Important Information for Researchers using Certain Toxins and/or Certain Animal or Plant Pathogens (“select agents”)

General Questions Concerning Select Agents

1. What is the Public Health Security and Bioterrorism Preparedness and Response Act of 2002?

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 (HHS). Section 213(b) of 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). These regulated toxins and biological agents are called “select agents.”

2. What is the USA PATRIOT Act and how does it relate to the Bioterrorism Preparedness and Response Act?

The USA PATRIOT Act is a law signed by President Bush on October 26, 2001, that places restrictions on persons who possess select agents and provides criminal penalties for possession of such agents that cannot be justified for specified peaceful purposes. More information on the PATRIOT Act can be found at: http://www.cdc.gov/od/sap/resource.htm.

3. What is a select agent or toxin?

The list of select agents continues to change. A listing of all select agents and toxins in the select agent regulation (42 CFR 73) is available at: http://www.cdc.gov/od/sap/resource.htm.

The select agent list includes “High Consequence Livestock Pathogens and Toxins” that the US Department of Agriculture (USDA) considers having the potential to pose a severe threat to animal or plant health, or to animal or plant products. The plant pathogens listed by USDA have been deemed a threat to plant health.
or products. The list also includes biological agents and toxins deemed by the Department of Health and Human Services to be a threat to public health.

4. What do I need to do if I want to work with select agents at NC State?

The USA PATRIOT Act requires registration prior to possession of select agents. Contact the NC State Biosafety Officer (Bruce_Macdonald@ncsu.edu, 515-6858) prior to accepting or procuring select agents. The Biosafety Officer will assist you with the approval process.

5. How long does it take to receive approval to work with select agents?

The approval process is rigorous and lengthy. Allow at least 3 months for approval. Application material must be submitted by the University Biosafety Officer, to the Centers for Disease Control (CDC). The CDC submits information to the Federal Bureau of Investigation. All users of select agents will be fingerprinted and the US Attorney General will conduct a background check. You may not possess select agents until approval is granted by federal regulators.

6. How do I comply with all of the select agent rules and regulations?

Information to help assure compliance is available at: http://www.cdc.gov/od/sap/resource.htm. The University Biosafety Officer is also available to provide guidance and assistance. However, select agent users have a personal responsibility to comply with all regulatory requirements. Penalties for non-compliance are both civil and criminal and the federal government has prosecuted faculty and graduate students who have not complied with applicable rules.