

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

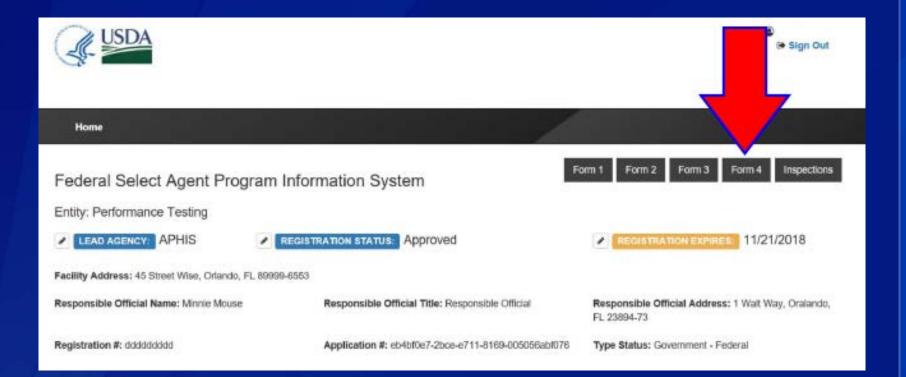
Immediate Notification Process

Immediate notifications are entered directly into eFSAP

NE, WE C74, Allorida, Georgia 30022; ATTH: FKA (6820-6576) Signature of Responsible Official or Laboratory Supervisor: Date Signed:
06/28/2019
responsible official
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Use same Immediate Notification to complete the Form 4A

eFSAP Form 4 Tab



eFSAP Form 4 Types

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	Select an Action				×	Sign Out
Home	APHIS/CDC FORM 4 TO REPORT 42 CFR 73).	THE IDENTIFICATION OF A	SELECT AGENT OR	TOXIN (as described in	7 CFR 331, 9 CFR 121, and	
Federal Sel	с	reate Form 4A - Section A&B	Create Form 4B View All	Create Form 4C		4 Inspections
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A Notif	Form 4B					

eFSAP Form 4 Sample Provider

2. Sample Provider Entity Name:		
3. Sample Provider Point of Contact: First M Last	14. Sample Provider E-mail Address:	15. Sample Provider Contact Number:
Sample Provider Entity Name	Name of Sample Provider E	Clear + Add Row mail Address Contact Number
6. 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

- 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

Apprisic DC FORM 4 TO REPORT THE IDENTIFICATION OF A SELECT AGENT OR TOXIN (as described in 7 CFR 331, 9 CFR 12 2 CFR 73). Create Form 4A - Section ABB Ivery AB Form 4 Section ABS Id Select Agent Select Agent Status Date Created Form 4B Select Agent Id Select Agent Select Agent Status Date Created Form 4B Select Agent Id Select Agent Select Agent Status Date Created Form 4B Select Agent Id Select Agent Status Date Created	Select	an Action			
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SECTION A - INFORMATION FOR LABORATORY THAT RECEIVED PROFICIENCY TESTING SAMPLE(S)

1. Name of individual completing the form	2. E-mail address:	3. Telephone #:
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intity name:	Registration #:	
Entity address:		
Felephone #:	E-mail:	

elect Agent or Toxin Identified:	2. Date obtained from sponsor	3. Date identified
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Saved Agents & Toxins		
1. Select Agent or Toxin Identified	2. Date obtained from sponsor	3. Date identified
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. Dispositions of select agents or toxin		
. Dispositions of select agents or toxin Aust answer at least one of the below		

○ 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: <u>https://www.selectagents.gov/supportform-efsap.html</u>

Form 4 Technical Reviewers:

- AgSAS: <u>AgSAS@aphis.usda.gov</u>
- DSAT: <u>cdcform4@cdc.gov</u>

Discussion

www.selectagents.gov

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

<u>APHIS</u>: <u>AgSAS@usda.gov</u> or 301-851-3300 option 3 (voice only)

