.
- The Federal Select Agent Program notified the Federal Bureau of Investigation of 24 matters for potential investigation. Based on the information provided, none of the notifications for security-related issues were considered by the FBI for criminal 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 and toxin regulations occurred. In 2022, the Federal Select Agent Program received one such report from the Health and Human Services Office of Inspector General about safety concerns involving a non-select agent, and the claims could not be verified. The report was referred to the Occupational Safety and Health Administration for further investigation.

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 the additional testing of identified biological select agents and toxins from diagnostic specimens, scientific or clinical research, and the production of therapeutics. In 2022, the Federal Select Agent Program approved 252 transfers: 192 (including 33 importations) by the Division of Select Agents and Toxins and 60 (including 19 importations) by the Division of Agricultural Select Agents and Toxins. During 2022, 220 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 2022, the Federal Select Agent Program received six reports of losses, 170 reports of releases, and no reports of thefts. The six losses were reported to the Federal Bureau of Investigation for investigation. None of the releases resulted in illness, nor did they result in any deaths or transmission among workers or to the outside of a laboratory into the surrounding environment or community.

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 892 such notifications in 2022, 159 to the Division of Agricultural Select Agents and Toxins and 733 to the Division of Select Agents and Toxins.

The biological select agents and toxins most frequently identified and reported to the Division of Select Agents and Toxins in 2022 were Botulinum neurotoxin (206), Botulinum neurotoxin producing species of *Clostridium* (135), *Francisella tularensis* (90), *Brucella melitensis* (overlap select agent) (86), and *Coxiella burnetii* (63). The biological select agents most frequently identified and reported to the Division of Agricultural Select Agents and Toxins in 2022 were Avian influenza virus (132), *Ralstonia solanacearum* (11), and *Bacillus anthracis* (overlap select agent) (6).

Conclusion

Overall, most of the 234 entities registered with the Federal Select Agent Program are compliant with the select agent and toxin regulations, as evidenced by the small number of compliance issues identified in this report. Also of note, none of the releases resulted in illness, nor did they result in death of or transmission among workers or transmission outside of a laboratory into the surrounding environment or community. None of the small number of reported incidents during the year resulted in a significant risk to public or agricultural health. Of the 8,516 individuals with access to biological select agents and toxins, 16 individuals were determined to be “restricted” and were prohibited access to biological select agents and toxins. With oversight from the Federal Select Agent Program, entities continue to work as safely and securely as possible with select agents and toxins.

FEDERAL SELECT AGENT PROGRAM:
BY THE NUMBERS
2022

234

entities registered

8,516

individuals approved to access biological select agents and toxins

197

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
SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors
Saxitoxin
South American hemorrhagic fever viruses:
- 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 November 17, 2021

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 involving biological select agents and toxins (BSAT). With oversight from FSAP, entities continue to work as safely and securely as possible with BSAT. This work 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)/Office of Readiness and Response (ORR)/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 and toxin regulations (SAR).[2]

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 SAR;
- 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 virtual and in-person trainings, workshops, and webinars, as well as participating in conferences.

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, BSAT that each entity is registered for, and the names of individuals with access to BSAT, as well as other information about each entity. 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, and strains/serotypes of BSAT in their possession; 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, providing a preview of items that will be assessed during the inspection and notification of when inspection findings are released, as well as permitting entities to directly respond to the inspection findings by uploading documented proof of any required corrective actions.

The use of the eFSAP information system has resulted in substantial increases in program efficiency and effectiveness. With eFSAP, 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.

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

Key Program Statistics

Registration

Registered Entities

BSAT are divided into three categories based on whether an agent or toxin causes disease in humans, animals or plants, or a combination of humans and animals (see current list found on page 24). 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; and
- Information about where the work will be performed.

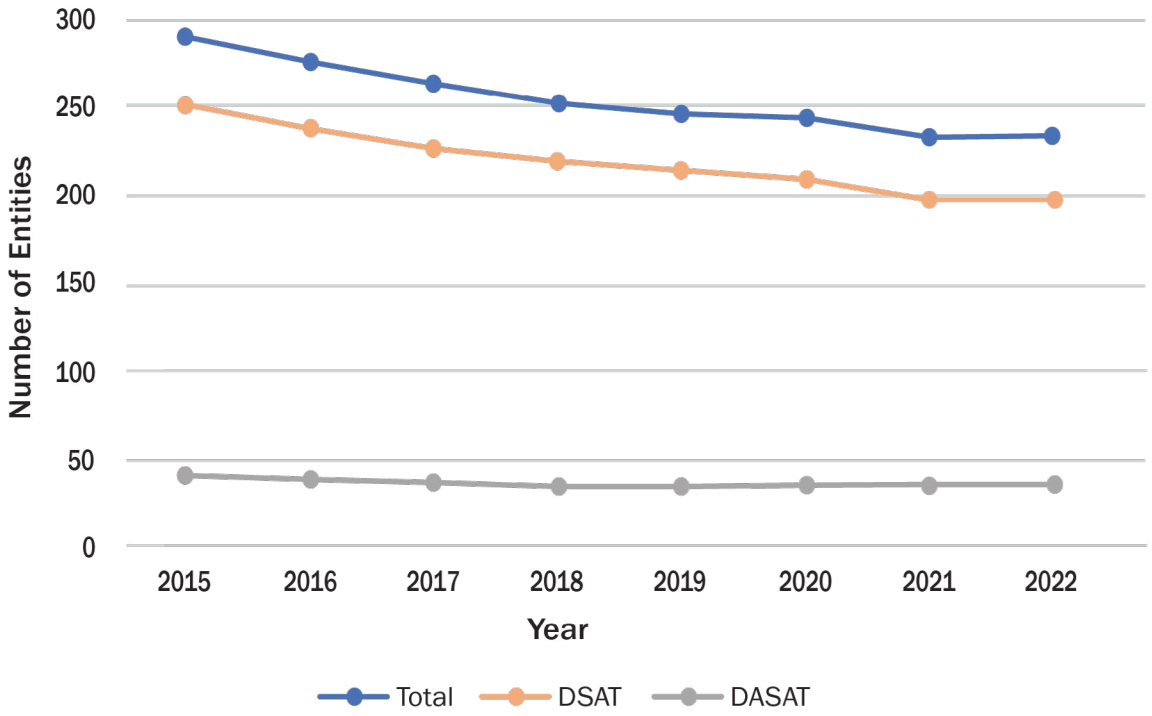
After submission of the APHIS/CDC Form 1, FSAP will review and schedule a site inspection to verify the submitted information and to confirm that the entity is compliant with the SAR. Once the inspection is complete and the entity fulfills all regulatory requirements, FSAP will issue a certificate of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

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 2022, 234 entities were registered with FSAP: 36 with DASAT and 198 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 2022, DASAT and DSAT jointly oversaw 51 of the 234 total entities registered with FSAP: DASAT served as the lead agency for 11 of those entities and DSAT served as the lead agency for 40 of those entities. While there has been a general downward trend in the number of registered entities since 2015, there was a slight increase (by one entity) in 2022.

Figure 1: Number of FSAP-Registered Entities by Agency and Year, 2015-2022.

For a description of the chart go to page 26.



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.

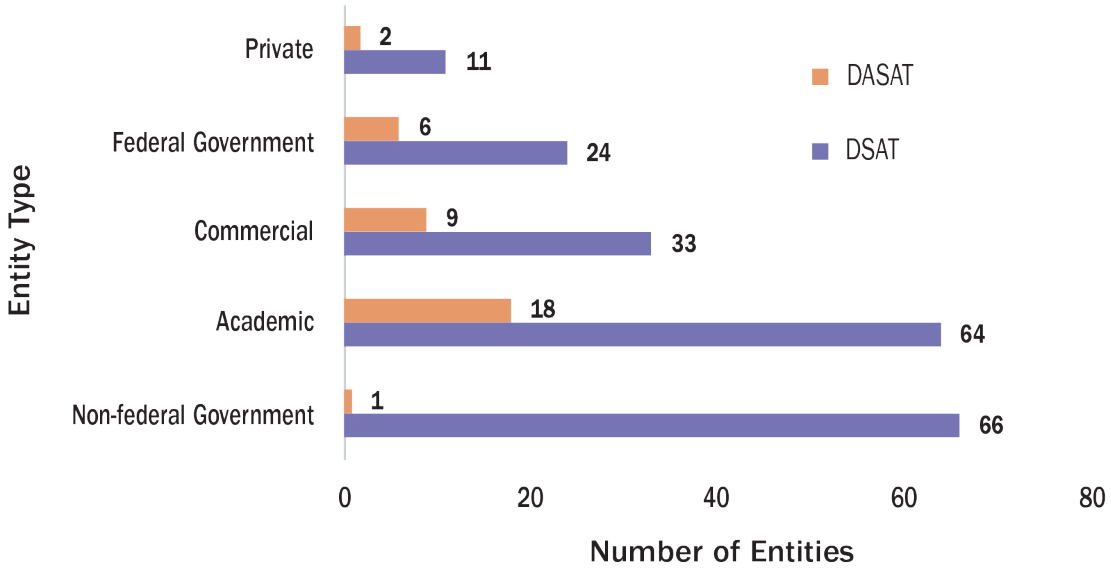
Regulated entities during calendar year 2022 consisted of:

- 35% academic,
- 29% non-federal government,
- 17% commercial,
- 13% 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 2022.

Figure 2: Number of FSAP-Registered Entities by Type, 2022.

For a description of the chart go to page 26.



New Registration Applications

During 2022, FSAP reviewed 15 new registration applications from entities that wished to register. FSAP received seven of those applications in 2022, and the approval process was still underway for six of those as of December 31, 2022 (the remaining one application from 2022 was withdrawn during the year). The other eight applications had been received in previous years: two in 2019, one in 2020, and five in 2021. Of these, three applications from 2021 were approved in 2022. Two applications (one from 2020 and one from 2021) were withdrawn, and the other three applications were still under review as of the end of 2022. In total, three new registration applications were approved in 2022.

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 documented proof 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 its registration, it must reapply to obtain a new FSAP certificate of registration.

As shown in Table 1, two entities (both registered with DSAT) withdrew their registration in 2022. The reason entities cited for withdrawing was that they no longer needed to possess or work with BSAT. A total of 95 entities withdrew their registrations during 2015-2022.

Table 1: Number of Entity Withdrawals by Entity Type, 2022

Entity Type	Number of Withdrawals
Academic	1
Private	1
Total	2

Renewals

Typically, a registered entity must renew its registration at least every three years. In 2022, FSAP approved a total of 96 renewals: 22 by DASAT and 74 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 the 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 938 amendments to registration approved in 2022 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, 2022

Registration Amendment Using APHIS/CDC Form 1	DASAT	DSAT	Total
Section 1 - Change Entity Physical or Additional Address	1	6	7
Section 4 - Change Responsible Official	7	40	47
Section 5A - Modify Entity-Wide Security Assessment and Incident Response	2	9	11
Section 5B - Modify Entity-Wide Biosafety/Biocontainment	3	8	11
Section 5C - Modify Entry Requirements for FSAP Inspectors	5	25	30
Section 6 - Modify Building	0	2	2
Section 6 - Modify Room or Suite	24	46	70
Section 7AC - Add New Work Objective	20	81	101
Section 7AC - Modify Work Objective and/or Attachment(s)	55	532	587
Section 7AC - Remove Approved Work Objective	12	58	70
Other Amendments (Including Registration Withdrawals)	0	2	2
Total Approved Amendments	**129**	**809**	**938**

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 removing 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 2022, 120 entities were registered with FSAP for Tier 1 BSAT: 10 with DASAT (representing 28% of all DASAT-led entities) and 110 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 51% of FSAP-regulated entities in 2022 (120 total entities).

Top BSAT Registered with Each Agency

Table 3 lists the BSAT most frequently registered with each agency. 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 seven years.

Table 3: Most Frequently Registered Agents with Each Agency, 2022

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. *Bacillus anthracis**
6. *Yersinia pestis**	6. *Francisella tularensis**,+ African swine fever virus *Brucella abortus*
7. Botulinum neurotoxin producing species of *Clostridium**	
8. Eastern Equine Encephalitis virus *Bacillus anthracis**	7. Rift Valley fever virus *Rathayibacter toxicus*
9. *Burkholderia pseudomallei**	

**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 2022, 28% of entities were approved to work in a BSL-2/ABSL-2 laboratory, 80% 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 approved to work at each BSL/ABSL by entity type, as well as the number of entities that are approved to work with Tier 1 BSAT at each BSL/ABSL.

Table 4: Number of Entities by Laboratory and Entity Type, 2022

Laboratory Type: Biosafety Level	Total Registered Laboratories	Registered for Tier 1 BSAT	Entity Type: Commercial	Entity Type: Federal Government	Entity Type: Academic	Entity Type: Non-Federal Government	Entity Type: Private
BSL-2/ABSL-2	66	49	19	13	20	10	4
BSL-3/ABSL-3	187	97	19	20	70	66	12
BSL-4/ABSL-4	8	8	0	5	2	0	1

Note: Entities may be approved to work in multiple 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 [18 USC 175b(d)(2)]. An SRA is a BRAG electronic records check to determine whether an entity or an individual is a "restricted person" as identified by one of the statutory restrictors which would either deny or limit access. The results of an SRA assist FSAP in determining whether an individual or entity can have access to BSAT. By regulation, an SRA is valid for three years, at which point access approval must be renewed.

At the end of 2022, there were 8,516 unique individuals with current SRAs approved for access to BSAT. In 2022, FSAP granted 3,861 approvals (new and renewal applications) for access to BSAT (Table 5). The total number of individuals approved for access to BSAT per entity type (8,846 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 a collaborator or guest researcher) based on one current SRA. Thirty-seven percent (37%) 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 eighth 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, 2022

Entity Type	Access Approvals (New Approvals and Renewals)	Total Access Approvals as of December 31
Academic	1,409	3,282
Federal Government	1,174	2,667
Non-Federal Government	400	922
Commercial	512	1,148
Private	366	827
Total	**3,861**	**8,846**

In 2022, 16 individuals were identified as a "restricted person" and were therefore not granted access to BSAT. This number is in the range observed from 2015-2021 (10 to 30 per year). Individuals can appeal their determination as a "restricted person," and in 2022, five individuals submitted appeals. Of the five, two appeals led to the "restricted person" determination being overturned.

Table 6 summarizes the reasons for restriction for the 22 individuals.

Table 6: Total Number of Restricted Persons Identified by Restrictor Type, 2022

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)	11
An alien illegally or unlawfully in the United States	3
Unlawful user of any controlled substance	1
Adjudicated as a mental defective	1
Total	**16**

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 biosecurity of the work with BSAT. The different types of FSAP inspections are:

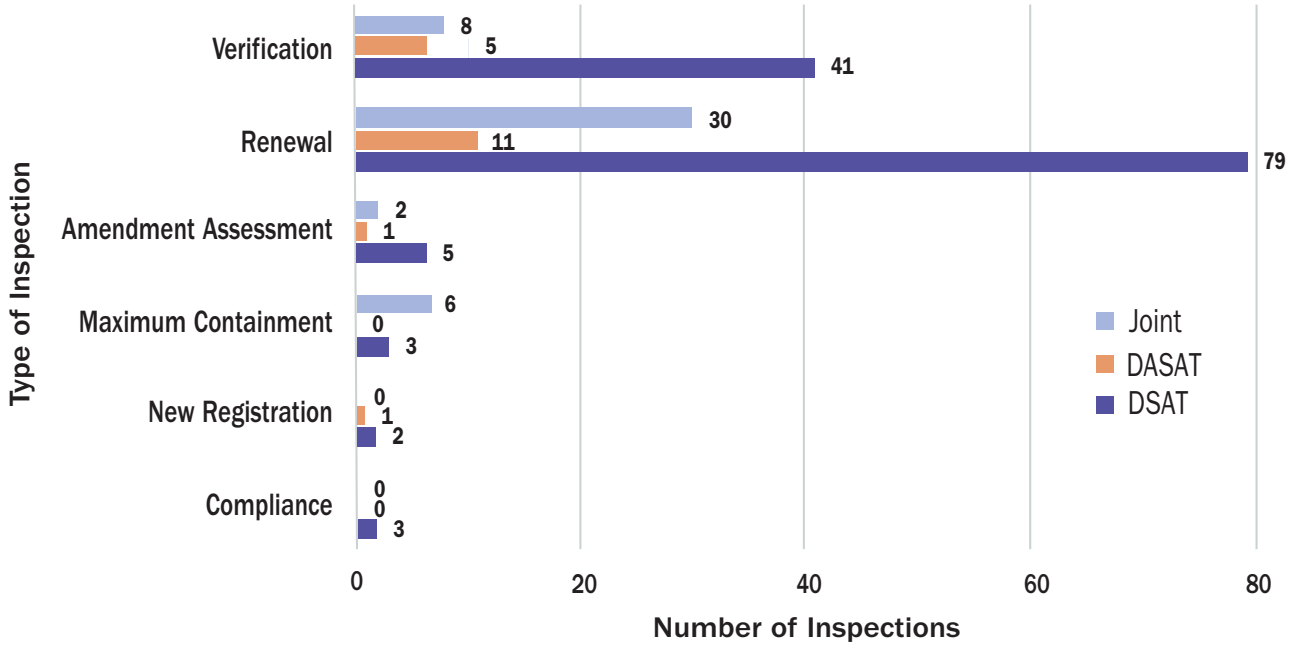
- **Compliance** – Review of entity's registration, including laboratory spaces and documents (e.g., plans, records, facility verification documentation), with a focus on compliance issues.
- **Maximum Containment** – Review of entity's registered maximum containment program, including laboratory spaces and documents specific to work that requires the highest levels of containment (BSL-4/ABSL-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.
- **Amendment Assessment/New Space** – Review of information submitted as part of an amendment to an entity's registration that requires an inspection before approval, or 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 that are the highest risk for compliance issues, 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 2022, FSAP performed 197 inspections: 18 by DASAT, 133 by DSAT, and 46 jointly.

Figure 3 compares the number of each type of inspection conducted in 2022 by either DSAT, DASAT, or both jointly.

Figure 3: Number of Inspections by Lead Agency and Type, 2022.

For a description of the chart go to page 26.



**Four of the maximum containment inspections, two of the compliance inspections, and one of the amendment assessment/new space inspections were also renewal inspections.*

Inspection Findings and Compliance

A goal of the SAR is to ensure a registered entity has and maintains the operating conditions necessary to minimize biosafety and security risks when dealing with select agents and toxins. FSAP works closely with all regulated entities to assist them with compliance to the SAR.

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.

No new entities joined the CAP program in 2022. During the year, three entities continued to participate in the CAP program (all of which began in 2020). Two of the three entities successfully completed the requirements of the CAP program, and one entity continued its participation in the CAP program into 2023. .

Registration Suspensions

An entity's registration can be suspended when a departure from the SAR poses a danger to human, animal, and/or plant health, or to public safety, or to protect animal or plant products. 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 may be suspended, allowing continuation of other work at another part of the entity. In 2022, no entities had their registrations suspended.

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 2022, FSAP received one report made to HHS OIG. The 2022 report did not involve BSAT, and the claims could not be verified. The report was referred to the Occupational Safety and Health Administration for further consideration. 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 2022, no entities were referred to the HHS OIG or APHIS IES. Since 2015, a range of zero to seven entities have been referred to either HHS OIG or APHIS IES each year.

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, a security breach of BSAT storage space, or the discovery of BSAT outside of registered space or not part of inventory) and any report of a theft or loss of BSAT. FSAP also supports FBI investigations upon request.

In 2022, FSAP notified the FBI of 24 security-related issues.

- Seventeen notifications concerned the discovery of BSAT that was either outside of registered space or not part of the entity's inventory of record for BSAT held in registered space.
- Seven notifications concerned the loss of BSAT. One loss was recovered by the entity after notification was made to the FBI but prior to submission of the APHIS/CDC Form 3. For the other six notifications, these were issues related to record keeping – either inventory record discrepancies of BSAT due to the BSAT being used or destroyed without updating the inventory record, or losses attributed to record keeping errors.

Based on the information provided, none of the notifications for security-related issues were considered by the FBI for criminal investigation.

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 three types of restricted experiments:

1. 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 select agents and toxins, USDA Veterinary Services (VS) select agents, and overlap select 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 Plant Protection and Quarantine (PPQ) select agents).

2. The deliberate formation of synthetic or recombinant DNA containing genes for the biosynthesis of a select toxin lethal for vertebrates at an LD50 < 100 ng/kg body weight. Currently, only one HHS-only select toxin (botulinum neurotoxin) possesses an LD50 < 100 ng/kg body weight.
3. Experiments that involve the creation of SARS-CoV/SARS-CoV-2 chimeric viruses (HHS-only select agent) resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors or vice versa.

In 2022, FSAP received one request that met the restricted experiment definition. The request involved the production of recombinant versions of botulinum neurotoxin and was approved.

Exclusion Requests

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 no new exclusion requests pursuant to the select agent and toxin regulations in 2022.

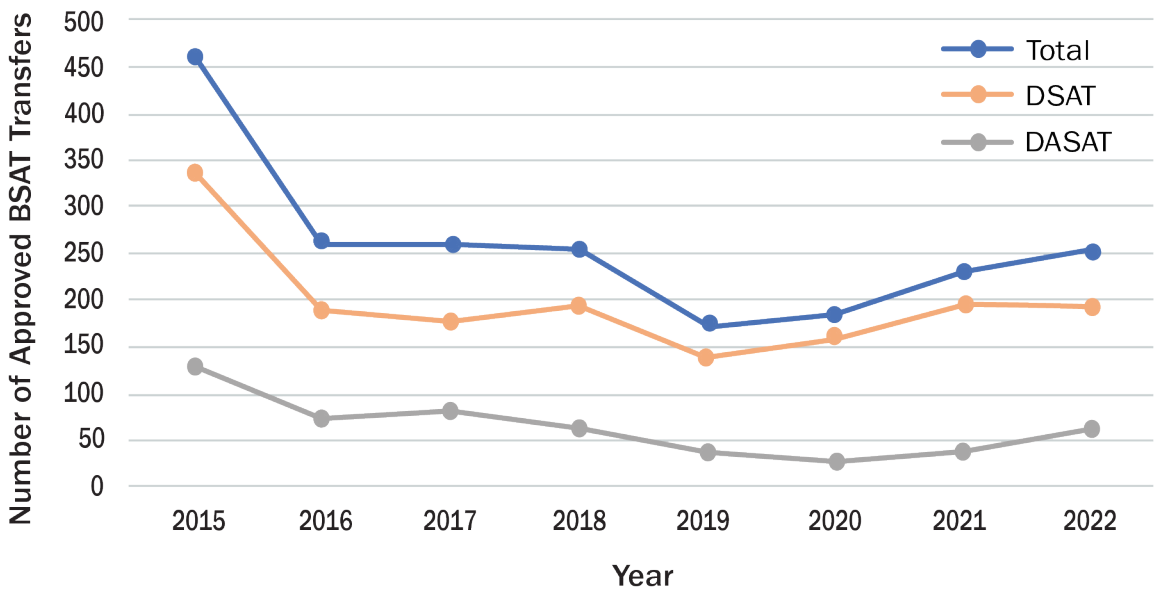
Transfers of BSAT

Entities (registered or not) use the Request to Transfer Select Agents and Toxins form (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 2022, FSAP approved 252 BSAT transfers – 60 by DASAT and 192 by DSAT (Figure 4). For the 60 transfers approved by DASAT, this represented 23 recipient entities requesting a transfer and 32 sender entities. For the 192 transfers approved by DSAT, this represented 50 recipient entities requesting a transfer and 48 sender entities. Seventy (28%) of the approved transfers in 2022 involved unregistered entities transferring BSAT to registered entities. These transfers were either imported BSAT (52) or occurred after the identification of BSAT in a diagnostic specimen (18). Of the 52 imported BSAT, DASAT approved 19 transfers, and DSAT approved 33. For the 18 BSAT identified in diagnostic specimens by unregistered entities, DASAT approved 16 transfers, and DSAT approved 2.

In 2022, 220 BSAT transfers occurred during the year, including five transfers that had been approved in 2021 but not shipped until 2022. Three transfers were approved towards the end of 2022 but had not yet been shipped as of December 31, 2022, and 34 approved transfers were cancelled by the entities before shipping the BSAT.

Figure 4: Total Number of Approved BSAT Transfers, 2015-2022.

For a description of the chart go to page 26.



The increases in the total number of approved transfers for FSAP and for DASAT were due to the outbreak of Highly Pathogenic Avian influenza virus in 2022, and the transfers of materials related to the outbreak.

For DASAT, Avian influenza virus was the most frequently transferred BSAT in 2022 (as well as in 2015-2020) (Table 7), while African swine fever virus was the most frequently transferred BSAT in 2021.

Table 7: Number of BSAT Transfers (APHIS/CDC Form 2) Approved by DASAT, 2022

BSAT	Total*
African swine fever virus	9
Avian influenza virus	35
Brucella abortus	1
Brucella melitensis	1
Coniothyrium glycines (formerly *Phoma glycinicola* and *Pyrenochaeta glycines*)	3
Foot-and-mouth disease virus	2
Newcastle disease virus	1
Ralstonia solanacearum	6
Xanthomonas oryzae	2

**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 2022 (Table 8) and has been since 2016.

Table 8: Number of BSAT Transfers (APHIS/CDC Form 2) Approved by DSAT, 2022

BSAT	Total*
Bacillus anthracis	4
Bacillus anthracis (Pasteur strain)	1
Botulinum neurotoxin producing species of *Clostridium*	29
Botulinum neurotoxins	75
Brucella abortus	15
Brucella melitensis	4
Brucella suis	2
Burkholderia mallei	6
Burkholderia pseudomallei	14
Coxiella burnetii	5
Crimean-Congo haemorrhagic fever virus	1
Eastern Equine Encephalitis virus	3
Ebola virus	5
Francisella tularensis	8
Hendra virus	5
Lassa fever virus	7
Marburg virus	4
Monkeypox virus	8
Nipah virus	4
Rickettsia prowazekii	5
Rift Valley fever virus	2
SARS-associated coronavirus (SARS-CoV)	10
South American Haemorrhagic Fever virus: Chapare	1
South American Haemorrhagic Fever virus: Junin	1
Staphylococcal enterotoxins A, B, C, D, E subtypes	1
Venezuelan equine encephalitis virus	6
Yersinia pestis	6

**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 non-registered entities 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 are to provide a list of federal, state, or local law enforcement agencies that were contacted, or are intended to be contacted, in the case of a theft or loss. All thefts or losses must be reported to FSAP, even if the BSAT is subsequently recovered and/or the responsible parties are identified.

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 biological safety cabinet;
- Failure or problem with personal protective equipment (PPE);
- Needlestick or other percutaneous exposures with contaminated sharp objects; or
- Open bench work involving diagnostic samples (later identified as BSAT) without appropriate PPE.

In 2022, FSAP received 6 reports of losses, 170 reports of releases, and no reports of thefts.

For the 170 reports of releases, 63 were submitted by registered entities and 107 by non-registered entities. FSAP reviews each report of a release to determine the potential for occupational exposure.

- FSAP agreed with the reporting entities that 27 releases presented minimal to no risk of occupational exposure.
- The remaining 143 releases involved occupational exposure to BSAT.
  - In 10 of the 143 releases, the reporting entity determined that no occupational health services were necessary based on the circumstances of the release.
  - In the remaining 133 releases, the reporting entities provided occupational health services (including medical assessments, diagnostic testing and/or pharmaceutical prophylaxis) to a total of 595 individuals (61 individuals from 32 registered entities and 534 individuals from 101 non-registered entities).

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

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 from a clinical or diagnostic specimen. 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 2022, FSAP received and processed 892 reports of the identification of BSAT on APHIS/CDC Form 4As as a result of diagnosis or verification. DSAT received and processed 733 of those APHIS/CDC Form 4A reports. Botulinum neurotoxin was the most commonly identified BSAT reported to DSAT, followed by botulinum neurotoxin-producing species of *Clostridium* and *Francisella tularensis* (Table 9). In recent years, Botulinum neurotoxin has been the most commonly identified BSAT (2016-18, 2020-21), with the exception of 2019 (Eastern Equine Encephalitis virus) and 2015 (*F. tularensis*).

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 16% 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 sample, transfer the sample to an entity registered to possess that BSAT, or destroy the sample.

In 2022, DSAT received 10 APHIS/CDC Form 4Bs reporting BSAT identified through proficiency testing, compared to an annual range of zero to 63 reports over the previous seven 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 9: BSAT Reported to DSAT on APHIS/CDC Form 4A by Sample Type, 2022

BSAT	Animal Specimens	Environmental Samples	Food Samples	Human Specimens	Total
Bacillus anthracis	1	0	0	1	2
Botulinum neurotoxin producing species of *Clostridium*	0	2	5	127	134
Botulinum neurotoxins	19	0	7	184	210
Brucella abortus	5	0	0	21	26
Brucella melitensis	0	0	0	86	86
Brucella suis	3	0	0	24	27
Burkholderia pseudomallei	7	6	0	18	31
Coxiella burnetii	52	0	0	9	61
Eastern Equine Encephalitis virus	50	5	0	0	55
Francisella tularensis	32	0	0	57	89
Mpox virus*	1	0	0	4	5
Ricin	0	1	0	0	1
Rickettsia prowazekii	0	0	0	1	1
Rift Valley fever virus	0	0	0	1	1
Staphylococcal enterotoxins A, B, C, D, E subtypes	0	0	1	0	1
T-2 toxin	0	0	1	0	1
Yersinia pestis	2	0	0	0	2
Total	**172**	**14**	**14**	**533**	**733**

**Both reports of Mpox virus were part of the 2022 U.S. outbreak of Mpox virus. The 2022 outbreak was due to an excluded clade of Mpox (Clade II). However, if the clade was not determined during identification, then it was to be reported on the APHIS/CDC Form 4A.*

DASAT received and processed 159 APHIS/CDC Form 4A reports in 2022 (Table 10). For DASAT, non-registered laboratories accounted for 15% of all reports of the identification of BSAT using the APHIS/CDC Form 4A. For DASAT, the most commonly identified BSAT has varied widely in recent years. In 2022, Avian influenza virus was the most identified BSAT for DASAT due to a large continuing outbreak during the year. *Ralstonia solanacearum* was the most identified BSAT in 2021, while *Bacillus anthracis* was the most identified BSAT in 2020. Avian influenza virus was the most identified BSAT for DASAT in 2019 and 2015. Newcastle disease virus was the most identified in 2018, 2017, and 2016.

In 2022, DASAT received one APHIS/CDC Form 4B reporting BSAT identified through proficiency testing, compared to an annual range of zero to two reports over the previous seven years. DASAT received no reports from federal law enforcement regarding seizure of BSAT in 2022 (APHIS/CDC Form 4C); nor did DASAT receive any such reports in the previous seven years.

Table 10: BSAT Reported to DASAT on APHIS/CDC Form 4A by Sample Type, 2022

BSAT	Animal Specimens	Plant Samples	Total
Avian influenza virus	132	0	132*
Ralstonia solanacearum	0	12	12
African swine fever virus	8	0	8
Bacillus anthracis	6	0	6
Brucella suis	1	0	1
Total	**147**	**12**	**159**

** The total number of identifications of Avian influenza virus is higher than the number of submitted APHIS/CDC Form 4As due to an approved exemption from the reporting requirements during the outbreak.*

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. When an event occurs, FSAP contacts the registered entities and assists them with safely transferring or securing BSAT as needed. In 2022, FSAP identified 7 such events, and as a result, contacted 43 affected entities. Table 11 summarizes FSAP's assistance efforts during weather, natural disasters, or other emergencies in 2022. 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 2022.

Table 11: FSAP Emergency Management, 2022

2022 Events	Number of Entities Contacted
Winter Storm Texas/Oklahoma/ Massachusetts/Rhode Island	10
Tornado Events	10
Hurricane Ian	13
Tropical Storm Fiona	2
Flooding Alabama/Texas	3
Wildfires New Mexico	1
Subtropical Storm Nicole	4
Total	**43**

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

To assist the regulated community in complying with the SAR and to notify them of any changes to regulatory requirements, FSAP periodically publishes Federal Register Notices, policy statements, regulatory interpretations, and guidance documents. Such items issued by FSAP in 2022 are located on the FSAP website and are summarized in Table 12.

Table 12: FSAP Federal Register Notices, Policy Statements, and Guidance, 2022

Federal Register Notices	Date
Draft FSAP Policy Statement on BSL-4/ABSL-4 Laboratory Verification for Public Comment	January
Determination That Vaccine Strain, TC-83(A3G) of Venezuelan Equine Encephalitis Virus (VEEV) Is a Regulated Strain of VEEV	September
Notice of Withdrawal of Select Agent Regulatory Exclusions for Two Strains of African Swine Fever Virus	October
Policy Statements	**Date**
Draft FSAP Policy Statement on BSL-4/ABSL-4 Laboratory Verification for Public Comment	January
Guidance	**Date**
Updated Guidance Document for the Completion of APHIS/CDC Form 1	April
Updated Suitability Assessment Program Guidance	June
Updated and Finalized Inventory Guidance Document	September
Regulatory Interpretations	**Date**
Transfer of excluded or permissible amounts of HHS toxins	February
Botulinum neurotoxin genes subject to the select agent regulations	April
Validation of inactivation procedures for regulated nucleic acids	December

Outreach

FSAP's outreach efforts provide opportunities for program staff to interact with members of the regulated community. Table 13 summarizes outreach events that FSAP either organized or participated in during 2022.

Table 13: FSAP Outreach Events, 2022

Conference Exhibits[1]	Date	Booth Visitors
Association of Public Health Laboratories Virtual Conference	May 17-20	132
17th CDC International Symposium on Biosafety	August 27-31	59

RO Webinar Series[2]	Date	Attendees
RO Webinar Series Session #1	May 25	180
RO Webinar Series Session #2	July 20	219
RO Webinar Series Session #3	August 17	183
RO Webinar Series Session #4	September 21	255
RO Webinar Series Session #5	October 26	147

Notes:

1. FSAP exhibited an informational booth at two scientific conferences (Association of Public Health Laboratories Annual Conference and the CDC International Symposium on Biosafety) to provide guidance and promote compliance with the SAR. Due to the COVID-19 pandemic, FSAP exhibited a virtual booth at one of these conferences to interact with attendees.
2. FSAP conducted a series of five webinars for Responsible Officials (ROs) and Alternate Responsible Officials (AROs) in order to share information to help assist with regulatory compliance, as well as to provide updates on the program. Discussion topics included inspections, the eFSAP information system, APHIS/CDC Forms 2-4, and adding new work areas to entity registrations, among other items. Attendance ranged from 147 to 255 ROs/AROs for each webinar. More information on the presentations can be found here: https://www.selectagents.gov/resources/training.htm

In addition to the above, FSAP distributes Select Agent (SA) Grams (an electronic communication used to disseminate information to the regulated community) which include important programmatic updates on topics such as new policies, guidance documents, regulatory interpretations, and training opportunities. In 2022, FSAP issued 37 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 234 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 illness, nor did they result in death of or transmission among workers or transmission outside of a laboratory into the surrounding environment or community. None of the small number of reported incidents during the year resulted in a significant risk to public or agricultural health. In 2022, 8,516 individuals were approved to have access to BSAT, and 16 individuals were determined to be "restricted" and were prohibited access to BSAT based on federal statute. With oversight from FSAP, entities continue to work as safely and securely as possible with select agents and toxins. This work has led to important scientific discoveries that have improved diagnostics and detection, treatment, and prevention of human, animal, and plant diseases. With oversight from FSAP, entities continue to work as safely and securely as possible with select agents and toxins.This work 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 2022. There are three 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 234 in 2022. For DSAT, the number of registered entities in 2015 was 251, and this decreased to 198 in 2022. For DASAT, the number of registered entities in 2015 was 40, and this decreased to 36 in 2022. (page 10)

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, 11 for DSAT), federal government (6 for DASAT, 24 for DSAT), commercial (9 for DASAT, 33 for DSAT), academic (18 for DASAT, 64 for DSAT), and non-federal government (1 for DASAT, 66 for DSAT). (page 11)

Figure 3. The number of inspections conducted by FSAP 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 10. 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 (8 for joint, 5 for DASAT, 41 for DSAT), renewal (30 for joint, 11 for DASAT, 79 for DSAT), amendment assessment/ new space (2 for joint, 1 for DASAT, 5 for DSAT), maximum containment (6 for joint, 0 for DASAT, 3 for DSAT), new registration (0 for joint, 1 for DASAT, 2 for DSAT), and compliance (0 for joint, 0 for DASAT, and 3 for DSAT). (page 16)

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 2022. There are three 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 252 in 2022. For DSAT, the number of registered entities in 2015 was 337, and this decreased to 192 in 2022. For DASAT, the number of registered entities in 2015 was 126, and this decreased to 60 in 2022. (page 19)

References

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

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