# GUIDANCE DOCUMENT FOR REPORTING THE IDENTIFICATION OF A SELECT AGENT OR TOXIN (APHIS/CDC FORM 4)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2008

## 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.

Clinical or diagnostic laboratories and other entities that have identified the following select agents and toxins contained in a specimen presented for diagnosis, verification, or proficiency testing are required by regulation (7 CFR 331, 9 CFR 121, and 42 CFR 73) to contact APHIS (telephone: 301-734-5960, facsimile: 301-734-3652, or e-mail: Agricultural.Select.Agent.Program@aphis.usda.gov) or CDC (telephone: 404-718-2000, facsimile: 404-718-2096, or e-mail: lrsat@cdc.gov) immediately: African horse sickness virus, African swine fever virus, Avian influenza virus (highly pathogenic), *Bacillus anthracis*, Botulinum neurotoxins, Bovine spongiform encephalopathy agent, *Brucella melitensis*, *Candidatus Liberobacter africanus, Candidatus Liberobacter asiaticus,* Classical swine fever virus, Foot-and-Mouth disease virus, *Francisella tularensis*, Ebola virus, Hendra virus, Lassa fever virus, Marburg virus, Newcastle disease virus (velogenic), Nipah virus, *Peronosclerospora philippinensis, Ralstonia solanacearum* race 3, biovar 2, Rift Valley fever virus, Rinderpest virus, *Schlerophthora rayssiae* var *zeae,* South American Hemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito), Swine vesicular disease virus, *Synchytrium endobioticum,* Variola major virus (Smallpox virus), Variola minor (Alastrim), Venezuelan equine encephalitis virus, *Xanthomonas oryzae* pv. *Oryzicola, Xylella fastidiosa* (citrus variegated chlorosis strain), and *Yersinia pestis*.

For all identified select agents and toxins, this form (APHIS/CDC Form 4) should be sent directly to APHIS or CDC within 7 calendar days after identification of the select agent or toxin contained in a specimen presented for diagnosis or verification or within 90 days of receipt for proficiency testing. In addition to the reporting requirement, the identified select agent or toxin must be secured against theft, loss, or release during the period between identification and final disposition. Within 7 calendar days after identification of the select agent or toxin contained in a specimen presented for diagnosis or verification or 90 days of receipt for proficiency testing, the identified select agent or toxin must be transferred in accordance with 7 CFR 331.16, 9 CFR 121.16 or 42 CFR 73.16 or destroyed on-site by a recognized sterilization or inactivation process. The select agent or toxin may be retained only if the entity is currently registered for the select agent and toxin identified. If the select agent or toxin is retained, the entity may need to amend its certificate of registration to reflect the addition of the agent and maintain records associated with any intra-entity transfers.

Any known select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of the regulations during the period between seizure of the agent and the transfer or destruction of such agent provided that (1) as soon as practicable, the Federal law enforcement agency transfers the seized agent to an entity registered for that agent or destroys the agent by a recognized sterilization or inactivation process; (2) the Federal law enforcement agency secures the seized agent against theft, loss, or release; and (3) the Federal law enforcement agency reports the seizure of the agent by submitting this form.

## PURPOSE

The purpose of this form is to report select agents or toxins contained in specimens presented for diagnosis, verification, or proficiency testing as defined under 7 CFR 331.1, 9 CFR 121.1 or 42 CFR 73.1 and seizure of select agents or toxins by federal law enforcement agencies. A copy of the completed form and attachments must be maintained by the entity for three years.

## INSTRUCTIONS

### Diagnosis and verification

1. Complete section 1A, 2, and 4 within seven calendar days after identification. This form should be completed by all entities in possession of the specimen or isolate even if the select agent or toxin was identified by another laboratory:
   a. For registered entities, the information provided for this form should match the information submitted for the entity's certificate of registration (blocks 1-15).
   b. For information not known at the time of form submission, indicate "not known" for block.
   c. If known, provide any information regarding morphological, biochemical, or molecular characterization of agent (block 29). Attach additional sheets if necessary.
   d. Complete block 51 for reporting multiple cases of select agents or toxins identified from specimens presented for diagnosis or verification.
2. To request prior authorization to transfer select agent(s) or toxin(s) identified, APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins," must be submitted to either APHIS or CDC. To receive approval prior to the transfer of select agent or toxin, the select agent or toxin must be transferred to an entity registered for that agent.
3. Less stringent reporting may be required based on extraordinary circumstances (e.g., agricultural emergencies, widespread outbreaks, endemic areas).

**Proficiency testing**

1. Complete sections 1A, 3, and 4 within 90 calendar days of receipt. For registered entities, the information provided for this form should match the information submitted for the entity's certificate of registration (blocks 1-15).
2. To request prior authorization to transfer select agent(s) or toxin(s) identified, APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins," must be submitted to either APHIS or CDC. To receive approval prior to the transfer of select agent or toxin, the select agent or toxin must be transferred to an entity registered for that agent.
3. A select agent or toxin that is contained in a specimen for proficiency testing may be transferred without prior authorization from CDC or APHIS provided that, at least seven calendar days prior to the transfer, the sender reports to CDC or APHIS the select agent or toxin to be transferred and the name and address of the recipient (See 7 CFR 331.16, 9 CFR 121.16 and 42 CFR 73.16).

**Reporting seized select agents or toxins by federal law enforcement agencies**

1. Complete sections 1A and 1B, 2, and 4 within seven calendar days after seizure and/or final disposition of select agents or toxins.
2. To request prior authorization to transfer select agent(s) or toxin(s) identified, APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins," must be submitted to either APHIS or CDC. To receive approval prior to the transfer of select agent or toxin, the select agent or toxin must be transferred to an entity registered for that agent.

**OBTAINING EXTRA COPIES OF THIS FORM**

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

# REPORT OF THE IDENTIFICATION OF A SELECT AGENT OR TOXIN (APHIS/CDC FORM 4)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2008

Read all instructions carefully before completing the form. Answer all items completely and type or print in ink. The form must be signed and submitted to either APHIS or CDC:

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

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

## SECTION 1 – ENTITY INFORMATION

### SECTION 1A – TO BE COMPLETED BY ALL

| | | | | |
|---|---|---|---|---|
| 1. Legal name of entity: | 2. Entity registration number (*if applicable*): | | | |
| 3. Address (NOT a post office address): | 4. City: | 5. State: | 6. Zip Code: | |
| 7. Responsible Official (RO) or facility director<br>First: MI: Last: | 8. Title: | 9. Telephone: | 10. FAX: | 11. E-mail: |
| 12. Address (If different; NOT a post office address): | 13. City: | 14. State: | 15. Zip Code: | |

### SECTION 1B – TO BE COMPLETED BY FEDERAL LAW ENFORCEMENT AGENCY

| | | | | |
|---|---|---|---|---|
| 16. Name of federal law enforcement agent<br>First: MI: Last: | 17. Badge #: | 18. Telephone: | 19. FAX: | 20. E-mail: |
| 21. Address: | 22. City: | 23. State: | 24. Zip Code: | |

## SECTION 2 – TO BE COMPLETED FOR SELECT AGENTS AND TOXINS FROM CLINICAL/DIAGNOSTIC SPECIMENS

| | |
|---|---|
| 25. Select agent or toxin being reported: | 26. Date(s) agent was identified: |
| 27. Agent identification number or sample reference number: | 28. Total quantity of select agent or toxin identified: |

29. Characterization of select agent or toxin (*see instructions*):

30. Type of sample: ☐ Clinical/diagnostic sample ☐ Environmental sample ☐ Isolate ☐ Other (specify): _____

31. Specimen type: ☐ Fluid: _____ ☐ Tissue: _____ ☐ Isolate ☐ Other (specify): _____

32. Source of sample: ☐ Human ☐ Animal (species: _____)
☐ Plant (species: _____) ☐ Other (specify): _____

33. Is this source expected to provide additional specimens? ☐ Unknown ☐ No ☐ Yes
If yes, give the anticipated quantity and end date): _____

| | |
|---|---|
| 34. Location where laboratory testing was conducted<br>Building: Room: | 35. Biosafety level (BSL) of laboratory or PPQ containment designation: |

36. Was select agent or toxin isolated under conditions prescribed by the Biosafety in Microbiological and Biomedical Laboratories (BMBL):
☐ No ☐ Yes; If "no" has appropriate medical surveillance been instituted? ☐ No ☐ Yes

37. Has the sender of the sample been notified of the identification of the select agent or toxin? ☐ No ☐ Yes

| | | | | |
|---|---|---|---|---|
| 38. Name of entity that sent sample (if different than Section 1): | | 39. Telephone: | | |
| 40. Address (NOT a post office address): | 41. City: | 42. State: | 43. Zip Code: | |
| 44. RO or facility director (if different than Section 1)<br>First: MI: Last: | 45. Title: | 46. Telephone: | 47. FAX: | 48. E-mail: |
| 49. Name of treating physician, veterinarian, botanist, or person most familiar with the case<br>First: MI: Last: | | 50. Telephone: | | |

51. If more than one case, date of index case: _____ Number of cases: _____ Reporting dates (inclusive): _____

| SECTION 3 – TO BE COMPLETED FOR SELECT AGENTS AND TOXINS IDENTIFIED FROM PROFICIENCY TESTING | |
|---|---|
| 52. Select agent and strain designation (if known) or toxin being reported: | 53. Total quantity identified: |
| 54. Location where proficiency testing was conducted<br>Building: Room: | 55. BSL of laboratory or PPQ containment designation: |
| 56. Name of laboratory test that proficiency test was designed to assess: | 57. Date obtained from sponsor: |
| 58. Sponsor/entity that you received select agent or toxin from:<br>☐ College of American Pathologists<br>☐ Registered entity (Entity name, APHIS or CDC registration number):_____<br>☐ Other (Explain): | |

| SECTION 4 – TO BE COMPLETED BY ALL |
|---|
| **INFORMATION ON FINAL DISPOSITION OF SELECT AGENTS AND TOXINS** |
| 59. Disposition of select agent or toxin:<br><br>☐ Transferred to a registered entity (Give entity name and APHIS/CDC registration number. Include a copy of the approved APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins"):_____<br><br>☐ Destroyed on site: ☐ Autoclaving ☐ Chemical (Describe:_____) ☐ Irradiation ☐ Other:_____<br>Date select agent or toxin was destroyed: _____<br><br>☐ Retained and transferred via intra-entity transfer to (Give name of Principal Investigator and/or Amendment #): _____<br>Date select agent or toxin was transferred: _____<br><br>☐ Other (Provide detailed explanation): _____ |

I certify that any select agent and/or toxin that is contained in a specimen (sample containing the isolate, or isolate) presented for diagnosis, verification, or proficiency testing has been transferred in accordance with 7 CFR 331, 9 CFR 121, or 42 CFR 73 or destroyed on-site by a recognized sterilization or inactivation process. If the identified select agent or toxin is retained, I certify that the entity listed in Section 1 maintains a current certificate of registration to possess, use, or transfer the identified select agent or toxin. 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, or 42 CFR 73 may result in civil or criminal penalties, including imprisonment.

Signature of Respondent: _____

Typed or printed name of Respondent: _____ Date: _____