

Appendix F—Select Agents and Toxins

The *Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Subtitle A of Public Law 107-188 (42 U.S.C. 262a)*, requires DHHS to regulate the possession, use, and transfer of biological agents or toxins (i.e., select agents and toxins) that could pose a severe threat to public health and safety. The *Agricultural Bioterrorism Protection Act of 2002, Subtitle B of Public Law 107-188 (7 U.S.C. 8401)*, requires the USDA to regulate the possession, use, and transfer of biological agents or toxins (i.e., select agents and toxins) that could pose a severe threat to animal or plant health, or animal or plant products. These Acts require the establishment of a national database of registered entities, and set criminal penalties for failing to comply with the requirements of the Acts. In accordance with these Acts, DHHS and USDA promulgated regulations requiring entities to register with the CDC or the APHIS if they possess, use, or transfer a select agent or toxin (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121). CDC and APHIS coordinate regulatory activities for those agents that would be regulated by both agencies (“overlap” select agents).

The Attorney General has the authority and responsibility to conduct electronic database checks (i.e., the security risk assessments) on entities that apply to possess, use, or transfer select agents, as well as personnel that require access to select agents and toxins. The FBI, Criminal Justice Information Services Division (CJIS), has been delegated authority for conducting these security risk assessments.

The regulations provide that, unless exempted, entities must register with CDC or APHIS if they possess, use, or transfer select agents or toxins. The current list of select agents and toxins is available on the CDC and APHIS Web sites (see below). The regulations set out a procedure for excluding an attenuated strain of a select agent or toxin and exemptions for certain products and for select agents or toxins identified in specimens presented for diagnosis, verification, or proficiency testing.

The regulations also contain requirements to ensure that the select agents and toxins are handled safely and secured against unauthorized access, theft, loss, or release. For example, entities and their personnel must undergo a security risk assessment by CJIS as part of their registration; entities must limit access to select agents and toxins and develop and implement biosafety, security, and incident response plans. In addition, all select agents or toxins must be transferred in accordance with the regulations and any theft, loss, or release of a select agent or toxin must be reported to CDC or APHIS.

For additional information concerning the select agent regulations, contact CDC or APHIS. Information is also available at the following Web sites: www.selectagents.gov; http://www.aphis.usda.gov/programs/ag_selectagent/index.shtml.