

## 12 Select Agents

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Select Agents are materials that have been identified by the U.S. Government as agents that have potential use in biological terrorism or warfare. The Department of Health and Human Services (DHHS), through the U.S. Centers for Disease Control and Prevention (CDC), and the Animal Plant Health Inspection Service (APHIS), through the United States Department of Agriculture (USDA) regulate Select Agents in the United States and its territories. Each agency has developed and will maintain a list of Select Agents, including human, animal and plant pathogens, high-risk toxins of biological origin, and prions. The current list of Select Agents is provided below and can be accessed at the CDC and USDA web sites (<http://www.cdc.gov/od/sap/faq.htm> and <http://www.aphis.usda.gov/vs/ncie/bta.html>)

### 12.1 List of Select Agents

The list of select agents below is current as of March 2004. The most current list can be found at <http://www.cdc.gov/od/sap/docs/salist.pdf>.

#### HHS NON-OVERLAP SELECT AGENTS AND TOXINS

- Crimean-Congo haemorrhagic fever virus
- Coccidioides posadasii*
- Ebola viruses
- Cercopithecine herpesvirus 1 (Herpes B virus)
- Lassa fever virus
- Marburg virus
- Monkeypox virus
- Rickettsia prowazekii*
- Rickettsia rickettsii*
- South American haemorrhagic fever viruses
  - o Junin
  - o Machupo
  - o Sabia
  - o Flexal
  - o Guanarito
- Tick-borne encephalitis complex (flavi) viruses
  - o Central European tick-borne encephalitis
  - o Far Eastern tick-borne encephalitis
  - o Russian spring and summer encephalitis
  - o Kyasanur forest disease
  - o Omsk hemorrhagic fever
- Variola major virus (Smallpox virus)
- Variola minor virus (Alastrim)
- Yersinia pestis*
- Abrin
- Conotoxins
- Diacetoxyscirpenol
- Ricin
- Saxitoxin
- Shiga-like ribosome inactivating proteins
- Tetrodotoxin

#### HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS/ SELECT AGENTS (OVERLAP AGENTS)

- Bacillus anthracis*
- Brucella abortus*
- Brucella melitensis*
- Brucella suis* *Burkholderia mallei* (formerly *Pseudomonas mallet*)
- Burkholderia pseudomallei* (formerly *Pseudomonas pseudomallei*)
- Botulinum neurotoxin producing species of *Clostridium*
- Coccidioides immitis*
- Coxiella burnetii*
- Eastern equine encephalitis virus Hendra virus
- Francisella tularensis*
- Nipah Virus
- Rift Valley fever virus
- Venezuelan equine encephalitis virus
- Botulinum neurotoxin
- Clostridium perfringens* epsilon toxin
- Shigatoxin
- Staphylococcal enterotoxin
- T-2 toxin

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**USDA HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS (NON-OVERLAP AGENTS AND TOXINS)**

- Akabane virus
- African swine fever virus
- African horse sickness virus
- Avian influenza virus (highly pathogenic)
- Blue tongue virus (Exotic)
- Bovine spongiform encephalopathy agent
- Camel pox virus
- Classical swine fever virus
- Cowdria *ruminantium* (Heartwater)
- Foot and mouth disease virus
- Goat pox virus
- Lumpy skin disease virus
- Japanese encephalitis virus
- Malignant catarrhal fever virus (Exotic)
- Menangle virus
- Mycoplasma capricoluml M.F38/M. mycoides capri
- Mycoplasma mycoides mycoides
- Newcastle disease virus (VVND)
- Peste Des Petits Ruminants virus
- Rinderpest virus
- Sheep pox virus
- Swine vesicular disease virus
- Vesicular stomatitis virus (Exotic)

**LISTED PLANT PATHOGENS**

- Liberobacter africanus*
- Liberobacter asiaticus*
- Peronosclerospora philippinensis*
- Phakopsora pachyrhizi*
- Plum Pox Potyvirus
- Ralstonia solanacearum* race 3, biovar 2
- Schlerophthora rayssiae* var *zeae*
- Synchytrium endobioticum*
- Xanthomonas oryzae*
- Xylella fastidiosa* (citrus variegated chlorosis strain)

**12.2 Toxin Amounts Permissible Per Principal Investigator**

Regulated toxins of biological origin (see table below) can be ordered, used, or maintained in the laboratory provided the total quantity per PI, for all areas under the PI's control, does not exceed the limits posted in the table below for each toxin. Toxins ordered used, or in the possession of a Yale Principal Investigator cannot exceed the current published maximum allowable exempt quantities (see below) unless both Yale University and the Principal Investigator are registered with the applicable governmental institution.

If the quantity of a toxin under one PI's control exceeds the "OEHS Watch List Quantity" please notify OEHS Biosafety, or the Safety Advisor for the area, to registration as a potential Select Agent Toxin user. OEHS will then inspect your toxin inventory more frequently to check against the maximum allowable exempt quantity.

The list of select agents below is current as of March 2004. The most current list of "Maximum Allowable Quantities" can be found at <http://www.cdc.gov/od/sap/toxinamt.htm>. For current OEHS Watch List Quantities please contact the Biosafety Office at 785-3550 or the area Safety Advisor.

### Toxin Amounts Permissible per Principal Investigator

HHS Toxins	Maximum Allowable Exempt Quantity	OEHS Watch List Quantity	Agency(ies)
Abrin	100 mg	50 mg	HHS
Botulinum neurotoxins	0.5 mg	0.25 mg	HHS/USDA
Clostridium perfringens epsilon toxin	100 mg	50 mg	HHS/USDA
Conotoxin	100 mg	50 mg	HHS
Diacetoxyscirpenol (DAS)	1000 mg	500 mg	HHS
Ricin	100 mg	50 mg	HHS
Saxitoxin	100 mg	50 mg	HHS
Shiga-like ribosome inactivating proteins	100 mg	50 mg	HHS
Shigatoxin	100 mg	50 mg	HHS/USDA
Staphylococcal enterotoxins	5.0 mg	2.5 mg	HHS/USDA
Tetrodotoxin	100 mg	50 mg	HHS
T-2 toxin	1000 mg	500 mg	HHS/USDA

### 12.3 Possession, Use, or Transfer of Select Agents

In order to possess, use, send or receive Select Agents, an institution and each individual who will have access to the Select Agent(s) must first satisfy the following requirements. Each requirement must be approved prior to possession, use or transfer.

Register with the applicable U.S. Governing bodies (CDC, APHIS, and/or USDA) through the Yale Office of Environmental Health & Safety (OEHS).

- ◆ Register with the State of Connecticut Department of Public Health through Yale OEHS. This is required for those Select Agents that are human pathogens.
- ◆ Official authorization granted for each individual requesting access to Select Agents provided by the U.S. Federal Bureau of Investigation, the applicable U.S. Governing body, and Yale University.

Please note that violations of Select Agent rules and regulations can lead to severe criminal or civil penalties. Imprisonment and fines up to 250,000.00 may be levied against individuals who are found in violation of these laws.

### 12.4 Registration of Possession, Use or Transfer of Select Agents.

All activity involving Select Agents must be registered with the Yale Office of Environmental Health & Safety prior to initiation. Please contact the Biosafety Office with Yale OEHS or contact your OEHS Safety Advisor at 785-3550 to initiate a registration for your proposed Select Agent activity. The following bullets summarize the Select Agent registration and compliance pathway at Yale University.

- ◆ Notify Yale OEHS of your intent to possess, use or transfer Select Agents.
- ◆ Complete an update of your Yale OEHS FORM 01 Registration with the new agents. (If the Select Agent is a human pathogen, Yale will help you also register with the State of CT Dept. of Public Health).
- ◆ Complete Yale Select Agent Patriot Act Declaration Form
- ◆ Complete FBI Form FD961 and file with Yale OEHS for registration with applicable federal entity
- ◆ Complete 2 sets of FBI fingerprint cards for initiation of background investigation check

- ◆ Complete all Yale OEHS applicable training programs (Biosafety, Bloodborne Pathogens, Laboratory Safety, Biosafety Level 3, Select Agent Biosecurity, and Shipping/Transport of Hazardous Biological Agents).
- ◆ Complete a Yale OEHS Request to Use Infectious Agents Form(s) and Researcher Experience Form.
- ◆ Complete the Yale OEHS researcher experience requirements (for BL2+ or BL3 agents)
- ◆ Satisfactory completion of OEHS laboratory inspection of proposed work practices, safety equipment, and facility for Yale, CDC/NIH, and Select Agent regulatory requirements. (Safety and Security)
- ◆ Receive final approval and authorization from Yale OEHS, FBI, and the applicable governing body that you and each individual requesting access to Select Agents, the proposed storage location for Select Agents, and the Select Agent research areas have been cleared. (This is provided in the form of an approval letter from the Yale Biological Safety Committee).

Your laboratory will be subject to Yale and federal inspection or audit prior to initiation of work and at any time during your possession of Select Agents.

### **12.5 Discovery of Select Agents or Unknown Samples**

Please notify OEHS immediately if:

- ◆ You identify any Select Agent pathogen or toxin listed on the current federal list that was not previously registered by your lab
- ◆ You discover a toxin not previously reported by your laboratory in excess of either the Yale Watch List or the federal maximum allowable quantities listed above.
- ◆ You discover any unknown materials in your laboratory for assistance with identification.

These discoveries must be reported to the applicable governmental institution.

### **12.6 Intrafacility Transfer of Select Agents**

Select agent pathogens and toxins may not be transferred outside of, to, or within Yale University unless OEHS and federal approval has been granted. An intrafacility transfer is defined as the transfer of a Select Agent from one OEHS and federally registered Select Agent lab to a similarly registered laboratory. Select Agents may not be transferred to a laboratory that is not registered with OEHS and the applicable governmental institution. Once approved, intrafacility transfers will be overseen by OEHS. Please contact the OEHS Biosafety Office for additional information.

### **12.7 Destruction of Select Agents or Unknown Samples**

Select Agent pathogens or toxins may not be destroyed until Yale OEHS and the applicable government institution has provided approval for the destruction. Once approval has been granted for the destruction of Select Agents, Yale OEHS will officially assume possession of the material and record its destruction. The governing institution will alert Yale if witnesses are required.

If you have any questions regarding the Yale of Federal Select Agent process, please don't hesitate to contact the OEHS Biosafety Office or your OEHS Safety Advisor at 785-3550. In addition, some Select Agents web sites are located below.

Additional Information on the Select Agent Program may be found at the following web sites:

Yale OEHS: <http://www.yale.edu/oehs/>

Centers for Disease Control and Prevention: <http://www.cdc.gov/od/sap/>

Notice of Exclusion for attenuated strains SAs: <http://www.cdc.gov/od/sap/exclusion.htm>

Animal Plant Health Inspection Service: <http://www.aphis.usda.gov/vs/ncie/bta.html>

United States Department of Agriculture: <http://www.usda.gov/>

FBI Form FD961: <http://www.fbi.gov/terrorinfo/fd-961.pdf>