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

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.

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. Upon receipt of a transfer request (APHIS/CDC Form 2) from the intended recipient, the sending entity's Responsible Official (RO) or facility director must obtain approval from APHIS or CDC prior to transfer of a select agent or toxin. To request approval, the sender must submit this form (APHIS/CDC Form 2) to either APHIS (facsimile: 301-734-3652) or CDC (facsimile: 404-718-2096).

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

Prior to transferring a select agent or toxin:

(A) Recipient Responsibilities:

1. Completes Section A and blocks 30 (including strain designation if known) and 37 (information should match the information submitted for the entity's certificate of registration). The recipient's RO then sends the form to the sender.
2. 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/ohs/biosfty/imprtper.htm or by calling 404-718-2077.
3. For importation of select agents, the recipient's RO completes Sections A and B as instructed; completes Sections C and D for sender, placing the "APHIS Permit Number or PHS Permit Number" in block 3 of the form; and transmits the form via facsimile to APHIS (FAX: 301-734-3652) or CDC (FAX: 404-718-2096).

(B) Sender Responsibilities:

1. Completes Section B and blocks 31-36. If known, please provide characterization of agent (e.g., strain designation, GenBank Accession number, publication citation, molecular characterization data, etc.). Provide additional information on attached sheet if needed. The sender's RO or facility director transmits the form via facsimile to APHIS (FAX: 301-734-3652) or CDC (FAX: 404-718-2096).
2. 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 to a registered entity (see also APHIS/CDC Form 4, "Report of the Identification of a Select Agent or Toxin").

(C) APHIS/CDC Responsibilities: APHIS or CDC will FAX the form back to the sender and/or recipient with an approval authorization number after verification of the information on the form.

After authorization of transfer:

(A) Sender Responsibilities: Must ship the material to the recipient only after the sender has received the approval authorization number from APHIS or CDC. The approval authorization number will be **valid for only 30 days** after issuance. 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. The sender completes blocks 38-40. 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. A copy of the completed form must be maintained for 3 years.

(B) Recipient Responsibilities: Upon receipt of the shipment, the recipient's RO must complete blocks 41 and 42 and FAX or mail the form to both the sender's RO and APHIS or CDC **within 2 business days of receipt**. 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", 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. A copy of the completed form must be maintained for 3 years.

OBTAINING EXTRA COPIES OF THIS FORM

Additional copies of this form are available on APHIS website (http://www.aphis.usda.gov/programs/ag_selectagent/index.html) or the CDC website (http://www.cdc.gov/od/sap) or by contacting APHIS at (301) 734-5960 or CDC at (404) 718-2000.

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

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

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

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

FOR APHIS/CDC USE ONLY

APHIS/CDC AUTHORIZATION NUMBER: _____

DATE: _____ **INI:**_____ **EXP DATE:** _____

SECTION A – RECIPIENT (REQUESTOR) INFORMATION			
1. Entity name:	2. Entity registration number:	3. a. APHIS Permit #: b. US PHS#:	
4. Recipient name (authorized personnel) First: MI: Last: Signature:	5. Date:	6. Phone:	7. FAX:
8. Principal investigator name (if different from line above) First: MI: Last: Signature:	9. Date:	10. Phone:	11. FAX:
12. Responsible Official name First: MI: Last: Signature:	13. Date:	14. Phone:	15. FAX:
SECTION B – SENDER (TRANSFEROR) INFORMATION			
16. Entity name:	17. ☐ Entity registration number: _____ ☐ Clinical/diagnostic laboratory ☐ Other: _____		
18. Sender name First: MI: Last: Signature:	19. Date:	20. Phone:	21. FAX:
22. Principal investigator name (if different from line above) First: MI: Last: Signature:	23. Date:	24. Phone:	25. FAX:
26. Responsible Official name First: MI: Last: Signature:	27. Date:	28. Phone:	29. FAX:

FOR APHIS/CDC USE ONLY

APHIS/CDC AUTHORIZATION NUMBER: _____

DATE: _____ **INI:**_____ **EXP DATE:** _____

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

	RECIPIENT	**SENDER**					
	30. Select agent or toxin:	31. Characterization of agent or toxin (*see instructions*):	32. Number of vials:	33. Form (e.g., powder/liquid/ slant):	34. Vol or wt per vial (e.g., ml, mg):	35. Total quantity:	36. Concentration/ vial (e.g., 10^8 cfu/ml):
a							
b							
c							
d							
e							
f							
g							
h							
i							
j							
k							
l							
m							

37. Proposed Use: ☐ Research ☐ Diagnostics ☐ Production ☐ Storage Only ☐ Other (explain):

SECTION D – SHIPPING INFORMATION (attach additional sheets if necessary)

38. Number of primary receptacles per outer package:____ Number of outer packages: _____ Carrier waybill (tracking) #(s):

39. Sender (Responsible Official or Facility Director) ensures select agents or toxins listed in section C were shipped First: MI: Last: Signature:	40. Date shipped:
41. Recipient (Responsible Official) ensures select agents or toxins listed in section C were received First: MI: Last: Signature:	42. Date received: