7. *Yersinia pestis*
Exemptions: vaccine strains as described in Title 9 CFR, 78.1 are exempt.

Rickettsiae

1. *Coxiella burnetii*
2. *Rickettsia prowazekii*
3. *Rickettsia rickettsii*

Fungi

1. *Coccidioides immitis*

Toxins

1. Abrin
2. Aflatoxins
3. Botulinum toxins
4. *Clostridium perfringens epsilon toxin*
5. Conotoxins
6. Diacetoxyscirpenol
7. Ricin
8. Saxitoxin
9. Shigatoxin
10. Staphylococcal enterotoxins
11. Tetrodotoxin
12. T-2 toxin
Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD_{50} for vertebrates of more than 100 nanograms per kilogram body weight are exempt. National standard toxins required for biologic potency testing as described in 9 CFR Part 113 are exempt.

RECOMBINANT ORGANISMS/MOLECULES

1. Genetically modified microorganisms or genetic elements from organisms on Appendix A, shown to produce or encode for a factor associated with a disease.

2. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in this Appendix, or their toxic subunits.

OTHER RESTRICTIONS

The deliberate transfer of a drug resistance trait to microorganisms listed in this Appendix that are not known to acquire the trait naturally is prohibited by NIH ''Guidelines for Research Involving Recombinant DNA Molecules,'' if such acquisition could compromise the use of the drug to control these disease agents in humans or veterinary medicine.

ADDITIONAL EXEMPTIONS

1. Products subject to regulation under the Federal Insecticide Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*) and the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*) are exempt.

2. Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents in this Appendix. Individuals seeking an exemption should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. Future exemptions will be published in the FEDERAL REGISTER for review and comment prior to inclusion in this Appendix.

[61 FR 55199, Oct. 24, 1996]

PART 73—SELECT AGENTS AND TOXINS

AUTHORITY: 42 U.S.C. 262a; sections 201–204, 221 and 231 of Title II of Public Law 107–188, 116 Stat. 637 (42 U.S.C. 262a)

SOURCE: 67 FR 76896, Dec. 13, 2002, unless otherwise noted.

§ 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 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.

(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 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.

§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.