Form Approved
OMB Control No. 0920-0576
Exp. Date xx/xx/2020

Guidance Document for the Completion of APHIS/CDC Form 2 (Request to Transfer Select Agents and Toxins)

Completion of all fields on Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2) is required unless otherwise noted in this guidance document. Please note that both pages of the form 2 are required in order to process the request. Prior to completing APHIS/CDC Form 2 please ensure that you are using the current, Office of Management and Budget (OMB) approved form and/or tables found at: http://www.selectagents.gov/form2.html. Submissions using expired or unapproved forms or tables will not be accepted.

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) [or the Alternate Responsible Official (ARO) if acting in the absence of the RO] must submit APHIS/CDC Form 2 to either APHIS or CDC:

Animal and Plant Health Inspection Service
Agriculture Select Agent Services
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
301-851-3300 option 3
FAX: (301) 734-3652
Email: cdcform2@cdc.gov

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30329
(404) 718-2000
FAX (404) 471-8468
Email: cdcform2@cdc.gov

Upon receipt of the transfer authorization from APHIS or CDC, entities have 30 calendar days to complete the approved transfer. If the transfer does not occur within the 30 calendar day authorization period, the recipient Responsible Official [or the Alternate Responsible Official (ARO) if acting in the absence of the RO] must complete *Block 42* of Section 3, sign and date below Section 3, and send the completed form to APHIS or CDC.

****If any Blocks on APHIS/CDC Form 2 are incomplete, illegible, or contain insufficient information we will be unable to process your transfer request. APHIS or CDC will contact your entity to obtain the necessary information before proceeding with the review of your request****

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Public reporting burden: Public reporting burden of this collection of information is estimated to average 1.5 hours 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 30329; ATTN: PRA (0920-0576).

Section 1 – To Be Completed By Recipient

Section A – Recipient Information

Block 1 – Recipient Entity Name:

- Please provide the name of the recipient entity exactly as it appears on the current certificate of registration.
  - If you do not know the recipient entity's "registration name", please contact the Responsible Official.
- Please do not abbreviate the entity name.

Block 2 – Recipient Entity Registration Number:

- Please enter the registration number of the recipient entity exactly as it appears on the current certificate of registration. Please do not provide the entity's application number; provide only the thirteen digit registration number (e.g. A00000000-0000 *or* C00000000-0000).
  - If you do not know the recipient entity's registration number, please contact the Responsible Official.

Block 3-6 – Recipient Entity Address:

- Please provide the recipient entity's complete address, exactly as it appears on the current certificate of registration.
  - If the recipient entity wishes to provide an address other than the address that appears on the current certificate of registration, written verification of the address being provided must be submitted along with the completed APHIS/CDC Form 2.
- Do not provide a P.O. Box address.
- Zip Code – please provide only the five digit zip code

Block 7 – Recipient Principal Investigator Name:

- Print the full name of the recipient entity's Principal Investigator (PI) who will be responsible for the requested select agents and/or toxins.
  - For the purposes of the APHIS/CDC Form 2, the term "PI" refers to the one individual who supervises all activities associated with the select agents and/or toxins being requested.
- The individual listed in *Block 7* must be approved to work with the requested select agents and/or toxins on the recipient entity's current certificate of registration.

- The individual listed in *Block 7* must have a current security risk assessment (SRA) approval.
    - Provide the individual's full name, exactly as it appears on the current certificate of registration.

Block 8 – Permit Number (if required):

- Please provide the APHIS Permit # if the importation was not authorized in accordance with 42 CFR § 73.16 or 9 CFR § 121.16.

Block 9 – Recipient Responsible Official Name:

- Please provide the complete name of the recipient entity's Responsible Official (RO), exactly as it appears on the current certificate of registration.
    - The recipient entity's Responsible Official must be listed in *Block 9* even if the Alternate Responsible Official signs the APHIS/CDC Form 2 in the absence of the Responsible Official.

Block 10 – Recipient Telephone #:

- Please provide the direct dial 10-digit telephone number for the Responsible Official; including any extension.

Block 11 – Recipient FAX #:

- Please provide the 10-digit Fax number for the Responsible Official.

Block 12 – Recipient E-Mail Address:

- Please provide the email address for the Responsible Official.
- Please print or type clearly and ensure the email domain (e.g., .org, .gov, .edu, .com, .net) is included.

Section B – Sender Information

Note: If the recipient entity does not know the sender entity's information they may have the sender complete Section B.

Block 13 – Sender Entity Name:

- For entities registered with APHIS or CDC, please provide the name of the entity exactly as it appears on the current certificate of registration.
    - If you do not know the entity's "registration name", please contact the Responsible Official.
- For non-registered entities, please provide the complete name of the entity under which the business conducts its operations (e.g. International Business Machine Corporation instead of IBM).
- Please do not abbreviate the entity name.

Block 14 – Sender Entity Type:

- For senders that are registered with APHIS or CDC, please check the box titled "Entity registration number" and enter the registration number exactly as it appears on the current certificate of registration. Please do not provide the entity's application number; provide only the thirteen digit registration number (e.g. A00000000-0000 *or* C00000000-0000).
    - If you do not know the registration number, please contact the Responsible Official.
- For non-registered senders, please check the box titled "Clinical/diagnostic laboratory" or "Other".
    - If you select "Other", please provide a detailed description of the entity type. (Example: non-US based entity)

Block 15-19 – Sender Entity Address:

- For sender entities registered with APHIS or CDC, please provide the sender entity's complete address, exactly as it appears on the current certificate of registration.
- For non-registered entities, please provide the complete address of the entity.
- Do not provide a P.O. Box address.
- Zip Code – please provide only the five digit zip code
- Country – please provide the unabbreviated country name

Block 20 – Sender Entity Responsible Official or Facility Director Name:

- For sender entities registered with APHIS or CDC, please provide the complete name of the sender entity's Responsible Official (RO), exactly as it appears on the current certificate of registration.
- For non-registered entities, please provide the full legal name of the entity's Facility Director.
    - For the purposes of the APHIS/CDC Form 2, the term "Facility Director" refers to the person ultimately responsible for the overall operation and administration of the laboratory and who ensures that quality standardized testing methods provide accurate and reliable results.

Block 21 – Sender Telephone #:

- Please provide the direct dial 10-digit telephone number for the individual listed in *Block 20*; including any extension.

Block 22 – Sender FAX #:

- Please provide the 10-digit Fax number for the individual listed in *Block 20*.

Block 23 – Sender E-mail Address:

- Please provide the email address for the individual listed in *Block 20*.
- Please print or type clearly and ensure the email domain (e.g., .org, .gov, .edu, .com, .net) is included.

Block 24 – Identification of a Select Agent or Toxin in a Clinical/Diagnostic Sample:

- Please identify whether the sample being transferred was identified in a clinical or diagnostic sample.
- If yes, please ensure that an APHIS/CDC Form 4 "Report of the Identification or a Select Agent or Toxin" is submitted to APHIS or CDC within 7 calendar days after identification. After identification, all entities that are not registered to possess the select agent or toxin must transfer or destroy the select agent or toxin on site by a recognized sterilization or inactivation process within seven calendar days.

Block 25 – A product of a restricted experiment:

- Please identify whether the sample being transferred represents the product of a restricted experiment. Products from the following restricted experiments need to be reported in block 25: (1) Experiments that involve the deliberate transfer of, or selection for, a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture. (2) Experiments involving the deliberate formation of synthetic or recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight.
- If yes, please provide the description used in the Federal Select Agent Program approval letter for the restricted experiment that produced the agent.

Section C – List of Select Agents and Toxins Requested

Note: The recipient entity must be registered for all select agents and/or toxins listed in *Block 26* prior to APHIS or CDC authorizing the requested transfer.

Block 26 – Select Agents and Toxins Requested:

- List all select agents and/or toxins being requested by the recipient entity.
  - Do not list strain designations in *Block 26*.
- List only one select agent or toxin per line.
- Do not abbreviate the name of a select agent or toxin.
- Use the name of the select agent or toxin exactly as it appears in the Select Agent regulations (Select Agent/Toxin List).
- Do not list an agent or toxin that is not a select agent.

Signature:

- The recipient Responsible Official [or the Alternate Responsible Official (ARO) if acting in the absence of the RO] must print the name, sign, and date below Section C.
    - If the Alternate Responsible Official is signing in the absence of the Responsible Official, the Responsible Official still must be listed in *Block 9*.

Section 2 – To Be Completed By Sender

Section D – List of Select Agents and Toxins Shipped

Block 27 – Select Agents and Toxins Shipped:

- List all select agents and/or toxins that will be transferred to the recipient entity listed in Section A.
    - Only those select agents and/or toxins listed in *Block 26* are authorized for transfer to the recipient entity.
- List only one select agent or toxin per line.
- Do not abbreviate the name of a select agent or toxin.
- Use the name of the select agent or toxin exactly as it appears in the Select Agent regulations (Select Agent/Toxin List).
- Do not list an agent or toxin that is not a select agent.

Block 28 – Characterization of Agents Shipped:

- List the strain designation(s) for all select agents and toxins listed in *Block 27* only if known, otherwise leave blank.

  Note: For the purposes of the APHIS/CDC Form 2, the term "strain" refers to a group of organisms of the same species, sharing certain hereditary characteristics not typical of the entire species but minor enough not to warrant classification as a separate breed or variety. Resistance to specific antibiotics is a feature of certain strains of bacteria. For select agents that have been genetically modified such as introduction of an antibiotic resistant gene, you would note that in the characterization of agent column.

Block 29 – Number of Items Shipped:

- For each select agent or toxin listed in *Block 27*, list the total number of items (primary containers) to be transferred for the particular select agent or toxin.

Block 30 – Form of Agents Shipped:

- Enter the form of each select agent or toxin that is to be transferred. (e.g., powder, liquid, agar slant, agar plate, etc.).
- If a select agent or toxin is to be transferred in more than one form, please list the select agent or toxin on two or more rows in the Section D table and complete *Blocks 27-31* for each form. (See example below.)

Block 31 – Total Volume/Weight of Agents Shipped:

- For each select agent or toxin listed in *Block 27*, enter the total volume or weight of all item contents to be transferred.

  Example: If you are shipping six vials with individual volumes of 50 µL, 100 µL, 500 µL, 125 µL, 250 µL, and 600 µL you would enter 1.625 mL in *Block 31*.
- If you are shipping agar slants or plates, please enter the total number of slants or plates to be shipped in *Block 29* and leave *Block 31* blank.

Example:

SECTION 2 – TO BE COMPLETED BY SENDER					
SECTION D – LIST OF SELECT AGENTS AND TOXINS SHIPPED (attach additional sheets if necessary)					
	27. Select agents and/or toxins:	28. Characterization of agent:	29. Number of items (e.g. vial, slant, plant, etc.):	30. Form (powder/liquid/ slant):	31. Total volume or weight of item contents (e.g., mL, mg, ng):
A	Yersinia pestis	CO92	1	Agar Slant	
B	Eastern Equine Encephalitis virus		18	Liquid	36.0 mL
C	Bacillus anthracis	Ames	3	Liquid	2.5 mL
D	Bacillus anthracis	Ames	5	Powder	5.0 mg
E	Botulinum neurotoxins	Type A	2	Liquid	2.0 mL
F					

Section E – Recipient Notification Information

Note: After approved by CDC or APHIS and **prior** to sending the shipment, the sender must place one copy of the completed and signed page 2 of APHIS/CDC Form 2 in the shipment and send one copy of the completed and signed page 2 of the form to CDC or APHIS.

Block 32 – Name of Individual at Recipient Entity Notified of Shipment Date:

- Print the name of the individual at the recipient entity who was notified of the expected (or actual) shipment date.
- The individual listed in *Block 32* must have a current security risk assessment (SRA) approval.
  - Provide the individual's complete name, exactly as it appears on the entity's current certificate of registration.

Block 33 – Date of Shipment Notification:

- Provide the exact date that the individual listed in *Block 32* was notified of the expected (or actual) shipment.

Block 34 – Method of Shipment Notification (check all applicable boxes)*:*

- Indicate the method(s) used to notify the individual listed in *Block 32* of the expected (or actual) shipment date.

Section F – Shipping Information

Block 35 – Name of Individual Who Packaged the Shipment:

- Print the name of the individual at the sender entity who packaged the select agents and/or toxins for shipment.
- The individual listed in *Block 35* must have a current security risk assessment (SRA) approval (For select agent registered entities only)

Block 36 – Number of Packages Shipped:

- Enter the total number of packages to be shipped to the recipient entity.

Block 37 – Shipment Date:

- Enter the exact date that all of the packages indicated in *Block 36* will be shipped to the recipient entity.

Block 38 – Package Description:

- Provide a detailed description of how the select agents and/or toxins were packaged for shipment. The description should include items such as the size, shape, and a description of the packaging and the number and type of inner packages.
  - In addition to the written package description in *Block 38*, you may also submit a photograph(s) of the package(s) to APHIS or CDC prior to sending the shipment. Please note that the photograph(s) does not replace the written package description requirement.

Note: All select agent and/or toxin transfers must be packaged, labeled, and shipped in accordance with all federal and international regulations.

Block 39 – Name of Shipment Carrier:

- Enter the name of the commercial carrier (e.g., FedEx, DHL, UPS, etc.) or individual hand-carrier that will deliver all packages indicated in *Block 36*. For hand-carried packages, the entity remains responsible for ensuring that all local, state or federal transportation requirements for the transportation of hazardous materials are followed.
- If all packages are to be hand-delivered, print the full name of the individual who will deliver the package(s).
  - The individual who will hand-carry the packages must have a current security risk assessment (SRA) approval.
  - Provide the individual's complete name, exactly as it appears on the entity's current certificate of registration.

Block 40 – Shipment Tracking Number:

- Enter the shipment tracking number(s) (e.g., airway bill number, bill of lading number, tracking number, etc.) for all packages being shipped.

Signature:

- For sender entities registered with APHIS or CDC, the Responsible Official must print the name, sign, and date below Section E.
- For non-registered sender entities, the Facility Director or the individual listed in *Block 20* must print the name, sign, and date below Section E.
- The entity provides the completed paperwork to CDC or APHIS.

Section 3 – To Be Completed By Recipient

Note: Upon receipt of the shipment, the recipient's RO [or the Alternate Responsible Official (ARO) if acting in the absence of the RO] must complete and sign Section 3 of APHIS/CDC Form 2 and send one copy of page 2 to the sender and one copy to APHIS or CDC within 2 business days of receipt of the shipment. If the select agents or toxins are not received within 48 hours after the expected delivery time or if the package(s) received containing select agents or toxins has/have been damaged to the extent that a release of the select agents or toxins may have occurred, the recipient's RO must immediately report this to APHIS or CDC and submit a completed APHIS/CDC Form 3, "Report of Theft, Loss, or Release of Select Agents and Toxins" to APHIS or CDC. Additional guidance for submitting an APHIS/CDC Form 3 is available.

Block 41 – Name of Individual Who Received the Shipment:

- Print the name of the individual who received the shipment upon delivery.
  - For the purposes of the APHIS/CDC Form 2, the individual who "received" the shipment refers to the individual that opened the package under appropriate biocontainment conditions and verified that:
    1) all select agents and/or toxins listed in Section D were received,
    2) no additional select agents and/or toxins not listed in Section D were received,
    3) the shipment was packaged, labeled, and shipped in accordance with all federal and international regulations, and that
    4) the package received containing select agents and/or toxins was not damaged to the extent that a release of the select agents and/or toxins may have occurred.
- The individual listed in *Block 41* must have a current security risk assessment (SRA) approval.
  - Provide the individual's complete name, exactly as it appears on the entity's current certificate of registration.

Block 42 – Shipment Event Acknowledgement:

- If the transfer occurred, check the "Transfer Occurred/Date of Receipt" box and provide the date that all packages listed in *Block 36* were received.
- If the transfer did not occur, check the "Transfer Did Not Occur" box.
    - The recipient Responsible Official [or the Alternate Responsible Official (ARO) if acting in the absence of the RO] must sign/date below Section 3, and send the completed page 2 of APHIS/CDC Form 2 to APHIS or CDC.

Block 43 – Agents/Toxins Receipt Acknowledgement:

- If all of the select agents and/or toxins listed in Section D of APHIS/CDC Form 2 were received, check the "Yes" box.
- If all of the select agents and/or toxins listed in Section D of APHIS/CDC Form 2 were not received (or if additional select agents and/or toxins not listed in Section D were received), check the "If no" box and explain any discrepancies in a separate attachment (e.g., Microsoft® Word document).

Block 44 – Shipment/Packaging Regulatory Compliance Acknowledgement:

- If the package(s) received by the recipient entity were packaged, labeled, and shipped in accordance with all federal and international regulations, check the "Yes" box.
- If the package(s) received by the recipient entity were not packaged, labeled, and shipped in accordance with all federal and international regulations, check the "If no" box and explain any discrepancies in a separate attachment (e.g., Microsoft® Word document).

Signature:

- The recipient Responsible Official [or the Alternate Responsible Official (ARO) if acting in the absence of the RO] must print the name, sign, and date below Section 3.

Document Change History

Version	Date	Summary of Changes
1.0	August 2009	Initial Release
1.1	September 2010	*Block 35 – Package Description*: Added guidance regarding the submission of package photographs
2.0	August 2011	Updated to reflect revisions to Form 2.
3.0	May 2014	Updated to reflect information not required in block #8
4.0	November 2015	Updated to reflect revisions to Form 2