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DEPARTMENT OF HEALTH AND HUMAN SERVICES**42 CFR Part 73****Possession, Use, and Transfer of Select Agents and Toxins****AGENCY:** Centers for Disease Control and Prevention, HHS.**ACTION:** Interim final rule and request for comments.

SUMMARY: We are amending an interim final rule published on December 13, 2002, that established requirements regarding possession and use in the United States, receipt from outside the United States, and transfer within the United States, of select agents and toxins. The requirements were established to implement provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The December 2002 interim final rule established a phase-in period for certain requirements to allow entities to comply without causing disruption or termination of research or educational projects. The phase-in for entities that on February 7, 2003, were already conducting activities under a certificate of registration issued under 42 CFR 72.6, or already were lawfully possessing select agents and toxins, required entities applying for registration with the select agent program, and individuals requiring access to select agents and toxins, to undergo a security risk assessment by the Attorney General before November 12, 2003. The regulations also provided that an entity that on February 7, 2003, was not already conducting activities under a certificate of registration issued under 42 CFR 72.6, or was not already lawfully possessing select agents and toxins, would be eligible for registration to possess, use, or transfer select agents and toxins as soon as the entity met all of the applicable requirements of Part 73, including the requirement for the Attorney General to conduct a security risk assessment. We are now amending the applicability requirements to allow for the issuance of provisional registration certificates for all entities, and provisional grants of access for all individuals, from whom, prior to November 12, 2003, the Attorney General has received all of the information required by the Attorney General to conduct a security risk assessment if those entities and

individuals otherwise meet all of the requirements of Part 73. This action is necessary to ensure that both ongoing and new research and educational efforts important to the national defense are not disrupted.

DATES: This interim final rule is effective as of November 3, 2003. Written comments must be submitted on or before January 2, 2004.

ADDRESSES: Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Rd., E-79, Atlanta, GA 30333. Comments may be e-mailed to: SAPcomments@CDC.GOV.

FOR FURTHER INFORMATION CONTACT: Mark Hemphill, Chief of Policy, Select Agent Program, Centers For Disease Control and Prevention, 1600 Clifton Rd., MS E-79, Atlanta Ga. 30333. (404) 498-2255.

SUPPLEMENTARY INFORMATION: The December 2002 interim final rule implements provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107-188 (referred to below as the Act). The Act bolstered the authority of the Secretary of the United States Department of Health and Human Services (referred to below as HHS) to protect the American public against the misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the United States homeland (such as the recent terrorist acts involving anthrax) or other criminal acts. The Act gave to the Secretary broad discretion in establishing and enforcing the new regulations to ensure that select agents and toxins would remain available for research, education, and other legitimate purposes.

In a document published in the **Federal Register** on December 13, 2002 (67 FR 76886), we promulgated an interim final rule to establish requirements regarding possession and use in the United States, receipt from outside the United States, and transfer within the United States, of certain biological agents and toxins (referred to below as select agents and toxins). This includes requirements concerning registration, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections, and notifications. The December 2002 interim final rule is set forth at 42 CFR part 73.

In general, the entities regulated under the December 2002 interim final rule are academic institutions and biomedical centers; commercial manufacturing (the pharmaceutical industry) or distribution facilities; federal, state, and local laboratories,

including clinical and diagnostic laboratories; and research facilities.

The Act also gives the United States Department of Agriculture (referred to below as USDA) the authority and responsibility for regulating activities regarding select agents and toxins to protect animal and plant health and animal and plant products. The Act gives the Secretary of HHS the authority and responsibility for regulating activities regarding select agents and toxins to protect the public health and safety. Some of the select agents and toxins regulated under the HHS December 2002 interim final rule are also regulated by USDA under 9 CFR part 121. The select agents and toxins subject to regulation by both agencies are identified as "overlap" select agents and toxins and those regulated solely by HHS are identified as HHS select agents and toxins. The Act provides for interagency coordination between the two departments regarding overlap select agents and toxins.

The December 2002 interim final rule established a phase-in period for certain requirements to allow entities to comply without causing disruption or termination of research or educational projects. The phase-in for entities that on February 7, 2003, were already conducting activities under a certificate of registration issued under 42 CFR 72.6, or already were lawfully possessing select agents and toxins, required that entities applying for registration with the select agent program, and individuals requiring access to select agents and toxins, to undergo a security risk assessment by the Attorney General before November 12, 2003. The regulations also provided that an entity that on February 7, 2003, was not already conducting activities under a certificate of registration issued under 42 CFR 72.6, or was not already lawfully possessing select agents and toxins, would be eligible for registration to possess, use, or transfer select agents and toxins as soon as the entity met all of the applicable requirements of Part 73, including the requirement for the Attorney General to conduct a security risk assessment.

The Attorney General has assigned the responsibility to conduct the security risk assessments required by the Act to the Federal Bureau of Investigation (FBI). The Criminal Justice Information Services (CJIS) Division is the component of the FBI responsible for implementing this program. The CJIS Division continues to receive complete application packages, which consist of completed FBI Information Forms (FD-961) and usable fingerprint cards, and has finalized over 5,000 security risk