UNIVERSITY OF KENTUCKY
Environmental Health & Safety

Note: The information contained in this page was gathered from the American Society for Microbiology

## Public Health Security and Bioterrorism Preparedness and Response Act

The House-Senate Conference Committee on the "Public Health Security and Bioterrorism Preparedness and Response Act" HR 3448 have reached agreement on legislation to improve the nation's capacity to respond to bioterrorism and other public health emergencies. Title II, Enhancing Controls on Dangerous Biological Agents and Toxins, requires persons and individuals who possess, use or transfer select agents, the 42 biological agents and toxins currently listed by the Secretary of Health and Human Services as posing "a severe threat to public health and safety, to register with the Secretary and be subject to reasonable safety and security requirements, including access controls and screening of personnel, and inspections. Current law requires registration only of those facilities transferring select agents. The legislation establishes a national database of the location and characterization of select agents and the identities of those who possess them. The legislation recognizes that some select agents pose a greater threat to public health and safety than others, and gives the Secretary the flexibility to impose different levels of security requirements on different select agents based on an evaluation of the level of threat to the public as is currently done with respect to laboratory biosafety levels.

The legislation requires that registered persons promptly notify the Secretary if a select agent is lost, stolen, or released outside a biocontainment area of a facility. The legislation requires prompt action by the Attorney General and the Secretary of HHS with respect to screening of and notification of affected individuals and provides an expedited review process where good cause has been demonstrated by the registered facility. The legislation also provides for the review of denials by the Secretary based on the screening process and judicial review, with provisions that classified or sensitive law enforcement information is not compromised during those reviews. Exemptions are provided consistent with the current select agent transfer rule, for products that are approved under specific federal laws unless the Secretary determines that additional regulation is necessary for a specific product to ensure protection of public health and safety. The Secretary is given discretionary authority to exempt on a case-by-case basis investigational products when they are being used in investigational or clinical trials authorized under federal laws, with attention to the time sensitivity of such trials the legislation mandates a prompt determination by the Secretary of such an exemption within 14 days after the applicant has submitted a complete exemption request and has notified the Secretary that the investigation may proceed as authorized under federal law. The Secretary shall exempt clinical or diagnostic laboratories that may come into possession of select agents when conducting specimen diagnosis, verification or proficiency testing, but only if they report the identification of select agents to the Secretary and either promptly transfer the agent to a registered facility or destroy the agent on site. The Secretary may not exempt laboratories that possess select agents for reference purposes. The legislation creates two temporary exemption authorities to deal with public health emergencies and agricultural emergencies whether domestic or foreign. The legislation requires notification to the Secretary of HHS by facilities and individuals possessing select agents within 90 days of enactment based on guidance issued by the Secretary within 30 days of enactment and the issuance of final rule within 180 days of enactment. The legislation provides that the interim final rule shall include time frames for applicability the rule that minimize disruption of research or educational projects that involve select agents and that were underway as of the effective date of the rule. The Managers statement on the legislation notes that the interim final rule and effective date provisions will result in the new regulations going into effect at approximately the same time as the National Institutes of Health begins to award fiscal year 2003 grants for research, some of which will be in the select agent area. The Managers expect the Secretary will ensure the timely registration and screening of such grantees so as not to delay this important research.