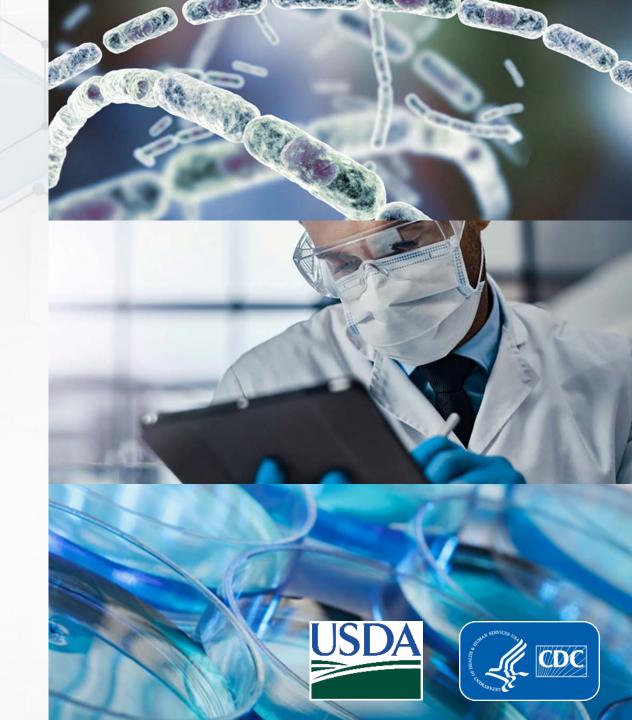
2021 Federal Select Agent Program (FSAP) Responsible Official Webinar Series

APHIS/CDC Form 3

Updates and Common Concerns

October 13, 2021



APHIS/CDC Form 3 – Report of a Release/Loss/Theft of a Select Agent or Toxin

Overview of Presentation

- Summary of APHIS/CDC Form 3 changes
- Most common concerns
 - Incident date
 - Immediate notification
 - Uploading response to Request for Information (RFI) letter
 - Return to Agency button
- Scenarios (3)

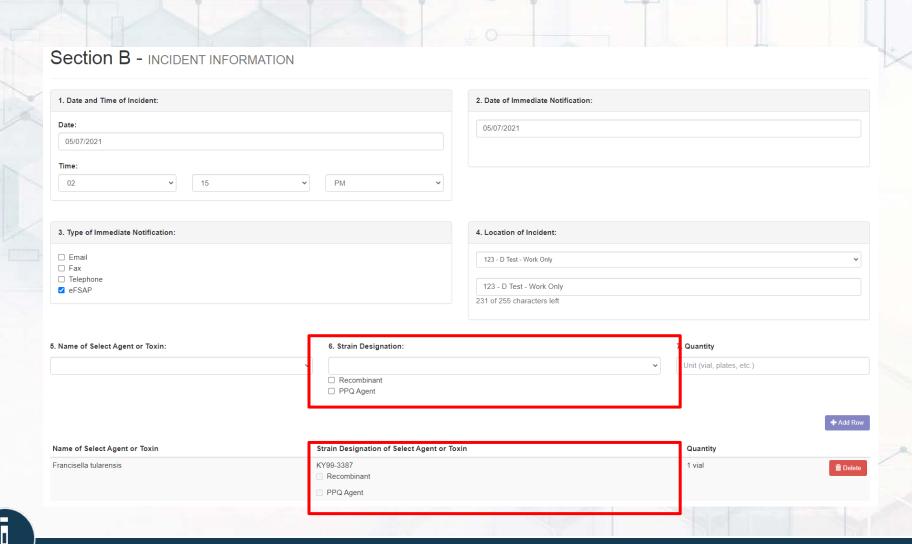






Incident Information:

Question B6:Recombinant agent selection box



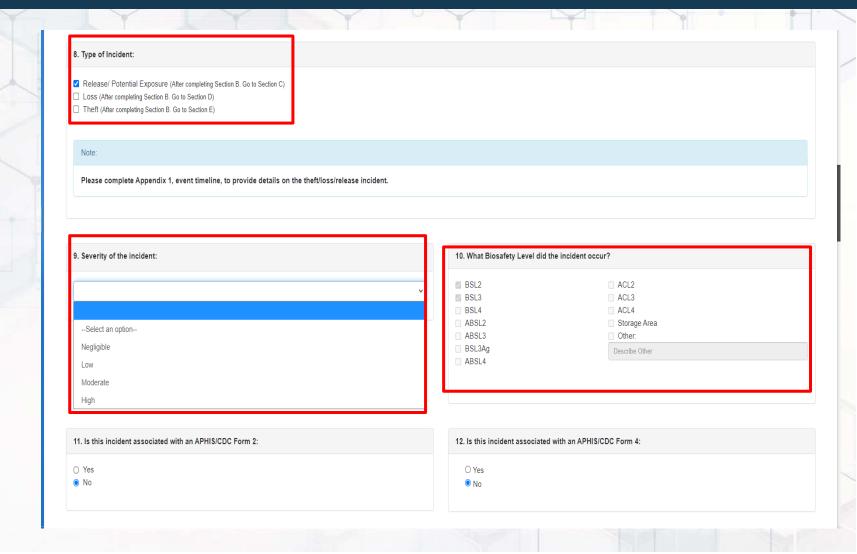








- Incident Information:
 - Question B8: Order change
 - Question B9: 'None' selection removed
 - Question B10:Containment levelsremoved
 - Recombinant (NIH)
 - Large animal (N)
 - Large scale (LS)
 - Plant pathogen (PPQ)





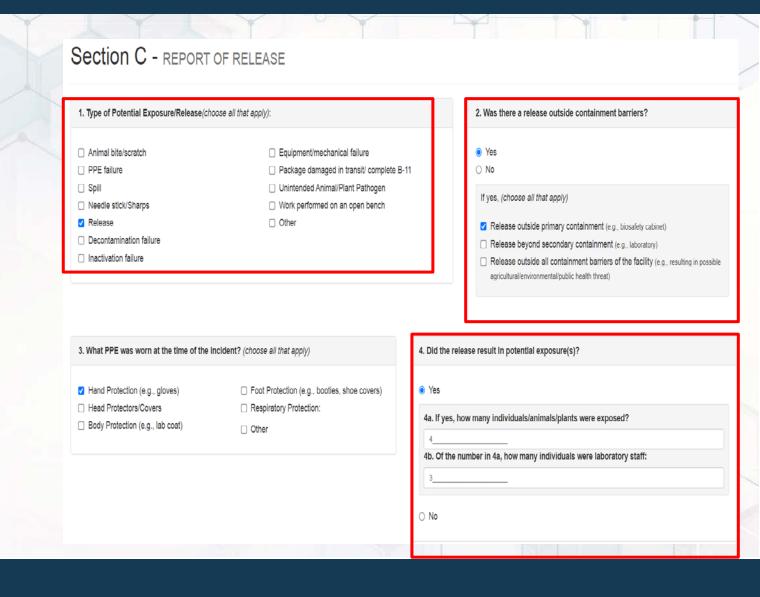






Report of a Release:

- Question C1: Accidental addition of 'Release' box selection
- Question C2: 'Yes' or 'No' response option
- Question C4b: Sub-question for the number of laboratory staff











Report of a Release:

- Question C6: Types of medical surveillance and treatment options
- Question C6a: Sub-question for the number of individuals
- Question C7b: Selection for the types of corrective action(s)

5. Did the release result in a laboratory acquired injection of an ii	nfection/outbreak in agriculture or in the environment?	6. What medical surveillance and/or treatment	was provided to individuals, if any?
○ Yes No Not currently known		○ No Treatment ② Physical evaluation ○ Fever/symptom watch ○ Serology screening ○ Antibiotics or other prophylaxis ○ Other 6a. Total number of individuals medical surveil	lance and/or treatment provided to:
7a. Has an internal investigation been initiated to lessen the likeli	ihood of recurrences of incident involving the select agents and	toxins at this entity?	
res (if yes, please provide additional details.)			
Yes (If yes, please provide additional details) No			
	nt (if any), and any root cause(s) identified.		
○ No	nt (if any), and any root cause(s) identified.		
No Describe the internal investigation initiated following the incide Tb. What corrective actions have been initiated to lessen the like		I toxins at this entity? (choose all that apply)	
No Describe the internal investigation initiated following the incide		I toxins at this entity? (choose all that apply)	□ New/updated SOP
No Describe the internal investigation initiated following the incide 7b. What corrective actions have been initiated to lessen the like Must answer at least one of the below	relihood of recurrence of incident involving the select agents and		New/updated SOP
No Describe the internal investigation initiated following the incide 7b. What corrective actions have been initiated to lessen the lik Must answer at least one of the below Retraining on existing policy	relihood of recurrence of incident involving the select agents and	☐ New training developed	



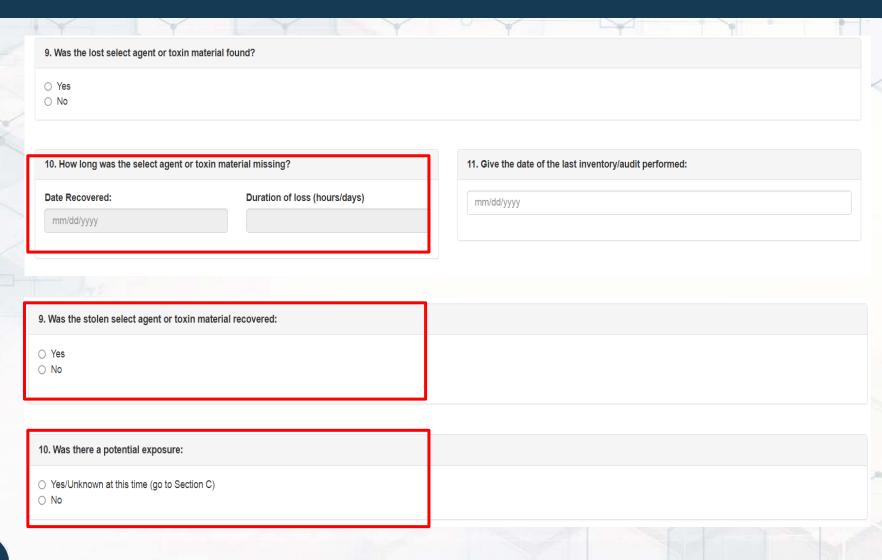








- Report of a Loss and Theft:
 - Question D10:Switches order of questions
 - Question E9: Adds'Date of recovery' for a 'Yes' response
 - Question E10:
 Removes the
 'unsure' box as a
 response selection











Section E

Section D



APHIS/CDC Form 3 – Most Common Concerns #1

- Question B1: Incident date
 - o For release, date of earliest exposure/manipulation outside of primary containment
 - o For loss, date when inability to account for Biological Select Agent or Toxin (BSAT) first identified

Section B - INCIDENT INFORMATION

1. Date and Time of Incident:	2. Date of Immediate Notification:
Date: 05/07/2021 Time:	05/07/2021
02 ~ 15 ~ PM ~	
3. Type of Immediate Notification:	4. Location of Incident:
□ Email □ Fax □ Telephone ☑ eFSAP	123 - D Test - Work Only 123 - D Test - Work Only 231 of 255 characters left



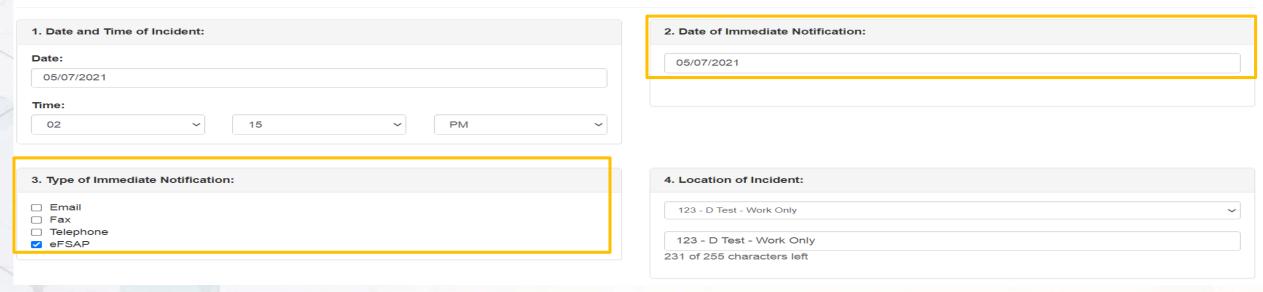






APHIS/CDC Form 3: Most Common Concerns #2

Section B - INCIDENT INFORMATION



- Question B2: What date constitutes Immediate Notification? (select one)
 - A) When incident happens
 - B) When Responsible Official or entity leadership is notified
 - C) When internal investigation is completed
 - D) When the entity first informs FSAP of the incident









APHIS/CDC Form 3: Most Common Concerns #2

- Block B2: What date constitutes Immediate Notification?
 - A) When incident happens
 - B) When Responsible Official or entity leadership is notified
 - C) When internal investigation is completed
 - D) When the entity first informs FSAP of the incident









APHIS/CDC Form 3 – Making an Immediate Notification

eFSAP information system Immediate Notification (Preferred Method)

- O When selecting the agent/toxin and if unclear what BSAT was manipulated, select the BSAT last worked with at time of incident
- Complete the required questions on the form and click the 'Immediate Notification' button

• eFSAP information system General Discussion

- FSAP may ask initial questions
- FSAP may request for minimal submission as Immediate Notification using the APHIS/CDC Form 3

• Email / Phone call

o FSAP will acknowledge on entity homepage



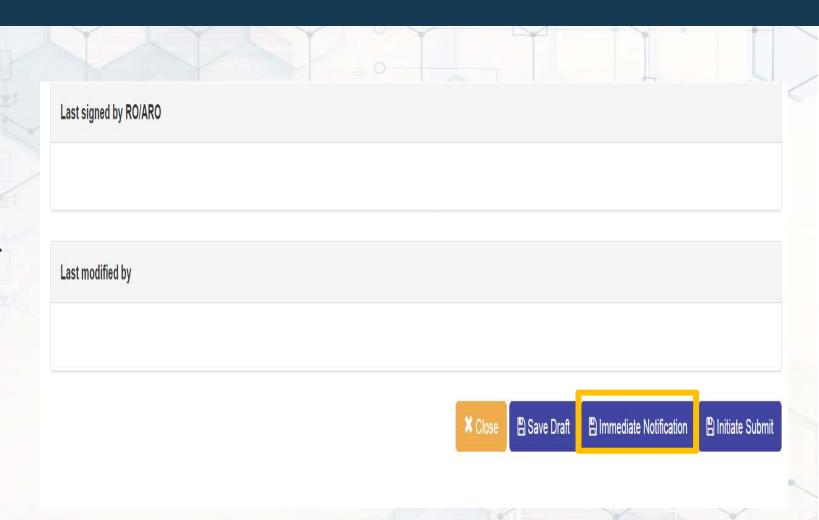






Immediate Notification in eFSAP information system

- Where is the 'Immediate Notification' button?
- What happens after Immediate Notification?
- Can changes be made after Immediate Notification?











APHIS/CDC Form 3 – Most Common Concerns #3

- What is the best way to respond to a Request for Information (RFI) letter? (select one)
 - A) Upload to Entity Documents section for the specific APHIS/CDC Form3
 - B) Upload to entity home landing page
 - C) Send response through email or fax

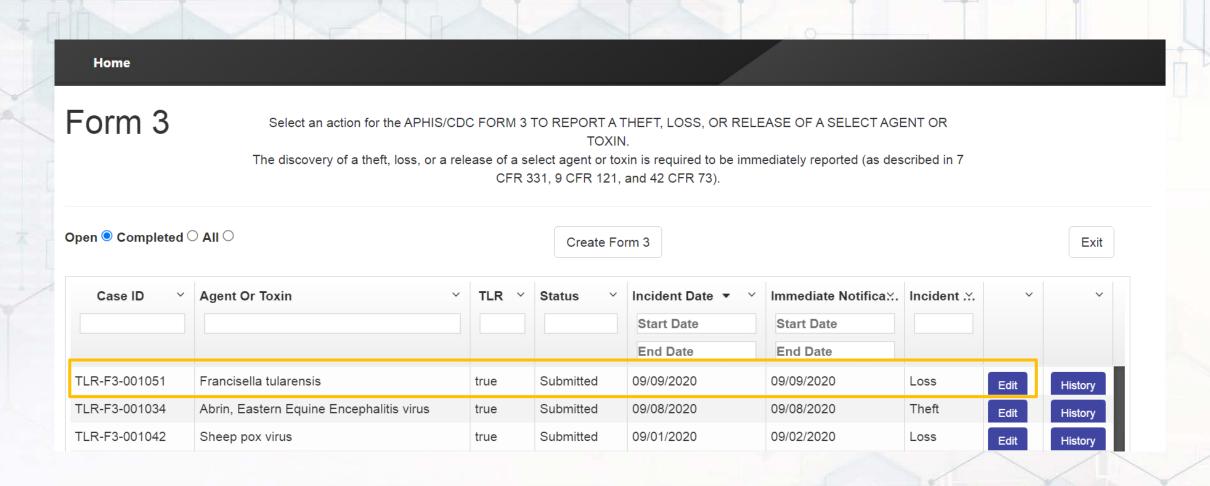


APHIS/CDC Form 3 – Most Common Concerns #3

- What is the best way to respond to a RFI letter?
 - A) Upload to Entity Documents section for the specific APHIS/CDC Form3
 - B) Upload to entity home landing page
 - C) Send response through email or fax



Uploading a Response to RFI Letter



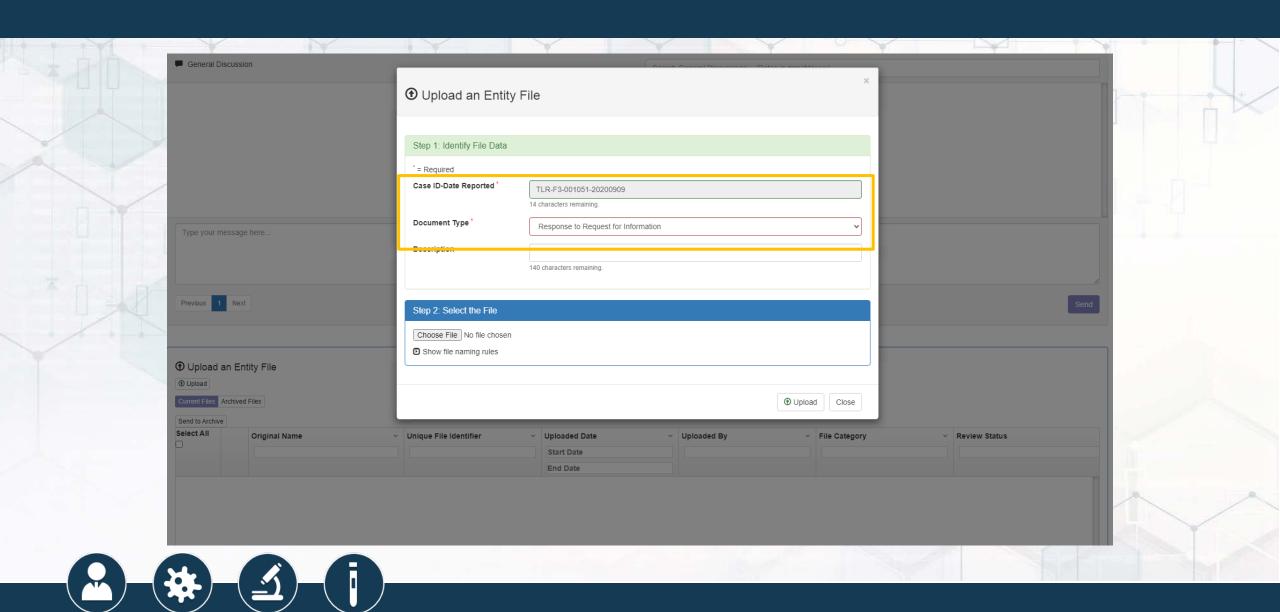








Uploading a Response to RFI Letter



APHIS/CDC Form 3 – Most Common Concerns #4

- When RFI letter is uploaded into eFSAP information system by the Form 3 team,
 the status of the report is changed to Request For More Information
- In this status, the report can be edited to change/correct information on the APHIS/CDC Form 3
- After making changes and uploading the responses to the RFI in the entity documents section of the report, select the Return to Agency button







Scenario 1 – Needle stick

- A laboratorian vaccinated for anthrax stuck their finger after loading a syringe with Bacillus anthracis spores while working in the biosafety cabinet
- o The laboratorian immediately stopped work and noticed blood in their double gloves
- After applying first aid and following appropriate doffing procedures to exit the laboratory, the laboratorian reported the incident to the Responsible Official (RO) before proceeding to Occupational Health
- How should this be reported on the APHIS/CDC Form 3 for questions C2 and C4? (select one)
- A) C2: Yes, there was a release outside containment barriers and C4: No, the release did not result in potential exposure(s)
- B) C2: No, there was not a release outside containment barriers and C4: No, the release did not result in potential exposure(s)
- C) C2: No, there was not a release outside containment barriers and C4: Yes, the release did result in potential exposure(s)
- D) C2: Yes, there was a release outside containment barriers and C4: Yes, the release did result in potential exposure(s)









- Scenario 1 Needle stick
 - How should this be reported on the APHIS/CDC Form 3 for questions C2 and C4?
 - C2: Yes, there was a release outside containment barriers and C4: No, the release did not
 - C2: No, there was not a release outside containment barriers and C4: No, the release did
 - C2: No, there was not a release outside containment barriers and C4: Yes, the release did result in potential exposure(s)
 - D) C2: Yes, there was a release outside containment barriers and C4: Yes, the release did result in potential exposure(s)









Scenario 2 – Cage injury

- An animal care technician scratches their hand on a piece of metal on the cage rack while bagging dirty mice cages used for non-BSAT work in the registered ABSL-3 laboratory
- One week prior, a Brucella abortus study with mice in this laboratory concluded and there has not been any work with select agents since that time
- All work surfaces including cages are routinely disinfected
- o The next day the animal care technician noticed some swelling at the scratched area and reported to the Occupational Health Office where the physician prescribed antibiotic prophylaxis

• Is this reportable? Yes or No



- Scenario 2 Cage injury
 - No
 - No recent work with BSAT, no spills reported, no BSAT-infected animals present
 - Work surfaces and caging were disinfected
 - o Initial questions likely



Scenario 3 – Loss

o During an inventory audit, the Responsible Official notices that there are multiple records for vials not in the physical select agent inventory. Multiple vials of B. anthracis are missing. All the missing vials involve a specific Principal Investigator (PI), who cannot explain why the vials are missing.

When must this be reported and to whom?

- A) Immediately report to law enforcement and FSAP
- B) After internal investigation then report to FSAP
- C) Next week report to campus police
- D) After completing an inventory audit under the control of the PI, then report to FSAP









- Scenario 3 Loss
- When must this be reported and to whom?
 - A) Immediately report to law enforcement and FSAP
 - B) After internal investigation then report to FSAP
 - C) Next week report to campus police
 - D) After completing an inventory audit under the control of the PI, then report to FSAP









CDC Contact Information Division of Select Agents and Toxins 404-718-2000

APHIS Contact Information Division of Agricultural **Select Agents and Toxins** 301-851-2070









