

2025 Annual Report of the
**Federal Select
Agent Program**



Note for Accessibility: Explanations for Figures 1–4 are located in
[Appendix for Accessibility Descriptions, page 27](#)

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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 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, 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 critical 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.
DRSC	The Division of Regulatory Science and Compliance , 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/DRSC 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 Act and the Agricultural Bioterrorism Protection Act of 2002, as amended, 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 is a cabinet-level agency that provides leadership on food, agriculture, natural resources, rural development, nutrition, and related issues based on public policy, the best available science, and effective management.
USDA OIG	The USDA Office of Inspector General is an independent office within USDA dedicated to conduct audits, investigations, and reviews.

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 Regulatory Science and Compliance 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, Foot-and-Mouth disease, and the bacterial wilt of plant caused by *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 possess, use, and transfer select agents and toxins, while helping to ensure this work is done as safely and securely as possible. Since the Federal Select Agent Program's inception in 2003, there have been no deaths among laboratory workers and no reported cases of illnesses or death in the general public due to work with select agents and toxins in regulated laboratories. There have also been no animal or plant disease outbreaks due to work with select agents in regulated laboratories.

The Federal Select Agent Program publishes an annual report to communicate operational metrics to increase understanding of its work. This is the eleventh annual report and summarizes data from calendar year 2025. 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, 2025, 219 entities were registered with the Federal Select Agent Program: 40 entities registered with the Division of Agricultural Select Agents and Toxins as the lead agency and 179 entities with the Division of Regulatory Science and Compliance 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 Regulatory Science and Compliance 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 2025, 45 of the 219 registered entities were jointly managed: The Division of Agricultural Select Agents and Toxins served as the lead agency for 11 of those entities and the Division of Regulatory Science and Compliance served as the lead agency for 34 of those entities.

In 2025, four entities applied to the Federal Select Agent Program for new registrations, and six additional applications were pending from previous years. One new entity registration application was approved in 2025. A total of 12 entities withdrew their registrations from the Federal Select Agent Program because they no longer needed to possess, use, or transfer biological select agents or toxins. Of the entities that withdrew from the Federal Select Agent Program, one was registered with the Division of Agricultural Select Agents and Toxins and 11 were registered with the Division of Regulatory Science and Compliance. There were 11 fewer entities registered with the Federal Select Agent Program at the end of 2025 than at the end of 2024.

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, 2025, the Federal Select Agent Program had 8,287 total individuals approved to access biological select agents and toxins. Based on security risk assessments conducted during 2025, the Federal Select Agent Program granted 3,446 approvals for access to biological select agents and toxins (i.e., new individuals, renewals, and individuals approved for access at multiple entities). In 2025, the Bioterrorism Risk Assessment Group identified 17 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 (6 of the 17 individuals) was due to a conviction in any court of a crime punishable by imprisonment for a term exceeding one year.

Inspections

The Federal Select Agent Program conducted 169 inspections in 2025: 20 conducted by the Division of Agricultural Select Agents and Toxins, 103 conducted by the Division of Regulatory Science and Compliance, and 46 conducted 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 violations of criminal law.

A summary of compliance actions taken in 2025 is as follows:

- One new entity entered the Federal Select Agent Program Corrective Action Plan program.
- No entities had their registrations fully suspended.
- No entities had their registrations revoked.
- No entities were referred to the Animal and Plant Health Inspection Service Investigative and Enforcement Services or the Health and Human Services Office of Inspector General.
- The Federal Select Agent Program notified the Federal Bureau of Investigation of 23 matters for potential investigation.

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)].

Confidential Reporting Systems

The Health and Human Services Office of Inspector General and the United States 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 2025, the Federal Select Agent Program received no such reports from the United States Department of Agriculture Office of Inspector General or the Health and Human Services Office of the Inspector General.

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 a registered entity 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 2025, the Federal Select Agent Program approved 147 transfers: 102 (including 17 importations) by the Division of Regulatory Science and Compliance and 45 (including 13 importations) by the Division of Agricultural Select Agents and Toxins. During 2025, entities completed 113 transfers.

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 immediately to the Federal Select Agent Program and appropriate Federal, State, or local law enforcement agencies, as applicable.

In 2025, the Federal Select Agent Program received 17 reports of losses, 165 reports of releases, and no reports of thefts. The 17 losses were reported to the Federal Bureau of Investigation for investigation. None of the reported 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 to select agents and toxins.

Report of the Identification of a Biological Select Agent or Toxin

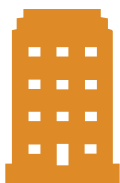
Registered entities and unregistered clinical, diagnostic, or public health laboratories must notify the Federal Select Agent Program of biological select agents and toxins identified through diagnosis, verification, or proficiency testing. The final disposition of the identified biological select agents or toxins must be included as part of the notification. The Federal Select Agent Program received 1,039 such notifications in 2025, 44 to the Division of Agricultural Select Agents and Toxins and 995 to the Division of Regulatory Science and Compliance.

The biological select agents and toxins most frequently identified and reported to the Division of Regulatory Science and Compliance in 2025 were Botulinum neurotoxins (237), *Francisella tularensis* (221), Botulinum neurotoxin producing species of *Clostridium* (167), Eastern equine encephalitis virus genomic material (124), and *Coxiella burnetii* (120). The biological select agents most frequently identified and reported to the Division of Agricultural Select Agents and Toxins in 2025 were *Ralstonia solanacearum* (40), Avian influenza virus (2), and *Bacillus anthracis* (overlap select agent) (2).

Conclusion

Overall, most of the 219 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 reported 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 or to agricultural products. 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 2025



219

entities
registered



8,287

individuals approved to
access biological select
agents and toxins



169

inspections
conducted

Biological Select Agents and Toxins²

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
*Ebolavirus**
*Francisella tularensis**
Lassa fever virus
Lujo virus
Marburg virus*
Monkeypox virus
Reconstructed 1918 Influenza virus
Ricin
Rickettsia prowazekii
Severe acute respiratory syndrome coronavirus (SARS-CoV)
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 (subtypes A, B, C, D, E)
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
*Burkholderia mallei**
*Burkholderia pseudomallei**
Hendra virus
Nipah virus*
Rift Valley fever virus
Venezuelan equine encephalitis virus

USDA Select Agents

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
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>

²List of regulated select agents and toxins effective as of January 16, 2025. Five previously regulated select agents were removed from the list as of this date.

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 Regulatory Science and Compliance (DRSC) 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).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 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 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. 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 and compliance with the SAR by registered entities. It also reflects FSAP’s commitment to program transparency.

Changes to the List of Select Agents and Toxins

On January 16, 2025, regulatory changes took effect following the December 2024 publication of two Final Rules in the *Federal Register* (89 FR 101837 (Dec. 17, 2024) (USDA Final Rule); 89 FR 101941 (Dec. 17, 2024) (HHS Final Rule). The Final Rules updated the list of select agents and toxins by removing *Brucella abortus*, *Brucella melitensis*, *Brucella suis*, African horse sickness virus, and *Peronosclerospora philippinensis* (also known as *Peronosclerospora sacchari*) from the list of regulated select agents and toxins. Additionally, Nipah virus was designated as a Tier 1 select agent. The changes to the list of regulated select agents and toxins subsequently influenced the patterns and trends presented in this report, resulting in notable differences compared with prior reporting years. Unless otherwise noted, data analyzed in this report reflects all information on regulated select agents and toxins reported to the program in calendar year 2025, regardless of whether the reported data was before or after the changes to the regulated list of select agents and toxins went into effect.

³ 42 CFR Part 73 (HHS), 7 CFR Part 331 (USDA plants), and 9 CFR Part 121 (USDA animals).

Key Program Statistics

Registration

Registered Entities

BSAT are divided into three categories based on whether a select agent or toxin causes disease in humans, animals or plants, or a combination of humans and animals (see current list found on [page 7](#)). The three categories of BSAT are:

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

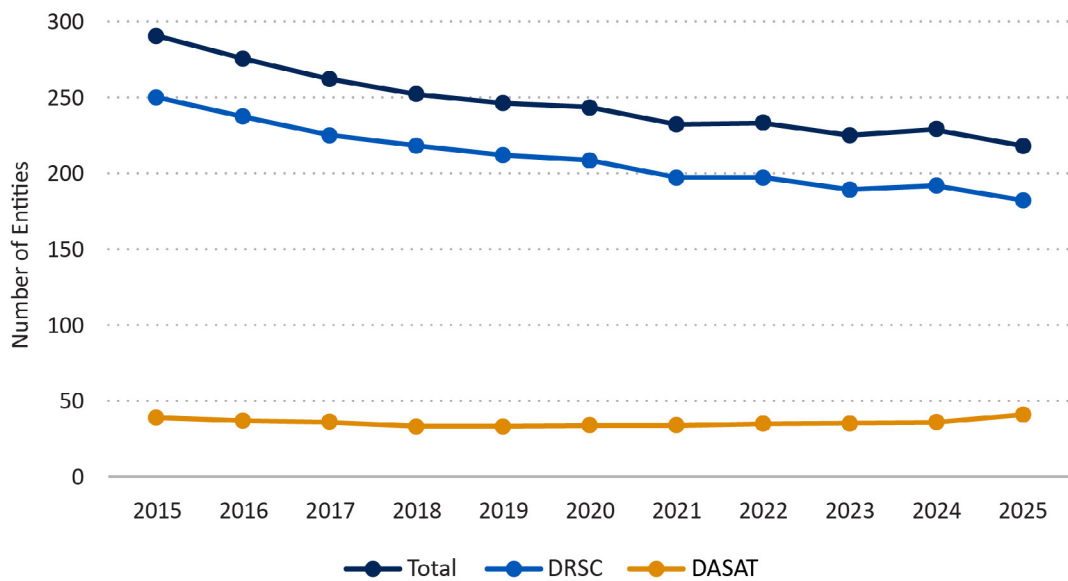
After submission of the APHIS/CDC Form 1, FSAP will review and schedule a site inspection to verify the submitted information and to confirm that the entity is compliant with the SAR. Once the inspection is complete and the entity fulfills all regulatory requirements, FSAP will issue a certificate of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

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

As of December 31, 2025, 219 entities were registered with FSAP: 40 with DASAT and 179 with DRSC (Figure 1). The lead agency, either DRSC 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 DRSC 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 2025, DASAT and DRSC jointly oversaw 45 of the 219 total entities registered with FSAP: DASAT served as the lead agency for 11 of those entities and DRSC served as the lead agency for 34 of those entities. The reduction in registered entities from 2024 to 2025 (-11) is consistent with the overall decline in registered entities since 2015. The reduction in registered entities was due, in part, to the entities no longer needing to be registered because of the removal of five select agents from the list of regulated select agents and toxins.

Figure 1: Number of FSAP-Registered Entities by Agency and Year, 2015-2025

[For a description of the chart, go to page 27.](#)



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.

Registered entities during calendar year 2025 consisted of:⁴

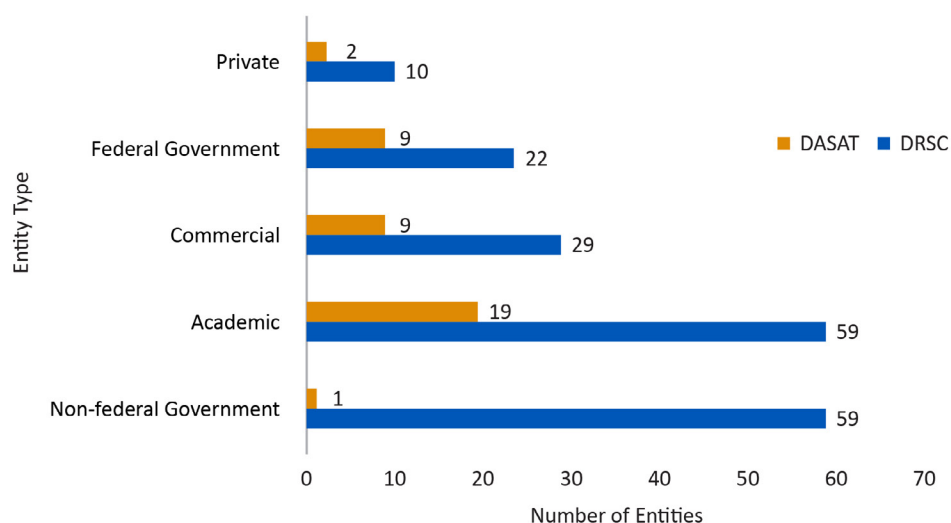
- 36% academic,
- 27% non-federal government,
- 17% commercial,
- 14% federal government, and
- 5% private.

The relative percentages of each entity type have remained consistent since 2015. Figure 2 details the number of entities registered either with DRSC or DASAT by entity type in 2025.

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, 2025

[For a description of the chart, go to page 27.](#)



New Registration Applications

During 2025, FSAP reviewed 10 new registration applications from entities that wished to register. FSAP received four of those applications in 2025. The approval process was still underway for all four of the applications received in 2025 as of December 31, 2025. The other six applications had been received in previous years: two in 2022, two in 2023, and two in 2024. Of these, one application (from 2024) was approved in 2025. Two applications were withdrawn (one from 2022 and one from 2024), and the other three applications were still under review at the end of 2025. In total, one new registration application was approved in 2025.

Entity Withdrawals and Revocations

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 destroyed or transferred to another registered entity in compliance with the SAR, or because of the changes to the list of regulated select agents and toxins effective January 16, 2025, the entity was no longer working with listed select agents or toxins. 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, 12 entities (11 registered with DRSC and one registered with DASAT) withdrew their registration in 2025. The reason the entities cited for withdrawing their registrations was that they no longer needed to possess or work with BSAT. The removal of five select agents from the list of regulated select agents and toxins, which took effect on January 16, 2025, contributed to the reduction in the number of registered entities in 2025. A total of 117 entities withdrew their registrations during 2015-2025.

Table 1: Number of Entity Withdrawals by Entity Type, 2025

Entity Type	DRSC	DASAT
Academic	4	1
Commercial	1	0
Non-federal Government	6	0
Total	11	1

If an entity is unable to comply with the select agent and toxin regulations, its registration may be revoked. Zero entities had their registrations revoked in 2025.

Renewals

Typically, a registered entity must renew its registration at least every three years. In 2025, FSAP approved a total of 82 renewals: 19 by DASAT and 63 by DRSC.

Amendments to Registration

When a registered entity needs to amend its approved registration, it must submit an updated APHIS/CDC Form 1 to FSAP via eFSAP. After reviewing the request, FSAP will approve or deny the amendment. Examples of amendments to registration include the addition or removal of laboratory rooms, adding a new BSAT, or updating a principal investigator's work objective(s). Table 2 lists the 1,248 approved amendments to registrations reviewed by FSAP in 2025, stratified by the approving agency and the sections of the APHIS/CDC Form 1 that were modified. More amendments were approved in 2025 compared to recent years due to the removal of five select agents from the list of regulated select agents and toxins, resulting in the elimination of many work objectives and prompting room and suite modifications. The range of approved amendments in the previous five years was 689 to 960.

Table 2: Number of Approved Amendments to Registration that Required FSAP Review, by Amended Section of the APHIS/CDC Form 1 and Agency, 2025

Registration Amendment Using APHIS/CDC Form 1	DASAT	DRSC	Total
Section 1 - Change Entity Physical or Additional Address	2	12	14
Section 4 - Change Responsible Official	8	28	36
Section 5A - Modify Entity-Wide Security Assessment and Incident Response	5	10	15
Section 5B - Modify Entity-Wide Biosafety/Biocontainment	4	18	22
Section 5C - Modify Entry Requirements for FSAP Inspectors	6	35	41
Section 6 - Modify Building	2	6	8
Section 6 - Modify Room or Suite	16	100	116
Section 7AC - Add New Work Objective	16	66	82
Section 7AC - Modify Work Objective and/or Attachment(s)	129	542	671
Section 7AC - Remove Approved Work Objective	35	196	231
Other Amendments (Including Registration Withdrawals)	3	9	12
Total Approved Amendments	226	1,022	1,248

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. As of December 31, 2025, 115 entities were registered with FSAP for Tier 1 BSAT: 11 entities with DASAT (representing 28% of all DASAT-led entities) and 104 entities with DRSC (representing 58% of all DRSC-led entities). Since 2015, the total percentage of entities registered for Tier 1 BSAT has averaged around 50%, including 53% of FSAP-registered entities in 2025.

Top BSAT Registered with Each Agency

Table 3 lists the BSAT most frequently registered with each agency as of December 31, 2025. For DRSC, the most commonly registered BSAT in 2025 were *Bacillus anthracis* (Pasteur strain) and *Francisella tularensis*. This shift reflects removing three *Brucella* species from the list of regulated select agents and toxins; these species had previously been the most frequently registered BSAT among DRSC-registered entities. For DASAT, Avian influenza virus and Newcastle disease virus have consistently ranked as the most frequently registered BSAT in previous years.

Table 3: Most Frequently Registered Agents with Each Agency, 2025

Registered with DRSC	Registered with DASAT
1. <i>Bacillus anthracis</i> (Pasteur strain)	1. Avian influenza virus
2. <i>Francisella tularensis</i> *	2. Newcastle disease virus
3. <i>Yersinia pestis</i> *	3. <i>Ralstonia solanacearum</i>
4. Botulinum neurotoxin producing species of <i>Clostridium</i> * Eastern equine encephalitis virus	4. <i>Xanthomonas oryzae</i>
5. <i>Bacillus anthracis</i> *	5. African swine fever virus
6. <i>Burkholderia pseudomallei</i> *	6. <i>Bacillus anthracis</i> *
7. <i>Burkholderia mallei</i> *	7. <i>Bacillus anthracis</i> (Pasteur strain) <i>Burkholderia mallei</i> * <i>Burkholderia pseudomallei</i> * Eastern equine encephalitis virus*
8. Botulinum neurotoxins*	N/A
9. <i>Coxiella burnetii</i> Genomic material: Eastern equine encephalitis virus	N/A

*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 a corresponding set of biosafety guidelines for work with animals designated as animal biosafety level 2 (ABSL-2) up 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 BSAT used and the work performed in those laboratories.

In of December 31, 2025, 30% 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 4% 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, 2025

Laboratory Type: Biosafety Level	Total Registered Entities	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	48	18	13	21	10	4
BSL-3/ABSL-3	172	94	17	20	65	59	11
BSL-4/ABSL-4	8	8	0	5	2	0	1

Note: Entities may be approved to work in multiple laboratories at different BSL/ABSL, 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 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 2025, 8,287 unique individuals held current SRAs approved for access to BSAT, a decrease from 8,902 individuals at the end of 2024. When an individual no longer requires access to BSAT, the individual's SRA is terminated. In 2025, FSAP granted 3,446 approvals (new and renewal applications) for access to BSAT (Table 5). The total number of individuals approved for access to BSAT per entity type (8,588 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. Individuals working at academic institutions made up thirty-eight percent of those approved for access to BSAT, followed by individuals working at federal government entities (28%). For the eleventh 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, 2025

Entity Type	Access Approvals Granted in 2025 (New Approvals and Renewals)	Total Access Approvals as of December 31, 2025
Academic	1,341	3,299
Federal Government	958	2,415
Non-Federal Government	332	908
Commercial	501	1,255
Private	314	711
Total	3,446	8,588

In 2025, BRAG identified 17 individuals as "restricted persons" and therefore, FSAP did not grant them access to BSAT. This number falls within the range observed from 2015-2024 (10 to 30 per year). Individuals can appeal their "restricted person" determination, and in 2025, four individuals submitted appeals. Two of the appeals resulted in the "restricted person" determination being overturned.

Table 6 summarizes the reasons for restriction for the 17 individuals.

Table 6: Total Number of Restricted Persons Identified by Restrictor Type, 2025

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)	6
An alien illegally or unlawfully in the United States	5
Adjudicated as a mental defective	3
Unlawful user of any controlled substance	2
Under indictment for a crime punishable by imprisonment for a term exceeding one year	1
Total	17

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:

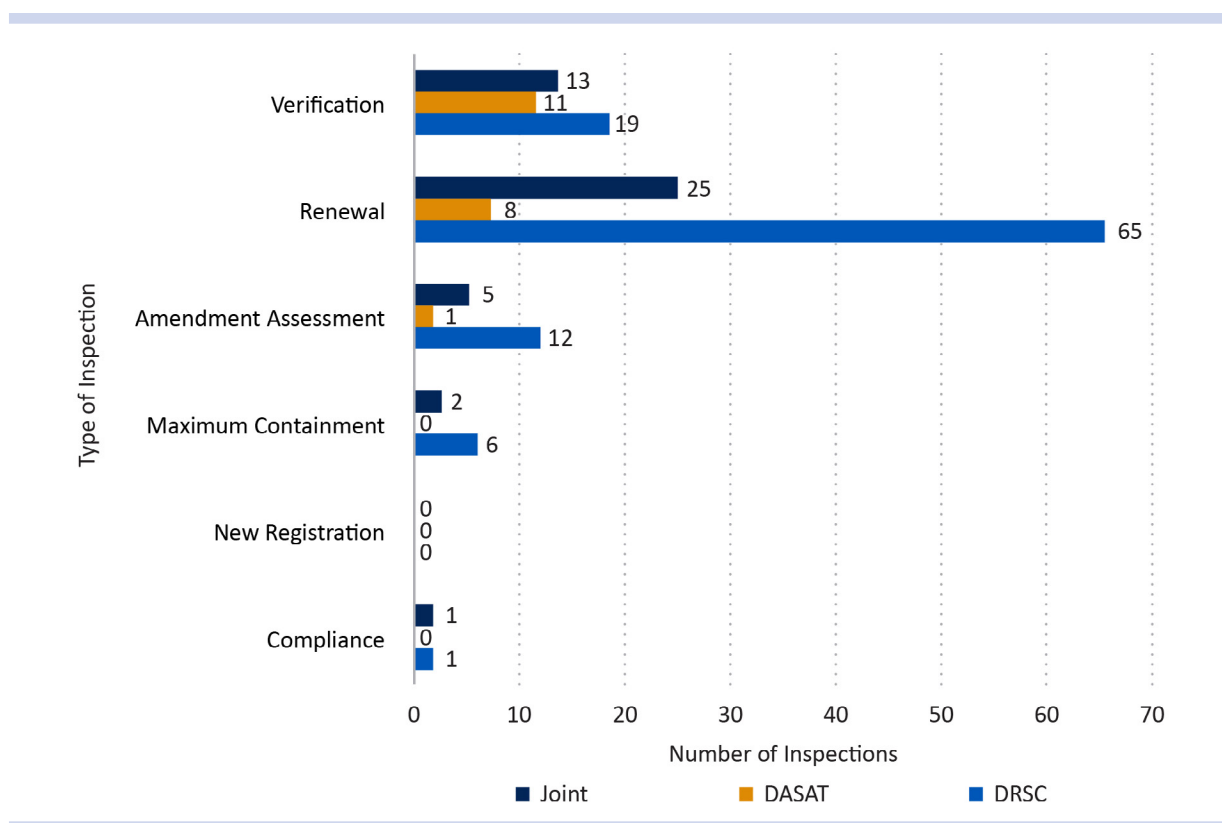
- **Compliance** – Review of entity’s registration, including laboratory spaces and documents (e.g., plans, records, facility verification documentation), with a focus on compliance issues.
- **Maximum Containment** – Review of entity’s registered maximum containment program, including laboratory spaces 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** – 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 DRSC or DASAT lead the inspection, depending on which is the lead agency and the BSAT for which the entity is registered. DRSC inspects entities registered for HHS-only BSAT and DASAT inspects entities registered for USDA-only select agents. DRSC and DASAT normally jointly inspect entities registered for both HHS and USDA BSAT. In 2025, FSAP performed 169 inspections: 20 by DASAT, 103 by DRSC, and 46 jointly.

Figure 3 compares the number of each type of inspection conducted in 2025 by either DRSC, DASAT, or both jointly.

Figure 3: Number of Inspections by Lead Agency and Type, 2025*

[For a description of the chart, go to page 27.](#)



*Inspections may have more than one purpose. To ensure that individual inspections are not counted multiple times, only the primary purpose for the inspection is displayed in the figure. Ten of the amendment assessment inspections and four of the maximum containment inspections were also renewal inspections. Five of the amendment assessment inspections and two of the maximum containment inspections were also verification inspections. Two maximum containment inspections were also amendment assessment and verification 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 target completion 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.

Two entities participated in CAPs during 2025. One entity started its CAP in 2024 and the other in 2025. Of these entities, one completed its CAP in 2025 and the other continued its participation into 2026.

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 2025, no entities had their registrations fully suspended. Two entities had their registrations partially suspended (one new and one carryover from the previous year) in 2025. The partial suspension of one entity's registration was lifted in 2025, and the other entity's registration remained partially suspended into 2026.

Revocation

In the most serious of circumstances, or in the case of repeated failures to maintain compliance with the regulations, FSAP has the authority to revoke an entity's registration to work with select agents and toxins (e.g., if the entity is unwilling or unable to meet the requirements of the regulations). No entities had their registrations revoked in 2025.

Reports and Referrals

Confidential Reporting System

The HHS Office of Inspector General (OIG) and the USDA OIG maintain confidential reporting systems for the public to report safety, security, or other concerns associated with BSAT. FSAP received no such reports from HHS OIG or USDA OIG in 2025. Since 2015, HHS and USDA OIGs have received between zero and 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 2025, no entities were newly referred to APHIS IES or HHS OIG. APHIS IES closed one referral from 2024 and issued a warning letter to the entity. Since 2015, between zero and 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 2025, FSAP notified the FBI of 23 security-related issues.

- 17 notifications concerned the loss of BSAT. In one case, the entity recovered the lost material after notifying the FBI. The other 16 notifications stemmed from record-keeping issues – including inventory discrepancies caused by using or destroying BSAT without updating records or by other record-keeping errors.
- Six notifications concerned the discovery of BSAT that was either outside of registered space or not included in the entity's inventory of record for BSAT held in registered space.

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 2025, FSAP received two requests that met the restricted experiment definition. Both requests involved the production of recombinant versions of botulinum neurotoxin and were 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. DRSC received one exclusion request for Bonded Botulinum neurotoxin (BiTox). The request was denied.

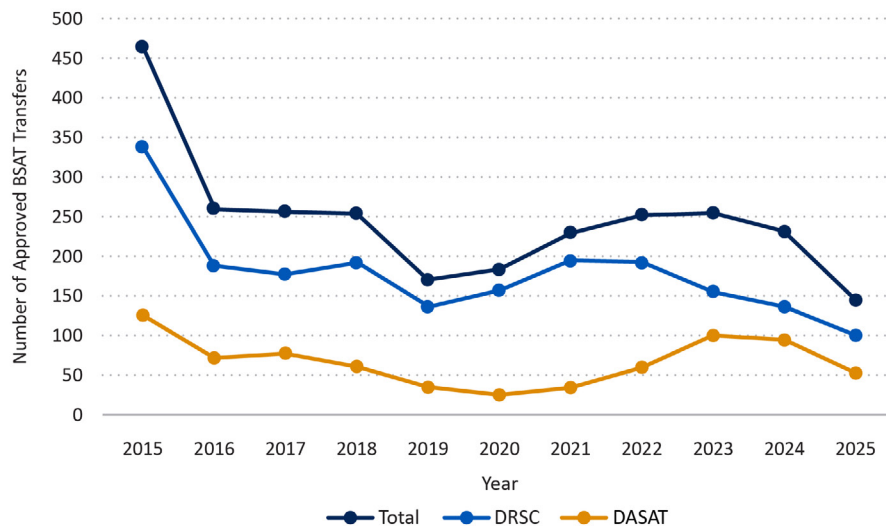
Transfers of BSAT

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 2025, FSAP approved 147 BSAT transfers – 45 by DASAT and 102 by DRSC (Figure 4). DASAT approved 45 transfers involving 13 recipient entities and 17 sender entities. DRSC approved 102 transfers involving 37 recipient entities and 43 sender entities. Fifty-nine of the approved transfers in 2025 involved unregistered entities transferring BSAT to registered entities, representing 40% of approved transfers. These transfers were either imported BSAT (30), occurred after the identification of BSAT in a diagnostic specimen (26), or occurred after the discovery of BSAT (3). Of the 30 imported BSAT, DASAT approved 13 transfers, and DRSC approved 17. For the 26 BSAT identified in diagnostic specimens by unregistered entities, DASAT approved three transfers, and DRSC approved 23. DASAT approved all three of the transfers that occurred after the discovery of BSAT.

In 2025, 113 BSAT transfers occurred during the year. This total includes two transfers approved in 2024 but shipped in 2025. One transfer approved late in the year had not shipped by December 31, 2025, and entities canceled 35 approved transfers before shipment.

Figure 4: Total Number of Approved BSAT Transfers, 2015-2025

[For a description of the chart, go to page 27.](#)



For DASAT, African swine fever virus was the most frequently transferred BSAT in 2025 (Table 7). Historically, avian influenza virus has been the most frequently transferred BSAT and has remained so since 2015, except in 2021 when African swine fever virus again ranked the highest.

Table 7: Number of BSAT Transfers (APHIS/CDC Form 2) Approved by DASAT, 2025

BSAT	Total*
African swine fever virus	21
Avian influenza virus	1
<i>Bacillus anthracis</i>	1
Classical swine fever virus	5
Foot-and-mouth disease virus	5
Genomic material: Classical swine fever virus	3
Genomic material: Foot-and-mouth disease virus	2
Genomic Material: Swine vesicular disease virus	3
Goat pox virus	2
Lumpy skin disease virus	5
<i>Mycoplasma capricolum</i>	2
<i>Mycoplasma mycoides</i>	2
Peste des petits ruminants virus	2
<i>Ralstonia solanacearum</i>	15
Rinderpest virus	1
Sheep pox virus	1
Swine vesicular disease virus	3
<i>Xanthomonas oryzae</i>	3

*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 DRSC, Botulinum neurotoxins, Eastern equine encephalitis virus genomic material, and Monkeypox virus were the most frequently transferred BSAT in 2025 (Table 8). Botulinum neurotoxins have been the most frequently transferred BSAT since 2016.

Table 8: Number of BSAT Transfers (APHIS/CDC Form 2) Approved by DRSC, 2025

BSAT	Total*
<i>Bacillus anthracis</i>	1
<i>Bacillus anthracis</i> Pasteur strain	1
Botulinum neurotoxin producing species of <i>Clostridium</i>	13
Botulinum neurotoxins	14
<i>Burkholderia pseudomallei</i>	8
<i>Coxiella burnetii</i>	2
Eastern equine encephalitis virus	5
<i>Ebolavirus</i>	8
<i>Francisella tularensis</i>	7
Genomic material: Eastern equine encephalitis virus	14
Genomic material: SARS-associated coronavirus (SARS-CoV)	2
Lassa fever virus	1
Lujo virus	1
Marburg virus	1
Monkeypox virus	14
Recombinant/synthetic nucleic acids encoding Botulinum neurotoxin	1
Reconstructed replication competent forms of the 1918 pandemic influenza virus	1
Severe acute respiratory syndrome coronavirus (SARS-CoV)	7
South American Hemorrhagic Fever virus: Chapare	1
South American Hemorrhagic Fever virus: Guanarito	1
South American Hemorrhagic Fever virus: Junín	1
South American Hemorrhagic Fever virus: Machupo	1
South American Hemorrhagic Fever virus: Sabia	1
Venezuelan equine encephalitis virus	2
<i>Yersinia pestis</i>	4

*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 form ([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.

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 2025, FSAP received 17 reports of losses, 165 reports of releases, and no reports of theft of BSAT.

For the 165 reports of releases, 83 were submitted by registered entities and 82 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 31 releases presented minimal to no risk of occupational exposure.
- The remaining 134 releases involved occupational exposure to BSAT.
 - ◆ In 10 of the 134 releases, the reporting entity determined that no occupational health services were necessary based on the circumstances of the release.
 - ◆ In the remaining 124 releases, the reporting entities provided occupational health services (including medical surveillance and/or treatment, such as physical evaluations, symptom monitoring, serology screening, antibiotics, or other prophylaxis) to a total of 506 individuals (88 individuals from 43 registered entity reports and 418 individuals from 81 non-registered entity reports).

None of the reported 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 due to releases.

Report of the Identification of BSAT

Entities use the Report of the Identification of a Select Agent or Toxin form ([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 2025, FSAP received and processed 1,039 total reports of the identification of BSAT on APHIS/CDC Form 4As as a result of diagnosis or verification. DRSC received and processed 995 of the APHIS/CDC Form 4A reports, and DASAT received and processed 44 of the APHIS/CDC Form 4A reports in 2025.

Botulinum neurotoxins were the most frequently identified BSAT reported to DRSC in 2025, followed by *Francisella tularensis* and Botulinum neurotoxin producing species of *Clostridium* (Table 9). In recent years, Botulinum neurotoxin has been the most frequently identified BSAT, with the exception of 2024 (Eastern equine encephalitis virus genomic material), 2019 (Eastern equine encephalitis virus) and 2015 (*Francisella tularensis*).

Table 9: BSAT Reported to DRSC on APHIS/CDC Form 4A by Sample Type, 2025

BSAT	Animal Specimens	Enviromental Samples	Food Samples	Human Specimens	Vectors/ Arthropods	Total
Abrin	0	1	0	0	0	1
<i>Bacillus anthracis</i>	1	1	0	1	0	3
Botulinum neurotoxin producing species of <i>Clostridium</i>	1	0	8	158	0	167
Botulinum neurotoxins	27	1	8	201	0	237
<i>Brucella melitensis</i> *	0	0	0	1	0	1
<i>Brucella suis</i> *	0	0	0	2	0	2
<i>Burkholderia pseudomallei</i>	2	2	0	46	0	50
<i>Coxiella burnetii</i>	71	0	0	49	0	120
Eastern equine encephalitis virus	17	0	0	0	0	17
Ebolavirus	0	0	0	1	0	1
<i>Francisella tularensis</i>	104	0	0	117	0	221
Genomic material: Eastern equine encephalitis virus	41	0	0	1	82	124
Lassa fever virus	0	0	0	1	0	1
Marburg virus	0	0	0	1	0	1
Monkeypox virus	0	0	0	23	0	23
Nipah virus	0	0	0	1	0	1
Ricin	0	2	0	0	0	2
<i>Rickettsia prowazekii</i>	0	0	0	0	1	1
Saxitoxin	0	7	0	0	0	7
South American Haemorrhagic Fever virus: Junín	1	0	0	0	0	1
T-2 toxin	0	0	6	0	0	6
<i>Yersinia pestis</i>	2	0	0	6	0	8
Total	267	14	22	609	83	995

*A small number of identifications of *Brucella melitensis* and *Brucella suis* were reported at the beginning of 2025, before these agents were removed from the select agent and toxin list effective January 16, 2025.

Ralstonia solanacearum was the most frequently identified select agent reported to DASAT in 2025, followed by Avian influenza virus and *Bacillus anthracis* (Table 10). *Ralstonia solanacearum* was also the most identified select agent for DASAT in 2021. Avian influenza virus was the most identified select agent for DASAT in 2022-2024, 2019, and 2015, and *Bacillus anthracis* was the most identified select agent in 2020. Newcastle disease virus was the most identified in 2018, 2017, and 2016.

Table 10: Select Agents Reported to DASAT on APHIS/CDC Form 4A by Sample Type, 2025

BSAT	Animal Specimens	Plant Samples	Total
Avian influenza virus*	2	0	2
<i>Bacillus anthracis</i>	2	0	2
<i>Ralstonia solanacearum</i>	0	40	40
Total	4	40	44

*On June 6, 2024, the H5 avian influenza virus was temporarily exempted from the requirements of the select agent regulations, including the reporting requirements.

Clinical, diagnostic, or public health laboratories that are not registered to work with BSAT may, in the course of their work, identify BSAT. For DRSC, non-registered laboratories accounted for 32% of all reports of the identification of BSAT using the APHIS/CDC Form 4A. For DASAT, non-registered laboratories accounted for 91% of all reports of the identification of BSAT using the APHIS/CDC Form 4A. Upon identification of BSAT, the non-registered 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 2025, DRSC received 15 APHIS/CDC Form 4Bs reporting BSAT identified through proficiency testing, compared to an annual range of 0 to 63 reports over the previous ten years. In 2025, DASAT received one APHIS/CDC Form 4B reporting BSAT identified through proficiency testing. DASAT has received an annual range of zero to three reports over the previous ten years.

DRSC 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 DRSC received three). DASAT received one report from federal law enforcement regarding seizure of BSAT (APHIS/CDC Form 4C), which was the first time DASAT has received this type of report in the past ten 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. When an event occurs, FSAP contacts the registered entities and assists them with safely transferring or securing BSAT as needed. In 2025, FSAP identified one such event (a tornado in the Midwest), and as a result, contacted one affected entity. The entity did not require FSAP assistance. There were no thefts, losses, or releases of BSAT as a result of any external threats in 2025.

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. FSAP did not publish any such items in 2025.

Outreach

FSAP's outreach efforts provide opportunities for program staff to interact with members of the regulated community. In 2025, FSAP held a multi-day workshop for Responsible Officials (ROs) and Alternate Responsible Officials (AROs) July 8-10, 2025, to provide information about maintaining regulatory compliance and to build community among those working in this area. The event had 356 registrants and was a hybrid event, with some attending online and others attending in-person.

FSAP also 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 2025, FSAP issued 18 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 219 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 reported 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 or to agricultural products. 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.

References

[Select Agents and Toxins Regulations](#). 7 CFR Part 331, 9 CFR Part 121, 42 CFR Part 73.

Past Annual Reports available at: [Publications by Federal Select Agent Program](#). U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and U.S. Department of Agriculture, Animal and Plant Health Inspection Service.

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

Accessibility Appendix

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 2025. There are three lines: one for the total number of entities registered with FSAP, one for the number of entities registered with DRSC, and one for the number of entities registered for DASAT. The total number of entities registered with FSAP in 2015 was 291, and this decreased to 219 in 2025. For DRSC, the number of registered entities in 2015 was 251, and this decreased to 179 in 2025. For DASAT, the number of registered entities in 2015 was 40, and remained 40 in 2025. ([page 10](#))

Figure 2. The number of entities registered with FSAP by type 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 70 in increments of 10. For each entity type, there are two bars representing the number of entities registered with either DASAT or DRSC. From top to bottom, the numbers of entities are: private (2 for DASAT, 10 for DRSC), federal government (9 for DASAT, 22 for DRSC), commercial (9 for DASAT, 29 for DRSC), academic (19 for DASAT, 59 for DRSC), and non-federal government (1 for DASAT, 59 for DRSC). ([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, amendment assessment, maximum containment, new registration, compliance), and the horizontal x-axis lists the number of inspections ranging from 0 to 70 in increments of 10. For each inspection type, there are three bars representing the number of inspections conducted by either DASAT or DRSC, or as a joint inspection. From top to bottom, the numbers of inspections are: verification (13 for joint, 11 for DASAT, 19 for DRSC), renewal (25 for joint, 8 for DASAT, 65 for DRSC), amendment assessment (5 for joint, 1 for DASAT, 12 for DRSC), maximum containment (2 for joint, 0 for DASAT, 6 for DRSC), new registration (0 for joint, 0 for DASAT, 0 for DRSC), and compliance (1 for joint, 0 for DASAT, and 1 for DRSC). ([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 2025. There are three lines: one for the total number of approved BSAT transfers for FSAP, one for the number of approved BSAT transfers for DRSC, 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 147 in 2025. For DRSC, the number of approved BSAT transfers in 2015 was 337, and this decreased to 102 in 2025. For DASAT, the number of approved BSAT transfers in 2015 was 126, and this decreased to 45 in 2025. ([page 19](#))

