

ALPHABETICAL LIST OF UPDATED SELECT AGENTS AND TOXINS

Proposed List, 28 August 2007

Except for exclusions listed in the Appendix, the viruses, bacteria, fungi, toxins, genetic elements, recombinant nucleic acids, and recombinant organisms specified in this list are HHS, USDA or HHS/USDA overlap select agents and toxins.

1. Abrin (HHS) [*See exclusion on last page*]
2. African horse sickness virus (USDA, Animal)
3. African swine fever virus (USDA, Animal)
4. Akabane virus (USDA, Animal)
5. Avian influenza virus (highly pathogenic) (USDA, Animal) [*See exclusions on last page*]
6. Bacillus anthracis (Overlap) [*See exclusions on last page*]
7. Bluetongue virus (exotic) (USDA, Animal)
8. Botulinum neurotoxin producing species of Clostridium (HHS)
9. Botulinum neurotoxins (HHS) [*See exclusion on last page*]
10. Bovine spongiform encephalopathy agent (USDA, Animal)
11. Brucella abortus (Overlap) [*See exclusions on last page*]
12. Brucella melitensis (Overlap)
13. Brucella suis (Overlap)
14. Burkholderia mallei (formerly Pseudomonas mallei) (Overlap)
15. Burkholderia pseudomallei (formerly Pseudomonas pseudomallei) (Overlap)
16. Camel pox virus (USDA, Animal)
17. Candidatus Liberobacter africanus (USDA, Plant)
18. Candidatus Liberobacter asiaticus (USDA, Plant)
19. Central European Tick-borne encephalitis virus (HHS)
20. Cercopithecine herpesvirus 1 (Herpes B virus) (HHS)
21. Classical swine fever virus (USDA, Animal)
22. Clostridium perfringens epsilon toxin (HHS) [*See exclusion on last page*]
23. Coccidioides immitis (HHS)
24. Coccidioides posadasii (HHS) [*See exclusion on last page*]
25. Conotoxins (HHS) [*See exclusions on last page*]
26. Cowdria ruminantium (Heartwater) (USDA, Animal)
27. Coxiella burnetii (HHS) [*See exclusion on last page*]
28. Crimean-Congo haemorrhagic fever virus (HHS)
29. Diacetoxyscirpenol (HHS) [*See exclusion on last page*]
30. Eastern Equine Encephalitis virus (HHS)
31. Ebola viruses (HHS)
32. Far Eastern Tick-borne encephalitis (HHS)
33. Flexal virus (HHS)
34. Foot-and-mouth disease virus (USDA, Animal)
35. Francisella tularensis (HHS) [*See exclusions on last page*]
36. Goat pox virus (USDA, Animal)
37. Guanarito, virus (HHS)
38. Hendra virus (Overlap)
39. Japanese encephalitis virus (USDA, Animal) [*See exclusion on last page*]
40. Junin virus (HHS) [*See exclusion on last page*]
41. Kyasanur Forest disease (HHS)
42. Lassa fever virus (HHS)
43. Lumpy skin disease virus (USDA, Animal)
44. Machupo virus (HHS)
45. Malignant catarrhal fever virus (exotic) (Alcelaphine herpesvirus type 1) (USDA, Animal)
46. Marburg virus (HHS)
47. Menangle virus (USDA, Animal)
48. Monkeypox virus (HHS)
49. Mycoplasma capricolum/ M. F38/M. mycoides capri (contagious caprine pleuropneumonia) (USDA, Animal)
50. Mycoplasma mycoides mycoides (contagious bovine pleuropneumonia) (USDA, Animal)

51. Newcastle disease virus (velogenic) (USDA, Animal)
52. Nipah virus (Overlap)
53. Omsk Hemorrhagic Fever (HHS)
54. Peronosclerospora philippinensis (USDA, Plant)
55. Peste des petits ruminants virus (USDA, Animal)
56. Ralstonia solanacearum, race 3, biovar 2 (USDA, Plant)
57. Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus) (HHS)
58. Ricin (HHS) [See exclusion on last page]
59. Rickettsia prowazekii (HHS)
60. Rickettsia rickettsii (HHS)
61. Rift Valley fever virus (Overlap) [See exclusion on last page]
62. Rinderpest virus (USDA, Animal)
63. Russian Spring and Summer encephalitis (HHS)
64. Sabia virus (HHS)
65. Saxitoxin (HHS) [See exclusion on last page]
66. Sclerophthora rayssiae var. zea (USDA, Plant)
67. Sheep pox virus (USDA, Animal)
68. Shiga-like ribosome inactivating proteins (HHS) [See exclusion on last page]
69. Shigatoxin (HHS) [See exclusion on last page]
70. Staphylococcal enterotoxins (HHS) [See exclusion on last page]
71. Swine vesicular disease virus (USDA, Animal)
72. Synchytrium endobioticum (USDA, Plant)
73. T-2 toxin (HHS) [See exclusion on last page]
74. Tetrodotoxin (HHS) [See exclusion on last page]
75. Variola major virus (Smallpox virus) (HHS)
76. Variola minor virus (Alastrim) (HHS)
77. Venezuelan Equine Encephalitis virus (Overlap) [See exclusions on last page]
78. Vesicular stomatitis virus (exotic) (USDA, Animal)
79. Xanthomonas oryzae pv. oryzicola (USDA, Plant)
80. Xylella fastidiosa (citrus variegated chlorosis strain) (USDA, Plant)
81. Yersinia pestis (HHS) [See exclusions on last page]

Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms:

1. Nucleic acids that can produce infectious forms of any of the select agent viruses . . .
2. Recombinant nucleic acids that encode for the functional forms of any toxin . . . if the nucleic acids:
 - (i) Can be expressed *in vivo* or *in vitro*; or
 - (ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.
3. Select agents and toxins . . . that have been genetically modified.

(The removed phrases, “. . .” refer to the Select Agent list)

APPENDIX

Exclusions:

1. Any select agent or toxin that is in its naturally occurring environment provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.
2. Non-viable select agent organisms or nonfunctional toxins.
3. Fixed tissues that bear or contain select agents or toxins.
4. Genetic elements or sub-units of agents or toxins, if the genetic elements or sub-units are not capable of causing disease.
5. The vaccine strain of Junin virus (Candid #1).
6. The vaccine strain of Rift Valley fever virus (MP-12).
7. Venezuelan Equine encephalitis virus vaccine strain TC-83.
8. Venezuelan equine encephalitis (VEE) virus vaccine candidate strain V3526.
9. Japanese encephalitis virus, SA14-14-2 strain.
10. *Coccidioides posadasii* Δ chs5 strain.
11. *Coccidioides posadasii* Δ cts2/ Δ ard1/ Δ cts3 strain.
12. *Coxiella burnetii* Phase II, Nine Mile Strain, plaque purified clone 4.
13. *Brucella abortus* strain RB51 (vaccine strain).
14. *Brucella abortus* Strain 19
15. *Yersinia pestis*:
 - strains which are Pgm⁻ due to a deletion of a 102-kb region of the chromosome termed the *pgm* locus (i.e., Δ *pgm*). Examples are *Y. pestis* strain E.V. or various substrains such as EV 76.
 - strains (e.g., Tjiwidej S and CDC A1122) devoid of the 75 kb low-calcium response (Lcr) virulence plasmid.
16. *Bacillus anthracis*
 - strains devoid of both plasmids pX01 and pX02.
 - strains devoid of the plasmid pX02 (e.g., *Bacillus anthracis* Sterne, pX01+pX02-).
17. *Francisella tularensis*:
 - subspecies *novicida* (also referred to as *Francisella novicida*) strain, Utah 112 (ATCC 15482).
 - subspecies *holartica* LVS (live vaccine strain; includes NDBR 101 lots, TSI-GSD lots, and ATCC 29684).
 - ATCC 6223 (also known as strain B38).
18. Avian Influenza virus: Several recombinant reference vaccine strains of highly pathogenic subtypes have been excluded based on results from in-vitro and in-vivo studies indicating that these strains were not pathogenic in avian species. The data requirements necessary for exclusion consideration under 9 CFR 121.3 (g) can be downloaded from http://www.aphis.usda.gov/programs/ag_selectagent/template-for-ai.pdf. Specific reference vaccine strains have not been listed here for proprietary reasons.
19. The following toxins (in the purified form or in combinations of pure and impure forms) if the aggregate amount under the control of a principal investigator does not, at any time, exceed the amount specified:
 - 100 mg of Abrin
 - 0.5 mg of Botulinum neurotoxins
 - 100 mg of *Clostridium perfringens* epsilon toxin
 - 100 mg of Conotoxins
 - Conotoxins specifically **excluded** are: the class of sodium channel antagonist μ -conotoxins, including GIIIA; the class of calcium channel antagonist ω -conotoxins, including GVIA, GVII, MVIIA, MVIIIC, and their analogs or synthetic derivatives; the class of NMDA-antagonist conantokins, including con-G, con-R, con-T and their analogs or synthetic derivatives; and the putative neurotensin agonist, contulakin-G and its synthetic derivatives.
 - 1,000 mg of Diacetoxyscirpenol
 - 100 mg of Ricin
 - 100 mg of Saxitoxin
 - 100 mg of Shigatoxin
 - 100 mg of Shiga-like ribosome inactivating proteins
 - 5 mg of Staphylococcal enterotoxins
 - 100 mg of Tetrodotoxin
 - 1,000 mg of T-2 toxin