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

FORM APPROVED
OMB NO. 0579-0213,
0579-XXXX, and
OMB NO. 0920-0576

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 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) 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 must report this identification to APHIS or CDC. 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. To report the identification of a select agent, the Responsible Official or Facility Director must submit this form (APHIS/CDC Form 4) 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
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

The following select agents and toxins contained in a specimen presented for diagnosis or verification are required to be **immediately** reported to APHIS or CDC:

African horse sickness virus
African swine fever virus
Avian influenza virus (highly pathogenic)
Bacillus anthracis
Botulinum neurotoxins
Bovine spongiform encephalopathy agent
Brucella melitensis
Classical swine fever virus
Foot-and-mouth disease virus
Francisella tularensis
Ebola virus
Hendra virus
Lassa fever virus
Marburg virus
Nipah virus
Peronosclerospora philippinensis (*Peronosclerospora sacchari*)
Phoma glycinicola (formerly *Pyrenochaeta glycines*)
Ralstonia solanacearum race 3, biovar 2
Rathayibacter toxicus
Rift Valley fever virus
Rinderpest virus
Sclerophthora 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
Virulent Newcastle disease virus
Xanthomonas oryzae
Xylella fastidiosa (citrus variegated chlorosis strain)
Yersinia pestis

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. The reference laboratory (laboratory that confirms the identification of the select agent) completes Section 1 within seven calendar days after identification for all entities in possession of the specimen or isolate at the time of the identification. Additional copies of Section C are available at http://www.selectagents.gov, http://www.aphis.usda.gov/programs/ag_selectagent/index.html and http://www.cdc.gov/od/sap.
   a. For registered entities, the information provided for this form should match the information submitted for the entity's certificate of registration.
   b. Please provide all information as it relates to the case. For example, the case (e.g., patient) generates multiple specimens (e.g., tissue, fluid) and/or multiple specimen types that are cultured on various media (e.g., 15 blood agar plates) would be listed as 1 case for block 15. Attach additional sheets if necessary.
   c. Indicate the disposition of materials generated from the case (e.g., specimens and cultures) in block 17.
2. To request prior authorization to transfer select agent(s) or toxin(s) identified for research purposes, APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins," must be submitted to either APHIS or CDC. To ensure that your entity receives authorization from APHIS or CDC to transfer the select agent or toxin, you need to verify that the recipient is 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 section 2 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.
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 ensure that your entity receives authorization from APHIS or CDC to transfer the select agent or toxin, you need to verify that the recipient is 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 APHIS or CDC provided that, at least seven calendar days prior to the transfer, the sender reports to APHIS or CDC 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 section 3 within seven calendar days after seizure and/or final disposition of select agents or toxins.
2. For registered entities, the information provided for this form should match the information submitted for the entity's certificate of registration.

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

FORM APPROVED
OMB NO. 0579-0213,
0579-XXXX, and
OMB NO. 0920-0576

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
E-mail: Agricultural.Select.Agent.Program@aphis.usda.gov

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

SECTION 1 – TO BE COMPLETED BY REFERENCE LABORATORY

SECTION A – REFERENCE LABORATORY INFORMATION

1. Entity name:	2. ☐ Entity registration number: _____ ☐ Clinical/diagnostic laboratory		
3. Address (NOT a post office address):	4. City:	5. State:	6. Zip Code:
7. Responsible Official or Facility Director name First: MI: Last:	8. Telephone #:		
9. FAX #:	10. E-mail address:		

SECTION B – SELECT AGENTS AND TOXINS IDENTIFIED FROM CLINICAL/DIAGNOSTIC SPECIMENS

11. Select agent or toxin being reported:	12. Date(s) agent was identified:

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

14. Original source of sample: ☐ Human ☐ Animal (species: _____)
☐ Plant (species: _____) ☐ Other (specify): _____

15. Provide a summary of the methodologies used to identify the select agent or toxin including specimen type(s), media, total quantity, and if the source expected to provide additional specimens (*see instructions*):

16. Was there a possibility that personnel in your laboratory were exposed to the select agent or toxin while working with this sample? ☐ No ☐ Yes (If Yes, please complete APHIS/CDC Form 3.)

17. Disposition of select agent or toxin:
☐ 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"): _____
☐ Destroyed on site: ☐ Autoclaving ☐ Chemical (Describe: _____) ☐ Incineration ☐ Irradiation ☐ Other: _____
Date select agent or toxin was destroyed: _____
☐ Retained and/or transferred via intra-entity transfer to (Give name of Principal Investigator and/or Amendment #):
_____
Date select agent or toxin was transferred: _____

SECTION C – SAMPLE PROVIDER

18. Has the sender(s) of the sample been notified of the identification of the select agent or toxin? ☐ No ☐ Yes
NOTE: Please complete Section C for each laboratory that was in possession of the sample or isolate. (Attach additional sheets if necessary.)

19. Entity name:	20. ☐ Entity registration number: _____ ☐ Clinical/diagnostic laboratory		
21. Address (NOT a post office address):	22. City:	23. State:	24. Zip Code:
25. Responsible Official (RO) or facility director First: MI: Last:	26. Telephone #:		
27. FAX #:	28. E-mail address:		

29. Was there a possibility of an exposure while working with this sample? ☐ No ☐ Yes (If Yes, please complete APHIS/CDC Form 3.)

30. Disposition of select agent or toxin: ☐ Destroyed on site ☐ Retained ☐ Transferred to a registered entity (Provide entity name if different than Block 1): _____

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 Responsible Official/Facility Director: _____ Date: _____

SECTION 2 – TO BE COMPLETED BY LABORATORY THAT RECEIVED PROFICIENCY TESTING

SECTION A – LABORATORY INFORMATION

31. Entity name:	32. Entity registration number:		
33. Address (NOT a post office address):	34. City:	35. State:	36. Zip Code:
37. Responsible Official or Facility Director name First: MI: Last:	38. Telephone #:		
39. FAX #:	40. E-mail address:		

41. Was there a possibility of an exposure while working with this sample? ☐ No ☐ Yes (If Yes, please complete APHIS/CDC Form 3.)

SECTION B – SELECT AGENTS AND TOXINS IDENTIFIED FROM PROFICIENCY TESTING

42. Select agent and strain designation (if known) or toxin being reported:	43. Total quantity identified:
44. Location where proficiency testing was conducted Building: Room:	45. BSL of laboratory or PPQ containment designation:
46. Name of laboratory test that proficiency test was designed to assess:	47. Date obtained from sponsor:

48. Sponsor/entity that you received select agent or toxin from:
☐ College of American Pathologists
☐ Registered entity (Entity name, APHIS or CDC registration number):_____
☐ Other (Explain):

49. Disposition of select agent or toxin:
☐ 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"):_____
☐ Destroyed on site: ☐ Autoclaving ☐ Chemical (Describe:_____) ☐ Incineration ☐ Irradiation ☐ Other:_____
Date select agent or toxin was destroyed: _____
☐ Retained and/or transferred via intra-entity transfer to (Give name of Principal Investigator and/or Amendment #):
_____
Date select agent or toxin was transferred: _____

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Signature of Responsible Official/Facility Director: _____ Date: _____

SECTION 3 – TO BE COMPLETED BY FEDERAL LAW ENFORCEMENT AGENCY			
SECTION A – FEDERAL LAW ENFORCEMENT INFORMATION			
50. Name of federal law enforcement agent First: MI: Last:	51. Telephone #:		
52. Badge #:	53. E-mail address:		
54. Select agent and strain designation (if known) or toxin being seized:	55. Total quantity identified:		
SECTION B – ENTITY INFORMATION			
56. Disposition of select agent or toxin: ☐ Transferred to a registered entity (Give entity name and APHIS/CDC registration number.):_____ ☐ Destroyed on site: ☐ Autoclaving ☐ Chemical (Describe:_____) ☐ Incineration ☐ Irradiation ☐ Other:_____ Date select agent or toxin was destroyed: _____			
57. Entity name:	58. Entity registration number:		
59. Address (NOT a post office address):	60. City:	61. State:	62. Zip Code:
63. Responsible Official name First: MI: Last:	64. Telephone #:		
65. FAX #:	66. E-mail address:		
67. Select agent and strain designation (if known) or toxin being seized:	68. Total quantity identified:		

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 Agent: _____ Date: _____

Public reporting burden: Public reporting burden of providing this information is estimated to average1 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).