

**§ 73.0 Applicability and related requirements.**

(a) For those entities that on February 7, 2003, were conducting activities under a certificate of registration issued under § 72.6 of this chapter, or were lawfully possessing select agents and toxins, the provisions of part 73 and § 72.6 of this chapter 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); § 73.9 (Responsible Official); § 73.10 (Safety); § 73.12 (emergency response); and §§ 73.15 through 73.21 (records; inspections; notification for theft, loss, or release; administrative review; civil money penalties; criminal penalties; and submissions and forms).

(2) On and after February 7, 2003, the provisions of § 73.13 concerning training related to safety and emergency response are applicable; and on and after September 12, 2003, the remaining provisions of § 73.13, including those concerning training related to security, are applicable.

(3) On and after March 12, 2003, the provisions of § 73.14 (transfers) are applicable.

(4) On and after April 12, 2003, the provisions of § 73.8 regarding security risk assessments for the entity, the Responsible Official, and any individual who owns or controls the entity are applicable; and on and after June 12, 2003, the remainder of § 73.8 (including the provisions regarding individual risk assessments for other than the Responsible Official or any individual who owns or controls the entity) is applicable.

(5) On and after June 12, 2003, the provisions of § 73.11 regarding the development of a security plan are applicable, and on and after September 12, 2003, the remainder of the provisions of § 73.11, including the provisions regarding the implementation of a security plan, is applicable.

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

(b) The following also applies to those entities that on February 7, 2003, already were conducting activities under a certificate of registration issued under § 72.6 of this chapter or already were lawfully possessing select agents and toxins:

(1) During the period from March 12, 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 (a)(1) of this section and the provisions in § 73.13 concerning training related to safety and emergency response.

(2) During the period from March 12, 2003, through April 11, 2003, such an entity may not conduct activities regulated under this part unless the entity has submitted applications for approval under § 73.8 (security risk assessment) to the Attorney General for the entity, the Responsible Official, and any individual who owns or controls the entity.

(3) During the period from April 12, 2003, through June 11, 2003, such an entity may not conduct activities regulated under this part unless the entity has submitted applications for approval under § 73.8 (security risk assessments) to the Attorney General for all individuals (other than the Responsible Official and any individual who owns or controls the entity) with access to select agents and toxins.

(4) Such an entity remains:

(i) Subject to the registration provisions of § 72.6 of this chapter until November 12, 2003, when superseded by § 73.7;

(ii) Subject to the security provisions of § 72.6 of this chapter regarding development of a security plan until June 12, 2003, when superseded by the requirement to develop a security plan under § 73.11;

(iii) Subject to the security provisions of § 72.6 of this chapter regarding implementation of a security plan until September 12, 2003, when superseded by the requirement to fully comply with § 73.11;

(iv) Subject to the training provisions of § 72.6 of this chapter related to security until September 12, 2003, when

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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,