



**REPORT OF A RELEASE/LOSS/THEFT
APHIS/CDC FORM 3 OF A
SELECT AGENT OR TOXIN**

FORM APPROVED
OMB NO. 0920-0578 EXP
DATE
01/31/2024

INSTRUCTIONS

Answer all items completely and type or print in ink. Detailed instructions are available at <http://www.selectagents.gov/form3.html>. This report must be signed and submitted to either APHIS or CDC:

Animal and Plant Health Inspection Service
Agriculture Select Agent Services
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: (301) 734-3652
Email: AqSAS@aphis.usda.gov

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop H21-7
Atlanta, GA 30329
FAX: (404) 471-8375
Email: form3@cdc.gov

Submit completed form only once by either eFSAP, fax, or email

| SECTION A – ENTITY INFORMATION | | | |
|---|--|---|--|
| 1. Name of Entity: | | | |
| 2. Physical Address (NOT a post office box): | | 3. City: | 4. State: |
| 5. Zip Code: | | 6. Name of Responsible Official or Laboratory Supervisor: | |
| 7. Name of Principal Investigator: | | 8. Telephone Number of Responsible Official: | |
| 9. Email address of Responsible Official: | | | |
| SECTION B – INCIDENT INFORMATION | | | |
| 1. Date and Time of Incident: | 2. Date of Immediate Notification to CDC or APHIS: | 3. Type of notification to CDC or APHIS: <input type="checkbox"/> E-mail <input type="checkbox"/> Fax <input type="checkbox"/> Telephone <input type="checkbox"/> eFSAP | 4. Location of Incident (bldg., room, equipment, etc.): |
| 5. Name of Select Agent or Toxin: | | 6. Strain designation of Select Agent or Toxin: | |
| | | <input type="checkbox"/> Recombinant Agent | |
| | | <input type="checkbox"/> Recombinant Agent | |
| 8. Type of Incident: <input type="checkbox"/> Release/ Potential Exposure (After completing Section B. Go to Section C) <input type="checkbox"/> Loss (After completing Section B. Go to Section D) <input type="checkbox"/> Theft (After completing Section B. Go to Section E) Note: Please complete Appendix 1, event timeline, to provide details on the theft/loss/release incident. | | 9. Severity of the incident: <input type="checkbox"/> Negligible <input type="checkbox"/> Low <input type="checkbox"/> Moderate <input type="checkbox"/> High | 10. What Biosafety Level did the incident occur? <input type="checkbox"/> BSL2 <input type="checkbox"/> ABSL2 <input type="checkbox"/> BSL3 <input type="checkbox"/> ABSL3 <input type="checkbox"/> BSL4 <input type="checkbox"/> ABSL4 <input type="checkbox"/> ACL 2 <input type="checkbox"/> ABSL3Ag <input type="checkbox"/> ACL 3 <input type="checkbox"/> Storage area <input type="checkbox"/> ACL 4 <input type="checkbox"/> Other _____ <input type="checkbox"/> _____ |
| 11. Is this incident associated with an APHIS/CDC Form 2 (Transfer): <input type="checkbox"/> Yes, APHIS/CDC Form 2 transfer #: _____ <input type="checkbox"/> No | | 12. Is this incident associated with an APHIS/CDC Form 4 (Identification): <input type="checkbox"/> Yes, APHIS/CDC Form 4 clinical ID#: _____ <input type="checkbox"/> No | |

SECTION C- REPORT OF RELEASE

| | | | | | | | | | | | | | |
|--|---|---|---|---|--|---|---|---|--|--|--|-------------------------------|--------------|
| <p>1. Type of Potential Exposure/Release (choose all that apply):</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> Animal bite/scratch <input type="checkbox"/> PPE failure <input type="checkbox"/> Spill <input type="checkbox"/> Needle stick/Sharps <input type="checkbox"/> Inactivation failure </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> Equipment/mechanical failure <input type="checkbox"/> Package damaged in transit (complete B-11) <input type="checkbox"/> Decontamination failure <input type="checkbox"/> Unintended exposure of animas or plants <input type="checkbox"/> Work performed on an open bench <input type="checkbox"/> Other: _____ </td> </tr> </table> | <input type="checkbox"/> Animal bite/scratch <input type="checkbox"/> PPE failure <input type="checkbox"/> Spill <input type="checkbox"/> Needle stick/Sharps <input type="checkbox"/> Inactivation failure | <input type="checkbox"/> Equipment/mechanical failure <input type="checkbox"/> Package damaged in transit (complete B-11) <input type="checkbox"/> Decontamination failure <input type="checkbox"/> Unintended exposure of animas or plants <input type="checkbox"/> Work performed on an open bench <input type="checkbox"/> Other: _____ | <p>2. Was there a release outside containment barriers?</p> <input type="checkbox"/> Yes <input type="checkbox"/> No <p>If yes, (choose all that apply)</p> <input type="checkbox"/> Release outside primary containment (e.g., biosafety cabinet) <input type="checkbox"/> Release beyond secondary containment (e.g., laboratory) <input type="checkbox"/> Release outside all containment barriers of the facility (e.g., resulting in possible agricultural/environmental/public health threat) | | | | | | | | | | |
| <input type="checkbox"/> Animal bite/scratch <input type="checkbox"/> PPE failure <input type="checkbox"/> Spill <input type="checkbox"/> Needle stick/Sharps <input type="checkbox"/> Inactivation failure | <input type="checkbox"/> Equipment/mechanical failure <input type="checkbox"/> Package damaged in transit (complete B-11) <input type="checkbox"/> Decontamination failure <input type="checkbox"/> Unintended exposure of animas or plants <input type="checkbox"/> Work performed on an open bench <input type="checkbox"/> Other: _____ | | | | | | | | | | | | |
| <p>3. What PPE was worn at the time of the incident (choose all that apply)?</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> Hand Protection (gloves) <input type="checkbox"/> Head Protectors/Covers <input type="checkbox"/> Body Protection (e.g., lab coat, BSL4 suit) </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> Foot Protection (e.g., booties, shoe covers) <input type="checkbox"/> Respiratory Protection (e.g., PAPR, N95): Type _____ <input type="checkbox"/> Other: _____ </td> </tr> </table> | <input type="checkbox"/> Hand Protection (gloves) <input type="checkbox"/> Head Protectors/Covers <input type="checkbox"/> Body Protection (e.g., lab coat, BSL4 suit) | <input type="checkbox"/> Foot Protection (e.g., booties, shoe covers) <input type="checkbox"/> Respiratory Protection (e.g., PAPR, N95): Type _____ <input type="checkbox"/> Other: _____ | <p>4. Did the release result in potential exposure(s)?</p> <input type="checkbox"/> No <input type="checkbox"/> Yes <p>4a. If yes, how many individuals/animals/plants were exposed? _____</p> <p>4b. Of the number in 4a, how many individuals were laboratory staff: _____</p> | | | | | | | | | | |
| <input type="checkbox"/> Hand Protection (gloves) <input type="checkbox"/> Head Protectors/Covers <input type="checkbox"/> Body Protection (e.g., lab coat, BSL4 suit) | <input type="checkbox"/> Foot Protection (e.g., booties, shoe covers) <input type="checkbox"/> Respiratory Protection (e.g., PAPR, N95): Type _____ <input type="checkbox"/> Other: _____ | | | | | | | | | | | | |
| <p>5. Did the release result in a laboratory acquired infection or an infection/outbreak in agriculture or in the environment?</p> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not currently known | <p>6. What medical surveillance and/or treatment was provided to individuals, if any? (choose all that apply)</p> <input type="checkbox"/> None <input type="checkbox"/> Physical evaluation <input type="checkbox"/> Fever/symptom watch <input type="checkbox"/> Serology screening <input type="checkbox"/> Antibiotics or other prophylaxis <input type="checkbox"/> Other: _____ <p>6a. Total number of individuals medical surveillance and/or treatment provided to: _____</p> | | | | | | | | | | | | |
| <p>7a. Has an internal investigation been initiated to lessen the likelihood of recurrences of incident involving the select agents and toxins at this entity?</p> <input type="checkbox"/> No <input type="checkbox"/> Yes (If yes, please provide additional details below) <p>Describe the internal investigation initiated following the incident (if any), and any root cause(s) identified.</p> <p>7b. What corrective actions have been initiated to lessen the likelihood of recurrence of incident involving the select agents and toxins at this entity? (choose all that apply)</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 25%;"><input type="checkbox"/> Retraining on existing policy</td> <td style="width: 25%;"><input type="checkbox"/> New/modified policy</td> <td style="width: 25%;"><input type="checkbox"/> New training developed</td> <td style="width: 25%;"><input type="checkbox"/> New/updated SOP</td> </tr> <tr> <td><input type="checkbox"/> New PPE provided</td> <td><input type="checkbox"/> New equipment provided</td> <td><input type="checkbox"/> Equipment repair</td> <td><input type="checkbox"/> Review/revise risk assessment</td> </tr> <tr> <td><input type="checkbox"/> Audit/remove faulty PPE</td> <td><input type="checkbox"/> Audit/remove faulty equipment</td> <td><input type="checkbox"/> None</td> <td>Other: _____</td> </tr> </table> | | <input type="checkbox"/> Retraining on existing policy | <input type="checkbox"/> New/modified policy | <input type="checkbox"/> New training developed | <input type="checkbox"/> New/updated SOP | <input type="checkbox"/> New PPE provided | <input type="checkbox"/> New equipment provided | <input type="checkbox"/> Equipment repair | <input type="checkbox"/> Review/revise risk assessment | <input type="checkbox"/> Audit/remove faulty PPE | <input type="checkbox"/> Audit/remove faulty equipment | <input type="checkbox"/> None | Other: _____ |
| <input type="checkbox"/> Retraining on existing policy | <input type="checkbox"/> New/modified policy | <input type="checkbox"/> New training developed | <input type="checkbox"/> New/updated SOP | | | | | | | | | | |
| <input type="checkbox"/> New PPE provided | <input type="checkbox"/> New equipment provided | <input type="checkbox"/> Equipment repair | <input type="checkbox"/> Review/revise risk assessment | | | | | | | | | | |
| <input type="checkbox"/> Audit/remove faulty PPE | <input type="checkbox"/> Audit/remove faulty equipment | <input type="checkbox"/> None | Other: _____ | | | | | | | | | | |

Additional details: Certification: I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of the select agent regulations may result in civil or criminal penalties, including imprisonment. of 7 CFR Part 331, 9 CFR Part 121, or 42 CFR Part 73.

Signature of Respondent: _____ Title: _____

Typed or printed name of Respondent: _____ Date: _____

SECTION D - REPORT OF LOSS

| | | | | | |
|---|--|--|--|--|--|
| 1. Type of Loss: (choose all that apply) <input type="checkbox"/> Inventory/Recordkeeping error <input type="checkbox"/> Sample lost/discarded at entity <input type="checkbox"/> Sample lost in transit (complete B-11) <input type="checkbox"/> Other: _____ | | 2. Has Local Law Enforcement been Notified: (If yes, complete D3-D5) <input type="checkbox"/> Yes <input type="checkbox"/> No | | 3. Local Law Enforcement Agency: | |
| 4. Local Law Enforcement Agent Name (First MI Last Name): | | | 5. Local Law Enforcement Contact Information (phone/email): | | |
| 6. Was the FBI Notified: (If yes, complete D7-D8) <input type="checkbox"/> Yes <input type="checkbox"/> No | 7. FBI Agent Name (First MI Last Name): | | 8. FBI Agent Contact Information (phone/email): | | |
| 9. Was the lost select agent or toxin material found? <input type="checkbox"/> Yes <input type="checkbox"/> No | 10. How long was the select agent or toxin material missing? Date recovered: _____ Duration of loss (hours/days): _____ | 11. Give the date of the last inventory/audit performed: | | 12. Was there a potential exposure: <input type="checkbox"/> Yes/Unknown at this time (go to Section C) <input type="checkbox"/> No | |

Certification: I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of the select agent regulations may result in civil or criminal penalties, including imprisonment. of 7 CFR Part 331, 9 CFR Part 121, or 42 CFR Part 73.

Signature of Respondent: _____ Title: _____

Typed or printed name of Respondent: _____ Date: _____

SECTION E – REPORT OF THEFT

| | | | | | |
|--|---|---|--|---|--|
| 1. Type of Theft:(choose all that apply) <input type="checkbox"/> Forced Entry <input type="checkbox"/> Insider/Insider assisted access <input type="checkbox"/> Unauthorized access | | 2. Has Local Law Enforcement been Notified: (If yes, complete sections E3-E5) <input type="checkbox"/> Yes <input type="checkbox"/> No | | 3. Local Law Enforcement Agency: | |
| 4. Local Law Enforcement Agent Name (First MI and Last name): | | | 5. Local Law Enforcement Contact Information (phone/email): | | |
| 6. Has the FBI been Notified: (If yes, complete E7-E8): <input type="checkbox"/> Yes <input type="checkbox"/> No | 7. FBI Agent Name: (First M. Last Name): | | 8. FBI Agent Contact Information (phone/email): | | |
| 9. Was the stolen select agent or toxin material recovered: <input type="checkbox"/> Yes; Date of Recovery: _____ <input type="checkbox"/> No | | 10. Was there a potential exposure: <input type="checkbox"/> Yes/Unknown at this time (go to Section C) <input type="checkbox"/> No | | | |

Certification: I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of the select agent regulations may result in civil or criminal penalties, including imprisonment. of 7 CFR Part 331, 9 CFR Part 121, or 42 CFR Part 73.

Signature of Respondent: _____ Title: _____

Typed or printed name of Respondent: _____ Date: _____

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, MS D74, Atlanta, Georgia 30329; ATTN: PRA (0920-0576).

APPENDIX 1
EVENTS TIMELINE

Provide a detailed summary of events, including a timeline of what occurred.

Save and continue on next page