

Updates from the Federal Select Agent Program (FSAP)

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2019 Responsible Official Workshop



July 23, 2019



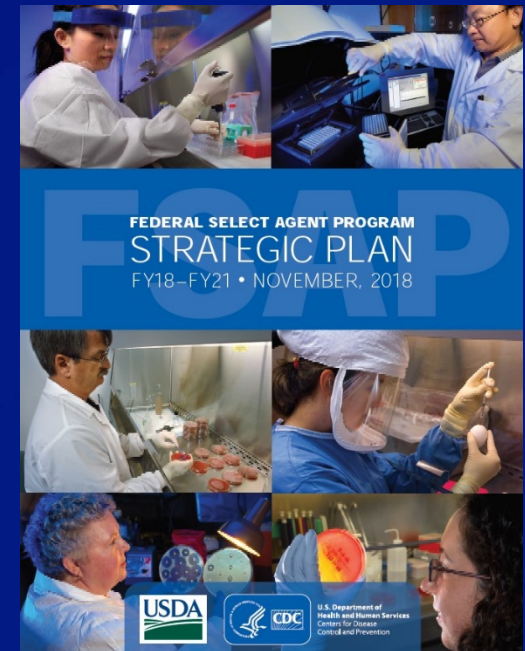
Recent Activities: Key Highlights

Key Highlights

- ❑ FSAP Strategic Plan**
- ❑ 2017 FSAP Annual Report**
- ❑ FSAP Compliance Infographics**
- ❑ Inspection Checklist App**
- ❑ Policy Statements**
- ❑ Regulatory Interpretations**
- ❑ Guidance Documents**
- ❑ Outreach**
- ❑ USDA Select Agent Regulations Technical Amendment**
- ❑ eFSAP Updates**

FSAP Strategic Plan

- ❑ Guides FSAP program efforts from fiscal year (FY) 2018 through FY 2021
- ❑ Developed with input from leadership at CDC and APHIS, regulated entities, and FSAP staff
- ❑ Published in November 2018
- ❑ Available at <https://www.selectagents.gov/publications.html>



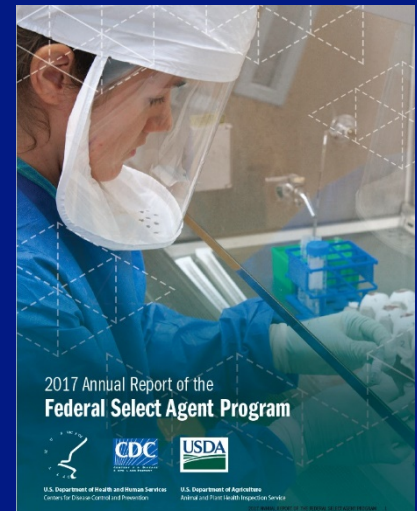
FSAP Strategic Plan (continued)

- **Outlines FSAP's mission, vision, and four key goals:**
 - Ensure the recruitment, development, and retention of a knowledgeable and professional FSAP workforce
 - Harmonize FSAP organizational processes and inspections
 - Leverage data-driven, risk-based approaches to guide FSAP operations
 - Engage, increase transparency, and highlight program benefits with FSAP's diverse stakeholders

2017 FSAP Annual Report

- ❑ Third annual report of aggregate program data - published in December 2018
- ❑ 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
- ❑ Reflects FSAP's ongoing commitment to increasing transparency

<https://www.selectagents.gov/annualreport2017.html>

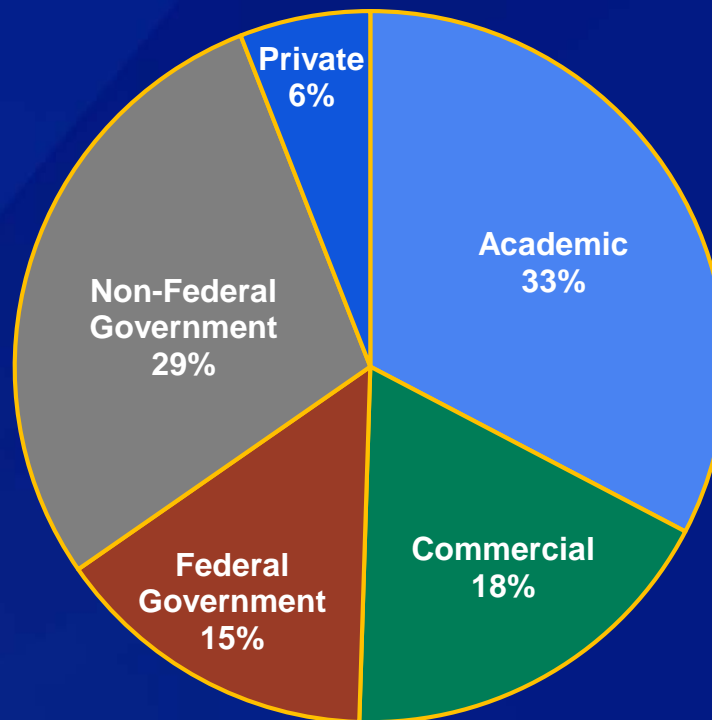


FSAP 2017: Key Facts

- ❑ 263 registered entities**
- ❑ 169 inspections conducted**
- ❑ 9,916 active individual security risk assessments**
- ❑ No reported releases resulted in an illness, death, or transmission in a laboratory or the community**

Types of Entities Registered with FSAP (2017)

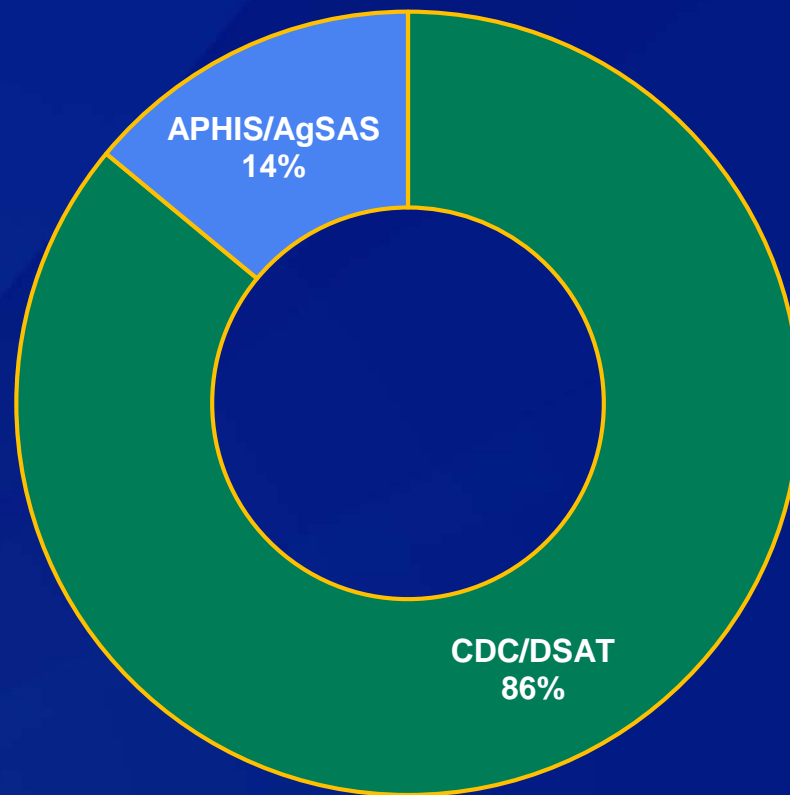
Total: 263



Source: 2017 Annual Report of the Federal Select Agent Program, <https://www.selectagents.gov/annualreport2017.html>

Registered Entities, by Lead Agency (2017)

Total: 263



Source: 2017 Annual Report of the Federal Select Agent Program, <https://www.selectagents.gov/annualreport2017.html>

FSAP Inspection Statistics (2017)

❑ Total inspections conducted: 169

- 106 by DSAT
- 31 by AgSAS
- 32 joint DSAT/AgSAS

❑ Average duration for an inspection: 2.6 days

- Range of 1-9 days



FSAP 2017 Annual Report

FEDERAL SELECT AGENT PROGRAM 2017 Annual Report | Key Statistics

The 2017 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 third report of aggregate program data, and reflects the program's ongoing commitment to transparency and increasing understanding of the program.

263

ENTITIES WERE
REGISTERED
WITH FSAP

33% ACADEMIC
18% COMMERCIAL
15% FEDERAL GOVERNMENT
29% NON-FEDERAL GOVERNMENT
6% PRIVATE
50% of entities are registered
for Tier 1* BSAT

LAB BIOSAFETY LEVELS (BSL)

ENTITIES MAY HAVE MULTIPLE TYPES

31% have BSL-2 and/or ABSL-2 labs
79% have BSL-3 and/or ABSL-3 labs
3% have BSL-4 and/or ABSL-4 labs

TOP REGISTERED AGENTS BY AGENCY

CDC's Division of Select Agents and Toxins

1. *Brucella melitensis*
2. *Brucella suis*
3. *Brucella abortus*
4. *Bacillus anthracis*
(Pasteur strain)
5. *Francisella tularensis**

APHIS's Agriculture Select Agent Services

1. Newcastle disease virus
2. Avian influenza virus
3. *Bacillus anthracis**
Brucella abortus
Ralstonia solanacearum

- 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

COMPLIANCE & ENFORCEMENT

- 8** total entities participated in a corrective action plan
(including **1** entity that newly agreed to participate in 2017)
- 4** total entities had suspended registrations
(including **2** entities newly put under suspension in 2017)
- 18** matters were shared with the Federal Bureau of Investigation for potential investigation (no action was needed in **17** of those cases, with one pending)
- 7** entities were referred to the HHS Office of Inspector General or APHIS Investigative and Enforcement Services

THEFT, LOSS, OR RELEASE

- 0** thefts reported
- 199** incidents reported involving potential occupational exposure of 1,152 laboratory workers
- 9** reports of losses determined to be records management errors
- 0** potential exposures resulting in illness, death, or transmission

TRANSFER APPROVALS: 177 DSAT | 79 AgSAS

- 29%** of the transfers were from unregistered entities to registered entities, mostly as a result of identification of BSAT in a diagnostic specimen

169

TOTAL INSPECTIONS CONDUCTED BY FSAP

106 by DSAT
31 by AgSAS
32 Joint DSAT & AgSAS

2.6

AVERAGE DURATION (IN DAYS) FOR INSPECTION

Range of
1 to **9** days

9,916

ACTIVE INDIVIDUAL SECURITY RISK ASSESSMENTS

Denied access
for **17** 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

FSAP Compliance Infographics

■ Developed a series of infographics to describe:

- How FSAP addresses serious biosafety or security concerns that may be identified at a laboratory
- What happens in the case of a theft or loss of a select agent or toxin
- What happens in the case of a release of a select agent or toxin



Available at: <https://www.selectagents.gov/infographics-compliance.html>

How the Federal Select Agent Program Addresses Serious Biosafety or Security Concerns



The Federal Select Agent Program (FSAP) routinely identifies biosafety and security concerns in laboratories through the inspection process, after which an entity must address these concerns. However, when particularly serious deficiencies in biosafety or security measures are identified – or in an instance of a theft, loss, or release – FSAP can take additional actions to address the risk and bring the entity back into compliance with the select agent regulations.

Addressing Serious Biosafety or Security Concerns

How the Federal Select Agent Program Addresses Serious Biosafety or Security Concerns

Options May Include:

Corrective Action Plan

- Addresses serious and recurrent concerns that do not present an imminent risk to public health and safety
- Participation is voluntary; if entity chooses not to participate, they must successfully resolve the regulatory departures identified within 30 days
- Entity submits a detailed plan to the Federal Select Agent Program (FSAP), including target completion dates and the specifics of how the entity will correct identified regulatory deficiencies
- Allows FSAP to monitor an entity's progress, as well as provide any needed technical assistance



Referral for Civil Penalties

- May include referral to the Department of Health and Human Services Office of Inspector General or the Animal and Plant Health Inspection Service Office of Investigative and Enforcement Services
- Reflects serious violations of the regulations (e.g., if a suspension is issued, false information is knowingly submitted, or in case of continued failure to resolve regulatory concerns)
- Referred for further investigation and may take place concurrently with other enforcement actions
- Can lead to civil monetary penalties levied by these agencies (up to \$250,000 for an individual for each violation and up to \$500,000 for an entity for each violation)



Notification to the Federal Bureau of Investigation

- Used when there may have been a violation of federal criminal law (e.g., in the case of security-related concerns, unauthorized possession, or reports of theft of a select agent or toxin)
- In addition, FBI is automatically informed of any reported loss for awareness and potential investigation
- May take place concurrently with other enforcement actions
- Can lead to criminal penalties



Suspension

- Used when FSAP has significant concerns for the health and safety of humans, animals, or plants because of the entity's failure to comply with the regulations
- Can be a complete or partial suspension of work
- Registration remains suspended until concerns are properly addressed



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)



Release of a Select Agent or Toxin

An entity is required by regulation to notify the Federal Select Agent Program (FSAP) immediately upon the discovery of the release of a select agent or toxin in a laboratory. Both entities registered with the program, as well as unregistered entities (such as clinical or diagnostic laboratories that may identify a select agent or toxin from a specimen for testing purposes), must immediately report this information.

While there is always some risk in working with these agents, our goal is to get as close to zero risk as possible. Unfortunately, sometimes incidents do occur, and this process helps to manage those situations.

What are the Potential Consequences?

- A release could result in potential exposure to and/or infection with a serious disease, either among individuals working in the laboratories or those in the surrounding communities. A release could also result in the infection of animals or plants or contaminate the environment.
- If an incident occurs and particularly serious deficiencies are identified, FSAP can take action as needed to address the risk and bring the entity back into compliance with the select agent regulations, including: suspending or revoking FSAP registration, or notification to federal enforcement agencies for consideration of civil or criminal penalties.

The majority of reported releases are potential occupational health exposures but **do not** result in illness.

What is a release?

- Occupational exposure (e.g., needle sticks, animal bites or scratches, failure of personal protective equipment)
- Release outside of the primary barriers of the biocontainment area (e.g., spill outside of a biologic safety cabinet or the laboratory itself)



Release of a Select Agent or Toxin – Who is involved in response?

Release of a Select Agent or Toxin: A Shared Responsibility Who is Involved in a Response?

Entity Working with Select Agents or Toxins

- Laboratory experiences the release and must immediately report it to FSAP
- Critical that the entity immediately assesses the scope of the situation and the health of potentially exposed individuals, and ensures that the select agent or toxin is contained
- All registered entities are required to have an incident response plan as a condition of program registration
 - This should include an assessment of risk and detail how the entity will handle those situations
 - It should be specific to the entity and the agents they are working with, up-to-date, effective, and ready to implement when needed



State/Local Public Health or Agriculture Officials

- Responsible for human and agriculture health and safety in their jurisdiction, and have the authority and responsibility to assist the entity
- Can play an active role in assessing the situation and responding to the event
- Will typically engage when the situation goes beyond the ability of the entity to manage
- May request assistance from other federal agencies



Federal Select Agent Program (FSAP)

- Receives report of a release from entity
- Works with the entity to get a complete picture of the incident – primary focus is on making sure the threat to public health or agriculture is contained, any exposed individuals have been properly evaluated, the select agent or toxin is secure, and helping the entity to assess why the failure occurred so that it does not happen again
- Can facilitate assistance between the affected entity and appropriate agencies
- May conduct an on-site visit to confirm corrective actions have been taken and/or provide technical expertise to the entity



Other Federal Agencies

- May get involved in the case of a significant threat to public health or agriculture, or when specific assistance is requested
- Assistance is typically coordinated through the state's emergency management process
- May include federal agencies such as the Environmental Protection Agency (EPA), Federal Emergency Management Agency (FEMA), or Federal Bureau of Investigation (FBI)

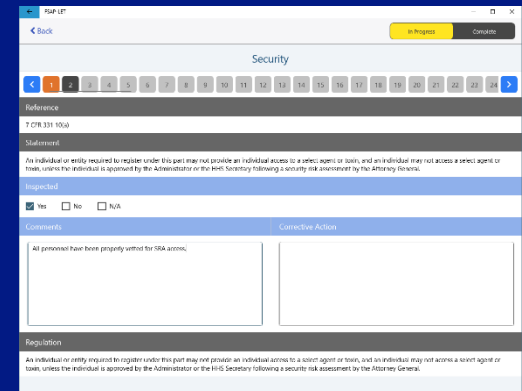
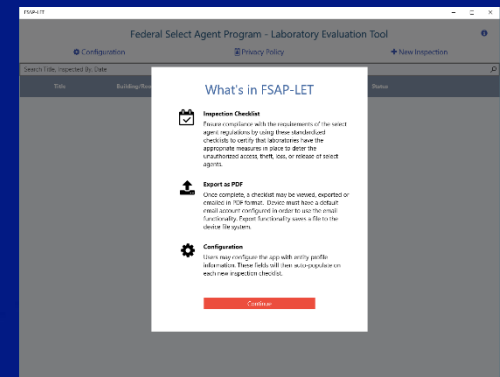


FSAP Inspection Checklist App: *Federal Select Agent Program Laboratory Examination Tool (FSAP-LET)*

- ❑ New mobile application to assist in performing internal laboratory inspections
- ❑ Contains checklists based on the select agent regulations and biosafety standards used by FSAP inspectors
- ❑ Covers a variety of areas such as biosafety, security, training, and incident response
- ❑ Available to download for use on Android, Apple, and Windows tablet devices

For more information:

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



Recent Policy Statements

- ❑ FSAP policy statement on select agent contained in formalin-fixed paraffin-embedded tissue (10/2018)
- ❑ Updated FSAP policy statement on entity annual internal inspections required by the select agent regulations (3/2019)

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

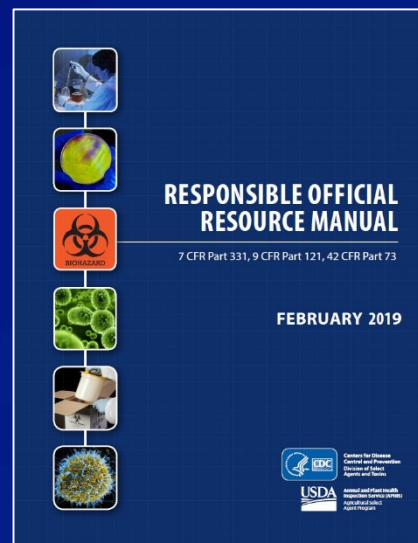
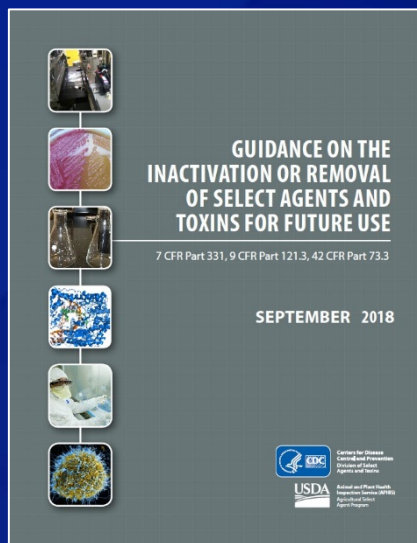
Recent Regulatory Interpretations

- ❑ Updated regulatory interpretation regarding requirement for inactivation certificates and intra-entity transfers (5/2019)
- ❑ Regulatory interpretation regarding transferring excluded amounts of toxins (6/2019)

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

Recent Guidance Documents

- ❑ Updated inactivation guidance (9/2018)
- ❑ Updated Responsible Official guidance (2/2019)



Available at <https://www.selectagents.gov/compliance.html>

Outreach

- ❑ FSAP webinar regarding the updated policy statement on entity annual internal inspections required by the select agent regulations (4/2019)
- ❑ FSAP webinars to provide training on recent updates to eFSAP (several sessions held in February and May 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:
 - ABSA (10/2018)
 - ASM Biothreats (1/2019)
 - USDA Agricultural Research Service (ARS) 5th International Biosafety & Biocontainment Symposium (2/2019)
 - ASM Microbe (6/2019)



Technical Amendment: USDA Select Agent Regulations

❑ Published September 24, 2018 in the Federal Register and contains non-substantive changes, including:

- Reclassifies *Phoma glycinicola* (formerly *Pyrenochaeta glycines*) to *Coniothyrium glycines* based on recent molecular and phylogenetic studies.
- Removes bovine spongiform encephalopathy from the list of USDA select agents and toxins whose seizure by any Federal law enforcement agency must be reported within 24 hours by telephone, facsimile, or e-mail since the agent was previously removed from the list of Veterinary Services (VS) select agents and toxins set out in 9 CFR 121.3(b) on October 5, 2012.
- Corrects the reference in paragraph (d)(9) for pigeon paramyxovirus-1 since the current numerical suffix appears as “12” instead of “1.”
- Corrects the name for the “Security Plan Guidance” from “Security Guidance for Select Agent or Toxin Facilities.”

❑ Full technical amendment available at <https://www.federalregister.gov/d/2018-20694>

DEPARTMENT OF AGRICULTURE
Animal and Plant Health Inspection
Service

7 CFR Part 331

9 CFR Part 121

[Docket No. APHIS-2009-0070]

RIN 0579-AD09

Agricultural Bioterrorism Protection
Act of 2002; Biennial Review and
Republication of the Select Agent and
Toxin List; Amendments to the Select
Agent and Toxin Regulations;
Technical Amendment

AGENCY: Animal and Plant Health
Inspection Service, USDA.

ACTION: Final rule; technical
amendment.

Electronic FSAP (eFSAP) Information System - Updates

eFSAP

- ❑ System to submit and share select agent program information was first unveiled to the regulated community in 2017
- ❑ Since then, many improvements and updates have been made – and more are on the way

The screenshot displays the Federal Select Agent Program Portal interface. At the top, there are logos for CDC and USDA. Below the logos, a navigation bar includes a 'Home' link and a 'Notifications' dropdown. The main heading is 'Federal Select Agent Program Portal'. Underneath, it identifies the 'Entity: eFSAP Test Entity'. A summary row shows 'LEAD AGENCY: CDC', 'REGISTRATION STATUS: Approved', and 'REGISTRATION EXPIRES: 10/10/2019'. Below this, specific details are listed: '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 #: cdc7c336-d1e-e711-80cf-0018d8003e2', and 'Type Status: Commercial - Profit'. On the right side, there are tabs for 'Forms' 1 through 4.

Field	Value
Entity	eFSAP Test Entity
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 #	cdc7c336-d1e-e711-80cf-0018d8003e2
Type Status	Commercial - Profit

eFSAP: Recent Major Updates

- ❑ **Redesigns and enhancements across APHIS/CDC Form 1 features and interfaces**
- ❑ **Additional APHIS/CDC Form 1 amendment types**
- ❑ **APHIS/CDC Form 1 Section 4 and 7b data export**
- ❑ **Notification enhancements**
- ❑ **Inspection module**
- ❑ **Printing of APHIS/CDC Forms 2-4**
- ❑ **File archiving**

eFSAP: Upcoming Features

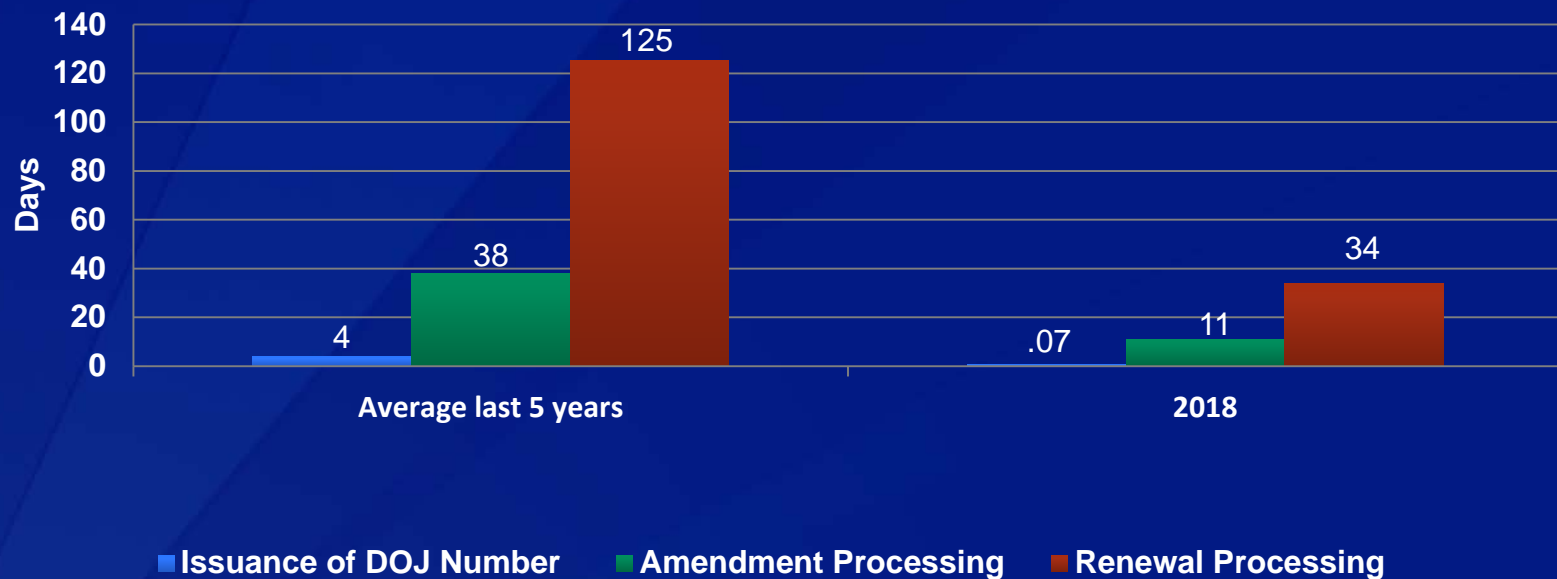
❑ Super Administrator role for entities

- User is able to draft technical amendments, draft APHIS/CDC Forms 2-4, draft inspection responses on behalf of RO/ARO (but not submit)
- Coming soon

❑ Section 7 Wizard

- Enables entities to assign principal investigators and rooms/suites to multiple work objectives without having to submit individual amendments to modify each work objective
- Expected in early 2020

eFSAP Information System: Accelerated Processing Times



Processing times for adding individuals, amendment & renewal processing

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 eFSAP information system
- ❑ Data analysis and publication of the 2018 FSAP inspection report processing annual summary and *2018 Annual Report of the Federal Select Agent Program*
- ❑ Monitoring and continuous program improvements through the FSAP Strategic Plan

Discussion

www.selectagents.gov

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

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

