



GUIDANCE DOCUMENT FOR REPORT OF TRANSFER OF SELECT AGENTS AND TOXINS



INTRODUCTION

The "Public Health Security and Bioterrorism Preparedness Response Act of 2002" (Public Law 107-188) signed into law on June 12, 2002, requires that the United States improve its ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies. It necessitates that individuals possessing, using or transferring agents or toxins deemed a threat to public, animal or plant health, or to animal or plant products, notify either the Secretary of the Department of Health and Human Services (HHS) or the Secretary of the Department of Agriculture (USDA). Subsequent to enactment of this law, requirements for possession, use, and transfer of select agents and toxins were published by HHS (42 CFR 73) and by USDA (9 CFR 121 and 7 CFR 331).

Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the Secretary, HHS, and to the Animal and Plant Health Inspection Service (APHIS) by the Secretary, USDA. In order to minimize the reporting burden to the public, HHS/CDC and the USDA/APHIS have developed a common reporting form for this data collection. This form is designed to assist entities in complying with this legal obligation.

A registered entity is required by law (42 CFR 73.14, 9 CFR 121 and 7 CFR 331) to file this form with either CDC or APHIS when they wish to transfer a select agent or toxin. The agency that the Responsible Official (RO) should contact is determined by the type of select agent or toxin involved in the transfer. For HHS agents, the RO should contact CDC by facsimile (404-498-2265). For HHS/USDA overlap agents, the RO should contact either APHIS or CDC. For USDA agents, the RO should contact APHIS (telephone: 301-734-5960; facsimile: 301-734-3652). A listing of HHS select agents and toxins is available at <http://www.cdc.gov/od/sap>. A listing of USDA animal agents and toxins is available at <http://www.aphis.usda.gov/vs/ncie/bta.html>. The list of plant agents and toxins is available at <http://www.aphis.usda.gov/ppq/permits>. A copy of each completed form must be kept by the RO for three years.

INSTRUCTIONS

The purpose of this form is to provide a method for the documentation of the transfer of a select agent or toxin. The form must be completed for each transfer of select agents.

Prior to transferring a select agent

The recipient's RO fills out blocks 1 and 2 of the form and submits it to the sender. The sender's RO fills out block 3 and transmits the form via facsimile to CDC (FAX: 404-498-2265) or APHIS (FAX: 301-734-3652). CDC or APHIS will then FAX the form back to the sender with an approval confirmation number after verification of the information on the form. If the sender has a suspicion that the agent may not be used for the requested purpose, or there are any other concerns, then the sender should consult with CDC or APHIS prior to the transfer.

Transfer:

(a) Shipment of the select agent or toxin to the recipient. The sender should ship the material to the receiver only after the sender has received a verification number from CDC or APHIS regarding the information in blocks 1 and 2 of the form. The sender completes Block 4, including the date the agent was shipped. Characterization of agent should include data such as strain designation, GenBank Accession number, publication citation with additional molecular characterization data, etc.; provide additional information on attached sheet, if needed. Select agents and toxins must be packaged, labeled, and shipped in accordance with all federal regulations (e.g., 42 CFR 72, 49 CFR 100-180, 9 CFR 121, and 7 CFR 331) and international (IATA) regulations. It is highly recommended that the sender utilize a method for tracking the movement of the select agents and toxins being shipped.

(b) Transmittal of the form to the CDC or APHIS. The RO from the recipient's entity must fill out Block 4 of the form with the date received and FAX or mail the form to both the Sender's RO and the CDC or APHIS within 2 business days of receipt.

(c) Destruction or depletion of a select agent. The RO of the recipient's entity should complete the appropriate boxes of Block 4 within 5 business days when any select agent or toxin associated with this transfer is completely depleted or destroyed. The recipient RO must sign and initial the box below section 4. A copy of the form must be mailed or faxed to the CDC or APHIS.

OBTAINING EXTRA COPIES OF THIS FORM

To obtain additional copies of this form, contact CDC at (404) 498-2255 or APHIS at (301) 734-5960.

Registration and transfer documents shall not be disclosed under the Freedom of Information Act. Under Public Law 107-188, information derived from this form is also protected from release.

CDC CONFIRMATION NUMBER: _____	DATE: _____	INI: _____	FOR CDC/APHIS USE ONLY	APHIS CONFIRMATION NUMBER: _____	DATE: _____	INI: _____
---------------------------------------	--------------------	-------------------	-------------------------------	---	--------------------	-------------------

4 – SHIPPING INFORMATION

List each select agent/toxin shipped, including the strain of the agent, if applicable (see example below).

Number of primary receptacles per outer package _____	Number of outer packages _____	Date agent shipped _____	Date agent received _____
Carrier waybill (tracking) # _____			

LIST OF SELECT BIOLOGICAL AGENTS AND TOXINS SHIPPED

No.	Select Agent	Characterization of Agent (<i>see instructions</i>)	No. of Vials	Form (e.g., powder/liquid/slant)	Vol or Wt per Vial (e.g., ml, mg)	Total Qty	Concentration/Vial (e.g., 10 ⁸ cfu/ml)	Date Depleted or Destroyed	RO Initials
	<i>Ebola virus</i>	Zaire (Mayinga strain); GenBank Accession NC_00254	5	liquid	5 ml	25 ml	10⁸ /ml		
	<i>Bacillus anthracis</i>	Ames strain	925	liquid	1 ml	25 ml	10⁸ /ml		
1									
2									
3									
4									
5									
6									
7									
8									

Recipient Responsible Official name (Complete this block and submit for declaration of depletion or destruction) Print: _____ Signature: _____	Responsible Official initials _____
---	-------------------------------------

Record keeping requirements: Both receiving and sending facilities must maintain records of all transfers.

Penalties: Knowingly providing false statements on any part of this form or its attachments will subject the offender to fines of up to \$250,000 (\$500,000 for organizations), imprisonment for up to 5 years or both (18 USC Section 1001). Failure to maintain records constitutes a 1 year misdemeanor (42 USC Section 271).

Public reporting burden: Public reporting burden of this collection of information is estimated to average 105 minutes 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-24, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).