

SELECT AGENT PROGRAM

WHAT IS THE PUBLIC HEALTH ISSUE?

CDC regulates the possession, use, and transfer of select biological agents and toxins that have the potential to pose a severe threat to public health and safety. CDC's Select Agent Program oversees these activities and registers all laboratories and other entities in the United States that possess, use, or transfer a select biological agent or toxin. *The Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (the *Act*) requires entities to register with the U.S. Departments of Health and Human Services (HHS) or Agriculture (USDA) if they possess, use, or transfer select biological agents or toxins that could pose a severe threat to public health and safety; to animal or plant health; or animal or plant products. In addition to ensuring that laboratories safely handle these select biological agents and toxins, the *Act* also requires increased safeguards and security measures of these agents, including controlling access, screening entities and personnel (i.e., security risk assessments), and establishing a comprehensive and detailed national database of registered entities. The *Act* also imposes criminal and civil penalties for the inappropriate use of select biological agents and toxins.

WHAT HAS CDC ACCOMPLISHED?

The Select Agent Program enhances the government's ability to prevent, prepare, and respond to bioterrorism and other public health emergencies. Prior to 2002, these agents were not systematically tracked. The *Act* provides a framework for monitoring threat agents that travel along the highways, railways, waterways, and airways of states.

The *Act* required that HHS promulgate an interim final rule in 180 days, published in the *Federal Register* on December 13, 2002. The December 2002 interim final rule established a phase-in period for certain requirements to allow for compliance without causing disruption or termination of research or educational projects. As a result of delays in completing security risk assessments for individuals and entities, an amendment to the interim final rule authorized provisional approvals to continue critical biodefense research. The December 2002 interim final rule regulated academic institutions and biomedical centers; commercial manufacturing (e.g., the pharmaceutical industry) or distribution facilities; federal, state, and local laboratories (including clinical and diagnostic laboratories); and research facilities.

The Select Agent Program helps to implement the *Act* through

- Evaluation and/or approval of requests to possess, use, and store threat agents.
- Approval of transfer of agents among registered laboratories.
- Registration of laboratories that possess threat agents (including specific viruses, bacteria, rickettsia, fungi, toxins, and recombinant organisms/molecules).
- Inspection of laboratories to ensure appropriate safety and security.
- A new regulation, effective February 7, 2003, which facilitated the registration of 332 entities as of November 12, 2003, and inspection of 211 entities.

WHAT ARE THE NEXT STEPS?

CDC expects to publish a final rule regarding select agents and toxins in late 2004 to address public comments and concerns that have emerged during implementation of the interim final rule. A new information management system, with a Web-based interface to improve customer service, timeliness and data reliability, is being developed.

For additional information on this or other CDC programs, visit www.cdc.gov/program

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