Chapter 14

Select Agents

The CDC and USDA have designated certain biological agents and toxins as Select Agents. A Select Agent has the potential to pose a severe threat to public, animal or plant health, or to animal or plant products. These materials require federal registration and approval to receive, posses, or transfer them.

The CDC Department of Health and Human Services (HHS) regulates select agents targeting humans, the United States Department of Agriculture (USDA) regulates select agents targeting animals, and the USDA Plant Protection and Quarantine (PPQ) regulates select agents targeting plants. Before possessing, using, or receiving select agents, the University and Principal Investigator must register with the CDC and/or the USDA to receive authorization for each individual that will access the select agents. Registration includes background checks for individuals seeking access to the agents, security plans, and inventories. For more information on Select Agents please visit the National Select Agent Registry website.

If you wish to begin work with a select agent contact EHS to begin the registration process.

To register a new select agent worker in your lab first contact EHS and when instructed follow the worker registration process here: [http://www.ehs.unc.edu/ih/biological/agents.shtml](http://www.ehs.unc.edu/ih/biological/agents.shtml)

If you want to transfer a select agent, within the University or to another entity, contact EHS to request a transfer approval.

If you discover a select agent in your lab that has not been registered, contact EHS immediately.

**HHS Select Agents and Toxins**

- Abrin
- Botulinum neurotoxins*
- Botulinum neurotoxin producing species of *Clostridium* *
- Conotoxins (short, paralytic alpha conotoxins containing the following sequence X₁CCX₂PACGX₃X₄X₅X₆CX₇)³
- *Coxiella burnetii*
- Crimean-Congo haemorrhagic fever virus
- Diacetoxyxirinol
- Eastern Equine Encephalitis virus³
- Ebola virus*
- *Francisella tularensis* *
- Lassa fever virus
- Lujo virus
- Marburg virus*
- Monkeypox virus³
- Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed1918 Influenza virus)
- Ricin
- *Rickettsia prowazekii*
- SARS-associated coronavirus (SARS-CoV)
- Saxitoxin
- South American Haemorrhagic Fever viruses: Guanarito, Junin, Machupo, Sabia, Chapare
- 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 disease virus
- Variola major virus (Smallpox virus)*
- Variola minor virus (Alastrim)*
- *Yersinia pestis*

**OVERLAP Select Agents and Toxins**

- *Bacillus anthracis*
- *Bacillus anthracis* Pasteur strain
- Bacillus abortus
- *Brucella melitensis*
- *Brucella suis*
- *Burkholderia mallei (formerly Pseudomonas mallei)*
- *Burkholderia pseudomallei (formerly Pseudomonas pseudomallei)*
- Hendra virus
- Nipah virus
- Rift Valley fever virus
- Venezuelan Equine Encephalitis virus

**USDA Select Agents and Toxins**

- African horse sickness virus
- African swine fever virus
- Avian influenza virus (highly pathogenic)
- Classical swine fever virus
- Foot-and-mouth disease virus*
- Goat pox virus
- Lumpy skin disease virus
- *Mycoplasma capricolum*
- *Mycoplasma mycoides*
- Newcastle disease virus
- 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 rayssiae
• Synchytrium endobioticum
• Xanthomonas oryzae

* Denotes Tier 1 Agent

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-MI and α-GI (shown above) as well as α-GIA, Ac1.1a, α-CnIA, α-CnIB; 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), any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, and Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3, provided that the individual or entity can verify that the agent is within the exclusion category.