

## § 73.1

superseded by the training provisions of § 73.13 relating to security; and

(v) Subject to the transfer provisions of § 72.6 of this chapter until March 12, 2003, when superseded by § 73.14.

(5) A provisional registration certificate may be issued to an entity if, as of November 12, 2003:

(i) The Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of the entity, including any individual who owns or controls the entity; and

(ii) The entity otherwise meets all of the requirements of this Part.

(6) A provisional registration certificate will be effective until the Secretary either issues a certificate of registration or suspends or revokes the provisional registration.

(7) A provisional grant of access may be issued to an individual identified by an entity as having a legitimate need to have access to a select agent or toxin from whom, as of November 12, 2003, the Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of that individual.

(8) A provisional grant of access will be effective until the Secretary either grants the individual access or denies access to a select agent or toxin.

(c) For those entities that on February 7, 2003, were not already were conducting activities under a certificate of registration issued under § 72.6 of this chapter and were not already lawfully possessing select agents and toxins, the provisions of part 73 are applicable as follows:

(1) On and after February 7, 2003, the following sections are applicable: §§ 73.1 through 73.6 (definitions, purpose and scope, general prohibition, HHS select agents and toxins, overlap select agents and toxins, exemptions from requirements under this part); §§ 73.8 through 73.10 (Security risk assessments, Responsible Official, Safety); §§ 73.12 through 73.21 (emergency response, training, transfers, records; inspections; notification for theft, loss, or release; administrative review; civil money penalties; criminal penalties; and submissions and forms) and must

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hold a valid permit under 9 CFR part 122 and/or 42 CFR part 71.54.

(2) The provisions of § 73.11 are applicable on and after September 12, 2003.

(3) On and after November 12, 2003, the provisions of § 73.7 (registration) are applicable.

(4) During the period from February 7, 2003, through November 11, 2003, such an entity may not conduct activities regulated under this part unless the entity has submitted to HHS or USDA an application package under § 73.7 certifying compliance with the provisions referred to in paragraph (b)(2) of this section.

(5) A provisional registration certificate may be issued to an entity if, as of November 12, 2003:

(i) The Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of the entity, including any individual who owns or controls the entity;

(ii) The entity otherwise meets all of the requirements of this Part; and

(iii) The HHS Secretary finds that circumstances warrant such action in the interest of the public health and safety or national security.

(6) A provisional registration certificate will be effective until the Secretary either issues a certificate of registration or suspends or revokes the provisional registration.

(7) A provisional grant of access may be issued to an individual identified by an entity as having a legitimate need to have access to a select agent or toxin from whom, as of November 12, 2003, the Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of that individual.

(8) A provisional grant of access will be effective until the Secretary either grants the individual access or denies access to a select agent or toxin.

[67 FR 76896, Dec. 13, 2002, as amended at 68 FR 62246, Nov. 3, 2003]

### § 73.1 Definitions.

For purposes of this part:

*Biological agent* means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae,

or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.

*CDC* means Centers for Disease Control and Prevention of the Department of Health and Human Services.

*Diagnosis* means the analysis of specimens for the purpose of identifying or confirming the presence of a listed select agent or toxin provided that such analysis is directly related to protecting the public health or safety.

*Entity* means any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

*HHS* means the Department of Health and Human Services.

*HHS Secretary* means the Department of Health and Human Services or his or her designee, unless otherwise specified.

*HHS select agent or toxin* means a biological agent or toxin included in § 73.4.

*Overlap select agent or toxin* means a biological agent or toxin included in § 73.5.

*Proficiency testing* means a sponsored, time-limited analytical trial whereby one or more analytes, previously confirmed by the sponsor, are submitted to the testing laboratory for analysis and where final results are graded, scores are recorded and provided to participants, and scores for participants are evaluated.

*Principal investigator* means the one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program.

*Select agent or toxin or select agent and toxin* without identification as HHS or overlap means all of those biological agents or toxins included in §§ 73.4 and 73.5 of this part.

*Toxin* means the toxic material or product of plants, animals, microorganisms (including, but not limited to,

bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.

*United States* means the United States of America, the District of Columbia, Puerto Rico, and the territories and possessions of the United States.

*USDA* means the United States Department of Agriculture.

*USDA Secretary* means the Department of Agriculture or his or her designee, unless otherwise specified.

*Verification* means the processes required to assure the accuracy, precision, and the analytical sensitivity and specificity of any procedure used for diagnosis.

#### § 73.2 Purpose and scope.

(a) This part sets forth requirements regarding the possession or use in the United States, receipt from outside the United States, or transfer within the United States, of select agents and toxins. The requirements are designed to implement provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). The Act was designed to provide protection against the effects of misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the United States homeland or other criminal acts. The agents and toxins subject to requirements under this part are those that have the potential to pose a severe threat to public health and safety. They are further identified as either HHS select agents and toxins or overlap select agents and toxins. The term HHS select agents and toxins refers to those select agents and toxins subject to these regulations but not subject to USDA requirements at 9 CFR part 121. The overlap group consists of those select agents and toxins subject to requirements promulgated by the HHS Secretary under this part