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

FORM APPROVED
OMB NO. 0920-0576
EXP DATE: 01/31/2024

Detailed instructions are available at http://www.selectagents.gov/form3.html.
This report must be signed and submitted to either DASAT or DRSC:

Animal and Plant Health Inspection Service
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

Centers for Disease Control and Prevention
Division of Regulatory Science and Compliance
1600 Clifton Road NE, Mailstop H21-4
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: {Select}	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: {Select}		6. Strain designation of Select Agent or Toxin: ☐ Recombinant Agent ☐ Unknown	7. Quantity (Unit (vial, plates, etc.)):
{Select}		☐ Recombinant Agent ☐ Unknown	
{Select}		☐ Recombinant Agent ☐ Unknown	

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) **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

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 animal or plants
- ☐ Work performed on an open bench
- ☐ Other:_____

2. Was there a release outside containment barriers?

- ☐ Yes
- ☐ No

2a. If yes, (choose all that apply)

- ☐ Release outside primary containment (e.g., biosafety cabinet)
- ☐ Release beyond secondary containment barrier (e.g., laboratory)
- ☐ Release outside all containment barriers of the facility

2b. Did the release pose a threat to animal or plant health, or animal or plant products, or a public health threat? ☐ Yes ☐ No

3. What PPE was worn at the time of the incident (choose all that apply)?

- ☐ Hand Protection (e.g., gloves)
- ☐ Head Protectors/Covers
- ☐ Body Protection (e.g.,labcoat)
- ☐ Eye/Face Protection (e.g.,goggles, face shield)
- ☐ Foot Protection (e.g., booties, shoe covers)
- ☐ Respiratory Protection (e.g.,PAPR, N95): Type _____
- ☐ Other: _____

3a. Number of individuals wearing the above described PPE?

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. Was medical surveillance and/or treatment provided to potentially exposed individuals? ☐ Yes ☐ No

6a. If yes, what medical surveillance and/or treatment was provided to individuals? (choose all that apply)

- ☐ None
- ☐ Physical evaluation
- ☐ Fever/symptom watch
- ☐ Serology screening
- ☐ Antibiotics or other prophylaxis
- ☐ Other: _____
- ☐ Signs and symptoms information provided

6b. 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/ SOP 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:_____

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)	2. Has Local Law Enforcement been Notified: (If yes, complete D3-D5)	3. Local Law Enforcement Agency:
☐ Inventory/Recordkeeping error ☐ Sample lost/discarded at entity ☐ Sample lost in transit (complete B-11) ☐ Other:_____	☐ Yes ☐ No	

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)	7. FBI Agent Name (First MI Last Name):	8. FBI Agent Contact Information (phone/email):
☐ Yes ☐ No		

9. Was the lost select agent or toxin material found?	10. How long was the select agent or toxin material missing?	11. Prior to this incident, provide the date of the last inventory/audit performed:	12. Was there a potential exposure:
☐ Yes ☐ No	Date recovered:_____ Duration of loss (hours/days): _____		☐ 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: _____

SECTION E – REPORT OF THEFT

1. Type of Theft:(choose all that apply)	2. Has Local Law Enforcement been Notified: (If yes, complete sections E3-E5)	3. Local Law Enforcement Agency:
☐ Forced Entry ☐ Insider/Insider assisted access ☐ Unauthorized access	☐ Yes ☐ No	

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):	7. FBI Agent Name: (First M. Last Name):	8. FBI Agent Contact Information (phone/email):
☐ Yes ☐ No		

9. Was the stolen select agent or toxin material recovered:	10. Was there a potential exposure:
☐ Yes; Date of Recovery: _____ ☐ No	☐ 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: _____

APPENDIX 1 **EVENTS TIMELINE**
Provide a detailed summary of events, including a timeline of what occurred. Do not include personal identifiable information (PII).