

APHIS/CDC FORM 2: REQUEST TO TRANSFER SELECT AGENTS OR TOXINS

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Office Of Public Health Preparedness and Response
Division Of Select Agents and Toxins
Program Services Branch

**Federal Select Agent
Program Training**



OVERVIEW

- Form 2 request/approval process
- Common problems/issues
- Program improvements

FORM 2 PROCESSING

□ **Step 1 - Authorization request**

- Recipient and sender make contact, determine what and when they would like to transfer.
- Recipient completes Section 1 of Form 2, signs and submits to CDC or APHIS for approval.

□ **Step 2 – Review by APHIS/CDC**

- Verification of information provided in Section 1.
- Decision letter or authorization granted within 48 hours.
- Entities have 30 days from date of authorization to complete transfer.

FORM 2 PROCESSING (CONT'D)

□ Step 3 - Shipment

- PRIOR to shipping select agent, Sender must complete Section 2, sign, and submit to APHIS or CDC.

□ Step 4 – Receipt Verification

- Upon receipt of shipment, Recipient must complete Section 3, sign, and submits to APHIS or CDC within 2 business days.
- Final recipient of package at receiving entity must be SRA-approved for access to select agents or toxins.

COMMON PROBLEMS/ISSUES

1. Incomplete Form 2's
 - Missing information (Administrative)
2. Recipient and Sender entities have not communicated (results in unauthorized transfer)
3. Sender does not submit Section 2 prior to shipment
 - CDC unaware select agent is in route
 - Recipient may not be aware select agent is in transit (no one at receiving entity available to pick up package)
4. Final recipient for select agent package at Recipient entity is not SRA-approved

COMMON PROBLEMS/ISSUES (2)



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



FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP. DATE: 11/30/2015

Detailed instructions are available at <http://www.selectagents.gov/TransferForm.html>. Answer all items completely and type or print in ink. This request 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
Email: ASAP@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) 471-8488
Email: form2@cdc.gov

Accession Number:

(For Program Use ONLY)

Submit completed form only once by either email, fax, or mail

APHIS/CDC AUTHORIZATION NUMBER: _____ EXPIRATION DATE: _____

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: M: Last:		8. a. APHIS Permit #: b. US PHS #:	
9. Responsible Official (RO) name: First: M: Last:		10. RO Telephone #:	
11. RO Fax #:		12. RO E-mail address:	
SECTION B – SENDER INFORMATION			
13. Entity name:		14. <input type="checkbox"/> Entity registration number: _____ <input type="checkbox"/> Clinical/diagnostic laboratory <input type="checkbox"/> Other:	
15. Address (NOT a post office address):		16. City:	17. State: 18. Zip Code:
19. Responsible Official (RO) or facility director: First: M: Last:		20. RO/Facility Director Telephone #:	
21. RO/Facility Director Fax #:		22. RO/Facility Director E-mail address:	
23. This transfer request is for a select agent or toxin that was identified in a clinical or diagnostic sample: <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please ensure that an APHIS/CDC Form 4 "Report of the Identification of a Select Agent or Toxin" is submitted to APHIS or CDC within 7 calendar days.			
SECTION C – LIST OF SELECT AGENTS AND TOXINS REQUESTED (attach additional sheets if necessary)			
24. Select agents and/or toxins to be transferred:			
A			
B			
C			
D			
E			
F			
G			

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 Signed: _____

5. Utilizing expired form. Current version 11/30/2015. New form to be released shortly. Entities will be allowed to utilize the expired forms until new ones are published. Information sent via SA gram.

6. POC information not current with information in our data base.

7. Question #23 - Is the transfer associated with a clinical diagnostic sample? Left blank.

COMMON PROBLEMS/ISSUES (3)



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

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EXP. DATE 11/30/2015

Detailed instructions are available at <http://www.selectagents.gov/TransferForm.html>. Answer all items completely and type or print in ink. This 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
Email: ASAP@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) 471-8468
Email: form2@cdc.gov

Accession Number: _____

(For Program Use ONLY)

Submit completed form only once by either email, fax, or mail

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)

25. Select agents and/or toxins:	26. Characterization of agent:	27. Number of items (e.g. vial, slant, plant, etc.):	28. Form (powder/liquid/slant):	29. Total volume or weight of item contents (e.g., mL, mg, ng):
A				
B				
C				
D				
E				
F				
G				

SECTION E – RECIPIENT NOTIFICATION INFORMATION

30. Name of Individual at Recipient Entity notified of Expected Shipment: First: _____ MI: _____ Last: _____	31. Date of notification: _____	32. Type of notification: <input type="checkbox"/> E-mail <input type="checkbox"/> Fax <input type="checkbox"/> Telephone
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SECTION F – SHIPPING INFORMATION

33. Name of individual who packaged shipment: First: _____ MI: _____ Last: _____	34. Number of packages shipped: _____	35. Shipment Date: _____
36. Package description (size, shape, description of packaging including number and type of inner packages): _____		
37. Name of carrier (if hand-delivered, please provide name of individual): _____	38. Airway bill number/roll 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 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 Signed: _____

SECTION 3 – TO BE COMPLETED BY RECIPIENT

39. Name of individual who received shipment: First: _____ MI: _____ Last: _____	40. <input type="checkbox"/> Transfer Did Not Occur <input type="checkbox"/> Transfer Occurred/Date of Receipt: _____
41. The agents/toxins listed in Section 2 were received: <input type="checkbox"/> Yes <input type="checkbox"/> If no, explain discrepancy in separate attachment.	
42. Shipment was packaged, labeled, and shipped in accordance with regulations: <input type="checkbox"/> Yes <input type="checkbox"/> 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 Signed: _____

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 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 CD/CAT/SDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0520-0576).
APHIS/CDC FORM 2 (11/30/2015)

8. Section D – Number of items, form, total volume and units of measure not fully completed by sender. Example: Ebola, 2 Vials, Liquid, 2ml.

9. Section E & F – Incomplete shipment information and not signed or dated by RO or ARO.

OTHER COMMON ISSUES NOTED

10. Entities fail to utilize the approved Form 2 when submitting Section's 2 & 3 (listing APHIS/CDC Authorization number and Expiration date). Complicates our ability to associate the form with a particular approved transfer file.

Submit completed form only once by either email, fax, or mail

APHIS/CDC AUTHORIZATION NUMBER: _____ EXPIRATION DATE: _____

11. Submits additional attachments (often in a word document) listing agents shipped without referencing CEA# or Expiration Date.

12. Quality of fax copy illegible. DSAT will often request a more legible copy. We recommend entities submit their forms via email to ensure receipt when CDC/APHIS offices are closed due to extenuating circumstances.

PROGRAM IMPROVEMENTS

- ❑ Added the “APHIS/CDC Select Agent Transfer Procedure document on [Federal Select Agent Program](#) website.
- ❑ Guidance Document for the Completion of APHIS/CDC Form 2 also available on the [Federal Select Agent Program](#) website.
- ❑ Continuously updating our FAQ concerning APHIS/CDC Form 2 transfer questions.
- ❑ Improved internal Quality Assurance/Quality Control process to identify any discrepancy with information received.
- ❑ Increased communication with entities and file managers.

APHIS/CDC FORM 4

Yvonne Walker
Form 4 Technical Reviewer
CDC
DSAT - PSB

**Federal Select Agent
Program Training**



FORM 4 : IDENTIFICATION OF A SELECT AGENT OR TOXIN

- Identification of a select agent or toxin as a result of a diagnosis, verification, or proficiency testing.*
- Identification and final disposition of agent or toxin is required.*
- Form 4A and 4C reported within 7 calendar days*
- Form 4B reported within 90 calendar days*
- Immediate notification: Within 24 hours either by phone, fax, e-mail*
- Immediate notification select agent and toxin list and form:*

[APHIS/CDC Form 4](#)

4A-: REFERENCE LABORATORY (SECTIONS A AND B)



REPORTING THE IDENTIFICATION OF A SELECT AGENT OR TOXIN FROM A CLINICAL/DIAGNOSTIC SPECIMEN (APHIS/CDC FORM 4A)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 10/31/2014

INSTRUCTIONS

Detailed instructions are available at <http://www.selectagents.gov/CDForm.html>. 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
Email: 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: CDCForm4@cdc.gov

Accession Number:

(For Program Use ONLY)

Submit completed form only once by either email, fax, or mail

SECTION A – REFERENCE LABORATORY INFORMATION					
1. Name of individual completing Sections A and B: First: _____ MI: _____ Last: _____		2. Email address: _____		3. Telephone #: _____	
4. <input type="checkbox"/> Registered Entity (APHIS or CDC Registration #: _____) <input type="checkbox"/> Clinical or Diagnostic Laboratory [non-registered entity (NRE)] (NRE # (provided by APHIS or CDC): _____)			9. Entity name: _____		
5. Responsible Official or Laboratory Supervisor name: First: _____ MI: _____ Last: _____			10. Address (NOT a post office address): _____		
6. Telephone #: _____	7. Fax #: _____	8. Email address: _____	11. City: _____	12. State: _____	13. Zip Code: _____
SECTION B – SELECT AGENT OR TOXIN IDENTIFIED FROM CLINICAL/DIAGNOSTIC SPECIMEN(S)					
1. Select Agent or Toxin Identified: _____			2. Date identified: _____		
3. Case/patient/sample ID #(s): _____	4. # of samples received: _____	5. Sample type(s) received: _____	6. Case/patient origin (zip code): _____		
7. Dispositions of select agent or toxin (complete all that apply): <input type="checkbox"/> Transferred (Provide entity name and date of transfer. Entity: _____ Date: _____) <input type="checkbox"/> Destroyed (Provide destruction method and date. Method: _____ Date: _____) <input type="checkbox"/> Retained (Provide name of person retaining sample. Name: _____)					
8. Were any samples containing a select agent or toxin handled outside of primary containment which may have led to an unintentional release and/or exposure to the public? <input type="checkbox"/> No Yes, you are required under 7 CFR Part 331.19, 9 CFR Part 121.19, and 42 CFR Part 73.19 to complete and submit an APHIS/CDC Form 3)					
9. Do you have any additional samples/specimens for this case/patient that originate from the initial case (e.g. patient, environmental sample)? <input type="checkbox"/> No Yes (If Yes, please refer to the guidance instructions at www.selectagents.gov for further directions.)					
10. Has the sample provider(s) of the specimen(s) been notified of the identification of the select agent or toxin? <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> N/A					
NOTE: Request completed and signed Sections C & D from each laboratory that was in possession of the specimen(s).					
11. Comments: _____					

I hereby certify that the information contained in Sections A and B 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, or 42 CFR 73 may result in civil or criminal penalties, including imprisonment.

Signature of Responsible Official/Laboratory Supervisor: _____ Date Signed: _____

Most Common Errors:

1. Sample type Received:
2. Case/patient Zip Code:
3. Disposition of Select Agent or Toxin:
4. Signature of RO/ Lab Supervisor & Date:

4A: SAMPLE PROVIDER LABORATORY (SECTIONS C AND D)

		REPORTING THE IDENTIFICATION OF A SELECT AGENT OR TOXIN FROM A CLINICAL/DIAGNOSTIC SPECIMEN (APHIS/CDC FORM 4A)		FORM APPROVED OMB NO. 0579-0213 OMB NO. 0920-0576 EXP DATE 10/31/2014	
SECTION C – SAMPLE PROVIDER INFORMATION					
1. Name of individual completing Sections C and D: First: _____ MI: _____ Last: _____		2. Email address: _____		3. Telephone #: _____	
4. <input type="checkbox"/> Registered Entity (APHIS or CDC Registration #: _____) <input type="checkbox"/> Clinical or Diagnostic Laboratory [non-registered entity (NRE)] (NRE # (provided by APHIS or CDC): _____)		9. Entity name: _____			
5. Responsible Official or Laboratory Supervisor name: First: _____ MI: _____ Last: _____		10. Address (NOT a post office address): _____			
6. Telephone: _____	7. Fax #: _____	8. Email address: _____	11. City: _____	12. State: _____	13. Zip Code: _____
SECTION D – SPECIMEN(S) CONTAINING SELECT AGENT OR TOXIN PROVIDED TO REFERENCE LABORATORY					
1. Date specimen shipped to Reference Laboratory: _____		2. # of specimens: _____		3. Case/patient/sample ID #(s): _____	
4. Sample type(s) provided: _____			5. Case/patient/sample origin (zip code): _____		
6. Date notified by Reference Laboratory of select agent or toxin identification: _____		7. Select agent or toxin identified by Reference Laboratory: _____			
8. Dispositions of select agent or toxin (complete all that apply): <input type="checkbox"/> Transferred (Provide entity name and date of transfer. Entity: _____ Date: _____) <input type="checkbox"/> Destroyed (Provide destruction method and date. Method: _____ Date: _____) <input type="checkbox"/> Retained (Name of person retaining sample. Name: _____)					
9. Were any specimens containing a select agent or toxin handled outside of primary containment which may have led to an unintentional release and/or exposure to the select agent or toxin? <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, you are required under 7 CFR Part 331.19, 9 CFR Part 121.19, and 42 CFR Part 73.19 to complete and submit an APHIS/CDC Form 3)					
10. Do you anticipate receiving additional samples/specimens for this case/patient that originate from the initial case (e.g. patient, environmental sample)? <input type="checkbox"/> No <input type="checkbox"/> Yes, please refer to the guidance instructions at www.selectagents.gov for further directions.)					
11. Comment: _____					
I hereby certify that the information contained in Sections C and D 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, or 42 CFR 73 may result in civil and criminal penalties, including imprisonment.					
Signature of Responsible Official/Laboratory Supervisor: _____			Date Signed: _____		
<small>Public reporting burden: Public reporting burden of providing this information is estimated to average 1 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 D74, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).</small>					

Most Common Errors:

1. Sample type Received:
2. Case/patient Zip Code:
3. Date notified by Reference Lab:
4. Disposition of Select Agent or Toxin:
5. Signature of RO/ Lab Supervisor & Date:

FORM 4 CONTACT

- ❑ **Email: CDCForm4@cdc.gov**
- ❑ **Fax: 404-471-8469**

- ❑ **Form 4 Technical Reviewer:
Canditra McLemore
WSK8@cdc.gov**