

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: "Public reporting burden: Public reporting burden of providing this information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MD D74, Atlanta, Georgia 30329; ATTN: PRA (0620-0578)." Below this, there are fields for "Signature of Responsible Official or Laboratory Supervisor:" and "Date Signed:" with a date of 09/29/2019. A "responsible official" field is also present. A warning message box is overlaid on the form, stating: "Missing Search Agent in Tools for immediate notification. Missing Date Identified for immediate notification. Missing Question 9 for immediate notification." Below the warning, there are buttons for "Immediate Notification", "Save", and "Submit". At the bottom, a chat window titled "General Discussion" shows a message from "Agency User" at 10/17/2018 3:21:47 PM: "VEE sample form 4 IN submitted". There are also messages from "responsible official" at 10/25/2019 11:02:25 AM and 10/25/2019 0:00:00 AM, both with "RO" status icons.

- Use same Immediate Notification to complete the Form 4A

eFSAP Form 4 Tab



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 89999-8553

Responsible Official Name: Minnie Mouse **Responsible Official Title:** Responsible Official **Responsible Official Address:** 1 Wait Way, Orlando, FL 23894-73

Registration #: dddddd **Application #:** eb4bf0e7-2bce-e711-8169-005056abf078 **Type Status:** Government - Federal

eFSAP Form 4 Types

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

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)

