

Select Agent Regulations, proposed changes, October 3, 2011

Comment period ends December 2, 2011

This summary organizes the proposed select agent changes into five categories: (1) additions of select agents to the list; (2) removal of select agents from the list; (3) nominated for removal from the list but not proposed for removal; (4) taxonomic changes to select agents, only; and (5) Tier 1 subset of the select agent list. The proposed regulations do not set these select agents out in lists, except the tier 1 agents, so the entire proposal should be reviewed for context, and other important changes to the rules.

Additions of select agents to the list

Lujo virus
Chapare virus

Removal of six select agents

Herpes B Virus (Ceropithecine herpesvirus 1)
Coccidioides posadasii
Coccidioides immitis
South American Genotypes of Eastern Equine Encephalitis Virus (EEEV)
Flexal virus
Venezuelan Equine Encephalitis (VEEV) IF and II-IV / “certain subtypes”
(only 1AB and 1C should remain)

Nominated for removal but NOT removed

Bacillus anthracis (Pasteur strain)
Monkeypox
Rickettsia prowazekii
Rickettsia rickettsia
Yersina pestis
Brucella abortus, *Brucella melitensis*,
Brucella mallei/pseudomallei

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Taxonomic changes

“Inclusion” on list:

Tick-borne encephalitis virus
Far Eastern subtype
Siberian subtype
Kyasanur Forest disease virus
Omsk Hemorrhagic fever virus
Staphylococcal enterotoxins A,B, C,D and E (G,H and I – not added)
(replacing the currently listed broad term “*Staphylococcal* enterotoxins”)

Tier 1

HHS

- Ebola virus
- Francisella tularensis
- Marburg virus
- Variola major virus
- Variola minor virus
- Yersinia pestis
- Botulinum neurotoxin
- Toxin-producing strains of Clostridium botulinum

Overlap select agents

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

To review the text of the proposed regulations:

[CDC/HHS 76 Fed Reg 61206-61226 \(Oct 3, 2011\) PR](http://www.federalregister.gov/?page=1&format=pdf&res=2011-09-27&link_id=18232)
[APHIS/SDA 76 Fed Reg 61228-61224 \(Oct 3, 2011\) PR](http://www.federalregister.gov/?page=1&format=pdf&res=2011-09-27&link_id=18233)



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