



National Plant Diagnostic Network

Standard Operating Procedure for Plant Diagnostic Laboratories

Disease Common Name
Pathogen Scientific Name



VERSION X.X

Month/Day/Year



Table of Contents

Background.....	#
Protocol.....	#
1-Submitter shipping.....	#
2-NPDN Laboratory Receipt and Examination.....	#
3-Sample Storage.....	#
4-Sample Screening.....	#
Disease Name Sample Processing Flowchart.....	#
Disease Name Diagnostics Summary.....	#
Initial Screening by Triage Laboratory.....	#
Serological Testing.....	#
Isolation of <i>Pathogen Name</i>	#
Advanced Screening by Expert Laboratory.....	#
Morphological Identification.....	#
Shipping Cultured Samples.....	#
Molecular Identification.....	#
DNA Extraction Protocols.....	#
PCR Protocols.....	#
Shipping DNA Samples to Beltsville.....	#
5-Communication.....	#
6-Confirmation.....	#
7-Sample Destruction.....	#
Appendix 1: Sampling Methods.....	#
Appendix 2: Media Recipes.....	#
Appendix 3: Specific Equipment and Reagent Information for DNA Extractions.....	#
Appendix 4: Lab Worksheets.....	#

Appendix 5: Documentation and Specimen Submission Forms.....#
 Inactivation of Significant Biological Agents.....#
 Transfer of Significant Biological Agents#
 APHIS-PPQ Form 391.....#
 APHIS/CDC Form 4.....#
 APHIS/CDC Form 2.....#

TEMPLATE

Background:

Include text and images that give the history of the disease/pathogen.

Hosts

List all hosts associated with the disease/pathogen.

Symptoms

Describe the symptoms on each host caused by the pathogen.

References

Include resources such as papers and websites.

Protocol:

Take the appropriate steps, listed below, when plant material suspected of containing *X. xxxxx* is submitted to your laboratory.

1-Submitter Shipping:

Sample submission may be directly from a homeowner/grower questioning the cause of symptomatic plants or from regulatory personnel that have reasons for suspecting a possible infection.

1. Suspect plant material must be placed in double ziplock bags and stored in a refrigerator awaiting shipment to a diagnostic facility. The preferred method for shipment is triple packaging, two ziplock bags and an outer container. Tubes and plates should be sealed with tape. Also, shatter proof containers should be used for the cultures. The outer shipping container should be an approved cardboard shipping box. The seams of the box should be closed with approved shipping tape.
2. If submitted by regulatory personnel, the inspector will label and complete the appropriate forms. The inspector should record the State, identifier, the grower's license number (if applicable), the host(s), the inspector's initials as well as the location and date of inspection. If submitted by the State's Department of Agriculture, please include the Department of Agriculture designation: XXX-state-XXX. Upon receipt of the sample, this number will be placed in the notes section of the laboratory's database program so that it can be cross referenced with NAPIS.
3. It is suggested that samples be accompanied by a supplementary data sheet indicating the number of hosts present at each site. Save this data sheet in accordance with the NPDN format.
4. Samples should be shipped via overnight delivery or hand delivered to the diagnostic facility.
5. Many of the NPDN regions have established fedex accounts that can be used to ship samples to expert labs. Please check with your regional center before forwarding samples.

2-NPDN Laboratory Sample Receipt and Examination:

Upon arrival, contact submitting entity and acknowledge receipt of sample. The suspect plant material should be examined within a certified biological safety cabinet. Any tools, supplies, and miscellaneous materials used during the examination must be separated and placed in sealed plastic bags awaiting sterilization by a certified autoclave. The surface of all materials must be disinfected prior to the removal from the biological safety cabinet.

3-Sample Storage:

While examination and testing is being conducted, suspect plant material and cultures must be stored in access controlled cabinets and/or refrigerators.

Keeping the suspect plant material and/or cultures for extended periods of time is not recommended. Plant material should be destroyed using the methods described in section #7, Sample Destruction. Sample destruction is recommended within 2 weeks of submission to your facility if no confirmation has been reported.

4-Sample Screening:

Both initial and advanced screening steps are listed below. Initial screening includes both serological testing methods and isolation of *P. ramorum*. Initial screening will be carried out by triage laboratories. If these facilities cannot perform the initial screening steps, samples can be referred to the appropriate regional center. Upon completion of the initial screening, advanced screening may be required depending upon initial screening results.

<p><u>Great Plains Region:</u> James Stack Kansas State University Department of Plant Pathology 4024 Throckmorton Hall Manhattan, KS 66506 (785) 532-1383</p>	<p><u>Western Region: OR, WA, ID, AK, UT</u> Melodie Putnam Oregon State University Plant Clinic 1089 Cordley Hall 2701 SW Campus Way Corvallis, OR 97331-2903 (541) 737-3472</p>
<p><u>North Central Region</u> Jan Byrne Michigan State University Diagnostic Services 114 Center for Integrated Plant Systems East Lansing, MI 48824 (517) 355-3504</p>	<p><u>Western Region: CA, NV, AZ, NM:</u> CDFA Plant Pest Diagnostic Center Timothy Tidwell 3294 Meadowview Road Sacramento, CA 95832-1448 (916) 262-1132 (916) 262-1190</p>
<p><u>Northeast Region:</u> Karen L. Snover-Clift Cornell University Plant Disease Diagnostic Clinic 334 Plant Science Building Ithaca, NY 14853 (607) 255-7850</p>	<p><u>Western Region: HI, Pacific Islands:</u> Anne Alvarez University of Hawaii Plant Pathology Department 3190 Maile Way Honolulu, HI 96822-2232 (808) 956-7764</p>
<p><u>Southern Region:</u> Anne Vitoreli Plant Disease Clinic UF Bldg 78 Mowry Road P.O. Box 110830 Gainesville, FL 32611-0830 (352) 392-1795 (352) 392-3631 Ext. 254 (Carrie Harmon)</p>	

Insert Disease/Pathogen Name Sample Flowchart if available

TEMPLATE

a. Initial Screening by Triage Laboratory

1. Serological Testing

Below is a listing of suggested serological test kits to be used for preliminary identification of *X. xxxxxxxx*.

2. Isolation and Morphological Identification of *X. xxxxxx*

b. Advanced Screening by Expert Laboratory

For plant disease samples, please contact Dr. Mary Palm, USDA/APHIS/PPQ/PHP/PSPI Molecular Diagnostic Lab by email (mary.palm@aphis.usda.gov) or telephone (301-504-7154 or 505-5700 ext. 327). If Mary Palm is not available, contact National Mycologists John McKemy or Joe Bischoff by e-mail (john.mckemy@aphis.usda.gov or joe.bischoff@aphis.usda.gov) or telephone (301-504-5280 or 301-504-5327).

Inform Dr. Palm of the suspected taxon of the disease. She will advise the submitter if the diagnosis is more appropriate for morphological confirmation, molecular, or perhaps both.

For molecular confirmation, send plant disease samples to the following address:

Dr. Mary E. Palm
USDA/APHIS/PPQ
PPQ Molecular Diagnostic Lab
9901 Powder Mill Rd.
B-580, BARC-East
Beltsville MD 20705

Phone: 301-504-7154 or 504-5700 ext 327

For morphological confirmation, send plant disease samples to the following address:

Drs. John McKemy / Joe Bischoff
USDA/APHIS/PPQ
Rm. 329, Building 011A
BARC-West
Beltsville MD 20705 - 2350

Phone: 301-504-5280 or 301-504-5327

Samples must be accompanied by an APHIS-PPQ 391 form. Each unique sample must have its own form.

DNA EXTRACTION PROTOCOLS

- i. Sample Preparation for DNA Extraction from Leaf Tissue**
- ii. DNA Extraction from Leaf Tissue**
- iii. Processing Bark Samples for DNA Extractions**

TEMPLATE

CONVENTIONAL PCR PROTOCOL

WORK INSTRUCTION:

TEMPLATE

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TEMPLATE

Shipping DNA to Beltsville

- i. Laboratory personnel should send extracted DNA samples to the address below. Label tubes with permanent fine marker in legible writing.
- ii. Seal tubes with parafilm to prevent sample spilling during shipping.
- iii. Place the labeled, parafilmed tubes in a ziplock bag and seal. Place this bag into another sealed ziplock bag.
- iv. Finally place both bags into a larger ziplock bag containing wet ice. Store samples in a -20 C freezer until package is ready for shipping. **Do not package the sample and 391 forms in the same bag.** All samples should be in one bag and all 391 forms in another bag.
- v. **Email notification is required for all shipments prior to shipping: Email Dr. Mary Palm (Mary.Palm@aphis.usda.gov).** This email notification must include the number of DNA samples to be shipped and the FedEx or UPS tracking number. Shipments should be made Monday through Wednesday only.
- vi. Send shipments of DNA and 391 forms to:

Dr. Mary E. Palm
USDA/APHIS/PPQ
PPQ Molecular Diagnostic Lab
9901 Powder Mill Rd.
B-580, BARC-East
Beltsville MD 20705

Phone: 301-504-7154 or 504-5700 ext 327

5-Communication:

If the culture/serological/molecular analysis produce a suspect **positive ID**, follow this communications protocol. If a **negative** result is produced, no further communications are necessary.

- a. Notify the appropriate NPDN Regional Center of the suspect sample being shipped to Dr. Palm's laboratory. Expect notification from Dr. Palm's laboratory when the sample arrives.

Primary Regional Center Contact: _____
Address: _____
Address: _____
Phone Number: _____
Cell Phone Number: _____
Fax Number: _____
Email: _____

Secondary Regional Center Contact:
Address: _____
Address: _____
Phone Number: _____
Cell Phone Number: _____
Fax Number: _____
Email: _____

- b. Contact the State Plant Health Director (SPHD) and the State Plant Regulatory Official (SPRO) in the sample state of origin.

State Plant Health Director: _____
Address: _____
Address: _____
Phone Number: _____
Fax Number: _____
Email: _____

State Plant Regulatory Official: _____
Address: _____
Address: _____
Phone Number: _____
Fax Number: _____
Email: _____

Fax the SPHD at the PPQ regional office:

1. A copy of the updated form 391 with the preliminary diagnosis and the responsible diagnostician's contact information,
2. a copy of the overnight delivery form used to submit the sample to the regional center,
3. and a copy of the state inspector's sample card information submitted with the sample.

- c. Notify your Institution's Environmental and Health Safety Official (if a select agent).

EHS Official: _____
Address: _____
Address: _____
Phone Number: _____
Fax Number: _____
Email: _____

- d. Alert Dr. Mary Palm's laboratory that a sample is being forwarded to her laboratory. Provide them with sample shipment time, delivery method, tracking number, sample number.

6-Confirmation:

- a. State regulatory officials will be notified of the results by the PPQ regional office. Once confirmation is made, state and federal regulatory officials will handle any actions dealing with containment and eradication.
- b. Diagnosticians will be notified of the results by state regulatory officials. Communication between diagnosticians and state and federal regulatory officials is permitted after confirmation is received.
- c. Notify the Regional NPDN Director of confirmed results.
- d. Notify your Institution's Environmental and Health Safety Official (if a select agent).

7-Sample Destruction:

Plant material, cultures and/or supplies used in the examination and isolation of the suspect sample must be destroyed using a biologically monitored autoclave. The autoclave must be set at a minimum of 15 psi, 121 °C for 30 minutes. All tools and other equipment must be sanitized and/or sterilized before re-use.

Select agent pathogens must follow guidelines for samples destruction and/or transfer that includes destruction and/or transfer of all materials within 7 days of a confirmed select agent pathogen identification.

For **non-select agent** pathogens, it is suggested that prior to the destruction of sample material, the diagnostician contact the SPHD and SPRO to determine if the SPHD or SPRO would like to take custody of the sample material.

University Documentation (Transfer of Significant Biological Agents) should be completed upon sample transfer. University Documentation (Inactivation of Significant Biological Agents) should be completed upon sample destruction.

Autoclaves are required to be tested periodically for their effectiveness. This can be achieved using a biological monitoring product. Information on one such product can be found at: <http://cms.3m.com/cms/US/en/2-21/cirFFFQ/view.jhtml>.

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Appendix 5: Documentation and Specimen Submission Forms

University Documentation

Inactivation of Significant Biological Agents

Name of Significant Biological Agent: _____

Accession number and description of diagnostic case: _____

Date(s) agent was isolated: Amount of agent on site prior to inactivation:

Significant agent was:

Inactivated on site

Date: _____

Method and description of inactivation: _____

If using an autoclave, provide location and cycle conditions (e.g., temperature, pressure, time): _____

Witness to the inactivation:

Print name: _____ Signature: _____

Other (provide detailed explanation): _____

I certify that all biological agents isolated by this facility have been inactivated or transferred to a registered facility pursuant to 7 CFR 331, and that all information on this form is true and correct to the best of my knowledge.

Print name: _____ Signature: _____

Date: _____

Received by Environmental Health and Safety:

Print name: _____ Signature: _____

Date: _____

University Documentation

Transfer of Significant Biological Agents

Name of Significant Biological Agent: _____

Accession number and description of diagnostic case: _____

Date(s) agent was isolated: Amount of agent on site prior to transfer:

Significant agent was:

o Transferred to a registered entity (give name, date, and USDA/APHIS confirmation number): _____

o All related material was transferred

o All plant material was transferred

o A portion of the plant material was transferred

o All cultures were transferred

o A portion of the cultures were transferred

o Other (provide detailed explanation): _____

I certify that all biological agents isolated by this facility have been inactivated or transferred to a registered facility pursuant to 7 CFR 331, and that all information on this form is true and correct to the best of my knowledge.

Print name: _____ Signature: _____

Date: _____

Received by Environmental Health and Safety:

Print name: _____ Signature: _____

Date: _____

This report is authorized by law (7 U.S.C. 147a). While you are not required to respond your cooperation is needed to make an accurate record of plant pest conditions.

See reverse for additional OMB information. **FORM APPROVED**
OMB NO. 0579-0010

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
SPECIMENS FOR DETERMINATION

Instructions: Type or print information requested. Press hard and print legibly when handwritten. Item 1 - assign number for each collection beginning with year, followed by collector's initials and collector's number. Example (collector, John J. Dingle): 83-JJD-001.
Pest Data Section - Complete Items 14, 15 and 16 or 19 or 20 and 21 as applicable. Complete Items 17 and 18 if a trap was used.

FOR IIBIII USE
LOT NO.
PRIORITY

1. COLLECTION NUMBER		2. DATE MO DA YR			3. SUBMITTING AGENCY <input type="checkbox"/> State Cooperator <input type="checkbox"/> PPQ <input type="checkbox"/> Other _____		
SENDER AND ORIGIN	4. NAME OF SENDER				INTERCEPTION SITE	5. TYPE OF PROPERTY (<i>Farm, Feedmill, Nursery, etc.</i>)	
	6. ADDRESS OF SENDER					7. NAME AND ADDRESS OF PROPERTY OR OWNER	
	ZIP					COUNTRY/ COUNTY	
	8. REASON FOR IDENTIFICATION ("x" ALL Applicable Items)						
PURPOSE	A. <input type="checkbox"/> Biological Control (Target Pest Name _____)			E. <input type="checkbox"/> Livestock, Domestic Animal Pest			
	B. <input type="checkbox"/> Damaging Crops/Plants			F. <input type="checkbox"/> Possible Immigrant (<i>Explain in REMARKS</i>)			
	C. <input type="checkbox"/> Suspected Pest of Regulatory Concern (<i>Explain in REMARKS</i>)			G. <input type="checkbox"/> Survey (<i>Explain in REMARKS</i>)			
	D. <input type="checkbox"/> Stored Product Pest			H. <input type="checkbox"/> Other (<i>Explain in REMARKS</i>)			
9. IF PROMPT OR URGENT IDENTIFICATION IS REQUESTED, PLEASE PROVIDE A BRIEF EXPLANATION UNDER "REMARKS".							
HOST DATA	10. HOST INFORMATION NAME OF HOST (<i>Scientific name when possible</i>)				11. QUANTITY OF HOST NUMBER OF ACRES/PLANTS		PLANTS AFFECTED (<i>Insert figure and indicate <input type="checkbox"/> Number <input type="checkbox"/> Percent</i>):
	12. PLANT DISTRIBUTION		13. PLANT PARTS AFFECTED				
	<input type="checkbox"/> LIMITED <input type="checkbox"/> SCATTERED <input type="checkbox"/> WIDESPREAD	<input type="checkbox"/> Leaves, Upper Surface <input type="checkbox"/> Leaves, Lower Surface <input type="checkbox"/> Petiole <input type="checkbox"/> Stem	<input type="checkbox"/> Trunk/Bark <input type="checkbox"/> Branches <input type="checkbox"/> Growing Tips <input type="checkbox"/> Roots	<input type="checkbox"/> Bulbs, Tubers, Corms <input type="checkbox"/> Buds <input type="checkbox"/> Flowers <input type="checkbox"/> Fruits or Nuts	<input type="checkbox"/> Seeds		
PEST DATA	14. PEST DISTRIBUTION		15. <input type="checkbox"/> INSECTS <input type="checkbox"/> NEMATODES <input type="checkbox"/> MOLLUSKS				
	<input type="checkbox"/> FEW <input type="checkbox"/> COMMON <input type="checkbox"/> ABUNDANT <input type="checkbox"/> EXTREME	NUMBER SUBMITTED	LARVAE	PUPAE	ADULTS	CAST SKINS	EGGS
		ALIVE					
		DEAD					
16. SAMPLING METHOD		17. TYPE OF TRAP AND LURE			18. TRAP NUMBER		
19. PLANT PATHOLOGY - PLANT SYMPTOMS (<i>"X" one and describe symptoms</i>) <input type="checkbox"/> ISOLATED <input type="checkbox"/> GENERAL							
20. WEED DENSITY <input type="checkbox"/> FEW <input type="checkbox"/> SPOTTY <input type="checkbox"/> GENERAL			21. WEED GROWTH STAGE <input type="checkbox"/> SEEDLING <input type="checkbox"/> VEGETATIVE <input type="checkbox"/> FLOWERING/FRUITING <input type="checkbox"/> MATURE				
22. REMARKS							

23. TENTATIVE DETERMINATION

24. DETERMINATION AND NOTES (*Not for Field Use*)

FOR IIBIII USE

DATE RECEIVED

NO.

LABEL

SORTED

PREPARED

DATE ACCEPTED

SIGNATURE _____

DATE _____

RR

PPQ FORM 391 *Previous editions are obsolete.*
(AUG 02)

This is a 6-Part form. Copies must be disseminated as follows:

- PART 1 - PPQ PART 2 - RETURN TO SUBMITTER AFTER IDENTIFICATION PART 3 - IIBIII OR FINAL IDENTIFIER
 PART 4 - INTERMEDIATE IDENTIFIER PART 5 - INTERMEDIATE IDENTIFIER PART 6 - RETAINED BY SUBMITTER

OMB Information

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0010. The time required to complete this information collection is estimated to average .25 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.

Instructions

Use PPQ Form 391, Specimens for Determination, for domestic collections (warehouse inspections, local and individual collecting, special survey programs, export certification).

BLOCK	INSTRUCTIONS
1	1. Assign a number for each collection beginning the year, followed by the collector's initials and collector's number EXAMPLE In 2001, Brian K. Long collected his first specimen for determination of the year. His first collection number is 01-BLK-001 2. Enter the collection number
2	Enter date
3	Check block to indicate Agency submitting specimens for identification
4	Enter name of sender
5	Enter type of property specimen obtained from (farm, nursery, feedmill, etc.)
6	Enter address
7	Enter name and address of property owner
8A-8L	Check all appropriate blocks
9	Leave Blank
10	Enter scientific name of host, if possible
11	Enter quantity of host and plants affected
12	Check block to indicate distribution of plant
13	Check appropriate blocks to indicate plant parts affected
14	Check block to indicate pest distribution
15	<ul style="list-style-type: none">• Check appropriate block to indicate type of specimen• Enter number specimens submitted under appropriate column
16	Enter sampling method
17	Enter type of trap and lure
18	Enter trap number
19	Enter X in block to indicate isolated or general plant symptoms
20	Enter X in appropriate block for weed density
21	Enter X in appropriate block for weed growth stage
22	Provide a brief explanation if Prompt or URGENT identification is requested
23	Enter a tentative determination if you made one
24	Leave blank

Distribution of PPQ Form 391

Distribute PPQ Form 391 as follows:

1. Send Original along with the sample to your Area Identifier.
2. Retain and file a copy for your records.



GUIDANCE DOCUMENT FOR REPORTING THE IDENTIFICATION OF A SELECT AGENT OR TOXIN (APHIS/CDC FORM 4)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2011

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.

Clinical or diagnostic laboratories and other entities that have identified select agents and toxins contained in a specimen presented for diagnosis, verification, or proficiency testing are required by regulation (7 CFR 331, 9 CFR 121, and 42 CFR 73) within 7 calendar days after identification of the select agent or toxin contained in a specimen presented for diagnosis or verification or within 90 days of receipt for proficiency testing must report this identification to APHIS or CDC. In addition to the reporting requirement, the identified select agent or toxin must be secured against theft, loss, or release during the period between identification and final disposition. Within 7 calendar days after identification of the select agent or toxin contained in a specimen presented for diagnosis or verification or 90 days of receipt for proficiency testing, the identified select agent or toxin must be transferred in accordance with 7 CFR 331.16, 9 CFR 121.16 or 42 CFR 73.16 or destroyed on-site by a recognized sterilization or inactivation process. The select agent or toxin may be retained only if the entity is currently registered for the select agent and toxin identified. If the select agent or toxin is retained, the entity may need to amend its certificate of registration to reflect the addition of the agent and maintain records associated with any intra-entity transfers. To report the identification of a select agent, the Responsible Official or Facility Director must submit this form (APHIS/CDC Form 4) 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: lsat@cdc.gov

The following select agents and toxins contained in a specimen presented for diagnosis or verification are required to be **immediately** reported to APHIS or CDC:

- | | |
|---|---|
| African horse sickness virus | <i>Phoma glycinicola</i> (formerly <i>Pyrenochaeta glycinis</i>) |
| African swine fever virus | <i>Ralstonia solanacearum</i> race 3, biovar 2 |
| Avian influenza virus (highly pathogenic) | Rift Valley fever virus |
| <i>Bacillus anthracis</i> | Rinderpest virus |
| Botulinum neurotoxins | <i>Sclerophthora rayssiae</i> var <i>zeae</i> |
| Bovine spongiform encephalopathy agent | South American Hemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito) |
| <i>Bruceella melitensis</i> | Swine vesicular disease virus |
| Classical swine fever virus | <i>Synchytrium endobioticum</i> |
| Foot-and-mouth disease virus | Variola major virus (Smallpox virus) |
| <i>Francisella tularensis</i> | Variola minor (Alastrim) |
| Ebola virus | Venezuelan equine encephalitis virus |
| Hendra virus | Virulent Newcastle disease virus |
| Lassa fever virus | <i>Xanthomonas oryzae</i> |
| Marburg virus | <i>Xylella fastidiosa</i> (citrus variegated chlorosis strain) |
| Nipah virus | <i>Yersinia pestis</i> |
| <i>Peronosclerospora philippinensis</i> (<i>Peronosclerospora sacchari</i>) | |

Any known select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of the regulations during the period between seizure of the agent and the transfer or destruction of such agent provided that (1) as soon as practicable, the Federal law enforcement agency transfers the seized agent to an entity registered for that agent or destroys the agent by a recognized sterilization or inactivation process; (2) the Federal law enforcement agency secures the seized agent against theft, loss, or release; and (3) the Federal law enforcement agency reports the seizure of the agent by submitting this form.

PURPOSE

The purpose of this form is to report select agents or toxins contained in specimens presented for diagnosis, verification, or proficiency testing as defined under 7 CFR 331.1, 9 CFR 121.1 or 42 CFR 73.1 and seizure of select agents or toxins by federal law enforcement agencies. A copy of the completed form and attachments must be maintained by the entity for three years.

INSTRUCTIONS

Diagnosis and verification

1. The reference laboratory (laboratory that confirms the identification of the select agent) completes Section 1 within seven calendar days after identification for all entities in possession of the specimen or isolate at the time of the identification. Additional copies of Section C are available at <http://www.selectagents.gov>, http://www.aphis.usda.gov/programs/ag_selectagent/index.html and <http://www.cdc.gov/od/sap>.
 - a. For registered entities, the information provided for this form should match the information submitted for the entity's certificate of registration.
 - b. Please provide all information as it relates to the case. For example, the case (e.g., patient) generates multiple specimens (e.g., tissue, fluid) and/or multiple specimen types that are cultured on various media (e.g., 15 blood agar plates) would be listed as 1 case for block 15. Attach additional sheets if necessary.
 - c. Indicate the disposition of materials generated from the case (e.g., specimens and cultures) in block 17.
2. To request prior authorization to transfer select agent(s) or toxin(s) identified for research purposes, APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins," must be submitted to either APHIS or CDC. To ensure that your entity receives authorization from APHIS or CDC to transfer the select agent or toxin, you need to verify that the recipient is registered for that agent.
3. Less stringent reporting may be required based on extraordinary circumstances (e.g., agricultural emergencies, widespread outbreaks, endemic areas).

Proficiency testing

1. Complete section 2 within 90 calendar days of receipt. For registered entities, the information provided for this form should match the information submitted for the entity's certificate of registration.
2. To request prior authorization to transfer select agent(s) or toxin(s) identified, APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins," must be submitted to either APHIS or CDC. To ensure that your entity receives authorization from APHIS or CDC to transfer the select agent or toxin, you need to verify that the recipient is registered for that agent.
3. A select agent or toxin that is contained in a specimen for proficiency testing may be transferred without prior authorization from APHIS or CDC provided that, at least seven calendar days prior to the transfer, the sender reports to APHIS or CDC the select agent or toxin to be transferred and the name and address of the recipient (See 7 CFR 331.16, 9 CFR 121.16 and 42 CFR 73.16).

Reporting seized select agents or toxins by federal law enforcement agencies

1. Complete section 3 within seven calendar days after seizure and/or final disposition of select agents or toxins.
2. For registered entities, the information provided for this form should match the information submitted for the entity's certificate of registration.

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>.



**REPORT OF THE IDENTIFICATION OF
A SELECT AGENT OR TOXIN
(APHIS/CDC FORM 4)**

FORM APPROVED
OMB NO. 0578-0213
OMB NO. 0920-0578
EXP DATE 12/31/2011

Read all instructions carefully before completing the form. Answer all items completely and type or print in ink. The 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
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 REFERENCE LABORATORY			
SECTION A – REFERENCE LABORATORY INFORMATION			
1. Entity name:		2. <input type="checkbox"/> Entity registration number: _____ <input type="checkbox"/> Clinical/diagnostic laboratory	
3. Address (NOT a post office address):		4. City:	5. State: 6. Zip Code:
7. Responsible Official or Facility Director name First: MI: Last:		8. Telephone #:	
9. FAX #:		10. E-mail address:	
SECTION B – SELECT AGENTS AND TOXINS IDENTIFIED FROM CLINICAL/DIAGNOSTIC SPECIMENS			
11. Select agent or toxin being reported:		12. Date(s) agent was identified:	
13. Type of sample analyzed: <input type="checkbox"/> Clinical/diagnostic sample <input type="checkbox"/> Environmental sample <input type="checkbox"/> Isolate <input type="checkbox"/> Other (specify): _____			
14. Original source of sample: <input type="checkbox"/> Human <input type="checkbox"/> Animal (species: _____) <input type="checkbox"/> Plant (species: _____) <input type="checkbox"/> Other (specify): _____			
15. Provide a summary of the methodologies used to identify the select agent or toxin including specimen type(s), media, total quantity, and if the source expected to provide additional specimens (<i>see instructions</i>):			
16. Was there a possibility that personnel in your laboratory were exposed to the select agent or toxin while working with this sample? <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, please complete APHIS/CDC Form 3.)			
17. Disposition of select agent or toxin: <input type="checkbox"/> Transferred to a registered entity (Give entity name and APHIS/CDC registration number. Include a copy of the approved APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins"): _____ <input type="checkbox"/> Destroyed on site: <input type="checkbox"/> Autoclaving <input type="checkbox"/> Chemical (Describe: _____) <input type="checkbox"/> Incineration <input type="checkbox"/> Irradiation <input type="checkbox"/> Other: _____ Date select agent or toxin was destroyed: _____ <input type="checkbox"/> Retained and/or transferred via intra-entity transfer to (Give name of Principal Investigator and/or Amendment #): _____ Date select agent or toxin was transferred: _____			
SECTION C – SAMPLE PROVIDER			
18. Has the sender(s) of the sample been notified of the identification of the select agent or toxin? <input type="checkbox"/> No <input type="checkbox"/> Yes NOTE: Please complete Section C for each laboratory that was in possession of the sample or isolate. (Attach additional sheets if necessary.)			
19. Entity name:		20. <input type="checkbox"/> Entity registration number: _____ <input type="checkbox"/> Clinical/diagnostic laboratory	
21. Address (NOT a post office address):		22. City:	23. State: 24. Zip Code:
25. Responsible Official (RO) or facility director First: MI: Last:		26. Telephone #:	
27. FAX #:		28. E-mail address:	
29. Was there a possibility of an exposure while working with this sample? <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, please complete APHIS/CDC Form 3.)			
30. Disposition of select agent or toxin: <input type="checkbox"/> Destroyed on site <input type="checkbox"/> Retained <input type="checkbox"/> Transferred to a registered entity (Provide entity name if different than Block 1): _____			

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

Signature of Responsible Official/Facility Director: _____ Date: _____

SECTION 2 – TO BE COMPLETED BY LABORATORY THAT RECEIVED PROFICIENCY TESTING			
SECTION A – LABORATORY INFORMATION			
31. Entity name:		32. Entity registration number:	
33. Address (NOT a post office address):		34. City:	35. State: 36. Zip Code:
37. Responsible Official or Facility Director name First: MI: Last:		38. Telephone #:	
39. FAX #:		40. E-mail address:	
41. Was there a possibility of an exposure while working with this sample? <input type="checkbox"/> No <input type="checkbox"/> Yes (If Yes, please complete APHIS/CDC Form 3.)			
SECTION B – SELECT AGENTS AND TOXINS IDENTIFIED FROM PROFICIENCY TESTING			
42. Select agent and strain designation (if known) or toxin being reported:		43. Total quantity identified:	
44. Location where proficiency testing was conducted Building: Room:		45. BSL of laboratory or PPQ containment designation:	
46. Name of laboratory test that proficiency test was designed to assess:		47. Date obtained from sponsor:	
48. Sponsor/entity that you received select agent or toxin from: <input type="checkbox"/> College of American Pathologists <input type="checkbox"/> Registered entity (Entity name, APHIS or CDC registration number): _____ <input type="checkbox"/> Other (Explain): _____			
49. Disposition of select agent or toxin: <input type="checkbox"/> Transferred to a registered entity (Give entity name and APHIS/CDC registration number. Include a copy of the approved APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins"): _____ <input type="checkbox"/> Destroyed on site: <input type="checkbox"/> Autoclaving <input type="checkbox"/> Chemical (Describe: _____) <input type="checkbox"/> Incineration <input type="checkbox"/> Irradiation <input type="checkbox"/> Other: _____ Date select agent or toxin was destroyed: _____ <input type="checkbox"/> Retained and/or transferred via intra-entity transfer to (Give name of Principal Investigator and/or Amendment #): _____ Date select agent or toxin was transferred: _____			

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

Signature of Responsible Official/Facility Director: _____ Date: _____

TEMP

SECTION 3 – TO BE COMPLETED BY FEDERAL LAW ENFORCEMENT AGENCY			
SECTION A – FEDERAL LAW ENFORCEMENT INFORMATION			
50. Name of federal law enforcement agent First: MI: Last:		51. Telephone #:	
52. Badge #:		53. E-mail address:	
54. Select agent and strain designation (if known) or toxin being seized:		55. Total quantity identified:	
SECTION B – ENTITY INFORMATION			
56. Disposition of select agent or toxin: <input type="checkbox"/> Transferred to a registered entity (Give entity name and APHIS/CDC registration number.): _____ <input type="checkbox"/> Destroyed on site: <input type="checkbox"/> Autoclaving <input type="checkbox"/> Chemical (Describe: _____) <input type="checkbox"/> Incineration <input type="checkbox"/> Irradiation <input type="checkbox"/> Other: _____ Date select agent or toxin was destroyed: _____			
57. Entity name:		58. Entity registration number:	
59. Address (NOT a post office address):		60. City:	61. State: 62. Zip Code:
63. Responsible Official name First: MI: Last:		64. Telephone #:	
65. FAX #:		66. E-mail address:	
67. Select agent and strain designation (if known) or toxin being seized:		68. Total quantity identified:	

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

Signature of Agent: _____ Date: _____

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 D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).

APHIS/CDC Form 4 (12/31/2011)

TEEA



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 12/31/2011

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.

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.
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...
b. Clinical and diagnostic laboratories that transfer select agents and toxins after identification...
c. The agency receiving the form (APHIS or CDC) will review the request and approve or disapprove the transfer...
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...
b. For block 36 ("Name of carrier"), please indicate the method of shipment...
c. If the sender has a suspicion that the agent may not be used for the requested purpose...
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.

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
OMB NO. 0920-0576
EXP DATE 12/31/2011

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: Irsat@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. <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: 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
OMB NO. 0920-0576
EXP DATE 12/31/2011

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: lsat@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: <input type="checkbox"/> E-mail <input type="checkbox"/> Fax <input type="checkbox"/> 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. <input type="checkbox"/> Transfer Did Not Occur <input type="checkbox"/> Transfer Occurred/Date of Receipt:
40. The agents/toxins listed in Section was received: <input type="checkbox"/> Yes <input type="checkbox"/> If no, explain discrepancy in separate attachment.	41. 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: _____

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 30333; ATTN: PRA (0920-0576).
APHIS/CDC FORM 2 (12/31/2011)