

CDC SELECT AGENTS & USDA HIGH CONSEQUENCE AGENTS

BACKGROUND

On June 12, 2002, President Bush signed the "Public Health Security and Bioterrorism Preparedness Response Act of 2002" (Public Law 107-188). The law is designed to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. Section 202(a) of the Law requires that all persons possessing biological agents or toxins deemed a threat to public health to notify the Secretary, Department of Health and Human Services (DHHS). Section 213(b) of the Law requires all persons possessing biological agents or toxins deemed a threat to animal or plant health and to animal or plant products notify the Secretary, United States Department of Agriculture (USDA).

DHHS and the USDA published regulations detailing the requirements for facilities or entities that possess, use, or transfer select agents and toxins. The DHHS regulation 42 CFR 73, and the USDA regulations 9 CFR 121 and 7 CFR 331 were published in the December 13, 2002, edition of the Federal Register. The Centers for Disease Control (CDC) has been designated as the responsible agency for DHHS and the Animal and Plant Health Inspection Service (APHIS) has been designated as the responsible agency for the USDA. The new USDA and DHHS regulations requires that entities **possessing** biological agents that are listed as CDC select agents, CDC/USDA overlap agents or USDA high consequence animal and plant pathogens and toxins must register with CDC and/or USDA-APHIS and demonstrate compliance with specific safety and security standards for handling these agents.

In the performance of scientific research, the NCI-Frederick may have occasion to use Select Agents as defined by 42 CFR §73, or High Consequence Animal or Plant Pathogens and Toxins as defined by 9 CFR §121 and 7 CFR §331. It is the policy of the NCI-Frederick to ensure that receipt, usage, storage, shipping and disposal of this material are performed in compliance with all applicable federal and state regulations and laws.

The NCI-Frederick Institutional Biosafety Committee (IBC), P&P #706, reviews and approves research with biologicals that is conducted or sponsored by NCI-Frederick. The IBC is responsible for main-training, maintains registries of projects, which use pathogens or recombinant DNA/RNA. These registries allow EHS and IBC to inform CDC or USDA-APHIS of those research projects at NCI-Frederick that will be affected by the DHHS or USDA regulations. Registration of biological research protects researchers from non-compliance with applicable regulations and legitimizes their possession of regulated biological agents and toxins. This is especially critical since The USA Patriot Act of 2001, amends Section 175 of the U.S. Criminal Code to allow prosecution of individuals who knowingly possess any biological agent, toxin, or delivery system of a type or in a quantity not reasonably justified by prophylactic, preventive, bona fide research or other peaceful purpose.

REQUESTING A SELECT AGENT

An NCI-Frederick employee requesting to obtain a “Select Agent” or USDA High Consequence Animal or Plant agents (listed on the following page) as defined by the applicable regulation shall contact the NCI-Frederick Biological Safety Officer who serves as the NCI-Frederick Responsible Official. Additional requirements for that receipt, usage, storage, transfer and disposal of regulated biological agents will be discussed at that time. Additional requirements for receiving a Select Agent may include:

- Registration of proposed work with EHS, IBC and the CDC or USDA-APHIS.
- Inspection of laboratory facilities.
- Review of research protocols and SOPs.
- Method of storage and disposal of material when the work has been completed.
- Review of training records of staff who will be involved with the project. This review will ensure proficiency of individuals working with select agents.
- Method of securing the agent.
- Enrollment in medical surveillance programs, as required.
- **FBI Security Risk Assessment DHHS and clearances for individuals having access to regulated agents.**

More information is available on this topic in the EHS Compliance Manual Chapter D-4 or by contacting the Biological Safety Officer at X1451.

HHS AND USDA SELECT AGENTS AND TOXINS
7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS SELECT AGENTS AND TOXINS

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

OVERLAP SELECT AGENTS AND TOXINS

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

USDA SELECT AGENTS AND TOXINS

African horse sickness virus
African swine fever virus
Akabane virus
Avian influenza virus (highly pathogenic)
Bluetongue virus (Exotic)
Bovine spongiform encephalopathy agent
Camel pox virus
Classical swine fever virus
Cowdria ruminantium (Heartwater)
Foot-and-mouth disease virus
Goat pox virus
Japanese encephalitis virus
Lumpy skin disease virus
Malignant catarrhal fever virus
 (Alcelaphine herpesvirus type 1)
Menangle virus
Mycoplasma capricolum/ M.F38/*M. mycoides* Capri
 (contagious caprine pleuropneumonia)
Mycoplasma mycoides mycoides
 (contagious bovine pleuropneumonia)
Newcastle disease virus (velogenic)
Peste des petits ruminants virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Vesicular stomatitis virus (Exotic)

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

Candidatus Liberobacter africanus
Candidatus Liberobacter asiaticus
Peronosclerospora philippinensis
Ralstonia solanacearum race 3, biovar 2
Schlerophthora rayssiae var *zea*
Synchytrium endobioticum
Xanthomonas oryzae pv. *oryzicola*
Xylella fastidiosa (citrus variegated chlorosis strain)