



Select Agent Program Workshop

November 2012

Agricultural Select Agent Program (USDA/APHIS)
CDC Select Agent Program (HHS/CDC)
Bioterrorism Risk Assessment Group (FBI/CJIS)



Panel Discussion with the Federal Select Agent Program Directors

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Keith Wiggins, DVM, Director, Plant Protection & Quarantine, APHIS,
USDA

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Agenda

- Selected topics for presentation by the Directors
- Open Discussion



Broader definition of Restricted Experiments (Section 13)

(a) An individual or entity may not conduct or possess products resulting from a restricted experiment with a select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary

(b)(1) Experiments that involve the deliberate transfer of, or selection for, a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture.

(b)(2) Experiments involving the deliberate formation of synthetic or recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight.



“Due Diligence” Requirements for Select Toxin Transfers (Section 16)

(l) a registered individual or entity transferring an amount of a HHS toxin otherwise excluded under the provisions of §73.3(d) must:

- (1) Transfer the amounts only after the transferor uses due diligence and documents that the recipient has a legitimate need (i.e. reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such toxins
- (2) Report to CDC if they detect a known or suspected violation of Federal law or become aware of suspicious activity related to a toxin listed in 73.3(d) of this part.



Responsible Official (Section 9)

An entity may designate one or more individuals to serve as an alternate responsible official who acts for the responsible official in his/her absence.

- Alternate Responsible Official should have knowledge of regulations.
- Should have the same authority as Responsible Official to carry out duties in the absence of the Responsible Official.
- Regulations do not require an entity appoint an Alternate Responsible Official.



Responsible Official (Section 9)

The Responsible Official should have a physical (and not merely a telephonic or audio/visual) presence at the entity to ensure that the entity is in compliance with the select agent regulations and be able to respond in a timely manner to onsite incidents involving select agents and toxins in accordance with the entity's incident response plan.

- Should be located in a place where they can reasonably meet the requirement above.
- No specific distance requirement provided in the regulation due to differing entity locations i.e., one entity may have multiple sites.



Generic Taxonomic Classification of Some Select Agents (Section 3 and 4)

...provided that the individual or entity can verify that the agent is within the exclusion category.

- Intent is to ensure that entities know whether biological agents in their possession are select agents or not.
- If have reasonable knowledge (based on testing done within your facility or by others) that the agent is not a select agent as defined by the exclusions, then do not have to treat as a select agent.
- If material is unknown or uncharacterized, then must treat as a select agent until can meet the exclusion category.
- No change in process for diagnostic laboratories, still excluded by select agent regulations.



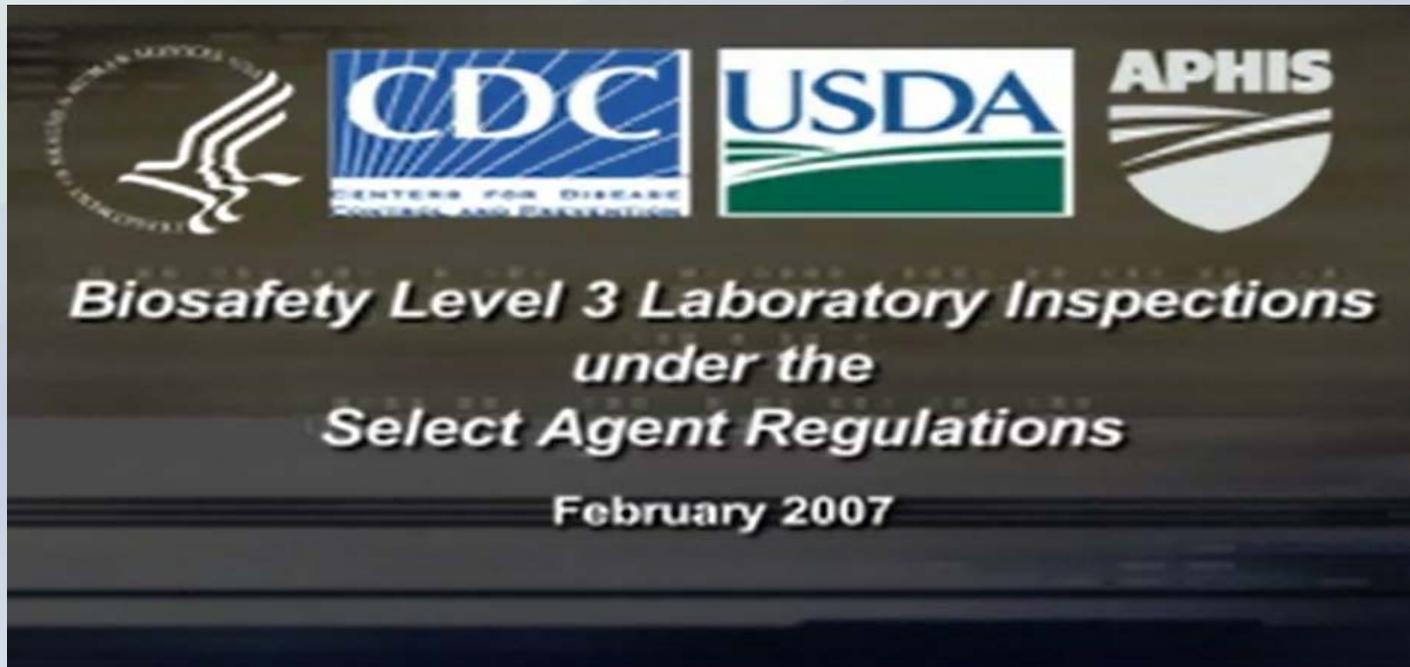
Shipping and Receiving (Section 16)

Transportation in commerce starts when the select agent(s) or toxin(s) are packaged for shipment and ready for receipt by a courier transporting select agent(s) or toxin(s) and ends when the package is received by the intended recipient who is an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins, following a security risk assessment by the Attorney General.

- Based on documented history of no issues with lost or stolen packages in shipping areas, provide relief to entities in registering these areas.
- Maintaining “lost in the crowd” concept allows for shipping areas to not be registered and shipping personnel to not need security risk assessment.
- If packages are identified as select agents or are packaged in the shipping areas, then registration and access approval would apply.



Facility Inspection Video



- [Facility Inspection Video \(Biosafety Level 3\)](#)
- [Facility Inspection Video \(Toxin\)](#)
- Submit input to lrsat@cdc.gov





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For more information, please contact the Select Agent Program

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Select Agent Program.

