Guidance Document for the Completion of APHIS/CDC Form 4

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) to report this identification to APHIS or CDC 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. 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 with APHIS or CDC 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
(301) 734-5960
(301) 734-3652 FAX
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
(404) 718-2000
(404) 718-2096 FAX
Email: cdcform4@cdc.gov

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.

DEFINITIONS

- **APHIS- Animal Plant Health Inspection Service-** The agency that is dedicated to protecting animal and plant health and promoting quality of life through the prevention and control of disease, injury and disability.
- **CDC- Centers for Disease Control and Prevention-** The agency that is dedicated to protecting health and promoting quality of life through the prevention and control of disease, injury, and disability.
- **Clinical or diagnostic laboratory-** A facility that is capable of analyzing or referring specimens or samples of environmental, food, veterinary, agriculture, and/or human origin that may contain microbial agents or biological toxins.
- **Clinical/Diagnostic Identification-** When a clinical or diagnostic laboratory, or other entity, has identified a select agent or toxin contained in a specimen or sample presented for diagnosis or verification.
- **Facility or Laboratory Director**- 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.
- **Federal Law Enforcement Seizure-** When a federal law enforcement agency has seized a select agent or toxin related to an investigation.
- **Full Legal Name-** An individual's first name, middle initial(s), and last name or surname, without use of nicknames.
- **Non-registered Entities-** Any entities that are not registered to store or work with select agents and toxins with the APHIS or CDC Select Agent Program.
- **Proficiency Testing Identification-** When a clinical or diagnostic laboratory, or other entity, has identified a select agent or toxin contained in a specimen or sample presented for proficiency testing.
- **Reference laboratory-** The laboratory which definitively identified the select agent or toxin being reported.
- **Registered Entities-** Entities that are approved to store or work with select agents or toxins and are registered with the APHIS or CDC Select Agent Program.
- **Sample Provider-** An entity that provides a presumptive sample to a reference laboratory for confirmation of a select agent or toxin.
- **Sponsor**- entity which sends proficiency testing samples to a testing laboratory.

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APHIS/CDC Form 4 Report

General Information for all entities:

- The identification of any of the select agents or toxins listed under 7 CFR §331.3, 9 CFR §121.5(a)(3)(i), 9 CFR §121.9(c)(1)), 42 CFR §73.5(a)(3)(i), or 42 CFR § 73.9(c)(1) must be immediately reported to APHIS or CDC by email, facsimile, or telephone.
- The identified or seized select agent or toxin must be secured against theft, loss, or release during the period between identification or seizure 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.
    - For select agents or toxins seized by a Federal law enforcement agency, the select agent or toxin must be destroyed or transferred to an entity eligible to receive such agent or toxin as soon as practicable.

APHIS/CDC Form 4A – Reference Laboratory Report

To report the identification of select agents or toxins contained in specimens presented for diagnosis or verification

The reference laboratory (see definition above) completes Form 4A within seven calendar days after identification for their possession of the specimen or isolate at the time of the identification. Less stringent reporting may be required based on extraordinary circumstances (e.g., agricultural emergencies, widespread outbreaks, endemic areas). Please see FAQs for further information.

Section A – Reference Laboratory Information

Block A1 – Name of individual completing the form:

- Please provide the full legal name of the personnel at your entity that is most familiar with the case(s) being reported on the APHIS/CDC Form 4 report (e.g. Principal Investigator; Microbiology Supervisor, Biosafety Officer, etc…).

Block A2 – Email address:

- Please provide the email address for the individual listed in *Block A1*.
- Please print or type clearly and ensure the email domain (e.g., .org, .gov, .edu, .com, .net) is included.

Block A3 – Telephone number:

- Please provide the direct dial 10-digit telephone number for the individual listed in *Block A1*; including any extension.

Block A4- Registration Information:

- For entities registered with the APHIS or CDC Select Agent Program, please check the box labeled "Registered Entity (APHIS or CDC registration number)" and enter the registration number exactly as it appears on your entity's 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 your entity's current registration number, please contact your Responsible Official.
- For entities not registered with the APHIS or CDC Select Agent Program, check the box titled "Clinical or diagnostic laboratory [non-registered entity (NRE)]" and enter your entity's NRE number. This number will be provided to your entity after the first APHIS/CDC Form 4 report is submitted.
  - If you do not know your entity's NRE number or have not received your NRE number, please contact APHIS or CDC to obtain the NRE number.

Block A5 – Responsible Official or Laboratory Supervisor Name:

- For entities registered with APHIS or CDC, please provide the complete name of your 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 your entity's Facility or Laboratory Supervisor or the individual who supervises the laboratory that handled or manipulated the identified select agent or toxin (e.g., Microbiology Supervisor).
  - For the purposes of the APHIS/CDC Form 4, the term "full legal name" refers to an individual's first name, middle initial(s), and last name or surname, without use of nicknames.
  - For the purposes of the APHIS/CDC Form 4, the term "Facility or Laboratory Supervisor" 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 A6 – Telephone #:

- Please provide the direct dial 10-digit telephone number for the individual listed in *Block A5*; including any extension.

Block A7 – FAX #:

- Please provide the 10-digit Fax number for the individual listed in *Block A5*.

Block A8 – E-mail Address:

- Please provide the email address for the individual listed in *Block A5*.
- Please print or type clearly and ensure the email domain (e.g., .org, .gov, .edu, .com, .net) is included.

Block A9- Entity Name:

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

Blocks A10-13 – Entity's Address:

- For entities registered with APHIS or CDC, please provide your entity's complete address, exactly as it appears on your current certificate of registration.
- For non-registered entities, please provide the complete address of your entity.
- A P.O. Box address is not acceptable
- Zip Code – please provide only the five digit zip code

Section B – Select Agents and Toxins Identified from Clinical/Diagnostic Specimens

Block B1 – Select Agent or Toxin Identified:

- List only one select agent or toxin.
- 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 or toxin.

Note: The following select agents and toxins identified in a specimen presented for diagnosis or verification are required to be immediately reported to APHIS or CDC by email, facsimile, or telephone. This list is also available at http://www.selectagents.gov/CDForm.html:

Immediate Notification Required		
African horse sickness virus	Hendra virus	South American Hemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
African swine fever virus	Lassa fever virus	Swine vesicular disease virus

Immediate Notification Required		
Avian influenza virus (highly pathogenic)	Marburg virus	*Synchytrium endobioticum*
Bacillus anthracis	Nipah virus	Variola major virus (Smallpox virus)
Botulinum neurotoxins	*Peronosclerospora philippinensis (Peronosclerospora sacchari)*	Variola minor (Alastrim)
Bovine spongiform encephalopathy agent	*Phoma glycinicola* (formerly *Pyrenochaeta glycines)*	Venezuelan equine encephalitis virus
Brucella melitensis	*Ralstonia solanacearum* race 3, biovar 2	Virulent Newcastle disease virus
Classical swine fever virus	*Rathayibacter toxicus*	*Xanthomonas oryzae*
Foot-and-mouth disease virus	Rift Valley fever virus	*Xylella fastidiosa* (citrus variegated chlorosis strain)
Francisella tularensis	Rinderpest virus	*Yersinia pestis*
Ebola virus	*Sclerophthora rayssiae* var *zeae*	

Block B2 – Date Identified:

- Enter the date that the identification of the select agent or toxin was confirmed.
- Enter only one date in *Block B2*.

Block B3 – Case/patient ID#:

- If your entity assigns a unique, internal tracking number, specimen ID, or reference number to the specimen, enter it in Block B2.
- More than one patient or animal can be submitted for each APHIS/CDC Form 4 as long as the identified select agent or toxin is the same. See Block B15 for more information.

Block B4 – Number of Samples:

- Enter the number of samples that were produced and tested by the patient or animal. If more samples are anticipated see Block B13 for more information.

Block B5 –Sample Type:

When selecting clinical/diagnostic specimen or isolate, indicate where the sample type originated from: human, animal, or plant. Refer to the description of the terms listed below for indicating the type of sample analyzed and select only one sample type. If more than one type of specimen or sample was analyzed, please select the one specimen or sample type that was used to definitively identify the select agent or toxin.

- **Clinical/diagnostic specimen** – a sample (not the isolate) that was directly derived from an individual human, animal, or plant.
  - For samples originating from an animal (nonhuman) or plant, please provide the genus and species of the organism from which the sample originated (e.g., *Capra aegagrus*, *Bos taurus*, *Zea mays*, *Triticum aestivum*).
- **Isolate** – A purified culture obtained from a specimen or sample taken from a host or the environment.

- For samples originating from an animal (nonhuman) or plant, please provide the genus and species of the organism from which the sample originated (e.g., *Capra aegagrus*, *Bos taurus*, *Zea mays*, *Triticum aestivum*).

- **Environmental sample** – a sample that was not directly derived from a human, animal, or plant (e.g., water sample, soil sample, air sample).
- **Food sample-** a sample that was directly derived from a food source, food container or food by-product.

Block B6 – Case/patient origin (zip code):

- Enter the zip code from which the patient or animal is located.
- If the zip code is unknown please enter the city and state.

Block B7- Disposition of Select Agent or Toxins (check all that apply)*:*

Transferred:

- Check the "Transferred" box if all *or* part of the identified select agent or toxin was transferred to an entity that is currently registered for the select agent or toxin identified.
- Please provide the name of the entity, exactly as it appears on their current certificate of registration and the date that the transfer request was submitted to the APHIS or CDC for approval. If you do not know the entity's registered name, please contact their Responsible Official to obtain this information.
- 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 or toxin.

Destroyed:

- Check the "Destroyed on site" box only if the *entire* identified select agent or toxin was destroyed on site.
- Indicate the method of destruction in the space provided. Below are the approved recognized methods that can be used:
  - Autoclave
  - Irradiation
  - Incineration
  - Chemical- Indicate the type of chemical was used.
  - Expended/Consumed
  - Commercial medical waste disposal company - please note that any confirmed select agent or toxin contained within a sample needs to be destroyed on site before releasing material to the commercial medical waste disposal company.
  - Other- If selected you must provide a description of the method.

- Provide the date on which the entire identified select agent or toxin was destroyed. *Do not* state that the identified select agent or toxin will be destroyed at a future date. If the identified select agent or toxin is to be destroyed at a future date you *must* check the "Retained" box and follow the procedures listed below under **Retained**.

Retained:

- Check the "Retained" box if all *or* part of the identified select agent or toxin was retained by your entity.
    - 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 will have to maintain records associated with any intra-entity transfers. Please refer to APHIS/CDC Form 1, Instructions, (D) Amending certification of registration to determine if an amendment to the entity's certificate of registration is needed.
- Please provide the name of the personnel who has responsibility over the use, storage, and disposition of the retained select agent or toxin.

For information pertaining to "long-term storage" of select agents or toxins please refer to http://www.selectagents.gov/LongTermStorage.html.

Block B8 – Exposure outside Primary Containment:

- If there is any possibility that personnel handled the sample containing a select agent or toxin outside primary containment (e.g., working with culture on open bench), this box should be checked "Yes" and an APHIS/CDC Form 3 must be submitted. Additional guidance for submitting an APHIS/CDC Form 3 is available at: http://www.selectagents.gov/TheftLossRelease.html.

Block B9 – Additional Samples Anticipated:

- If there is possibility that the case/patient will produce additional samples, this box should be checked "Yes".

Block B10 – Sample Provider Notified:

- Please select "Yes" if the facility that provided the specimen has been notified of the identification of the select agent or toxin. If the sample provider has not been notified of the identification select "No". If your facility processed the original sample select "N/A".
- If there is a sample provider for the specimen, please request sections C and D be completed and signed by each laboratory that was in possession of the specimen.

Block B11 – Comments/Notes:

- Please provide any pertinent information as it relates to the case. Attach additional sheets if necessary.

Signature

- For all entities, the individual named in Block A5 (RO, ARO, Facility Director or Laboratory Supervisor), must sign and date the signature line.

Section C – Sample Provider Information

Block C1 – Name of individual completing the form:

- Please provide the full legal name of the personnel at your entity that is most familiar with the case(s) being reported on the APHIS/CDC Form 4 report (e.g. Principal Investigator; Microbiology Supervisor, Biosafety Officer, etc…).

Block C2 – Email address:

- Please provide the email address for the individual listed in *Block A1*.
- Please print or type clearly and ensure the email domain (e.g., .org, .gov, .edu, .com, .net) is included.

Block C3 – Telephone number of individual completing the form:

- Please provide the direct dial 10-digit telephone number for the individual listed in *Block A1*; including any extension.

Block C4- Registration Information:

- For entities registered with the APHIS or CDC Select Agent Program, please check the box labeled "Registered Entity (APHIS or CDC registration number)" and enter the registration number exactly as it appears on your entity's current certificate of registration. Please <u>do</u> <u>not</u> 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 your entity's current registration number, please contact your Responsible Official.
- For entities not registered with the APHIS or CDC Select Agent Program, check the box titled "Clinical or diagnostic laboratory [non-registered entity (NRE)]" and enter your entity's NRE number. This number will be provided to your entity after the first APHIS/CDC Form 4 report is submitted.
  - If you do not know your entity's NRE number or have not received your NRE number, please contact APHIS or CDC to obtain the NRE number.

Block C5 – Responsible Official or Laboratory Supervisor Name:

- For entities registered with APHIS or CDC, please provide the complete name of your 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 your entity's Facility or Laboratory Supervisor or the individual who supervises the laboratory that handled or manipulated the identified select agent or toxin (e.g., Microbiology Supervisor).

- For the purposes of the APHIS/CDC Form 4, the term “full legal name” refers to an individual's first name, middle initial(s), and last name or surname, without use of nicknames.
- For the purposes of the APHIS/CDC Form 4, the term “Facility or Laboratory Supervisor” 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 C6 – Telephone #:

- Please provide the direct dial 10-digit telephone number for the individual listed in *Block C5*; including any extension.

Block C7 – FAX #:

- Please provide the 10-digit Fax number for the individual listed in *Block C5*.

Block C8 – E-mail Address:

- Please provide the email address for the individual listed in *Block C5*.
- Please print or type clearly and ensure the email domain (e.g., .org, .gov, .edu, .com, .net) is included.

Block C9- Entity Name:

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

Blocks C10-13 – Entity’s Address:

- For entities registered with APHIS or CDC, please provide your entity’s complete address, exactly as it appears on your current certificate of registration.
- For non-registered entities, please provide the complete address of your entity.
- A P.O. Box address is not acceptable.
- Zip Code – please provide only the five digit zip code

Section D – Specimen (s) Containing Select Agent or Toxin Provided to Reference Laboratory

Block D1 – Date Specimen (s) shipped to reference laboratory:

- Enter the date that the specimens (s) were sent to the reference laboratory for identification/confirmation.

- Enter only one date in Block D1.

Block D2 – Number of Specimen (s) provided:

- Enter the number of samples that were produced and tested by the patient or animal. If more samples are anticipated see Block B13 for more information.

Block D3 – Case/patient ID#:

- If your entity assigns a unique, internal tracking number, specimen ID, or reference number to the specimen enter it in Block D3.

Block D4 –Sample Type:

When selecting clinical/diagnostic specimen or isolate, indicate where the sample type originated from: human, animal, or plant. Refer to the description of the terms listed below for indicating the type of sample analyzed and select only one sample type. If more than one type of specimen or sample was analyzed, please select the one specimen or sample type that was used to definitively identify the select agent or toxin.

- **Clinical/diagnostic specimen** – a sample (not the isolate) that was directly derived from an individual human, animal, or plant.
  - For samples originating from an animal (nonhuman) or plant, please provide the genus and species of the organism from which the sample originated (e.g., *Capra aegagrus*, *Bos taurus*, *Zea mays*, *Triticum aestivum*).
- **Isolate** – A purified culture obtained from a specimen or sample taken from a host or the environment.
  - For samples originating from an animal (nonhuman) or plant, please provide the genus and species of the organism from which the sample originated (e.g., *Capra aegagrus*, *Bos taurus*, *Zea mays*, *Triticum aestivum*).
- **Environmental sample** – a sample that was not directly derived from a human, animal, or plant (e.g., water sample, soil sample, air sample).
- **Food sample-** a sample that was directly derived from a food source, food container or food by-product.

Block D5 – Case/patient origin (zip code):

- Enter the zip code from which the patient or animal is located.
- If the zip code is unknown please enter the city and state.

Block D6 – Date notified by reference laboratory of the select agent identification:

- Enter the date that your facility was notified about the identification of the select agent or toxin was confirmed by the reference laboratory.
- Enter only one date in *Block D6*.

Block D7 – Select Agent or Toxin Identified by reference laboratory:

- List only one select agent or toxin.
- 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 D8 – Disposition of Select Agent or Toxins (check all that apply)*:*

Transferred:

- Check the "Transferred" box if all *or* part of the identified select agent or toxin was transferred to an entity that is currently registered for the select agent or toxin identified.
- Please provide the name of the entity, exactly as it appears on their current certificate of registration and the date that the transfer request was submitted to the APHIS or CDC for approval. If you do not know the entity's registered name, please contact their Responsible Official to obtain this information.
- 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.

Destroyed:

- Check the "Destroyed on site" box only if the *entire* identified select agent or toxin was destroyed on site.
- Indicate the method of destruction in the space provided. Below are the approved recognized methods that can be used:
  - Autoclave
  - Irradiation
  - Incineration
  - Chemical- Indicate the type of chemical was used.
  - Expended/Consumed
  - Commercial medical waste disposal company - please note that any confirmed select agent or toxin contained within a sample needs to be destroyed on site before releasing material to the commercial medical waste disposal company.
  - Other- If selected you must provide a description of the method.
- Provide the date on which the entire identified select agent or toxin was destroyed. *Do not* state that the identified select agent or toxin will be destroyed at a future date. If the identified select agent or toxin is to be destroyed at a future date you *must* check the "Retained" box and follow the procedures listed below under **Retained**.

Retained:

- Check the "Retained" box if all *or* part of the identified select agent or toxin was retained by your entity.
  - 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 will have to maintain records associated with any intra-entity transfers. Please refer to APHIS/CDC Form 1, Instructions, (D) Amending certification of registration to determine if an amendment to the entity's certificate of registration is needed.
- Please provide the name of the personnel who has responsibility over the use, storage, and disposition of the retained select agent or toxin.
- For information pertaining to "long-term storage" of select agents or toxins please refer to http://www.selectagents.gov/LongTermStorage.html.

Block D9 – Exposure outside Primary Containment:

- If there is any possibility that personnel handled the sample containing a select agent or toxin outside primary containment (e.g., working with culture on open bench), this box should be checked "Yes" and an APHIS/CDC Form 3 must be submitted. Additional guidance for submitting an APHIS/CDC Form 3 is available at: http://www.selectagents.gov/TheftLossRelease.html.

Block D10 – Additional Samples Anticipated:

- If there is possibility that the case/patient will produce additional samples, this box should be checked "Yes".
- All samples relating to the initial case will not require an additional APHIS/CDC Form 4. Please provide the disposition of all additional samples to either APHIS or CDC along with the accession number (provided to you by APHIS or CDC).

Block D11 – Comments/Notes:

- Please provide any information as it relates to the case. Attach additional sheets if necessary.

Signature

- For all entities, the individual named in Block A5 (RO, ARO, Facility Director or Laboratory Supervisor), must sign and date signature line.

Section 4B – Proficiency Testing

To report the identification of select agents or toxins contained in specimens presented for proficiency testing

Section A – Information for Laboratory That Received Proficiency Testing Sample(s)

Complete Form 4C within 90 calendar days of receipt of samples. For registered entities, the information provided on this form should match the information submitted for the entity's certificate of registration. 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/sponsor 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).

Block A1 – Name of individual completing the form:

- Please provide the full legal name of the personnel at your entity that is most familiar with the case(s) being reported on the APHIS/CDC Form 4 report (e.g. Principal Investigator; Microbiology Supervisor, Biosafety Officer, etc…).

Block A2 – Email address:

- Please provide the email address for the individual listed in *Block A1*.
- Please print or type clearly and ensure the email domain (e.g., .org, .gov, .edu, .com, .net) is included.

Block A3 – Telephone number of individual completing the form:

- Please provide the direct dial 10-digit telephone number for the individual listed in *Block A1*; including any extension.

Block A4- Registration Information:

- For entities registered with the APHIS or CDC Select Agent Program, please check the box labeled "Registered Entity (APHIS or CDC registration number)" and enter the registration number exactly as it appears on your entity's 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 your entity's current registration number, please contact your Responsible Official.
- For entities not registered with the APHIS or CDC Select Agent Program check the box titled "Clinical or diagnostic laboratory [non-registered entity (NRE)]" and enter your entity's NRE number. This number will be provided to your entity after the first APHIS/CDC Form 4 report is submitted.
  - If you do not know your entity's NRE number or have not received your NRE number, please contact APHIS or CDC to obtain the NRE number.

Block A5 – Responsible Official or Facility Director Name:

- For entities registered with APHIS or CDC, please provide the complete name of your 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 your entity's Facility or Laboratory Supervisor or the individual who supervises the laboratory that handled or manipulated the identified select agent or toxin (e.g., Microbiology Supervisor).
    - For the purposes of the APHIS/CDC Form 4, the term "full legal name" refers to an individual's first name, middle initial(s), and last name or surname, without use of nicknames.
    - For the purposes of the APHIS/CDC Form 4, the term "Facility or Laboratory Supervisor" 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 A6 – Telephone #:

- Please provide the direct dial 10-digit telephone number for the individual listed in *Block A5*; including any extension.

Block A7 – FAX #:

- Please provide the 10-digit Fax number for the individual listed in *Block A5*.

Block A8 – E-mail Address:

- Please provide the email address for the individual listed in *Block A5*.
- Please print or type clearly and ensure the email domain (e.g., .org, .gov, .edu, .com, .net) is included.

Block A9- Entity Name:

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

Blocks A10-13 – Entity's Address:

- For entities registered with APHIS or CDC, please provide your entity's complete address, exactly as it appears on your current certificate of registration.
- For non-registered entities, please provide the complete address of your entity.
- A P.O. Box address is not acceptable.
- Zip Code – please provide only the five digit zip code

Block A14 – Sponsor/Entity that you received select agent or toxin from:

- Please provide the following information for any entity that provided you with a proficiency sample for testing:
  - For entities registered with APHIS or CDC, please provide the name of their entity, their entity registration number (if known), and their entity contact information (telephone, e-mail, and address).
  - For non-registered entities, please provide the name of their entity, and their entity contact information (telephone, e-mail, and address).
  - Please do not abbreviate the entity name.

Section B – Select Agents and Toxins Identified from Proficiency Testing

Multiple select agents identified in proficiency testing samples can be entered into the table containing blocks B1-3.

Block B1 – Select Agent or Toxin Identified:

- List only one select agent or toxin.
- 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 or toxin.
- List the strain designation for the identified select agent (if known).

Block B2 – Date obtained from Sponsor:

- Please provide the date that the proficiency sample was received by your entity.

Block B3 – Date Identified:

- Please provide the date that the select agent or toxin within the proficiency sample was identified by your entity.

Block B4 – Disposition of Select Agent or Toxins (check all that apply)*:*

Transferred:

- Check the "Transferred" box if all *or* part of the identified select agent or toxin was transferred to an entity that is currently registered for the select agent or toxin identified.
- Please provide the name of the entity, exactly as it appears on their current certificate of registration and the date that the transfer request was submitted to the APHIS or CDC for approval. If you do not know the entity's registered name, please contact their Responsible Official to obtain this information.
- 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.

Destroyed:

- Check the "Destroyed on site" box only if the *entire* identified select agent or toxin was destroyed on site.
- Indicate the method of destruction in the space provided. Below are the approved recognized methods that can be used:
  - Autoclave
  - Irradiation
  - Incineration
  - Chemical- Indicate the type of chemical was used.
  - Expended/Consumed
  - Commercial medical waste disposal company - please note that any confirmed select agent or toxin contained within a sample needs to be destroyed on site before releasing material to the commercial medical waste disposal company.
  - Other- If selected you must provide a description of the method.
- Provide the date on which the entire identified select agent or toxin was destroyed. *Do not* state that the identified select agent or toxin will be destroyed at a future date. If the identified select agent or toxin is to be destroyed at a future date you *must* check the "Retained" box and follow the procedures listed below under **Retained**.

Retained:

- Check the "Retained" box if all *or* part of the identified select agent or toxin was retained by your entity.
  - 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 will have to maintain records associated with any intra-entity transfers. Please refer to APHIS/CDC Form 1, Instructions, (D) Amending certification of registration to determine if an amendment to the entity's certificate of registration is needed.
- Please provide the name of the personnel who has responsibility over the use, storage, and disposition of the retained select agent or toxin.
- For information pertaining to "long-term storage" of select agents or toxins please refer to http://www.selectagents.gov/LongTermStorage.html.

Block B5 – Exposure outside Primary Containment:

- If there is a possibility that personnel handled the sample containing a select agent or toxin outside primary containment (e.g., working with culture on open bench), this box should be checked "Yes" and an APHIS/CDC Form 3 must be submitted.

Additional guidance for submitting an APHIS/CDC Form 3 is available at: http://www.selectagents.gov/TheftLossRelease.html.

Signature

- For all entities, the individual named in Block A5 (RO, ARO, Facility Director or Laboratory Supervisor), must sign and date the signature line.

Section 4C –Federal Law Enforcement Seizure Report

To report the seizure of select agents or toxins
by a federal law enforcement agency

Reporting seized select agents or toxins by federal law enforcement agencies
Complete this section within seven calendar days after seizure and/or final disposition of select agents or toxins. Section 4D is *only* for use by Federal Law Enforcement Agencies who are reporting the seizure of a select agent or toxin. If you need assistance completing this section, please contact APHIS or CDC directly.

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
(301) 734-5960
(301) 734-3652 FAX
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
(404) 718-2000
(404) 718-2096 FAX
Email: cdcform4@cdc.gov

Document Change History

Version	Date	Summary of Changes
1.0	August 2009	Initial Release
1.1	December 2009	Additional clarification regarding *Blocks 29* and *30* for reference laboratories that are unable to obtain responses from the sample provider(s)
1.2	February 2011	Revised for APHIS/CDC Form 4 revision