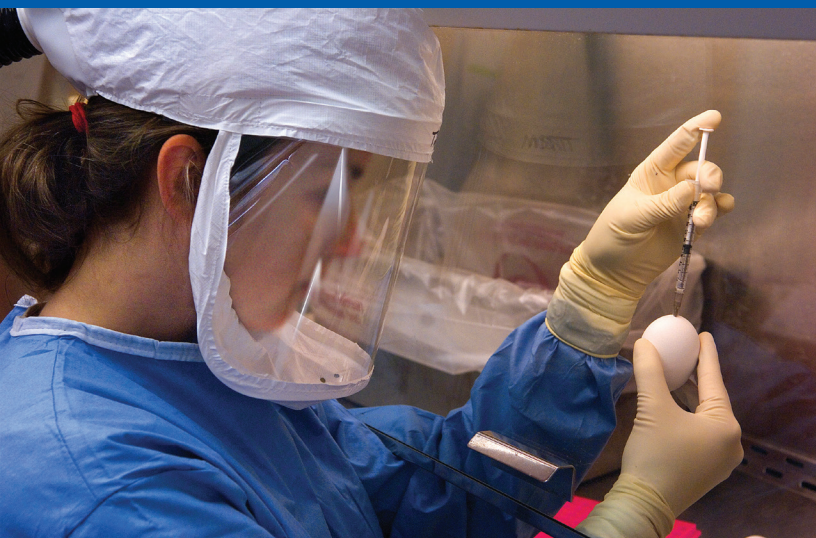


# FEDERAL SELECT AGENT PROGRAM STRATEGIC PLAN

FY18–FY21 • NOVEMBER, 2018



U.S. Department of  
Health and Human Services  
Centers for Disease  
Control and Prevention

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# Introduction

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The Federal Select Agent Program (FSAP) is jointly comprised of the Centers for Disease Control and Prevention (CDC)/Division of Select Agents and Toxins (DSAT) and the Animal and Plant Health Inspection Service (APHIS)/Agriculture Select Agent Services (AgSAS). FSAP oversees the possession, use, and transfer of biological select agents and toxins (BSAT), which have the potential to pose a severe threat to public, animal, or plant health or to animal or plant products.

We are pleased to share this FSAP Strategic Plan, which will guide our efforts for the remainder of fiscal year (FY) 2018 through FY2021. Our joint strategic planning effort serves as a clear reminder of the many successes we have achieved together over nearly two decades as FSAP, as well as the myriad challenges against which we must continue to focus in order to sustain and enhance biosafety and security of BSAT in the United States.

We are proud of FSAP's accomplishments. Since 2003 (the beginning of the program in its current regulatory form), FSAP has provided the nation with:

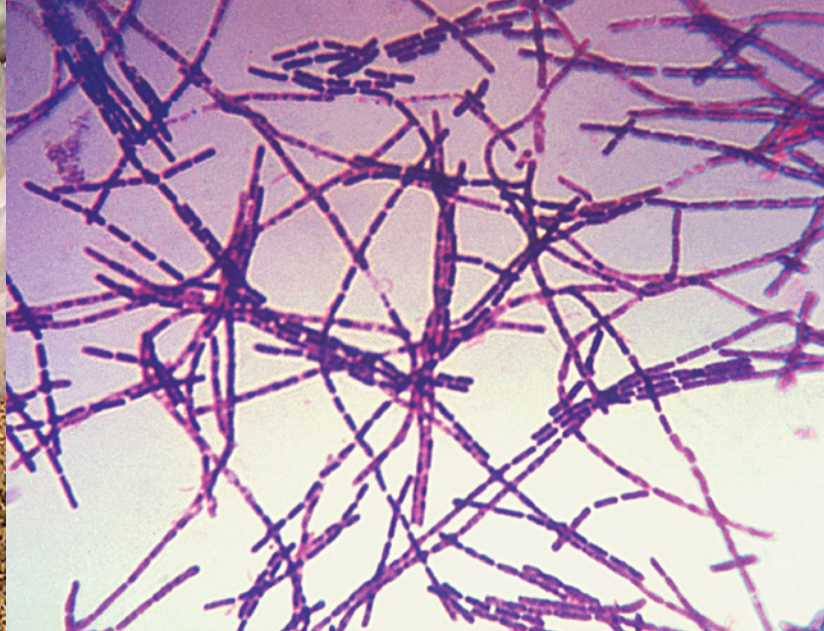
- A comprehensive database (now in real-time) containing information on all entities registered to possess BSAT, including the location of the agents, the individuals who work with them, and associated activities
- Standard safety and security regulatory requirements for all entities working with BSAT
- A national system for reporting the theft, loss, or release of BSAT
- A personal risk assessment system based on background checks for all individuals accessing BSAT performed by the Federal Bureau of Investigation (FBI)
- A system to provide state emergency preparedness and response planners with information on BSAT facilities within their jurisdictions
- A surveillance system to track the isolation and identification of BSAT by front-line laboratories
- A confidential system for reporting safety and security concerns regarding BSAT
- A tracking mechanism to monitor BSAT shipments and to ensure that senders and recipients are adequately registered for possession of BSAT.

In September 2017, FSAP initiated development of this joint DSAT/AgSAS Strategic Plan with input from CDC and APHIS leadership, regulated entities, and FSAP staff. In addition, the enclosed content reflects our intent to prioritize activities, placing particular emphasis on the strategies we believe will most effectively and efficiently support achievement of FSAP goals and objectives. We are pleased to share this Strategic Plan with you, and look forward to continuing to strengthen our efforts towards ensuring the safety and security of work with BSAT at laboratories across the country.

Sincerely,

Dr. Samuel S. Edwin, Ph.D.  
Director of DSAT

Dr. Adis Dijab, DVM  
Director of AgSAS



## FSAP Plan Overview

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### FSAP Mission

To regulate the safe and secure 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 in the United States.

### FSAP Vision

To provide coordinated, efficient oversight and be the preeminent regulatory resource for ensuring the safety and security of biological select agents and toxins.

### FSAP Goals

1. Ensure the recruitment, development, and retention of a knowledgeable and professional FSAP workforce.
2. Harmonize FSAP organizational processes and inspections.
3. Leverage data-driven, risk-based approaches to guide FSAP operations.
4. Engage, increase transparency, and highlight program benefits with FSAP's diverse stakeholders



# FSAP Plan Detail

This section provides a detailed explanation of each goal as well as a description of associated objectives and strategies.

## GOAL 1 **Ensure the recruitment, development, and retention of a knowledgeable and professional FSAP workforce**

In order to provide coordinated, efficient oversight and to be the preeminent regulatory resource in our field, FSAP must continue to focus squarely on recruitment, development, and retention of staff. FSAP employees provide essential, front-line service to the organization's mission and, therefore, leadership must continue to invest in their growth and development, provide opportunities to enhance their knowledge, and support them in applying and refining collective talents.

### **Objective 1: Apply Lessons Learned from FSAP Work Assessment**

FSAP is a joint complex program undertaken by both DSAT and AgSAS. Each agency has unique human resource requirements and expectations. FSAP needs to conduct a comprehensive workforce assessment study to help inform CDC and APHIS regarding strategic staffing decisions, alignment of current and future staffing, and any investment in training and/or education for staff that would yield higher outputs and outcomes to ensure the highest degree of effectiveness and efficiency in the program with mitigating or minimizing existing risks. The information gained in the study will assist in the harmonization of FSAP policies. The evaluation of both the CDC and APHIS staffing is needed to identify the current as-is state of the program and the to-be or needed state of the program based upon legal and operational needs and requirements.

#### **Strategy 1: Conduct FSAP Workforce Assessment to identify crosscutting needs**

*Anticipated Completion: End of FY19*

We will complete a joint Workforce Assessment in support of an ultimate FSAP-wide Workforce Plan. DSAT and AgSAS are

already coordinating workforce development as well as looking to leverage each Agency's strengths further to enhance policies, procedures, and operations. For example, DSAT and AgSAS currently rely on each other's expertise during inspections of entities (i.e., veterinarians reviewing biosafety protocols for work with large animals, microbiologists reviewing protocols and procedures involving advanced molecular diagnostics). This Workforce Assessment will assess the feasibility of further coordinating activities to remove duplicative oversight functions, allowing both programs to leverage the strengths of one program to perform a function for both Agencies. The Workforce Assessment is essential to identify gaps, and to ensure staff training and development needs and retention of experienced staff. FSAP contacted the Animal and Plant Health Inspection Service (APHIS) Policy and Program Development (PPD) to perform the Workforce Assessment. APHIS PPD has provided FSAP with a timeline and plan for the assessment to be completed by the end of September 2019.

#### **Strategy 2: Refine and implement associated FSAP Workforce Plan** *Anticipated Completion: End of Quarter 2, FY19*

FSAP will review and, if necessary, refine the Workforce Plan developed in Strategy 1, for implementation by March 2020. Implementing this Workforce Plan will ensure that FSAP hires positions in a strategic, coordinated manner, prioritizing vacancies and funding positions most critical to overall success. Ultimately, however, implementation of the final FSAP Workforce Plan, including hiring, will be dependent on Administration/Department factors and budget.

**Strategy 3:****Monitor progress against FSAP Workforce Plan elements****Anticipated Completion: Ongoing through FY21**

FSAP views the upcoming Workforce Plan as a “living” document, which should be assessed and modified as necessary. FSAP will establish a method to solicit feedback and measure the efficacy of the Workforce Plan activities in achieving intended outcomes. FSAP leadership will review the feedback information, and revise the Workforce Plan as necessary to ensure progress toward overall goals.

**Objective 2:****Build and maintain a well-trained, skilled workforce**

FSAP must continue to develop a well-trained, skilled workforce. As such, the program intends to invest in the growth and development of its entire workforce. The FSAP Training Program will include curricula related to key technical skills, as well as soft skills (e.g., customer-focused behaviors). FSAP will also continue to provide staff external training whenever possible, based on the availability of funds.

**Strategy 1:****Refine FSAP Training Needs Analysis to identify training needs**

In January 2018, FSAP completed a Training Needs Analysis. The objective of the analysis was to identify performance requirements and the knowledge, skills, and abilities needed by the FSAP workforce to achieve the requirements within the role of FSAP inspectors. Based on the analysis, FSAP determined that its inspector training must include new/emerging science and policy/regulations changes, amongst other topics. A Curricula Design Plan for FSAP New Hire and Experienced Staff has been created based on the analysis findings. Currently, FSAP is designing and developing the courses listed and described in the Curricula Design Plan.

**Strategy 2:****Refine existing, and develop new, curricula per coordinated, easily accessible, FSAP Training Program****Anticipated Completion: End of CY19**

Courses under development for new FSAP inspector training include biosafety, risk assessment, inspection processes, regulatory compliance, communications,

and BSAT. The training will be conducted via electronic media (eLearning). It will apply adult learning principles and include materials for new/emerging science and policy/regulations changes. Updates to training course materials will be an ongoing effort and FSAP expects to complete new inspector curricula by end of FY19 and refresher material by end of CY19.

**Strategy 3:****Gauge effectiveness and continuously improve FSAP Training Program****Anticipated Completion: Ongoing through FY21**

FSAP will develop a method to gather feedback and modify its Training Plan and related curricula, as necessary, to ensure that training remains current/high quality, and supports intended outcomes. This methodology will include two types of measures and assessment - formative (evaluate course materials prior to launch) and summative (evaluate levels of learning that occur post-launch as a result of completing the training).

**Objective 3:****Maximize employee retention across FSAP**

Another important contributor to workforce excellence is staff retention. It takes FSAP considerable effort to hire, onboard, and train personnel. For example, it can take 6 months to 1 year before a new inspector is sufficiently trained to lead an inspection. Therefore, maximizing retention of well-trained, experienced staff is critical to achievement of FSAP’s mission.

**Strategy 1:****Identify key retention factors****Anticipated Completion: End of FY19**

FSAP will conduct a FSAP Workforce Assessment highlighted in Goal 1, Objective 1. During the assessment, FSAP will identify factors influencing retention of its trained and experienced employees.

**Strategy 2:****Develop Succession Planning****Anticipated Completion: End of FY20**

FSAP will incorporate succession planning into the FSAP Workforce Assessment highlighted in Goal 1, Objective 1. Succession planning is an important

component of employee retention to ensure that there is an increase in the availability of experienced and

capable employees that are prepared to assume these roles as they become available.

# GOAL 2

## Harmonize FSAP organizational processes and inspections

FSAP will continue to build on longstanding efforts to harmonize DSAT and AgSAS activities as much as possible in order to build an even stronger, resilient program.

### **Objective 1: Drive consistency in FSAP policies and procedures**

FSAP needs to provide for seamless, coordinated regulatory oversight of the possession, use, and transfer of BSAT. At the same time, FSAP understands the regulated community's desire for a regulatory system that minimizes conflict and administrative burdens.

#### **Strategy 1:**

##### **Ensure common standard operating procedures**

*Anticipated Completion: Ongoing through FY21*

DSAT and AgSAS will each continue to assess their own standard operating procedures (SOPs) to ensure that these can be leveraged into joint processes followed consistently across FSAP. FSAP has already completed considerable joint work in the areas of conducting inspections, eFSAP, and other key operational activities.

#### **Strategy 2:**

##### **Continue joint communications exchange and lessons learned**

*Anticipated Completion: Ongoing through FY21*

One of FSAP's most effective communication exchange achievements has been the development, implementation, and refinement of its secure information system, eFSAP. For the first time, this two-way portal is accessible to both FSAP and the regulated community. The system increases efficiency by greatly enhancing information exchange with FSAP. In addition to continuing to leverage eFSAP, FSAP will also continue to focus on communications exchange

through joint meetings (e.g., weekly coordination calls, a weekly compliance meeting, and operational meetings). FSAP also currently holds, and will continue to facilitate, joint-training sessions with recurring discussions of lessons learned. FSAP will also gather feedback annually to assist in evolving this strategy as appropriate.

#### **Strategy 3:**

##### **Enhance ability to measure FSAP performance via joint measures, audit mechanisms, and periodic review**

*Anticipated Completion: End of second quarter, FY19*

FSAP will develop a Performance Monitoring Plan by mid FY2019, related to this Strategic Plan, to identify performance measures, build a measures dashboard, design and implement a performance review approach, and conduct ongoing performance monitoring.

### **Objective 2:**

### **Drive consistency in FSAP inspections**

FSAP performs inspections to ensure that regulated entities comply with the regulations, plus identify and facilitate response to serious biosafety or security concerns as quickly as possible. FSAP plans to build upon intensive work conducted over recent years to improve the consistency of its inspection processes.

#### **Strategy 1:**

##### **Continue to utilize interchangeable pool of inspectors across FSAP**

*Anticipated Completion: Ongoing through FY21*

FSAP will continue the process of cross-utilizing inspectors from AgSAS and DSAT to perform joint reviews, leveraging specific Agency expertise to benefit the entire program. Currently, inspections are staffed through a pool of inspectors based off workload and availability. The inspectors enhance their knowledge of critical skills and expand areas of expertise by proactively engaging in a range of different inspection

types and opportunities. Critical to such an effort is a methodology for knowledge management and cross training, which FSAP will build and incorporate as an aspect of this strategy.

**Strategy 2:**

**Ensure routine dialog and communication venues for inspectors**

*Anticipated Completion: Ongoing through FY21*

FSAP will continue to utilize joint inspector training sessions and weekly email correspondence as two key methods to communicate trends/changes in the enforcement of regulations. In addition, as another communications venue related to inspectors, FSAP holds a weekly compliance meeting that is open to all FSAP staff. Going forward, FSAP will also evaluate and implement additional methods, as appropriate, to support its inspectors in sharing lessons learned/best practices, as well as facilitating knowledge transfer.

**Strategy 3:**

**Ensure consistent inspections scheduling**

*Anticipated Completion: Ongoing through FY21*

FSAP will continue to conduct bi-weekly inspections coordination calls to identify priorities, coordinate inspection schedules, and determine the most effective use of staff resources. The calls ensure that inspection activities and staff expertise are aligned with the FSAP's mission priorities. In addition, as highlighted in Goal 2, Objective 1, FSAP has developed SOPs on inspection preparation. These involve multiple layers of staffing and review through multiple tiers of FSAP leadership to ensure consistency and promote transparency in the scheduling and staffing process.

**Strategy 4:**

**Conduct regular review/Root Cause Analysis of inspections results**

*Anticipated Completion: Ongoing through FY21*

FSAP has developed a plan to analyze the data from eFSAP to identify common inspection findings and to develop mitigations, including training and sharing best practices within the regulated community through in-person workshops and broadcasted webinars, as appropriate.

# GOAL 3 **Leverage data-driven, risk-based approaches to guide FSAP operations**

FSAP will become more effective and efficient by leveraging data-driven, risk-based approaches. In addition to increasing performance, using these approaches will help ensure that oversight is targeted to the highest risk activities and program decisions are supported by scientific fact and risk analysis.

**Objective 1:  
Ensure a robust, available electronic FSAP (eFSAP) information system**

FSAP's secure information system, eFSAP, is used to submit select agent program information. This two-way portal is accessible by both FSAP and the regulated community. The system increases efficiency by greatly enhancing information exchange and collaboration within FSAP. FSAP continues to develop eFSAP system enhancements and improve

its capabilities (e.g., through new features such as an inspection module and report function). Moreover, FSAP will continue to make eFSAP further available to approved stakeholders.

**Strategy 1:**

**Identify and develop a dedicated, interagency, eFSAP team blending science and IT expertise**

*Anticipated Completion: End of FY19*

FSAP has employed a temporary team of microbiologists and veterinary medical officers to assist IT personnel in understanding operational requirements and to design development parameters for eFSAP. FSAP will explore permanent options for making operational subject matter experts part of the IT development and testing team.



**Strategy 2:****Continue to develop and increase eFSAP functionality***Anticipated Completion: Ongoing through FY21*

FSAP continues to increase the functionality of the eFSAP information system. Functionality is being provided in quarterly releases against a long-term master list of Steering Committee priorities.

**Strategy 3:****Review and evaluate user input and incorporate user group needs***Anticipated Completion: Ongoing through FY21*

FSAP continually engages with the regulated community to gather input and provide training on the use of eFSAP. Even though FSAP has already opened up read-only access to certain users, it needs to make eFSAP available to all approved stakeholders. This strategy relies on the development of a plan to identify approved stakeholders, highlight their specific access needs, and determine how FSAP will enhance the system functionality to address those needs.

**Objective 2:****Improve efficiency and reporting via eFSAP data analytics**

Real-time data is critical to making data-driven decisions and providing current information for better and faster reporting of issues of potential agriculture and public health concerns.

**Strategy 1:****Improve employee efficiencies, quality, and timeliness through the use of eFSAP***Anticipated Completion: Initial implementation through end of FY19 with revision thereafter through FY21*

To improve the quality and timeliness of program data, FSAP will develop accountability standards for program employees using the eFSAP system. By focusing on timely responses to amendments, transfer requests, and inspection report issuance, FSAP will ensure that important research is not delayed. Additionally, up-to-date metrics in eFSAP will assist managers in addressing concerns such as poor performance, workload leveling, or other constraints that could affect program performance.

**Strategy 2:****Investigate data coordination efforts with the Criminal Justice Information Services (CJIS) Division of the****Federal Bureau of Investigation (FBI)***Anticipated Completion: end of FY19*

A Security Risk Assessment (SRA) is the electronic records check performed by CJIS to determine whether an entity or an individual that wishes to register to possess, use, or transfer a select agent or toxin, or an individual who has been identified by a registered entity as having a legitimate need to access a select agent or toxin, meets one of the statutory restrictors which would either prohibit registration or restrict access, respectively. FSAP will investigate data coordination efforts with CJIS regarding security risk assessment information to prevent delays in individual's access to BSAT.

**Objective 3:****Prioritize operational activities via risk-based approaches**

FSAP will develop and implement a plan to identify which laboratory activities carry the highest biological safety and security risks and respond to those risks by aligning inspections and other oversight efforts to target those activities.

**Strategy 1:****Develop analysis tools to quantify risks in real time***Anticipated Completion: Ongoing through FY21*

FSAP will continue to develop analysis tools to analyze the data from eFSAP to align inspections and other oversight efforts with the highest biological safety and security risks. FSAP recently completed a plan to analyze the data from eFSAP to place entities into a specific risk category, based on such criteria as the agents in possession, laboratory activities, past inspection findings, staff turnover, etc. FSAP is also looking at alternative tools to quantify risks, such as development of a Real-Time Risk Analysis Module in eFSAP, which will assist in prioritizing entity activities based on risk criteria.

**Strategy 2:****Improve transparency in determining biosafety and security risks***Anticipated Completion: Ongoing through FY21*

Based upon the risk categories developed in Strategy 1, FSAP will develop related tools for inspectors and the regulated community to provide them with information about high-risk activities and mitigation strategies.

# GOAL 4 **Engage, increase transparency, and highlight program benefits with FSAP's diverse stakeholders**

FSAP will effectively communicate its value to key audiences, which could include, for example, the regulated community, national and international scientific communities, policymakers, and the general public.

## **Objective 1: Share information more effectively with regulated community**

Communication between FSAP and the regulated community is critical, and FSAP will investigate ways (in addition to methods currently being employed) to share information more effectively with registered entities.

### **Strategy 1: Reduce burden and increase registered entity customer satisfaction**

*Anticipated Completion: Ongoing through FY21*  
FSAP will continue to work to make this a more responsive program (e.g., using eFSAP to provide more timely interaction with the regulated community).

### **Strategy 2: Seek feedback on draft program documents before implementation**

*Anticipated Completion: Ongoing through FY21*  
As appropriate, FSAP will continue to share materials (such as guidance documents) with the regulated community before these are finalized to allow stakeholders opportunity to provide valuable input on matters that have significant impact (both positive and negative) on their work.

### **Strategy 3: Effectively leverage current, and evaluate/ apply new, communication methods**

*Anticipated Completion: Ongoing through FY21*  
FSAP will evaluate current methods of communication with the regulated community (such as listserv messages—known as SA Grams—and program publications such as the Annual Report of the Federal Select Agent Program) and investigate new ways to share information with registered entities.

### **Strategy 4: Provide an environment for sharing information and lessons learned**

*Anticipated Completion: Ongoing through FY21*  
FSAP will continue to utilize existing mechanisms (e.g., conducting workshops and/or training for the regulated community plus continuing to support an independent forum to encourage routine peer-to-peer sharing) to provide the regulated community with opportunities to share information, discuss lessons learned, and network with their peers.

## **Objective 2: Engage non-regulated community more effectively**

FSAP will investigate ways to share information more effectively with key audiences, not part of the regulated community, to highlight the importance of FSAP.

### **Strategy 1: Inform policy makers on significant events and trends**

*Anticipated Completion: Ongoing through FY21*  
FSAP will share information with the policy community including existing program publications such as the Annual Report of the Federal Select Agent Program as well as explore additional ways to share information on events and trends.

### **Strategy 2: Share information and best practices with stakeholders at the federal, state, and international levels**

*Anticipated Completion: Ongoing through FY21*  
FSAP will continue to share information and best practices with U.S. government and international organizations. FSAP will also continue to participate in the International Expert Group of Biosafety and Biosecurity Regulators.

### **Strategy 3: Inform and educate the general public**

*Anticipated Completion: Ongoing through FY21*  
FSAP will continue to develop transparent and effective outreach efforts to the general public.

**Strategy 4:**  
**Leverage workforce, as appropriate, as effective**  
**FSAP advocates**  
*Anticipated Completion: Ongoing through FY21*

FSAP will encourage staff to serve as program ambassadors by attending and/or presenting at key national/international events and publishing FSAP-related information in scientific journals.

## Conclusion

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FSAP feels strongly that by effectively implementing the strategies in this joint Strategic Plan, the program can best realize its vision of providing coordinated, efficient oversight and being the preeminent regulatory resource for ensuring the safety and security of BSAT. This FSAP Strategic Plan will serve

as a guide to align staff and resource allocation, assist DSAT and AgSAS in harmonizing policies and procedures, increase efficiencies within FSAP, and help us understand the needs of our regulated/non-regulated communities (and how best to meet these through effective communication).

