

# Safetygram

NCI-Frederick

ISM-185

Laboratory Personnel

August 2013

## 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, are 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, must 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 require 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) reviews and approves research with biologicals that are conducted or sponsored by NCI-Frederick. The IBC is responsible for training and 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

A 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 the 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 C-23 or by contacting the Biological Safety Officer at 301-846-1451.