



GUIDANCE DOCUMENT FOR REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS (APHIS/CDC FORM 3)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE XX/XX/XXXX

INTRODUCTION

The U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) published final rules (7 CFR 331, 9 CFR 121, and 42 CFR 73), which implement the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) setting forth the requirements for possession, use, and transfer of select agents and toxins. The select agents and toxins identified in the final rules have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the HHS Secretary and to the Animal and Plant Health Inspection Service (APHIS) by the USDA Secretary. In order to minimize the reporting burden to the public, APHIS and CDC have developed a common reporting form for this data collection.

An entity is required by regulation (7 CFR 331.19, 9 CFR 121.19, and 42 CFR 73.19) to notify APHIS or CDC immediately upon discovery of a theft (unauthorized removal of select agent or toxin), loss (failure to account for select agent or toxin), or release (occupational exposure or release of an agent or toxin outside of the primary barriers of the biocontainment area) of a select agent and toxin. In addition, clinical or diagnostic laboratories and other entities that possess, use or transfer a select agent or toxin contained in a specimen presented for diagnosis, verification, or proficiency testing must immediately report upon discovery of a theft, loss, or release of select agent or toxin. After the initial reporting, this form (APHIS/CDC Form 3) must be sent to APHIS or CDC within 7 calendar days after the discovery of theft, loss, or release of select agents or toxins:

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3652
E-mail: Agricultural.Select.Agent.Program@aphis.usda.gov

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2096
Email: lrsat@cdc.gov

For theft or loss of select agents or toxins, the entity must notify the appropriate local, state, or federal law enforcement agencies. For release of select agents or toxins, the entity should notify the appropriate local, state, and federal health agencies.

PURPOSE

This form is to be used by the Responsible Official or Facility Director to report the theft, loss, or release of select agents or toxins. A copy of the completed form and attachments must be maintained by the entity for three years.

INSTRUCTIONS

1. Immediately notify APHIS or CDC via telephone, fax, or e-mail and appropriate local, state, or federal law enforcement agencies (theft or loss) or appropriate local, state, and federal health agencies (release).
2. The RO or Facility Director must complete, sign and date this form. For registered entities, the information provided for this form should match the information submitted for the entity's certificate of registration.
 - a. For reporting of a theft or loss, complete sections 1 and 2. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified. For reporting a theft or loss that occurred during transfer, complete sections 1, 2, and 3 and include a copy of the approved APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins."
 - b. For reporting a release, complete sections 1, 2, and 4. For reporting a release that occurred during transfer, complete all sections and include a copy of the approved APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins."
3. The RO or Facility Director signs and sends the form to APHIS or CDC **within 7 calendar days** of the theft, loss, or release.

OBTAINING EXTRA COPIES OF THIS FORM

To obtain additional copies of this form, contact APHIS at (301) 734-5960 or CDC at (404) 718-2000. This guidance document and form are also available at <http://www.selectagents.gov>, http://www.aphis.usda.gov/programs/ag_selectagent/index.html and <http://www.cdc.gov/od/sap>.



REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS (APHIS/CDC FORM 3)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE XX/XX/XXXX

Read all instructions carefully before completing the report. Answer all items completely and type or print in ink. The report must be signed and submitted to either APHIS or CDC within 7 days of the theft, loss or release:

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3652
E-mail: Agricultural.Select.Agent.Program@aphis.usda.gov

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Atlanta, GA 30333
FAX: 404-718-2096
Email: lrsat@cdc.gov

| SECTION 1 – TO BE COMPLETED BY ALL ENTITIES | | | | | |
|---|--|--|--|--|--------------|
| 1. Entity name: | | | 2. Entity registration number (if applicable): | | |
| 3. Entity address (NOT a post office address): | | 4. City: | | 5. State: | 6. Zip Code: |
| 7. Responsible Official (RO) or Facility Director First: MI: Last: | | | 8. Telephone #: | | |
| 9. FAX #: | | | 10. E-mail address: | | |
| 11. RO or Facility Director address (NOT a post office address): | | | 12. City: | | 13. State: |
| 14. Zip Code: | | 15. Type of incident: <input type="checkbox"/> Theft <input type="checkbox"/> Loss <input type="checkbox"/> Release | | 16. Immediate notification provided to: <input type="checkbox"/> APHIS <input type="checkbox"/> CDC | |
| 17. Date of immediate notification: | | 18. Type of immediate notification: <input type="checkbox"/> E-mail <input type="checkbox"/> Fax <input type="checkbox"/> Telephone | | | |
| 19. An internal review of laboratory procedures and policies has been initiated to prevent recurrences of theft/loss/release of select agents and toxins at this entity: <input type="checkbox"/> No <input type="checkbox"/> Yes (If yes, please provide additional details in an attachment.) | | | | | |

| SECTION 2 – TO BE COMPLETED BY ALL ENTITIES | | | | | |
|---|----------------------------------|--|----------------------|--|---|
| LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED (attach additional sheets if necessary) | | | | | |
| | 20. Select agents and/or toxins: | 21. Characterization of agent: | 22. Number of vials: | 23. Form (powder/liquid/ slant): | 24. Volume or weight of vial contents (e.g., mL, mg, ng): |
| A | | | | | |
| B | | | | | |
| C | | | | | |
| D | | | | | |
| 25. Date and time of incident: | | 26. Date of last inventory: | | 27. Name of principal investigator responsible for laboratory with select agents and toxins: First: MI: Last: | |
| 28. Location of incident (building and room #): | | 29. Location of incident (within room (e.g., freezer, incubator)): | | 30. Biosafety level of laboratory where incident occurred: | |
| 31. Agent was recovered (theft/loss): <input type="checkbox"/> No <input type="checkbox"/> Yes | | | | | |
| 32. Provide a detailed summary of events including a timeline of events and name and telephone numbers of agencies notified. The summary should also include description of containers (e.g., size, color, type, brand, and any symbols or markings), supporting documentation (e.g., access and inventory records), identified weaknesses, and any corrective actions taken (attach additional sheets if necessary): | | | | | |
| <input type="checkbox"/> Continued as an attachment | | | | | |

| SECTION 3 – IF THE INCIDENT OCCURRED DURING TRANSFER PROVIDE THE FOLLOWING INFORMATION AND INCLUDE A COPY OF THE RELEVANT APHIS/CDC FORM 2 | |
|---|---|
| 33. Transfer authorization number from APHIS/CDC Form 2: | 34. Date shipped: |
| 35. Name of carrier: | 36. Airway bill number/bill of lading number/tracking number: |
| 37. Package description (size, shape, description of packaging including number and type of inner packages; attach additional sheets if necessary): | |
| | |
| 38. Package with select agents and toxins received by requestor: <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, date of receipt: | 39. Package with select agents and toxins appears to have been opened: <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, include in explanation above for Box #37) |
| 40. Sender was contacted regarding incident: <input type="checkbox"/> No <input type="checkbox"/> Yes | 41. Carrier/courier was contacted regarding incident: <input type="checkbox"/> No <input type="checkbox"/> Yes |

| SECTION 4 – TO BE COMPLETED ONLY FOR RELEASE OF SELECT AGENTS AND TOXINS |
|--|
| 42. Hazards posed by release: <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, explain. Attach additional sheets if necessary.) |
| |
| 43. Exposures: <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, provide number of persons, animals, and plants exposed. Attach additional sheets if necessary.) |
| |
| 44. Area was decontaminated: <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, explain. Attach additional sheets if necessary.) |
| |
| 45. Medical treatment was provided: <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, explain. Attach additional sheets if necessary.) |
| |

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 7 CFR 331, 9 CFR 121, and 42 CFR 73 may result in civil or criminal penalties, including imprisonment.

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 D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).