

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Parts 72 and 73**

**Office of Inspector General**

**42 CFR Part 1003**

**RIN 0920-AA09**

**Possession, Use, and Transfer of Select Agents and Toxins**

**AGENCY:** Centers for Disease Control and Prevention, Office of Inspector General, Department of Health Human Services (HHS).

**ACTION:** Final rule.

**SUMMARY:** This document establishes a final rule regarding possession, use, and transfer of select agents and toxins. The final rule implements provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and is designed to protect public health and safety.

In a companion document published in this issue of the **Federal Register**, the United States Department of Agriculture has established corresponding final rules designed to protect animal and plant health and animal and plant products.

**DATES:** The final rule is effective April 18, 2005.

**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. Telephone: (404) 498-2255.

**SUPPLEMENTARY INFORMATION:** This document establishes a final rule regarding possession, use, and transfer of select agents and toxins. The final rule is based on the interim final rule, as amended (amended interim final rule). The initial interim final rule was published in the **Federal Register** on December 13, 2002 (67 FR 76886). It was amended by a second interim final rule published in the **Federal Register** on November 3, 2003 (68 FR 62245). The initial interim final rule established a comprehensive set of regulations that

included requirements concerning registration and security risk assessments. The second interim final rule amended the first interim final rule by allowing for the issuance of provisional certificates of registration and provisional grants of access to select agents and toxins, subject to completion of security risk assessments, and compliance with all of the requirements of the initial interim final rule. The final rule, which is set forth at 42 FR part 73, implements provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act) and is designed to protect public health and safety.

In general, this final rule contains provisions that apply to academic institutions and biomedical centers; commercial manufacturing facilities; federal, state, and local laboratories, including clinical and diagnostic laboratories; and research facilities.

For the initial interim final rule, we provided for a 60-day comment period for written comments that ended February 11, 2003. We also held a public meeting on December 16, 2002. Relevant issues raised by the comments (oral comments made at the public meeting and 110 written comments) are discussed below. For the second interim final rule, we provided for a 60-day comment period for written comments that ended January 2, 2004. We received no comments in response to the second interim final rule. Based on the rationale set forth in the initial interim final rule, the second interim final rule, and this document, we are affirming the provisions of the amended interim final rule as a final rule with changes discussed below.

The final rule is designed to implement authorities under the Act to protect public health and safety. The United States Department of Agriculture (USDA) has established corresponding sets of regulations designed to protect animal and plant health and animal and plant products (9 CFR part 121 and 7 CFR part 331).

**42 CFR Part 1003**

The initial interim final rule amended 42 CFR part 1003 to establish

delegations of authority and other provisions involving the Office of Inspector General (OIG) of HHS. In addition to adding a new paragraph (b)(16) to § 1003.102 to authorize the imposition of civil money penalties for violations of the regulatory provisions, the interim final rule also sought public comments on the possible inclusion of specific factors that might be used to assess specific penalty amounts. The amended interim final rule had no effect on the OIG amendments and we received no comments regarding these amendments. However, since amendatory language to the OIG regulations addressing determinations regarding the amount of a penalty was not originally included in the initial interim final rule, we are now revising § 1003.106(a)(1) to reference the newly codified § 1003.102(b)(16) and the factors to be taken into account when the OIG assesses civil money penalties. We are affirming all other amendments set forth in the interim final rule.

**42 CFR 72.6 and Its Accompanying Appendix A**

The provisions of the final rule supersede all of the provisions at 42 CFR 72.6 (captioned “Additional requirements for facilities transferring or receiving select agents”) and its accompanying Appendix A. However, the provisions of 18 U.S.C. 175b include prohibitions that are based on the list of select agents in Appendix A of 42 CFR part 72 and exemptions to such list in § 72.6(h). Accordingly, we have deleted the superseded provisions and in their place have added language to indicate that for purposes of 18 U.S.C. 175b the list of select agents are set forth in §§ 73.3 and 73.4 and the exemptions are set forth in §§ 73.5 and 73.6.

**Changes in Structure in Part 73**

With respect to the sections in part 73, we changed the final rule to make the structure and format of the HHS regulations and the USDA regulations at 9 CFR part 121 more similar. The following chart shows the changes.

Amended interim final rule	Final rule
73.1 Definitions .....	73.1 Definitions.
73.2 Purpose and scope .....	73.2 Purpose and scope.
73.3 General prohibition .....	73.3 HHS select agents and toxins.
73.4 HHS select agents and toxins .....	73.4 Overlap select agents and toxins.
73.5 Overlap select agents and toxins .....	73.5 Exemptions for HHS select agents and toxins.
73.6 Exemptions from requirements under this part .....	73.6 Exemptions for overlap select agents and toxins.
73.71 Registration .....	73.7 Registration and related security risk assessments.
73.8 Security Risk Assessments .....	73.8 Denial, revocation, or suspension of registration.
73.9 Responsible Official .....	73.9 Responsible Official.