



APHIS/CDC Form 4: Reporting, Outbreaks, and Common Problems

2019 Responsible Official Workshop
July 25, 2019



Form 4A

- ❑ Identification of a select agent
- ❑ Immediate notification
- ❑ Seven days to report
- ❑ eFSAP for registered entities
- ❑ All sample types:
 - Clinical (human/animal)
 - Isolates (human/animal)
 - Environmental
 - Food

Immediate Notification

□ Select agents that require immediate notification include:

- *Bacillus anthracis*
- *Bacillus cereus* Biovar *anthracis*
- Botulinum neurotoxins
- Botulinum neurotoxin producing species of *Clostridium*
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- Ebola virus
- Foot-and-mouth disease virus
- *Francisella tularensis*
- Marburg virus
- Rinderpest virus
- Variola major virus (Smallpox virus)
- Variola minor virus (Alastrim)
- *Yersinia pestis*



Immediate Notification Process

- ❑ Immediate notifications are entered directly into eFSAP

The screenshot displays the eFSAP Immediate Notification process. At the top, there is a public reporting burden notice. Below this, the form includes fields for the 'Signature of Responsible Official or Laboratory Supervisor' and 'Date Signed' (09/23/2019). A warning message box is overlaid on the form, stating: 'Missing Search Agent in Tools for Immediate notification', 'Missing Date identified for immediate notification', and 'Missing Question 9 for immediate notification'. The form also features buttons for 'Immediate Notification', 'Save', and 'Submit'. Below the form, a chat window titled 'General Discussion' is visible, showing a message from 'Agency User' at 10/17/2018 3:21:47 PM: 'VET sample form 4 IN submitted'. The chat window also shows messages from 'responsible official' at 10/25/2019 11:02:25 AM and 10/25/2019 6:00:00 AM, both with 'RO' status.

- ❑ Use same Immediate Notification to complete the Form 4A


eFSAP Form 4 Tab





Home

Federal Select Agent Program Information System

Entity: Performance Testing

 LEAD AGENCY: APHIS

 REGISTRATION STATUS: Approved

 REGISTRATION EXPIRES: 11/21/2018

Facility Address: 45 Street Wise, Orlando, FL 89999-6553

Responsible Official Name: Minnie Mouse

Responsible Official Title: Responsible Official

Responsible Official Address: 1 Walt Way, Orlando, FL 23894-73

Registration #: dddddddd

Application #: eb4bf0e7-2bce-e711-8169-005056abf076

Type Status: Government - Federal

Form 1Form 2Form 3Form 4Inspections

eFSAP Form 4 Types

File Edit View Favorites Tools Help

USDA

Home

Federal Select Agent Program

Entity: Performance

LEAD AGENCY

Facility Address: 4

Responsible Officer

Registration #: dd

Notif

Sign Out

Inspections

21/2018

t Way, Orlando,

Select an Action

APHIS/CDC FORM 4 TO REPORT THE IDENTIFICATION OF A SELECT AGENT OR TOXIN (as described in 7 CFR 331, 9 CFR 121, and 42 CFR 73).

Create Form 4A - Section A&B Create Form 4B Create Form 4C

View All

Form 4 Section ABs

Id	Select Agent	Status	Date Created
No Section A & B's have been created			

Form 4A- Section CD's

Id	Select Agent	Status	Date Created	
CID-F4-000069	Abrin	Required	01/30/2019	View

Form 4B

eFSAP Form 4 Sample Provider

Note

Please request completed and signed Sections C & D from each facility that was in possession of the specimen(s).

12. Sample Provider Entity Name:

13. Sample Provider Point of Contact:

14. Sample Provider E-mail Address:

15. Sample Provider Contact Number:

[Clear](#)[+ Add Row](#)

Sample Provider Entity Name	Name of Sample Provider	Email Address	Contact Number
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16. Comments / Notes:



Recent Outbreaks involving USDA Agents

- ❑ **Declared agricultural outbreaks**
 - Exemptions under 121.9 (c) (3) and 331.9 (c) (2)
 - Approval from USDA Secretary
 - Formal requests
 - Report batching
 - Select agent regulations still apply

Common Issues

❑ Sample information

- Enter information for Form 4s into eFSAP
- Paper copy of the Form 4s do not need to be uploaded into eFSAP
- Verification of information (e.g., sample provider contact information)
- Quantity received vs quantity sent
 - Ensure number of samples sent from sample provider match with the number of samples received
- Identification date
 - Notify sample provider of identification
 - Seven days to destroy, transfer or retain if registered entity
- Zip code is for patient location, not laboratory location
- Use of case/patient/ID number - NOT the CID-F4 number

Communication

- ❑ **Use of general discussion box versus email**
- ❑ **Status changes:**
 - Immediate notification
 - Request for more information (4A - C/D) – additional information is needed to close out the Form 4 (i.e., follow up with sample provider)
 - Need to login into eFSAP to check status and updates

Form 4B

□ Form 4B

- Proficiency testing
- Report within 90 days from receipt
- Not required to report the identification of excluded strains
- Required to report identified toxins, regardless of amount

Form 4B

Select an Action

APHIS/CDC FORM 4 TO REPORT THE IDENTIFICATION OF A SELECT AGENT OR TOXIN (as described in 7 CFR 331, 9 CFR 121, and 42 CFR 73).

Create Form 4A - Section A&B

Create Form 4B

Create Form 4C

View All

Form 4 Section ABs

Id	Select Agent	Status	Date Created
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Form 4A- Section CD's

Id	Select Agent	Status	Date Created
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Form 4B

Id	Select Agent	Status	Date Created
No 4B's have been created			

Form 4C

Id	Law Enforcement Agency	Status	Date Created
No 4C's have been created			

Exit

Form 4B

SECTION A – INFORMATION FOR LABORATORY THAT RECEIVED PROFICIENCY TESTING SAMPLE(S)

1. Name of individual completing the form

First M Last

2. E-mail address:

3. Telephone #:

() - ext.

14. Sponsor/entity that you received select agent or toxin from:

Entity name:

Registration #:

Entity address:

Telephone #:

E-mail:

Form 4B

SECTION B – SELECT AGENTS AND TOXINS IDENTIFIED FROM PROFICIENCY TESTING

1. Select Agent or Toxin Identified:

2. Date obtained from sponsor

3. Date identified

Clear

Add

Saved Agents & Toxins

1. Select Agent or Toxin Identified

2. Date obtained from sponsor

3. Date identified

4. Dispositions of select agents or toxins (complete all that apply):

Must answer at least one of the below

☐ Transferred

☐ Destroyed

☐ Retained

5. Were any of the samples containing a select agent or toxin, listed in the table above, and handled outside of primary containment which may have led to an unintentional release and/or exposure to the select agent or toxin?

☐ No ☐ Yes

eFSAP IT Issues?

❑ Report IT issues directly to eFSAP

- eFSAP Customer Support
- Tel: 1-877-232-3322
- Email: eFSAPsupport@cdc.gov
- eFSAP Customer Support Request Form:
<https://www.selectagents.gov/supportform-efsap.html>

❑ Form 4 Technical Reviewers:

- AgSAS: AgSAS@aphis.usda.gov
- DSAT: cdcform4@cdc.gov

Discussion

www.selectagents.gov

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

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

