



# Updates from the Federal Select Agent Program (FSAP)

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**Federal Select Agent Program**

2018 Responsible Official Workshop



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# **Recent Activities: Key Highlights**

## FSAP Program Improvement Emphasis on:

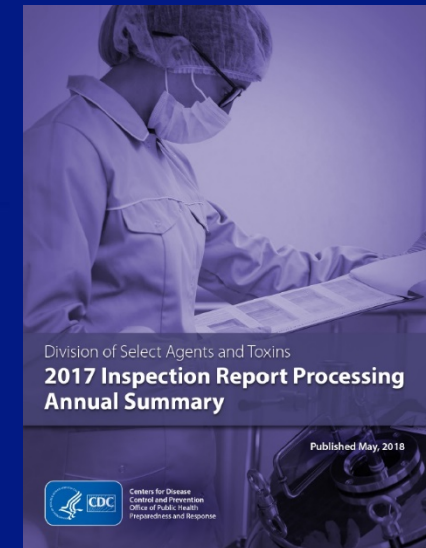
- ❑ Improving entity oversight, including:
  - Facility inspections
  - Inspection reporting
- ❑ Improving customer service
- ❑ Improving incident response
- ❑ Increasing transparency and engagement



For updates, visit [https://www.cdc.gov/phpr/dsat/review\\_initiatives.htm](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](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>

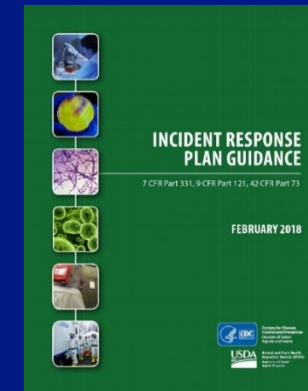
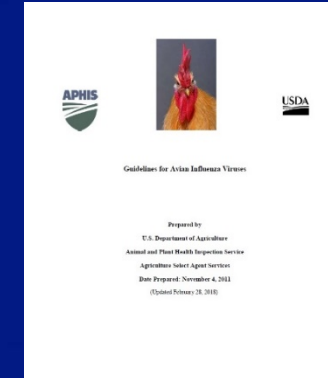


## Recent Guidance Documents

- ❑ 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*  $\Delta asd$  strains (effective 12/13/17)
  - DL2  $\Delta asd$
  - DL25  $\Delta asd$
  - DL28  $\Delta asd$
  - MSHR503  $\Delta asd$
  - NAU44A6  $\Delta asd$
  - MSHR840  $\Delta asd$
  - MSHR1655  $\Delta asd$
  - MSHR87  $\Delta asd$
  - MSHR367b  $\Delta asd$



## Recent Exclusions (cont.)

- ❑ ***Burkholderia mallei*  $\Delta asd$  strains (effective 12/13/17)**
  - ATCC23344  $\Delta asd$
  - Ivan  $\Delta asd$
  - China 5  $\Delta asd$
  - 2002721278  $\Delta asd$

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 eFSAP portal interface. At the top, there are logos for the 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'. Below this, the user's entity is identified as 'Entity: eFSAP Test Entity'. A summary section shows 'LEAD AGENCY: CDC', 'REGISTRATION STATUS: Approved', and 'REGISTRATION EXPIRES: 10/10/2019'. To the right of this section are links for 'Form 1', 'Form 2', 'Form 3', and 'Form 4'. The bottom of the page contains detailed information: '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-001dd98003e2', and 'Type Status: Commercial - Profit'.

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 #	c0c7e336-f01e-e711-80cf-001dd98003e2
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](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

*Faster 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](http://www.selectagents.gov)

CDC: [lsat@cdc.gov](mailto:lsat@cdc.gov) or 404-718-2000

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

