



Updates from the Federal Select Agent Program (FSAP)

Samuel S. Edwin, Ph.D. & Keith Wiggins, DVM
Federal Select Agent Program

2018 Responsible Official Workshop



August 15, 2018



Recent Activities: Key Highlights

FSAP Program Improvement Emphasis on:

- ❑ Improving entity oversight, including:
 - Facility inspections
 - Inspection reporting

- ❑ Improving customer service

- ❑ Improving incident response

- ❑ Increasing transparency and engagement



For updates, visit https://www.cdc.gov/phpr/dsat/review_initiatives.htm

Publication of 2017 DSAT Inspection Report Processing Annual Summary

- ❑ Third annual report, released in May 2018
- ❑ Data show that DSAT continues to make substantial improvements in its ability to provide timely feedback to entities.
- ❑ Key findings:
 - Nearly all inspection reports – 96% – issued by DSAT in 2017 were issued within DSAT’s target of 30 business days. Only 6 reports out of 142 did not meet this goal.
 - This reflects an improvement of 32% over 2016 data, even with an increase in the number of inspection reports issued, and a 50% improvement since 2015.
 - Once again, improvements in report timeliness occurred across all inspection types, with particularly notable improvements in maximum containment inspections.



Full report is available at https://www.cdc.gov/phpr/dsat/review_reports.htm

Recent Policy Statements

- ❑ FSAP policy statement on chemical inactivation of whole tissue or homogenized tissue (2/2018)
- ❑ AgSAS policy statement regarding biosafety level requirements for virulent Newcastle Disease virus (2/2018)
- ❑ AgSAS policy statement regarding live bird lethality testing requirements for pathogenicity testing of reverse genetically derived viruses for avian influenza virus (2/2018)

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

Recent Policy Statements (cont.)

- ❑ FSAP policy statement on inactivation certificates (8/2018)
- ❑ FSAP policy statement on registration and inspection of effluent decontamination systems (8/2018)
- ❑ FSAP policy statement (and accompanying guidance) on entity annual internal inspections required by the select agent regulations (8/2018)
- ❑ Revised FSAP policy statement on the application of the requirement for a “validated inactivation procedure” (8/2018)

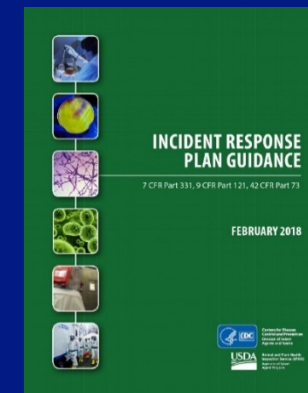
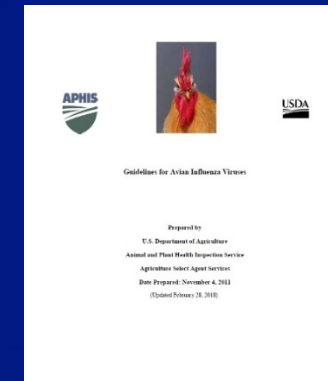
Available at <https://www.selectagents.gov/regulations-policy.html>

Recent Guidance Documents

- ❑ Updated avian influenza virus guidance (2/2018)
- ❑ Updated incident response plan guidance and template (3/2018)
- ❑ Updated biosafety/biocontainment plan guidance (7/2018)
- ❑ New guidance on entity annual internal inspections required by the select agent regulations (8/2018)

Available at

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



Recent Exclusions

- ❑ **Foot-and-mouth disease, FMD-LL3B3D A24 Cruzeiro, vaccine virus (effective 4/30/18)**

- ❑ ***Burkholderia pseudomallei* Δasd strains (effective 12/13/17)**
 - *DL2 Δasd*
 - *DL25 Δasd*
 - *DL28 Δasd*
 - *MSHR503 Δasd*
 - *NAU44A6 Δasd*
 - *MSHR840 Δasd*
 - *MSHR1655 Δasd*
 - *MSHR87 Δasd*
 - *MSHR367b Δasd*

Recent Exclusions (cont.)

- ***Burkholderia mallei* Δasd strains (effective 12/13/17)**
 - ATCC23344 Δasd
 - Ivan Δasd
 - China 5 Δasd
 - 2002721278 Δasd

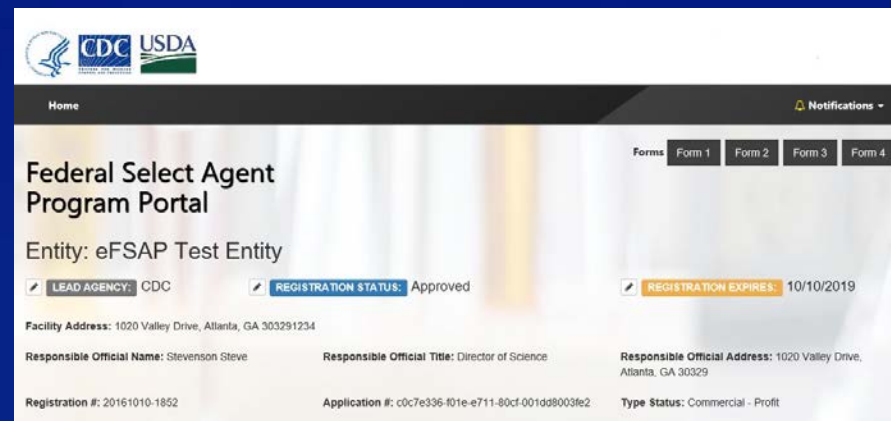
For more information:

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

Electronic FSAP (eFSAP) Information System - Updates

eFSAP

- ❑ New secure information system used to submit and share select agent program information with entities
- ❑ System will increase efficiency by greatly enhancing information exchange between FSAP and registered entities
- ❑ Currently being rolled out to users at registered entities



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". The user is logged in 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-e711-80cf-001d98003e2
Type Status: Commercial - Profit		

eFSAP: Benefits

- ❑ Secure, web-based user interface (portal)
- ❑ Reduced paperwork
- ❑ Increased ease of validating and submitting information
- ❑ Reduced processing time for requests
- ❑ Increased efficiency
- ❑ Searchable; will provide immediate, real-time information on *who* has *what* select agents, and *where*

eFSAP: Major Updates

- ❑ **APHIS/CDC Form 1 amendments**
 - Section 1
 - Section 5
 - Section 7b
- ❑ **Ability to view or download supporting documents**
- ❑ **Use for immediate notification submissions for APHIS/CDC Forms 3 and 4A**
- ❑ **Email notifications**
- ❑ **View-only user feature**
- ❑ **System-wide data table redesigns and enhancements to file upload features**
- ❑ **Regional training workshops in five cities across the country**

eFSAP: Major Updates (continued)

- ❑ **Launched online 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>



Permitting Programs

- ❑ Both APHIS and CDC have import permitting units, for non-select biological materials that could cause or introduce agricultural or human disease (respectively)
- ❑ These programs ensure that the importation (CDC + APHIS) and/or interstate transport (APHIS) of these agents is monitored and that facilities receiving permits have appropriate biosafety measures in place to work with the permitted agents.

CDC Import Permit Program (IPP)

<https://www.cdc.gov/phpr/ipp/index.htm>

APHIS Organisms and Vector Permitting

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/ct_organisms_and_vectors

ePermitting

- APHIS Organisms and Vectors → ePermits → eFile
- CDC IPP → eIPP

NEW
eIPP

Secure, electronic-based, user-friendly information system, featuring a two-way portal for submitting and sharing information, accessible by IPP and customers

Applicant Benefits



- Shorter permit processing time*
- Centralized location for status updates*
- Historical record of permits*
- Saves user time when applying in future*

Ongoing and Future Efforts

- ❑ Continuing to develop and increase capabilities of eFSAP information system
- ❑ Annual Report of the Federal Select Agent Program
- ❑ Joint FSAP strategic planning
- ❑ Policy on select agents contained in formalin-fixed, paraffin-embedded tissue
 - Draft sent to the regulated community for comment in July 2018

Discussion

www.selectagents.gov

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

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

