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

- 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

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