ENVIRONMENTAL HEALTH AND SAFETY
University of Nebraska-Lincoln

Guidance Document

(Created 06/23)

REPORTING REQUIREMENTS FOR SELECT AGENTS AND TOXINS IDENTIFIED IN FIELD COLLECTED SAMPLES

Scope

This document provides guidance and instructions related to reporting requirements following the identification of Select Agents and Toxins listed in the Federal Select Agent Regulations (7 CFR 331, 42 CFR 73 and 9 CFR 121). This guidance document specifically applies to non-registered labs at UNL that are not conducting Clinical and/or Diagnostic activities but may still identify a select agent or toxin through various testing methods.

Introduction

The APHIS/CDC Form 4, Report of the Identification of a Select Agent or Toxin is used by clinical or diagnostic laboratories and other entities to notify the Federal Select Agent Program of the identification of a select agent or toxin as the result of diagnosis, verification, or proficiency testing and of the final disposition of that identified agent or toxin.

https://www.selectagents.gov/forms/docs/APHIS-CDC_Form_4A_AB_English_Fillable.pdf

For non-registered entities, Tier 1 select agents and toxins listed below are required to be immediately reported to Federal Select Agent Program and then submit APHIS/CDC Form 4 within 7 calendar days of identifications and within 90 days of receipt of the proficiency sample.

Tier 1 Select Agents and Toxins

HHS(CDC) Agents and Toxins

- *Bacillus cereus* Biovar *anthracis*
- Botulinum neurotoxins
- Botulinum neurotoxin producing species of *Clostridium*
- Ebola virus
- *Francisella tularensis*
- Marburg virus
- Variola major virus (Smallpox virus)
- Variola minor virus (Alastrim)
- *Yersinia pestis*

Overlap Agents (CDC or USDA have authority)

- *Bacillus anthracis*
- *Burkholderia mallei*
- *Burkholderia pseudomallei*

USDA Agents

- Foot-And-Mouth Disease virus
- Rinderpest virus

Genomic Material subject to the Select Agent Regulations

The following genetic elements, recombinant and/or synthetic nucleic acids, and recombinant and/or synthetic organisms are select agents (See section 3(c) of 42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331):

- Nucleic acids that can produce infectious forms of any of the select agent viruses.
- Recombinant and/or synthetic nucleic acids that encode for the functional form(s) of select agent toxins if the nucleic acids:
  - Can be expressed *in vivo* or *in vitro* or,
  - Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.
- Select agents and toxins that have been genetically modified.

Additional information is available in the Guidance on the Regulation of Select Agent and Toxin Nucleic Acids.

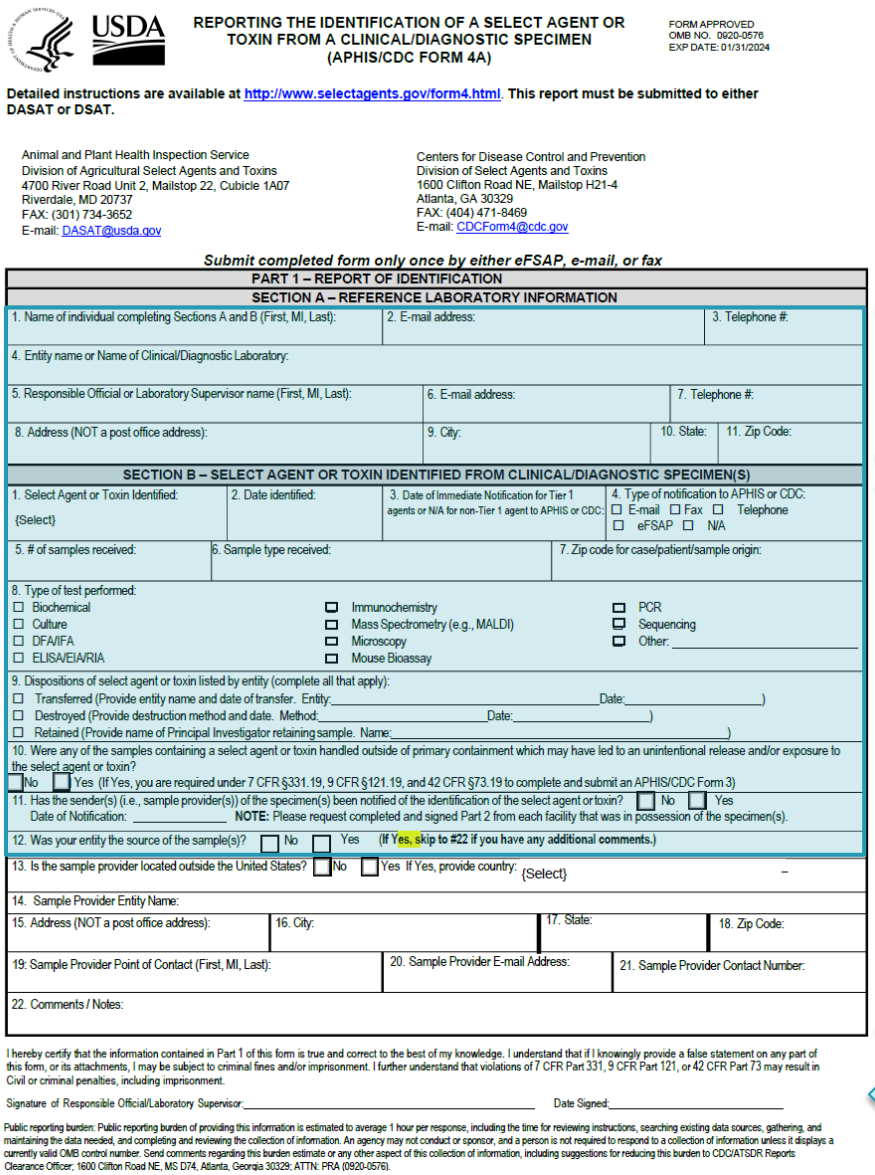
Procedures

Reporting of identification of Select Agents and Toxins is only required if the lab performing the sample analysis declares that they have “identified” the agent or toxin. According to CDC, the definition of what is meant by “identification” must be determined by the lab. It is important to note that “identification” is also implied if a scientific publication or presentation states that the agent or toxin was detected via an analysis method (e.g. PCR).

Once a select agent or toxin is declared “identified”, the clock starts and depending on the agent or toxin identified, there may be a requirement for immediate notification of the agency with oversight of the agent followed by the submission of Form 4 within 7 days of identification.

The lab must complete Form 4 regardless of the requirement for immediate notification of the agency with authority. Below is abbreviated guidance for completing Form 4. More detailed instructions on completing the form can be found at:
https://www.selectagents.gov/forms/docs/Form4_Instructions_AB_508.pdf
The form must be sent to the proper agency with authority as detailed in the listing of agents above.

Completing APHIS/CDC Form 4 - Parts A and B



USDA

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

FORM APPROVED
OMB NO. 0920-0576
EXP DATE: 01/31/2024

Detailed instructions are available at http://www.selectagents.gov/form4.html. This report must be submitted to either DASAT or DSAT.

Animal and Plant Health Inspection Service
Division of Agricultural Select Agents and Toxins
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: (301) 734-3652
E-mail: DASAT@usda.gov

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop H21-4
Atlanta, GA 30329
FAX: (404) 471-8469
E-mail: CDCForm4@cdc.gov

Submit completed form only once by either eFSAP, e-mail, or fax

PART 1 – REPORT OF IDENTIFICATION

SECTION A – REFERENCE LABORATORY INFORMATION

1. Name of individual completing Sections A and B (First, MI, Last): | 2. E-mail address: | 3. Telephone #:
4. Entity name or Name of Clinical/Diagnostic Laboratory:
5. Responsible Official or Laboratory Supervisor name (First, MI, Last): | 6. E-mail address: | 7. Telephone #:
8. Address (NOT a post office address): | 9. City: | 10. State: | 11. Zip Code:

SECTION B – SELECT AGENT OR TOXIN IDENTIFIED FROM CLINICAL/DIAGNOSTIC SPECIMEN(S)

1. Select Agent or Toxin Identified: {Select} | 2. Date identified: | 3. Date of Immediate Notification for Tier 1 agents or N/A for non-Tier 1 agent to APHIS or CDC: | 4. Type of notification to APHIS or CDC: ☐ E-mail ☐ Fax ☐ Telephone ☐ eFSAP ☐ N/A
5. # of samples received: | 6. Sample type received: | 7. Zip code for case/patient/sample origin:
8. Type of test performed:
☐ Biochemical ☐ Immunochemistry ☐ PCR
☐ Culture ☐ Mass Spectrometry (e.g., MALDI) ☐ Sequencing
☐ DFA/IFA ☐ Microscopy ☐ Other: _____
☐ ELISA/EIA/RIA ☐ Mouse Bioassay
9. Dispositions of select agent or toxin listed by entity (complete all that apply):
☐ Transferred (Provide entity name and date of transfer. Entity:_____Date:_____)
☐ Destroyed (Provide destruction method and date. Method:_____Date:_____)
☐ Retained (Provide name of Principal Investigator retaining sample. Name:_____)
10. Were any of the 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 select agent or toxin?
☐ No ☐ Yes (If Yes, you are required under 7 CFR §331.19, 9 CFR §121.19, and 42 CFR §73.19 to complete and submit an APHIS/CDC Form 3)
11. Has the sender(s) (i.e., sample provider(s)) of the specimen(s) been notified of the identification of the select agent or toxin? ☐ No ☐ Yes
Date of Notification: _____ **NOTE:** Please request completed and signed Part 2 from each facility that was in possession of the specimen(s).
12. Was your entity the source of the sample(s)? ☐ No ☐ Yes **(If Yes, skip to #22 if you have any additional comments.)**
13. Is the sample provider located outside the United States? ☐ No ☐ Yes If Yes, provide country: {Select}
14. Sample Provider Entity Name:
15. Address (NOT a post office address): | 16. City: | 17. State: | 18. Zip Code:
19: Sample Provider Point of Contact (First, MI, Last): | 20. Sample Provider E-mail Address: | 21. Sample Provider Contact Number:
22. Comments / Notes:

I hereby certify that the information contained in Part 1 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 Part 331, 9 CFR Part 121, or 42 CFR Part 73 may result in Civil or criminal penalties, including imprisonment.

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

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 30329; ATTN: PRA (0920-0576).

- Complete Boxes 1-11. Indicate the lab supervisor's name in box 5.

- Complete boxes 1, 2
- Box 3 only applies to Tier 1 Select Agents, if you have not identified a Tier 1 agent, mark "N/A" in this box. (*See list on page 2*)
- Complete boxes 5-8.
- For box 9, consider material that may contain viable agent.
  - *Some nucleic acids from select agents and toxins are regulated (see guidance on page 2).*
- Check "No" for boxes 10-11
- Check "Yes" for box 12.
- Boxes 13-21 can be skipped if 12 is "Yes".

Sign and Date form and send to DASAT@usda.gov or CDCForm4@cdc.gov and copy selectagents@unl.edu

(Created 6/23)