

APPENDIX A: HHS and USDA Select Agents & Toxins

The Federal Select Agent Program is jointly comprised of the Centers for Disease Control and Prevention/Division of Select Agents and Toxins and the Animal and Plant Health Inspection Services/Agriculture Select Agent Services to regulate the possession, use, and transfer of biological agents listed in 7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73 (select agents and toxins). The FSAP administers the select agents and toxins regulations in close coordination with the Federal Bureau of Investigation's Criminal Justice Information Services (CJIS).

For biological agents and toxins determined by HHS to have the potential to pose a severe threat to public health and safety (select agents and toxins), the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 262a) directs the promulgation of regulations to establish and enforce safety procedures for the possession and use of select agents and toxins, including measures to ensure proper training and appropriate skills to handle such agents and toxins. 42 U.S.C. § 262a(c)

For biological agents and toxins determined by USDA to have the potential to pose a severe threat to animal health or animal products (select agents and toxins), the Agricultural Bioterrorism Act of 2002 (7 U.S.C. 8401) directs the promulgation of regulations to establish and enforce safety procedures for the possession and use of such select agents and toxins, including measures to ensure proper training and appropriate skills to handle such select agents and toxins. (7 U.S.C. 8401(c))

If you have an intention to engage in research involving any of the Select Agents and Toxin below, please contact IUEHS Biosafety for your respective campus for initial instructions.

HHS SELECT AGENTS AND TOXINS

Abrin
Bacillus cereus Biovar anthracis*
Botulinum neurotoxins*
Botulinum neurotoxin producing species of *Clostridium**
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7)

Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus¹
Ebola virus*
*Francisella tularensis**
Lassa fever virus
Lujovirus
Marburg virus*
Monkeypox virus¹
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)
Ricin
Rickettsia prowazekii
SARS-associated coronavirus (SARS-CoV) Saxitoxin

South American Haemorrhagic Fever

viruses:
Chapare
Guanarito
Junin
Machupo
Sabia
Staphylococcal enterotoxins A,B,C,D,E subtypes
T-2 toxin
Tetrodotoxin
Tick-borne encephalitis complex (flavi)
viruses:
Far Eastern subtype
Siberian subtype
Kyasanur Forest disease virus
Omsk hemorrhagic fever virus
Variola major virus (Smallpox virus)*
Variola minor virus (Alastrim)*
*Yersinia pestis**

OVERLAP SELECT AGENTS AND TOXINS

Bacillus anthracis *
Bacillus anthracis Pasteur strain
Brucella abortus
Brucella melitensis
Brucella suis

*Burkholderia mallei**
*Burkholderia pseudomallei**
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan equine encephalitis virus¹

USDA SELECT AGENTS AND TOXINS

African horse sickness virus
African swine fever virus Avian
influenza virus¹
Classical swine fever virus
Foot-and-mouth disease virus*
Goat pox virus
Lumpy skin disease virus
*Mycoplasma capricolum*¹
*Mycoplasma mycoides*¹

Newcastle disease virus^{1, 2}
Peste des petits ruminants virus
Rinderpest virus*
Sheep pox virus
Swine vesicular disease virus

USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS

Peronosclerospora philippinensis
(*Peronosclerospora sacchari*)
Phoma glycinicola (formerly *Pyrenochaeta glycinis*)
Ralstonia solanacearum
Rathayibacter toxicus
Sclerophthora ayssiae
Synchytrium endobioticum
Xanthomonas oryzae

*Denotes Tier 1 Agent

GENETIC ELEMENTS

Nucleic acids that can produce infectious forms of any of the select agent viruses.
Nucleic acids that encode for the functional forms of any select agent toxin
Genetically modified select agents and toxins

1 C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins α -M1 and α -G1 (shown above) as well as α -G1A, Ac1.1a, α -Cn1A, α -Cn1B; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; "Des X" = "an amino acid does not have to be present at this position." For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

2 A virulent Newcastle disease virus (avian paramyxovirus serotype 2) has an intracerebral pathogenicity index in day-old chicks (*Gallus gallus*) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

3 Select agents that meet any of the following criteria are excluded from the requirements of this part: Any low pathogenic strains of avian influenza virus, South American genotype of eastern equine encephalitis virus, west African clade of Monkeypox viruses, any strain of Newcastle disease virus which does not meet the criteria for virulent Newcastle disease virus, all subspecies *Mycoplasma capricolum* except subspecies *capripneumoniae* (contagious caprine pleuropneumonia), all subspecies *Mycoplasma mycoides* except subspecies *mycoides* small colony (Mmm SC) (contagious bovine pleuropneumonia), and any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, provided that the individual or entity can verify that the agent is within the exclusion category. 9/10/13