

Instructions

Answer all items completely and type or print in ink. Questions concerning the completion of this form can be directed to the respective agency below:

Division of Agricultural Select Agents and Toxins
Telephone: (301) 851-2070
Email: DASAT@usda.gov

Division of Regulatory Science and Compliance
Telephone: (404) 718-2000
Email: form3@cdc.gov

This form must be signed and submitted to either:

Division of Agricultural Select Agents and Toxins
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: (301) 734-3652
Email: DASAT@usda.gov

Division of Regulatory Science and Compliance
1600 Clifton Road NE, Mailstop H21-4
Atlanta, GA 30329
FAX: (404) 471-8375
Email: form3@cdc.gov

Section A – Entity Information

Block A1-A6 and A8-A9:

- For an entity registered with FSAP, provide all information exactly as it appears on your entity's current certificate of registration.
- For a non-registered entity, provide all information under which the entity conducts its operations. Provide the telephone number, including the area code, including any extension and email address for the individual listed in Block A6.

Block A7 – Name of Principal Investigator:

- For an entity registered with FSAP, provide the complete name of Principal Investigator the select agent or toxin is registered under.
- For a non-registered entity, provide the full legal name of the person responsible for the area in which the incident occurred (e.g., Microbiology Section leader or Supervisor).

Section B – Incident Information

Block B1-B4 and B7-B10:

- Enter complete data or select all that apply.

Block B5 – Select Agent or Toxin Name:

- List all select agents and/or toxins involved in the incident exactly as it appears in the select agent regulations ([Select Agent/Toxin List](#)).

Block B6 – Strain Designation of Select Agent or Toxin:

- List the strain designation(s) for all select agents and/or toxins, if known; otherwise **select unknown**.
Note: For the purposes of the APHIS/CDC Form 3, the term 'strain' refers to a group of organisms of the same species, sharing certain hereditary characteristics not typical of the entire species but minor enough not to warrant classification as a separate breed or variety (e.g., resistance to specific antibiotics).
- Select if Recombinant.

Block B11 – Associated with an APHIS/CDC Form 2 (Transfer):

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- Select 'Yes' if the sample involved was part of an APHIS/CDC Form 2 transfer and provide the APHIS/CDC Form 2 Transfer#; otherwise, select 'No'.

Block B12 – Associated with an APHIS/CDC Form 4 (Identification):

- Select 'Yes' if the sample was a clinical/diagnostic specimen and an APHIS/CDC Form 4 and provide the APHIS/CDC Form 4 Clinical ID#; otherwise, select 'No'.

Section C – Report of Release/Potential Exposure

Block C1 – Type of Release (Select the Appropriate Type of Release/Potential Exposure That Occurred):

- Select 'animal bite/scratch' if an entity personnel was scratched or bitten by an animal used in select agent or toxin work.
- Select 'Other' if the type of release is not listed. Describe in the space provided.

Note: Complete B11, if damaged in transit.

Block C2 – Release Outside Containment:

- Select 'Yes' if the release was outside containment barriers then choose all that apply below. Otherwise, select 'No'. If 'Yes', choose all options that apply for 2a.
- 2b. Select 'Yes' or 'No' if the release poses a threat.

Block C3 – PPE Worn at the Time of the Incident:

- Select the type of PPE worn at the time of the incident. Select all that apply. If a respirator was used, provide the type of respirator used.
- Select 'Other' if the type of PPE is not listed. Describe in the space provided.
- 3a. Provide the number of individuals wearing the described PPE.

Block C4 –Potential Exposures:

- Select 'Yes' if the incident resulted in potential exposures. Otherwise, select 'No' if there was no potential exposure.
- Block C4a.: If 'Yes', please indicate how many individuals/animals/plants were exposed during the release.
- Block C4b.: For the number provided in C4a, how many were laboratory staff?

Block C5 – Lab Acquired Infection/Outbreak:

- Select 'Yes' if the incident resulted in a laboratory acquired infection or an infection/outbreak in agriculture or in the environment. Otherwise select 'No' or 'Not currently known'.

Block C6 – Medical Surveillance Provided:

- Block C6. Select Yes or No if medical surveillance and/or treatment provided. 6a. If 'Yes', select all that apply.
- 6b. Provide the total number of individuals provided medical surveillance.

Block C7a. – Internal Investigation:

- Select 'Yes' if an internal investigation has been initiated to identify the root cause to lessen the likelihood or recurrence. Otherwise, select 'No'.
- If 'Yes' is selected, describe the internal investigation and any root cause(s) identified for this incident.

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Block C7b. – Corrective Actions:

- Select all that apply.
- Select 'Other' if the corrective action is not listed. Describe in the space provided.

Signature:

- For all entities, the individual named in Block A6 (Responsible Official or Laboratory Supervisor), must type/print, sign, and date the appropriate section(s) of the form.

Section D – Report of Loss

Block D1 – Type of Loss:

- Select all that apply. If none of these options apply, select 'Other' and describe the nature of the loss.

Block D2 – Local Law Enforcement Notification:

- Select 'Yes' if the entity notified local Law Enforcement of the loss. Otherwise select 'No'.

Block D3 – Local Law Enforcement Agency:

- Provide the full legal name of the local law enforcement agency to which the loss was reported.

Block D4 – Local Law Enforcement Agent Name:

- Provide the full name of the local law enforcement agent to whom the loss was reported.

Block D5 – Local Law Enforcement Contact Information:

- Provide the contact information for the person listed in Block D4.

Block D6 – FBI Notification:

- Select 'Yes' if the entity notified the FBI of the loss. Otherwise select 'No'.

Block D7 – FBI Agent Name:

- Provide the full name of the FBI agent to whom the loss was reported.

Block D8 – FBI Agent Contact Information:

- Provide the contact information for the person listed in Block D7.

Block D9 – Select Agent or Toxin Found:

- Select 'Yes' if the entity recovered the select agent or toxin. Otherwise select 'No'.

Block D10 – Duration Material Missing:

- Enter the date the select agent or toxin was recovered.

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- Enter the estimated duration of time the select agent or toxin was lost (i.e., 2 days, 3 weeks, 1 hour, not recovered, etc.).

Block D11 – Inventory/Audit:

- Enter the date of the last inventory/audit that was performed for the affected loss.

Block D12 – Potential Exposure:

- Select 'Yes/Unknown' if you have reason to believe that an occupational exposure occurred during the loss. Otherwise select 'No'.

Signature:

- For all entities, the individual named in Block A6 (Responsible Official or Laboratory Supervisor), must type/print, sign, and date the appropriate section(s) of the form.

Section E – Report of Theft

Block E1 – Type of Theft:

- Select the type of theft that occurred. Select all that apply.

Block E2 – Local Law Enforcement Notification:

- Select 'Yes' if the entity notified local law enforcement of the theft. Otherwise select 'No'.

Block E3 – Local Law Enforcement Agency:

- Provide the full name of the local law enforcement agency to which the theft was reported.

Block E4 – Local Law Enforcement Agent Name:

- If applicable, provide the full name of the local law enforcement representative to whom the theft was reported.

Block E5 – Local Law Enforcement Contact Information:

- Provide the contact information for the person listed in Block E4.

Block E6 – FBI Notification:

- Select 'Yes' if the entity notified the FBI of the theft. Otherwise select 'No'.

Block E7 – FBI Agent Name:

- Provide the full name of the FBI agent to whom the theft was reported.

Block E8 – FBI Agent Contact Information:

- Provide the contact information for the person listed in Block E7.

Block E9 – Select Agent or Toxin Found:

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- Select 'Yes' if the entity recovered the select agent or toxin. Otherwise select 'No'.

Block E10 – Potential Exposure:

- Select 'Yes/Unknown' if you have reason to believe that an exposure occurred during the theft. Otherwise, select 'No'.

Signature:

- For all entities, the individual named in Block A6 (Responsible Official or Laboratory Supervisor), must type/print, sign, and date the appropriate section(s) of the form.

Appendix 1 – Events Timeline

Provide a detailed summary of events, including a timeline of what occurred and when. For a discovery of a select agent or toxin in unregistered locations, include your entity's plan of action to assure no future discoveries; how discovered agents were found and disposition of the discovered agents; inventory reconciliation; and assurance that the discovered material was safeguarded against unauthorized access, theft, loss, or release. **Do not include personal identifiable information (PII).**