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| **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**.](http://www.selectagents.gov/form3.html) **This report must be signed and submitted to either APHIS or CDC:**

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| 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: [AgSAS@aphis.usda.gov](mailto:AgSAS@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](mailto:form3@cdc.gov) |

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

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| **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:   E-mail  Fax  Telephone  eFSAP | | | | | 4. Location of Incident (bldg., room, equipment, etc.): | | |
| 5. Name of Select Agent or Toxin: | | 6. Strain designation of Select Agent or Toxin: | | | | | 7. Quantity (Unit (vial, plates, etc.)): | | |
|  | |  Recombinant Agent | | | | |  | | |
|  | |  Recombinant Agent   | | | | |  | | |
| 8. Type of Incident:   * Release/ Potential Exposure (After completing Section B. Go to Section C) * Loss (After completing Section B. Go to Section D) * Theft (After completing Section B. Go to Section E[)](http://www.selectagents.gov/resources/CompleteTHEFT%20LOSS%20%20RELEASE%20guidance%20document%20June82010_FINAL.pdf)   Note: Please complete Appendix 1, event timeline, to provide details on the theft/loss/release incident. | | | 9. Severity of the incident:   * Negligible * Low * Moderate * High | | | 10. What Biosafety Level did the incident occur?   * BSL2 ABSL2 * BSL3 ABSL3 * BSL4 ABSL4 * ACL 2 ABSL3Ag * ACL 3 Storage area * ACL 4  Other\_\_\_\_\_\_\_\_    | | | |
| 11. Is this incident associated with an APHIS/CDC Form 2 (Transfer):   * Yes, APHIS/CDC Form 2 transfer #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ * No | | | | 12. Is this incident associated with an APHIS/CDC Form 4 (Identification):   * Yes, APHIS/CDC Form 4 clinical ID#: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ * No | | | | | |

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

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| **SECTION D - REPORT OF LOSS** | | | | | | | | |
| 1. Type of Loss: (choose all that apply)   * Inventory/Recordkeeping error * Sample lost/discarded at entity * Sample lost in transit (complete B-11) * Other: | | | | 2. Has Local Law Enforcement been Notified: (If yes, complete D3-D5)   * Yes * 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)   * Yes * 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?   * Yes * 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:   * Yes/Unknown at this time (go to Section C) * No |

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Signature of Respondent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Typed or printed name of Respondent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **SECTION E – REPORT OF THEFT** | | | | | | |
| 1. Type of Theft:(choose all that apply)   * Forced Entry * Insider/Insider assisted access * Unauthorized access | | 2. Has Local Law Enforcement been Notified:  (If yes, complete sections E3-E5)   * Yes * 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):   * Yes * 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:   * Yes; Date of Recovery: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ * No | | | 10. Was there a potential exposure:   * Yes/Unknown at this time (go to Section C) * 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).

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| ***APPENDIX 1***  **EVENTS TIMELINE** |
| Provide a detailed summary of events, including a timeline of what occurred. |

Save and continue on next page