

Updates from the Federal Select Agent Program (FSAP)

Directors, Federal Select Agent Program
2020 Responsible Official Webinar Series

May 27, 2020



Recent Activities: Key Highlights

Key Highlights

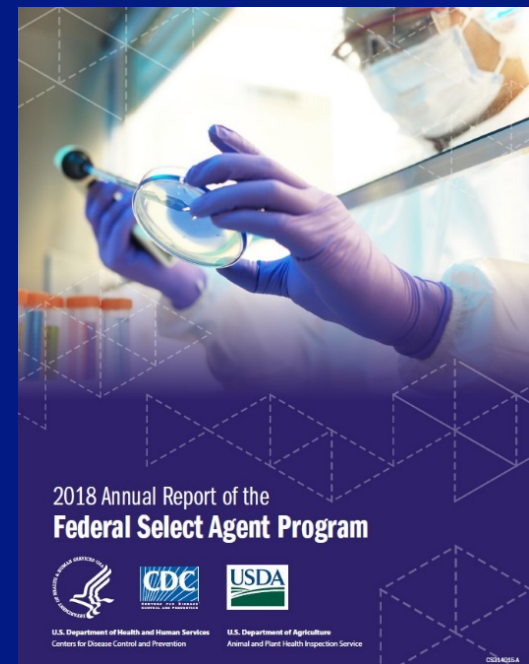
- ❑ *2018 Annual Report of the Federal Select Agent Program*
- ❑ *2018 FSAP Inspection Report Processing Annual Summary*
- ❑ **Federal Register Notices**
- ❑ **Policy Statements**
- ❑ **Guidance Documents**

Key Highlights (Cont.)

- ❑ Exclusions
- ❑ Outreach
- ❑ eFSAP Updates
- ❑ Overview of FSAP operations during the pandemic

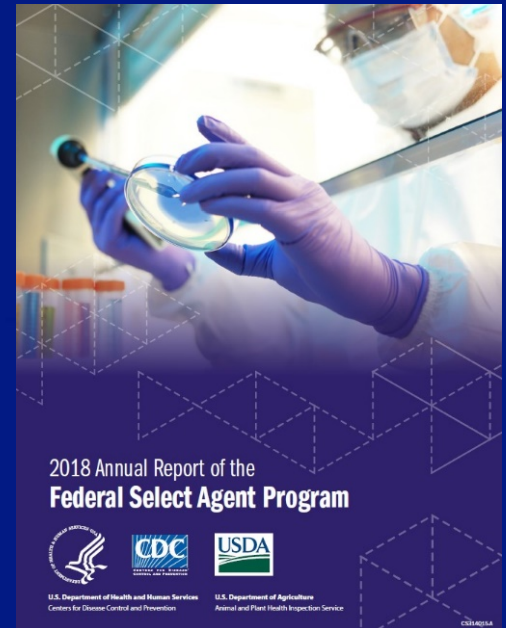
2018 Annual Report of the Federal Select Agent Program

- ❑ Annual report of aggregate program data
- ❑ Provides a look at both the regulatory functions of the program, as well as compliance with the select agent regulations at laboratories across the nation



2018 Annual Report of the Federal Select Agent Program (Cont.)

- ❑ Reflects FSAP's ongoing commitment to increasing transparency
- ❑ Available at <https://www.selectagents.gov/annualreport2018.html>
- ❑ Work on the 2019 Annual Report is currently underway



Federal Select Agent Program 2018 Annual Report

FEDERAL SELECT AGENT PROGRAM 2018 ANNUAL REPORT | KEY STATISTICS

The *2018 Annual Report of the Federal Select Agent Program* continues to provide insight into the regulatory activities of the Federal Select Agent Program (FSAP). The report includes a look at both the regulatory functions of the program, as well as compliance with the select agent regulations at laboratories across the nation. This annual report is FSAP's fourth report of aggregate program data, and reflects the program's ongoing commitment to transparency and increasing understanding of the program.

- FSAP is managed jointly by the Centers for Disease Control and Prevention's Division of Select Agents and Toxins and the Animal and Plant Health Inspection Service's Agriculture Select Agent Services
- FSAP regulates the possession, use, and transfer of biological select agents and toxins (BSAT) so that important work with potentially dangerous and deadly pathogens is conducted as safely and securely as possible
- BSAT are materials that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products

253

ENTITIES WERE REGISTERED WITH FSAP

- 33% ACADEMIC
- 17% COMMERCIAL
- 15% FEDERAL GOVERNMENT
- 29% NON-FEDERAL GOVERNMENT
- 6% PRIVATE

51% of entities were registered for Tier 1* BSAT

LAB BIOSAFETY LEVELS (BSL)

ENTITIES MAY HAVE MULTIPLE TYPES

- 30% had BSL-2 and/or ABSL-2 labs
- 79% had BSL-3 and/or ABSL-3 labs
- 3% had BSL-4 and/or ABSL-4 labs

TOP REGISTERED AGENTS BY AGENCY

CDC's Division of Select Agents and Toxins

- Brucella melitensis*
- Brucella suis*
- Brucella abortus*
- Bacillus anthracis* (Pasteur strain)
- Francisella tularensis**

APHIS's Agriculture Select Agent Services

- Newcastle disease virus
- Avian influenza virus
- Ralstonia solanacearum*
- Xanthomonas oryzae*
- Brucella abortus*

COMPLIANCE & ENFORCEMENT

- 3 total entities participated in a corrective action plan (including 1 entity that newly agreed to participate in 2018)
- 0 total entities had fully suspended registrations (with 5 entities newly put under partial suspension in 2018)
- 9 matters were shared with the Federal Bureau of Investigation for potential investigation (FBI determined no action was needed in any of those cases)
- 4 entities were referred to the HHS Office of Inspector General or APHIS Investigative and Enforcement Services

THEFT, LOSS, OR RELEASE

- 0 thefts reported
- 8 reports of losses determined to be inventory accounting errors or inadvertent destruction of BSAT
- 0 occupational exposures resulting in illness, death, or transmission, out of the 185 incidents reported involving occupational exposures

TRANSFER APPROVALS: 192 DSAT | 61 AgSAS

- 26% of the transfers were from unregistered entities to registered entities, and occurred after the identification of BSAT in a diagnostic specimen or represented imports from outside the U.S.

206

TOTAL INSPECTIONS CONDUCTED BY FSAP

- 149 by DSAT
- 18 by AgSAS
- 39 joint DSAT & AgSAS

2.5

AVERAGE DURATION (IN DAYS) FOR INSPECTION

Range of 1 to 10 days

8,434

ACTIVE INDIVIDUAL SECURITY RISK ASSESSMENTS

Denied access for 24 individuals

KEY ABBREVIATIONS:

FSAP: Federal Select Agent Program DSAT: Division of Select Agents and Toxins BSAT: Biological select agents and toxins ABSL: Animal biosafety level
 CDC: Centers for Disease Control and Prevention APHIS: Animal and Plant Health Inspection Service AgSAS: Agriculture Select Agent Services

*Tier 1 agent, those that pose the greatest risk through misuse

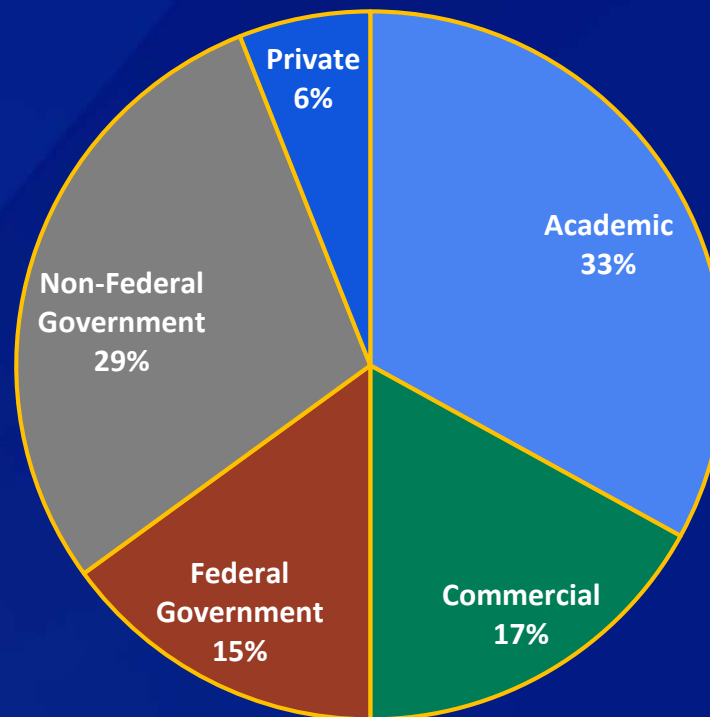
Source: 2018 Annual Report of the Federal Select Agent Program, January 2020 | www.selectagents.gov/annualreport2018.html

FSAP 2018: Key Facts

- ❑ **253 registered entities**
- ❑ **206 inspections conducted**
- ❑ **8,434 active individual security risk assessments**
 - Denied access for 24 individuals
- ❑ **No potential exposures resulted in illness, death, or transmission in laboratories or the community**

Types of Entities Registered with FSAP, 2018

Total: 253



Source: 2018 Annual Report of the Federal Select Agent Program, <https://www.selectagents.gov/annualreport2018.html>

Enforcement Actions, 2018

- ❑ **3 total entities participated in a Corrective Action Plan**
 - Including 1 entity that newly agreed to participate

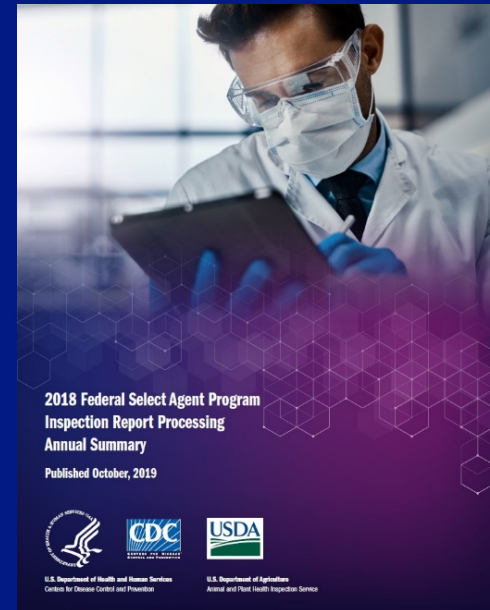
- ❑ **0 entities had fully suspended registrations**
 - With 5 entities newly put under partial suspension

- ❑ **9 matters were shared with the FBI for potential investigation**
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- ❑ **4 entities were referred to the HHS Office of Inspector General or APHIS Investigative and Enforcement Services**

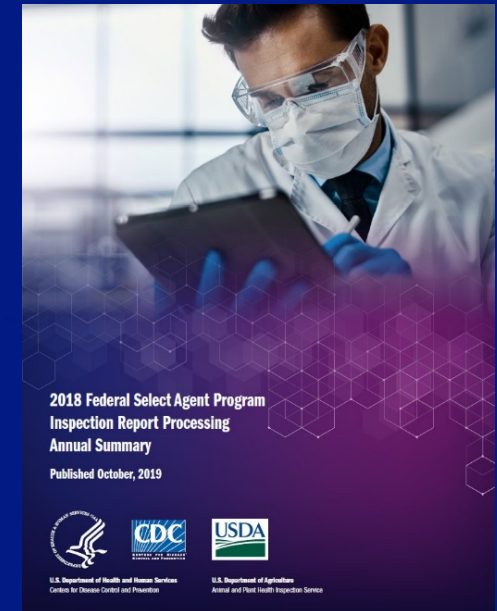
2018 FSAP Inspection Report Processing Annual Summary

- ❑ **First joint program analysis of inspection report timeliness data**
- ❑ **Released in October 2019**
- ❑ **Data show that nearly all inspection reports (93%) were sent to entities within FSAP's goal of 30 business days, underscoring the program's continued commitment to provide timely feedback**



2018 FSAP Inspection Report Processing Annual Summary (Cont.)

- ❑ Full report is available at <https://www.selectagents.gov/publications.html>
- ❑ Work on the 2019 report is currently underway



2018 FSAP Inspection Report Processing Annual Summary (Cont.)

□ Key Findings

- FSAP issued 194 final inspection reports in 2018 – with **93% overall** (181/194) issued within the 30 business day target
- Among reports issued by CDC/DSAT, **95%** met this goal
- Among reports issued by APHIS/AgSAS, **84%** met this goal
- For the small number of reports that were delayed (**13 total**), analysis by inspection type found that the most common inspections conducted (verification inspections) were also the most commonly delayed report type

Federal Register Notices

❑ **Select agent forms available for public comment**

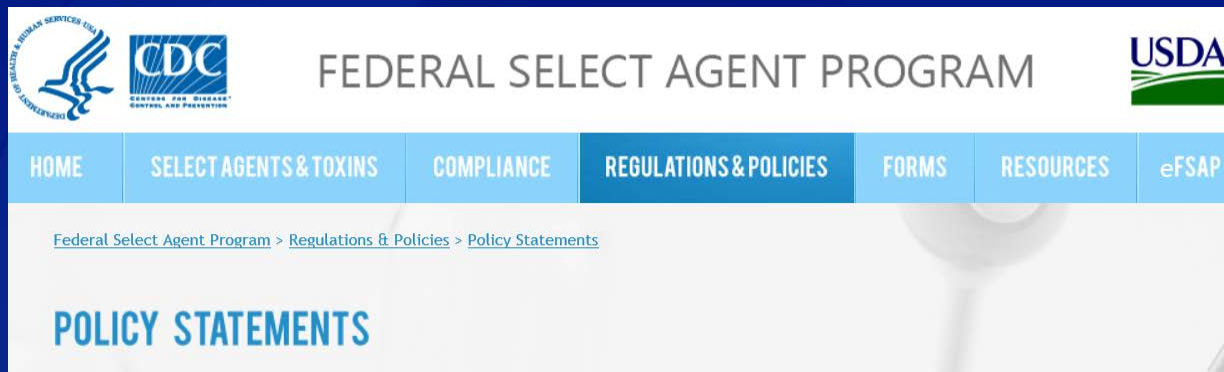
- Seeks public comment on FSAP's request for continued approval by the Office of Management and Budget to collect select agent and toxin information through the use of APHIS/CDC Forms 1-5
- See <https://www.federalregister.gov/d/2020-06948> for more information
- Public comment period ends June 2, 2020

❑ **HHS and USDA Advance Notices of Proposed Rulemaking regarding the biennial review and republication of the list of select agents and toxins**

- Public comment period closed on May 18, 2020

Policy Statements

- ❑ Revised policy statement regarding regulated genomes (2/20)



Available at <https://www.selectagents.gov/regulations-policy.html>

Guidance Documents

- ❑ Revised guidance regarding the regulation of select agent and toxin nucleic acids (2/2020)
 - Available at <https://www.selectagents.gov/na-guidance.html>
- ❑ Revised security plan guidance (2/2020)
 - Available at <https://www.selectagents.gov/spg-intro.html>
- ❑ Updated Responsible Official knowledge check self-exam (2/2020)
 - Available at <https://www.selectagents.gov/roquizes/>



Exclusions

- ❑ African swine fever viruses, ASFV-G- Δ I177L, ASFV-G- Δ 9GL/ Δ UK and ASFV-G- Δ MGF
- ❑ *Burkholderia pseudomallei* strain PBK001 (Δ tonB Δ hcp1)
- ❑ *Clostridium botulinum* Beluga Ei strain
- ❑ *Yersinia pestis* CO92 strain Δ lpp Δ msbB Δ pla
- ❑ Catalytically inactive Botulinum neurotoxin (ciBoNT)/D

More information is available at

<https://www.selectagents.gov/SelectAgentsandToxinsExclusions.html>

Outreach

- ❑ **FSAP webinars to provide training on recent updates to eFSAP (several sessions held in March 2020 and September 2019)**
- ❑ **Continued support of ABSA-led independent forum to encourage routine peer-to-peer sharing of information and best practices**
- ❑ **FSAP information booth exhibited at several meetings, including:**
 - **ASM Microbe (6/2019)**
 - **ABSA (11/2019)**
 - **CDC International Symposium on Biosafety (2/2020)**



Electronic FSAP (eFSAP) Information System - Updates

Electronic FSAP (eFSAP) Information System

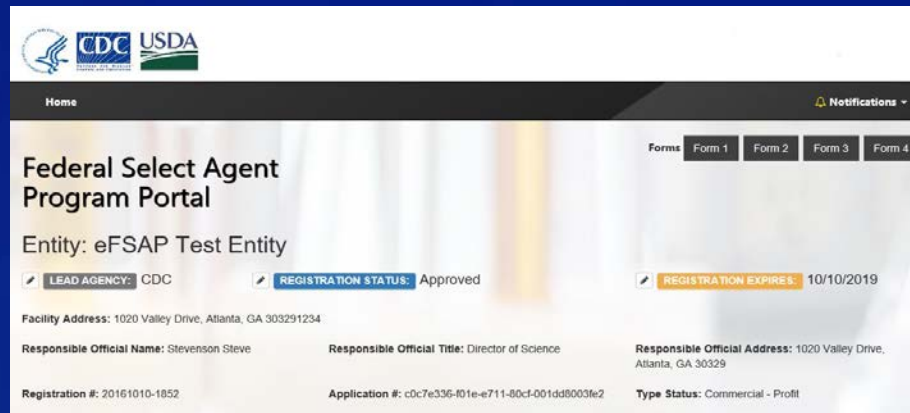
- ❑ Secure, web-based user interface (portal)
- ❑ Searchable by FSAP; will provide immediate, real-time information on who has what select agents, how they are being used in the work, and where they are located
- ❑ Increased efficiency; FSAP can be more timely and effective

The screenshot displays the Federal Select Agent Program Portal interface. At the top, there are logos for CDC and USDA. Below the logos, the page title is "Federal Select Agent Program Portal" and the entity is identified as "Entity: eFSAP Test Entity". The registration details are as follows:

LEAD AGENCY: CDC	REGISTRATION STATUS: Approved	REGISTRATION EXPIRES: 10/10/2019
Facility Address: 1020 Valley Drive, Atlanta, GA 303291234	Responsible Official Name: Stevenson Steve	Responsible Official Title: Director of Science
Responsible Official Address: 1020 Valley Drive, Atlanta, GA 30329	Registration #: 20161010-1852	Application #: c0c7e336-f01e-e711-80c4-001dd8003fe2
Type Status: Commercial - Profit		

Electronic FSAP (eFSAP) Information System (cont.)

- ❑ FSAP and regulated entities will both use the set of data
- ❑ Reduced paper
- ❑ New method of releasing inspection findings can help entities work towards resolution in days vs. weeks or months



The screenshot displays the Federal Select Agent Program Portal for an eFSAP Test Entity. The page features the CDC and USDA logos at the top left. A navigation bar includes 'Home' and 'Notifications'. The main content area shows the entity name 'eFSAP Test Entity' and a 'Forms' section with buttons for Form 1, Form 2, Form 3, and Form 4. Key information is presented in a structured layout:

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Burden Reduction and Customer Satisfaction

- ❑ **Many aspects of entity registration maintenance have been revamped to be self-service**
 - Reduces administrative burden for both program and entity
 - Significantly speeds up processing
- ❑ **Increased ease of validating and submitting information**
- ❑ **Entities have immediate visibility of where their submissions are in life cycle**
- ❑ **Direct interaction between SMEs and entity representatives**

eFSAP: Recent Major Updates

- ❑ Principal Investigator (PI) user role
- ❑ Entity admin center
- ❑ Simple PI replacement
- ❑ Printable registration certificate
- ❑ APHIS/CDC Form 2, 3, 4 printing
- ❑ APHIS/CDC Form 1 Section 4, 7B data export
- ❑ Notification and amendment flagging/archiving

eFSAP: Recent Major Updates (Cont.)

- ❑ File archiving
- ❑ Notice of final inspection findings
- ❑ Inspection histories
- ❑ APHIS/CDC Forms 3, 4 histories
- ❑ Work objective histories
- ❑ Redesigned entity landing page

eFSAP: Upcoming Features

- ❑ **APHIS/CDC Form 1 Section 7B redesign**
 - Reconfiguration of Section 7B into a compact grid table design
 - Detailed strain/serotype information no longer required
 - Users simply choose the classical strain/serotype from a drop-down menu
 - Strains/serotypes can be edited/deleted in bulk

- ❑ **Ability to request extension or cancel an APHIS/CDC Form 2 transfer authorization**

eFSAP: Upcoming Features (Cont.)

- ❑ Ability for entities to cancel draft APHIS/CDC Forms 2, 3, 4**
- ❑ Administrative editing of “unassigned” buildings and rooms/suites**
- ❑ APHIS/CDC Form 1 Section 4 drop-down choices for “reason for removal”**
- ❑ Enhancements to general discussion (metadata, searching)**
- ❑ Notification center filters**

eFSAP Resource Center

- ❑ Contains information to help users gain access to and use eFSAP
- ❑ Includes a full library of training materials, reference guides, instructional videos, FAQs, etc.
- ❑ Materials continue to be added over time



<https://www.selectagents.gov/efsap.html>

Ongoing and Future Efforts

- ❑ Continuing to develop and increase capabilities of the eFSAP information system
- ❑ Data analysis and publication of the *2019 Annual Report of the Federal Select Agent Program* and the *2019 FSAP Inspection Report Processing Annual Summary*
- ❑ Monitoring and continuous program improvements through the FSAP Strategic Plan

Discussion

www.selectagents.gov

CDC: Irsat@cdc.gov or 404-718-2000

APHIS: AgSAS@usda.gov or
301-851-3300 option 3 (voice only)

