

Federal Select Agent Program Responsible Official (RO) Webinar Series, 2022

FSAP Report Cards and eFSAP
Information System Updates

August 17, 2022

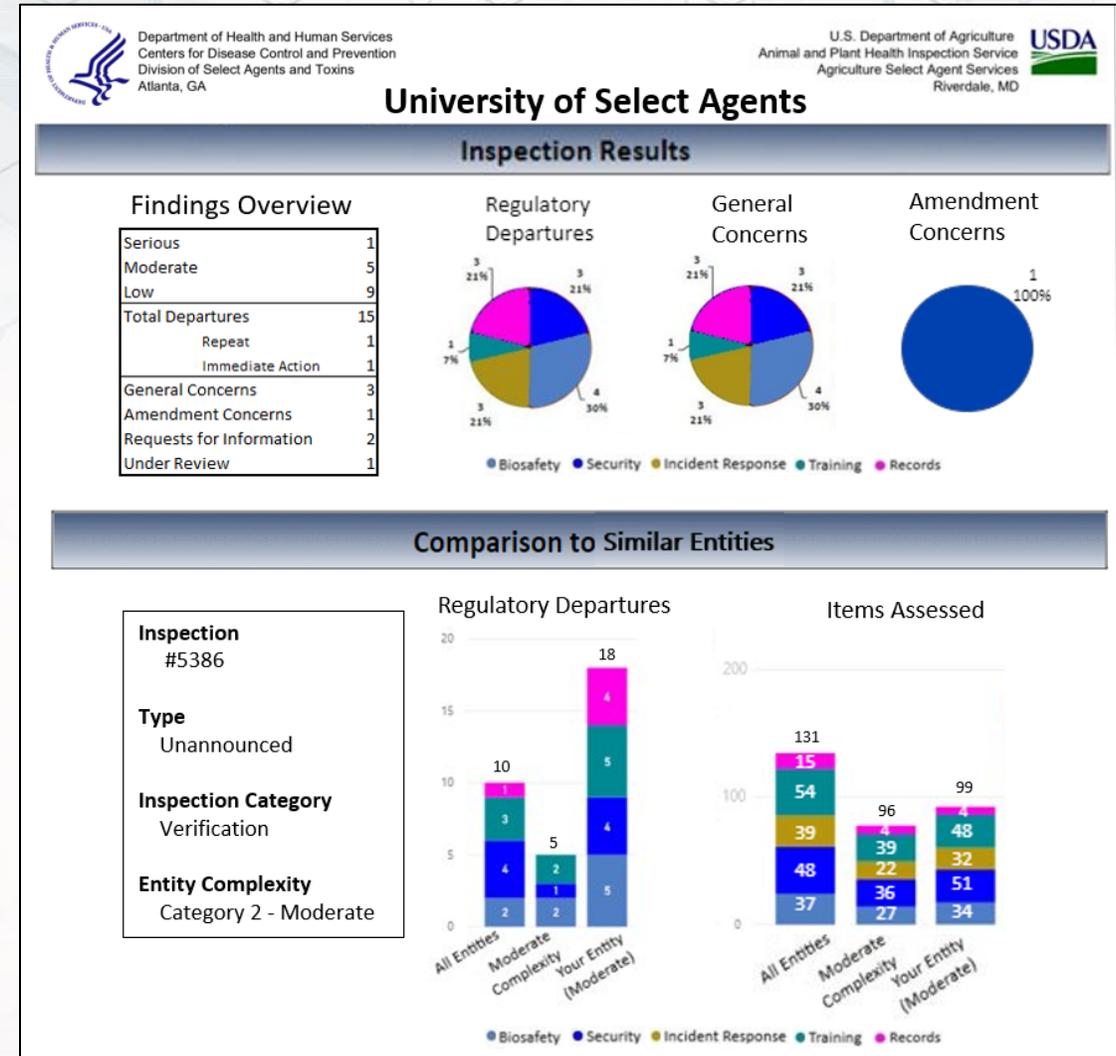


Inspection Report Cards



Inspection Report Cards

- FSAP reintroduction of inspection report cards
- The report card breaks down your most recent inspection to show:
 - The types of inspection findings
 - Areas of the regulations to which the findings apply
 - The number of findings versus the total number of items assessed on the inspection
 - How your entity's inspection results compare to all entities versus your peers (entities of similar complexity)



February 2022 Updates



eFSAP Information System - Inspection Module Updates

Hybrid Inspections

- eFSAP Information System links an initial remote inspection with an on-site follow-up visit
- Follow-up inspections are denoted with a “.1” appended to the original inspection number
- Inspector’s checklists alert them to items previously assessed remotely to reduce redundancy during the follow-up visit

Notifications

Filter: All

Archive Selected

Current Archived Flagged

Select All	From	Type	Date And Time	Notification	
<input type="checkbox"/>				7734	
<input type="checkbox"/>	fte advanced	Inspections View	8/10/2021 10:22:59 AM	Inspection #7734.1 status changed from Scheduled to In Progress.	Flag
<input type="checkbox"/>	fte advanced	Inspections View	8/9/2021 3:34:15 PM	Inspection #7734.1 has been scheduled.	Flag

Inspections

Inspection #	Inspection Type	Start Date	Stop Date	Lead Inspector	Inspection Status
7734		Start Date End Date	Start Date End Date		
7734.1	Announced	08/10/2021	08/10/2021	Albert Einstein	In Progress
7734	Announced	07/28/2021	07/28/2021	Albert Einstein	Closed



eFSAP Information System - Inspection Module Updates

Enhancements to Uploads for Supporting Documentation

- Each departure or request for information contains an “upload” button that automatically associates the document with the checklist unique identifier (UID)
- Note: Users must enter and send their text response before the “upload” button is available

Entity Response

The biosafety cabinet has been re-certified. Attached is the certification record.

← New “upload” button

Upload a file

Step 1: Identify File Data

* = Required

Non-Form *

Inspection # *
32 characters remaining.

Sub-Category *

Post-Inspection Documents

Description *
123 characters remaining.

Unique Identifier *

Step 2: Select the File

No file chosen

Show file naming rules

← Pre-populated checklist UID



eFSAP Information System - Inspection Module Updates

“Closed Conditionally” Status for Departures

- FSAP provides a justification when a departure is closed conditionally
- No further action is needed, but may be necessary in the future to fully close the requirement

Departure UID: 42-12-39700

Departure Type: Final	Severity: Low	Initial Response Due: 08/14/2021	Repeat Departure: No	Status: Closed Conditionally
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Current Response Due:
08/14/2021

Assigned Work Objective(s): WO002045.001.003

CFR/Section	Requirement
42 CFR 73 - 12(b) - Biosafety: General	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).

Observation

Did not provide evidence that BSCs were certified for the year 2020.

Corrective Action:

Provide the evidence that the BSCs were certified for the year 2020.

8/12/2021 9:17 AM

Will no longer use the BSCs and in the process of decommissioning the labs.

8/12/2021 9:18 AM

This finding has been closed conditionally for the following reason: Room Or Suite Removed. Note from Branch Chief: Entity states they will no longer use the laboratories and will be decommissioning them.

New Status for departures

Agency response with justification



eFSAP Information System - Inspection Module Updates

"Closed Conditionally" status for inspection

- "Closed Conditionally" displays if one or more departures is closed conditionally

New
Inspection
Status



Inspections

Inspection #	Inspection Type	Start Date	Stop Date	Lead Inspector	Inspection Status		
		Start Date End Date	Start Date End Date				
7761	Announced	08/11/2021	08/11/2021	Branch Chief	Closed Conditionally	Details	History
7760	Unannounced	08/11/2021	08/11/2021	Branch Chief	Inspection Closeou...	Details	History



June 2022 Updates



Updated Personnel Statuses (APHIS/CDC Form 1 Section 4)



Updated Personnel Statuses (Form 1 Section 4)

- Terminology in eFSAP information system matches terminology in the select agents and toxins regulations

<u>Former eFSAP statuses</u>	<u>New eFSAP statuses</u>
Unrestricted	Approved
Restricted	Denied/Restricted Revoked/Restricted
Denied	Denied (For Cause) Revoked (For Cause)
Withdrawn	Terminated



APHIS/CDC Form 2 Auto-Expiration



APHIS/CDC Form 2 (Request to Transfer Select Agents and Toxins) - New Status - “Transfer Approval Expired”

- APHIS/CDC Form 2s in “Approved Section 2 Pending” status for 30 days auto-expires on the 31st calendar day
- Transfer approvals set to expire within 7 days shows in **bold** on the grid table

Agents	Transfer Id	Date Created	Status	Approval Date	Expiration
<input type="text"/>	<input type="text"/>	<input type="text"/> Start Date <input type="text"/> End Date	<input type="text"/>	<input type="text"/> Start Date <input type="text"/> End Date	<input type="text"/> Start Date <input type="text"/> End Date
Botulinum neurotoxins	T-F2-010385	04/04/2022	Approved Section2 Pending	04/04/2022	05/04/2022
Botulinum neurotoxins,Brucella suis,SAR...	T-F2-010379	03/25/2022	Transfer Approval Expired	03/28/2022	04/27/2022



APHIS/CDC Form 2 (Request to Transfer Select Agents and Toxins) - New Status - “Transfer Approval Expired”

- Prior to the APHIS/CDC Form 2 auto-expiring, notifications are generated to the grid table at 7 days, 3 days, and 1 day prior to auto-expiration

 Notifications

Filter:

Current Archived Flagged

Select All	From	Type	Date And Time	Notification	
<input type="checkbox"/>	<input type="text"/>	form2 <input type="button" value="x"/>	<input type="text"/>	<input type="text"/>	
<input type="checkbox"/>	branch chief	Form2 View	6/29/2022 5:20:06 AM	Form 2 transfer authorization T-F2-010396 will expire in 7 days.	<input type="button" value="Flag"/>
<input type="checkbox"/>	branch chief	Form2 View	6/29/2022 5:20:06 AM	Form 2 transfer authorization T-F2-010379 has expired.	<input type="button" value="Flag"/>



Reclassification of File Uploads



Reclassification of File Uploads

- Users can reclassify previously uploaded files, if needed
- Select “file uploads” on the entity’s landing page, APHIS/CDC Forms 1 – 4, or Inspection Module
- Select the green “Reclassify” button

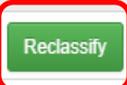
Upload a file

Upload

Current Files Archived Files

Send to Archive

All Review Not Complete

Select All	Original N.∞	Unique File Identifier	Uploaded ∞∞ Start Date End Date	Uploaded ∞∞	File Categ.∞∞	Review St.∞∞	
<input type="checkbox"/>							
<input type="checkbox"/>	 RFI Respon...	F2-010386-5/2/2022 3:18:54 PM-Supporting Documentation-Imp...	5/2/2022 3:1...	responsible ...	Form 2	Review Complete	



Reclassification of File Uploads

- Users can make changes to the sub-category and description
- Press “Save changes”
- A pop-up message confirms changes and asks if you wish to continue

The screenshot displays a web interface for file management. At the top, there is a section titled 'Upload a file' with an 'Upload' button and tabs for 'Current Files' and 'Archived Files'. Below this, there is a 'Send to Archive' button and radio buttons for 'All' (selected) and 'Review Not Complete'. A table with a 'Select All' checkbox is partially visible. A modal window titled 'Reclassify File' is open, containing the following fields:

- Transfer # (last 6 digits) ***: A text input field containing '010386' with a note '30 characters remaining.' and a green 'Reclassify' button to its right.
- Sub-Category ***: A dropdown menu with 'Supporting Documentation' selected. The dropdown list is open, showing options: 'Supporting Documentation', 'Response to Request for Information' (highlighted with a red underline), and 'Other'.
- Description**: A text input field.

At the bottom of the modal, there are 'Save changes' and 'Close' buttons. The background interface shows pagination controls at the bottom, including '1 / 1' and 'items per page', and '1 - 1 of 1 items'.



Reclassification of File Uploads

- The file displays the new sub-category and description
- Reclassification does not affect the original upload date/time or the current review status

Upload a file

Upload

Current Files Archived Files

Send to Archive

All Review Not Complete

Select All	Original N.:	Unique File Identifier	Uploaded .:	Uploaded .:	File Categ.:	Review St.:	
<input type="checkbox"/>			Start Date				
			End Date				
<input type="checkbox"/>	RFI Respon...	F2-010386-5/2/2022 3:18:54 PM-Supporting Documentation-Imp...	5/2/2022 3:1...	responsible ...	Form 2	Review Complete	Reclassify



Upload a file

Upload

Current Files Archived Files

Send to Archive

All Review Not Complete

Select All	Original ...:	Unique File Identifier	Uploaded Date .:	Uploaded.:	File Cate.:	Review S.:	
<input type="checkbox"/>			Start Date				
			End Date				
<input type="checkbox"/>	RFI Respo...	F2-010386-5/2/2022 3:18:54 PM-Response to Request for Inform...	5/2/2022 3:18 PM	responsible...	Form 2	Review Complete	Reclassify



August 2022 Updates



APHIS/CDC Form 2 Reuse/Reapply



Reuse/ Reapply- APHIS/CDC Form 2 Transfer Requests

- Users can now quickly create a new transfer request from the entity Form 2 grid table by selecting “Reuse” or “Reapply” button
- “Reuse” applies to forms in “approved section 2 pending”, “section 3 pending”, “completed” and “cancelled” statuses
- “Reapply” is used for forms in “Transfer approval expired” status

Approved Section2 P...	07/06/2022	Reuse
Transfer Approval Exp...	05/04/2022	Reapply
Transfer In Review		



Reuse/ Reapply- APHIS/CDC Form 2 Transfer Requests

- Once “Reuse”/ “Reapply” is selected, a new draft APHIS/CDC Form 2 is created
- Section B is pre-populated with information from the previous transfer request
- Sections A and C should be completed with information for the current transfer request
- Once these sections are completed, the user submits the form

SECTION B – SENDER INFORMATION

2. Entity name:
eFSAP Entity |

3. Address (NOT a post office address):
12 Road Street

4. City:
Plains

5. State:
Illinois

6. Zip Code:
43566-6777

7. Country:
United States

8. Responsible Official (RO) or Facility Director:
Dr. X
250 of 255 characters left

9. RO/Facility Director telephone #:
459-493-0988

10. RO/Facility Director e-mail address:
x@mail.com
40 of 50 characters left

11. This transfer request is for a select agent or toxin that was identified in a clinical or diagnostic sample: Yes No

12. Is the agent a product of a restricted experiment, as defined in section 13 of the select agent regulations? Yes No



APHIS/CDC Form 1 (Registration for Possession, Use, and Transfer of Select Agents and Toxins) Attachment Libraries



APHIS/CDC Form 1 Attachment Libraries

- eFSAP information system allows users to select a previously completed attachment from the library and apply it a new work objective
- The attachment library can be used to modify an existing work objective
- If an existing attachment is modified further, the system automatically saves the modified attachment as a new version and adds it to the library for future use

9. Will work be performed with:

a. agents that will be propagated and produce regulated amounts of toxins or with registered toxins at or b

Yes No

If yes, choose an attachment to reuse or complete **Attachment A - Work With Toxins** on the Amendment

[Use This Attachment](#)

b. regulated nucleic acids, genetic modification of select agents or toxins, recombinant/synthetic nucleic a

Yes No

If yes, choose an attachment to reuse or complete **Attachment B - Work with Regulated Nucleic Acids**

[Use This Attachment](#)



General Discussion – Conversation View



General Discussion – Conversation View

- General Discussion supports grouping messages together into conversations
- Threads are separated by discussion topics (auto-generated by the system) and grouped by subject line

The screenshot displays a user interface for a 'Conversation Mode'. At the top, there is a search bar labeled 'Search General Discussions... (Dates in mm/dd/yyyy)' and a 'New Conversation' button. The main content area shows a list of conversation threads. Each thread is represented by a row with a collapse/expand icon on the left, a subject line, a user profile picture, and a 'Reply' button on the right. The threads are as follows:

- Thread 1: Collapse icon, subject 'branch chief - regarding: Conversation 1 Message 1', no profile picture, Reply button.
- Thread 2: Expand icon, subject 'agency user - regarding: Conversation 1 Message 2', profile picture 'AU', Reply button.
- Thread 3: Expand icon, subject 'agency user - regarding: Conversation 1 Message 3', profile picture 'AU', Reply button.
- Thread 4: Expand icon, subject 'agency user - regarding: Conversation 1 Message 4', profile picture 'AU', Reply button.
- Thread 5: Expand icon, subject 'branch chief - regarding: Conversation 1 Message 1', no profile picture, Reply button.
- Thread 6: Expand icon, subject 'branch chief - regarding: Conversation 3 Message 1', no profile picture, Reply button.
- Thread 7: Expand icon, subject 'agency user - regarding: Conversation 4 Message 1', profile picture 'AU', Reply button.
- Thread 8: Expand icon, subject 'cj - regarding: Conversation 5 Message 1', profile picture 'C', Reply button.



Future Updates



Science Module



Science Module- Submitting Science Office Requests

- Responsible Officials and Alternate Responsible Officials will use eFSAP information system to directly interact with the FSAP Science Office
- Users will be able to submit requests, respond to requests for information and track the progress of requests
- Users will be informed of decisions through eFSAP information system



Unregistered Areas



Unregistered Areas

- Occasionally, entities submit APHIS/CDC Form 3s and APHIS/CDC Form 4s for locations not listed on their Form 1
- When this information is received, FSAP staff “tag” the Form as an event occurring in an unregistered area
- In these instances, eFSAP information system puts an asterisk * at the start of the entity’s name



www.selectagents.gov

CDC Contact Information
Division of Select Agents and Toxins
Irsat@cdc.gov
404-718-2000

APHIS Contact Information
Division of Agricultural
Select Agents and Toxins
DASAT@usda.gov
301-851-2070

