GUIDANCE DOCUMENT FOR REQUEST TO TRANSFER SELECT AGENTS AND TOXINS (APHIS/CDC FORM 2)

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.

A select agent or toxin may only be transferred under the conditions described in 7 CFR 331.16, 9 CFR 121.16, and 42 CFR 73.16 and must be authorized by APHIS or CDC prior to transfer. To request approval, the recipient's Responsible Official (RO) must submit this form (APHIS/CDC Form 2) 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

PURPOSE

The purpose of this form is to request prior authorization of a transfer of select agent(s) or toxin(s) and to provide a method for the documentation of the transfer. The form must be completed for each transfer of select agents or toxins and maintained for three years.

INSTRUCTIONS

1. Prior to transferring a select agent or toxin, the **recipient RO** must complete section 1, sign and date at the bottom of the page, and send the completed form to APHIS or CDC for transfer approval. For registered entities, the information provided for this form must match the information submitted in the entity's certificate of registration.
   a. Transfer of select agents or toxins may require the intended recipient to obtain a valid USDA and/or PHS permit prior to the transfer (See 7 CFR Part 330.200, 9 CFR Part 122.2, and 42 CFR Part 71.54) The application and instructions for obtaining USDA transport or import permits are available through the APHIS website at: http://www.aphis.usda.gov/vs/ncie/ or the PPQ website at: http://www.aphis.usda.gov/ppq/permits/ or by calling 301-734-5960. The application and instructions for obtaining PHS import permits are available through the CDC website at: http://www.cdc.gov/od/eaipp/ or by calling 404-718-2077. A copy of the APHIS and/or PHS permit should be included with the transfer request.
   b. Clinical and diagnostic laboratories that transfer select agents and toxins after identification (See 7 CFR 331, 9 CFR 121, and 42 CFR 73) are required to submit this form for approval prior to transferring the select agent or toxin for research purposes to a registered entity (see also APHIS/CDC Form 4, "Report of the Identification of a Select Agent or Toxin").
   c. The agency receiving the form (APHIS or CDC) will review the request and approve or disapprove the transfer. The agency will return the form to the recipient RO and will send a copy of the form to the sender. The transfer must be completed within 30 days of issuance of the Transfer Authorization.

2. When the **sender** receives the Form 2 with CDC or APHIS authorization for transfer, the **sender** must complete Section 2 and sign and date at the bottom of Section 2.
   a. For block 25 ("Characterization of agent"), please provide characterization of agent (e.g., strain designation, GenBank Accession number, publication citation, molecular characterization data, etc.). If unknown, indicate "not known" for block.
   b. For block 36 ("Name of carrier"), please indicate the method of shipment (e.g., Fed-Ex delivery or hand-delivered by sender, recipient, or federal law enforcement agency. For hand-deliveries, please include the name of the individual).
   c. If the sender has a suspicion that the agent may not be used for the requested purpose, then the sender should consult with APHIS or CDC prior to the transfer. Select agents and toxins must be packaged, labeled, and shipped in accordance with all federal and international regulations. It is highly recommended that the sender utilize a method for tracking the movement of the select agents and toxins being shipped.
   d. The sender must place one copy of page 2 of the Form in the shipment and send one copy of page 2 of the form to CDC or APHIS.

3. Upon receipt of the shipment, the **recipient's RO** must complete Section 3 and send one copy of page 2 of the form to the sender and one copy to APHIS or CDC **within 2 business days of receipt**. If the select agent or toxin has not been received within 48 hours after the expected delivery time or the package received containing select agents or toxins has been damaged to the extent that a release of the select agent or toxin may have occurred, the recipient's RO must immediately report to APHIS or CDC and complete APHIS/CDC Form 3, "Report of Theft, Loss, or Release of Select Agents and Toxins." A copy of the completed form must be maintained for 3 years. **NOTE: If the transfer does not occur within 30 days of authorization, the recipient RO completes block 39 of Section 3 and sends the completed form to APHIS or CDC.**

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.

REQUEST TO TRANSFER SELECT AGENTS AND TOXINS (APHIS/CDC FORM 2)

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

Read all instructions carefully before completing the report. Answer all items completely and type or print in ink. This report 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

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

SECTION 1 – TO BE COMPLETED BY RECIPIENT

SECTION A – RECIPIENT INFORMATION

1. Entity name:	2. Entity registration number:		
3. Address (NOT a post office address):	4. City:	5. State:	6. Zip Code:
7. Principal Investigator name First: MI: Last:	8. a. APHIS Permit #: b. US PHS#:		
9. Responsible Official name First: MI: Last:	10. Telephone #:		
11. FAX #:	12. E-mail address:		

SECTION B – SENDER INFORMATION

13. Entity name:	14. ☐ Entity registration number: _____ ☐ Clinical/diagnostic laboratory ☐ Other: _____		
15. Address (NOT a post office address):	16. City:	17. State:	18. Zip Code:
19. Responsible Official (RO) or facility director First: MI: Last:	20. Telephone #:		
21. FAX #:	22. E-mail address:		

SECTION C – LIST OF SELECT AGENTS AND TOXINS REQUESTED (attach additional sheets if necessary)

23. Select agents and/or toxins to be transferred:	
A	
B	
C	
D	
E	
F	

I hereby certify that the information contained in Section 1 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 Responsible Official: _____ Title: _____

Typed or printed name of Responsible Official: _____ Date: _____

REQUEST TO TRANSFER SELECT AGENTS AND TOXINS (APHIS/CDC FORM 2)

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

Read all instructions carefully before completing the report. This report 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

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

APHIS/CDC AUTHORIZATION NUMBER: _____ **EXPIRATION DATE:** _____

SECTION 2 – TO BE COMPLETED BY SENDER

SECTION D – LIST OF SELECT AGENTS AND TOXINS SHIPPED (attach additional sheets if necessary)

	24. Select agents and/or toxins:	25. Characterization of agent:	26. Number of vials:	27. Form (powder/liquid/ slant):	28. Volume or weight of vial contents (e.g., mL, mg, ng):
A					
B					
C					
D					
E					
F					

SECTION E – SHIPPING INFORMATION

29. Recipient Notified of Expected Shipment Date: First: MI: Last:	30. Date of notification:	31. Type of notification: ☐ E-mail ☐ Fax ☐ Telephone
32. Name of individual who packaged shipment: First: MI: Last:	33. Number of packages shipped:	34. Shipment Date:
35. Package description (size, shape, description of packaging including number and type of inner packages):		
36. Name of carrier (If hand-delivered, please indicate and include name of individual):	37. Airway bill number/bill of lading number/tracking number:	

I hereby certify that the select agents and/or toxins were packaged, labeled, and shipped in accordance with all federal and international regulations and information contained on in Section 2 of 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 Sender: _____ Title: _____

Typed or printed name of Sender: _____ Date: _____

SECTION 3 – TO BE COMPLETED BY RECIPIENT

38. Name of individual who received shipment: First: MI: Last:	39. ☐ Transfer Did Not Occur ☐ Transfer Occurred/Date of Receipt:
40. The agents/toxins listed in Section was received: ☐ Yes ☐ If no, explain discrepancy in separate attachment.	41. Shipment was packaged, labeled, and shipped in accordance with regulations: ☐ Yes ☐ If no, explain discrepancy in separate attachment.

I hereby certify that the information contained in Section 3 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 Responsible Official: _____ Title: _____

Typed or printed name of Responsible Official: _____ Date: _____