



## 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](mailto:Agricultural.Select.Agent.Program@aphis.usda.gov)) or CDC (telephone: 404-718-2000, facsimile: 404-718-2096, or e-mail: [irsat@cdc.gov](mailto:irsat@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](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  
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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 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 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: <input type="checkbox"/> Clinical/diagnostic sample <input type="checkbox"/> Environmental sample <input type="checkbox"/> Isolate <input type="checkbox"/> Other (specify): _____	
31. Specimen type: <input type="checkbox"/> Fluid: _____ <input type="checkbox"/> Tissue: _____ <input type="checkbox"/> Isolate <input type="checkbox"/> Other (specify): _____	
32. Source of sample: <input type="checkbox"/> Human <input type="checkbox"/> Animal (species: _____) <input type="checkbox"/> Plant (species: _____) <input type="checkbox"/> Other (specify): _____	
33. Is this source expected to provide additional specimens? <input type="checkbox"/> Unknown <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, give the anticipated quantity and end date): _____	
34. Location where laboratory testing was conducted 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): <input type="checkbox"/> No <input type="checkbox"/> Yes; If "no" has appropriate medical surveillance been instituted? <input type="checkbox"/> No <input type="checkbox"/> Yes	
37. Has the sender of the sample been notified of the identification of the select agent or toxin? <input type="checkbox"/> No <input type="checkbox"/> 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) 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 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 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: <input type="checkbox"/> College of American Pathologists <input type="checkbox"/> Registered entity (Entity name, APHIS or CDC registration number): _____ <input type="checkbox"/> 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: <input type="checkbox"/> 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"): _____ <input type="checkbox"/> Destroyed on site: <input type="checkbox"/> Autoclaving <input type="checkbox"/> Chemical (Describe: _____) <input type="checkbox"/> Irradiation <input type="checkbox"/> Other: _____ Date select agent or toxin was destroyed: _____ <input type="checkbox"/> Retained and transferred via intra-entity transfer to (Give name of Principal Investigator and/or Amendment #): _____ Date select agent or toxin was transferred: _____ <input type="checkbox"/> 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: \_\_\_\_\_

**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).