

## **Questions and Answers: Biennial Review of Lists of Select Agents and Toxins**

### **When will the rules be effective?**

November 17, 2008

### **What revisions have been made to the overlap list and the HHS list?**

Based on the publication of the Final Rules, the following ten biological agents and toxins were moved from the overlap select agents and toxins section in 42 CFR Part 73.4 to the HHS select agents and toxins list in 42 CFR Part 73.3:

- Botulinum neurotoxins
- Botulinum neurotoxin producing species of *Clostridium*
- *Coxiella burnetii*
- *Francisella tularensis*
- *Coccidioides immitis*
- Eastern Equine Encephalitis virus
- T-2 toxin
- Staphylococcal enterotoxins
- Shigatoxin
- *Clostridium perfringens* epsilon toxin

### **Why did APHIS choose to no longer regulate these ten biological agents and toxins?**

APHIS convened an interagency working group that considered each of the agents and toxins using the criteria found in Subtitle B of the Public Health Service Act and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188). Based on the group's analysis, APHIS has determined that the select agents and toxins should be removed from the list because they are naturally found in the United States, do not pose a significant impact to animal health, and are not likely candidates for use in an agroterrorism event directed toward animal health.

### **How will this affect my registration if I am only registered for these select agents and toxins?**

APHIS and CDC will be working with those identified entities affected based on the changes to the lists.

### **Why was Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight segments (Reconstructed 1918 Influenza virus) not included in the HHS Final Rule published in the *Federal Register* on October 16, 2008?**

Reconstructed 1918 influenza virus was inadvertently omitted from the October 16, 2008 re-publication of the select agent list. A technical correction was published on October 30, 2008 in the *Federal Register* to add the Reconstructed 1918 Influenza virus.

### **What modifications were made to the list of plant pathogens?**

APHIS made the following changes regarding plant pathogens listed in 7 CFR Part 331.3:

The following plant pathogens were **removed** from the list in 7 CFR Part 331.3:

- *Candidatus Liberobacter africanus*

- *Candidatus Liberobacter asiaticus*

The following plant pathogens were **added** to the select agent plant pathogen list in 7 CFR Part 331.3:

- *Phoma glycinicola*, which causes red leaf blotch of soybean plants
- *Rathayibacter toxicus*, a bacterium that causes gumming disease in ryegrass
- *Xanthomonas oryzae* pv. *Oryzae*
- *Peronosclerospora sacchari*

*Other modifications to the Select Agent Plant Pathogen List:*

- APHIS has removed the pathovar designation (pv. *oryzicola*) from *Xanthomonas oryzae* and thus APHIS now regulates both pathovars of *Xanthomonas oryzae* (i.e., both *oryzicola* and *oryzae*).

#### **What other modifications were made to USDA List of select agents?**

The VS select agents were **renamed** in USDA list for 9 CFR Part 121:

- *Ehrlichia ruminantium* (Heartwater)
- *Mycoplasma capricolum* subspecies *capripneumoniae* (contagious caprine pleuropneumonia)
- *Mycoplasma mycoides* subspecies *mycoides* small colony (*MmmSC*) (contagious bovine pleuropneumonia)
- Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3
- Virulent Newcastle disease virus

#### **Why did AHIS change the listing of Newcastle disease virus (veologenic)?**

The World Organization for Animal Health (OIE) defines reportable Newcastle disease as an infection of birds caused by an avian paramyxovirus 1 virus possessing certain in vivo and/or molecular characteristics. To be consistent with OIE's guideline for reporting an outbreak of Newcastle disease, APHIS changed how the causative agent of this disease is listed in 9 CFR Part 121.3.