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
- 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 89999-6553

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

Registration #: dddddddddd
Application #: eb40fe07-2bce-e711-8169-005056abf676
Type Status: Government - Federal
eFSAP Form 4 Types

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

Form 4 Section ABs

<table>
<thead>
<tr>
<th>Id</th>
<th>Select Agent</th>
<th>Status</th>
<th>Date Created</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

No Section A & B's have been created

Form 4A- Section CD's

<table>
<thead>
<tr>
<th>Id</th>
<th>Select Agent</th>
<th>Status</th>
<th>Date Created</th>
</tr>
</thead>
<tbody>
<tr>
<td>CID-F4-000069</td>
<td>Abrin</td>
<td>Required</td>
<td>01/30/2019</td>
</tr>
</tbody>
</table>

View
eFSAP Form 4 Sample Provider

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:

**Table:**

<table>
<thead>
<tr>
<th>Sample Provider Entity Name</th>
<th>Name of Sample Provider</th>
<th>Email Address</th>
<th>Contact Number</th>
</tr>
</thead>
</table>

16. Comments / Notes:

[Add Row button]
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
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 AB & B
Create Form 4B
Create Form 4C

Form 4 Section ABs
Id | Select Agent | Status | Date Created
---|-------------|-------|-------------

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

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)**

<table>
<thead>
<tr>
<th>1. Name of individual completing the form</th>
<th>2. E-mail address:</th>
<th>3. Telephone #:</th>
</tr>
</thead>
<tbody>
<tr>
<td>First M Last</td>
<td></td>
<td>(<em><strong>)</strong></em>-<strong><strong>ext</strong></strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14. Sponsor/entity that you received select agent or toxin from:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Entity name:</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Entity address:</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Telephone #:</strong></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
**Form 4B**

**SECTION B – SELECT AGENTS AND TOXINS IDENTIFIED FROM PROFICIENCY TESTING**

<table>
<thead>
<tr>
<th>1. Select Agent or Toxin Identified</th>
<th>2. Date obtained from sponsor</th>
<th>3. Date identified</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Dropdown)</td>
<td>mm/dd/yyyy</td>
<td>mm/dd/yyyy</td>
</tr>
</tbody>
</table>

**Saved Agents & Toxins**

<table>
<thead>
<tr>
<th>1. Select Agent or Toxin Identified</th>
<th>2. Date obtained from sponsor</th>
<th>3. Date identified</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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