agent, in accordance with the CDC/NIH publication ''Biosafety in Microbiological and Biomedical Laboratories.''

Requestor means any person who receives or seeks to receive through any means a select agent subject to this part from any other person.

Responsible facility official means an official authorized to transfer and receive select agents covered by this part on behalf of the transferor's and/or requestor's facility. This person should be either a safety officer, a senior management official of the facility, or both. The responsible facility official should not be an individual who actually transfers or receives an agent at the facility.

Secretary means the Secretary of the Department of Health and Human Services or her or his designee.

Select agent means a microorganism (virus, bacterium, fungus, rickettsia) or toxin listed in Appendix A of this part. The term also includes:

(1) Genetically modified microorganisms or genetic elements from organisms on Appendix A of this part, shown to produce or encode for a factor associated with a disease, and

(2) Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins on Appendix A of this part, or their toxic submits.

Single geographic site means a building or complex of buildings at a single mailing address.

Transfer means:

(1) The conveyance or movement from a point or origination to a point of destination either:

(i) From one state or territory to another or;

(ii) Entirely within one contiguous state or territory.

(2) Intrafacility transfers within a registered facility located at a single geographic site are not covered by the provisions of § 72.6 (d), (e), and (f) provided that:

(i) The intended use of the agent remains consistent with that specified in the most current transfer form; and

(ii) For each intrafacility transfer, the facility maintains records that include the name and location of the recipient; the amount of agent transferred, and the date transferred. Such records must be maintained for a period of five (5) years after the date of transfer or for five (5) years after the agents are consumed or properly disposed, whichever is longer.

Transferor means any person who transfers or seeks to transfer through any means a select agent subject to this part to any other person.

[61 FR 55197, Oct. 24, 1996, as amended at 66 FR 45945, Aug. 31, 2001]

§ 72.7 Penalties.

Individuals in violation of this part are subject to a fine of no more than $250,000 or one year in jail, or both. Violations by organizations are subject to a fine or no more than $500,000 per event. A false, fictitious, or fraudulent statement or representation on the Government forms required in the part for registration of facilities or for transfers of select agents is subject to a fine or imprisonment for not more than five years, or both for an individual; and a fine for an organization.

[61 FR 55199, Oct. 24, 1996]

APPENDIX A TO PART 72—SELECT AGENTS

Viruses

1. Crimean-Congo haemorrhagic fever virus
2. Eastern Equine Encephalitis virus
3. Ebola viruses
4. Equine Morbillivirus
5. Lassa fever virus
6. Marburg virus
7. Rift Valley fever virus
8. South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
9. Tick-borne encephalitis complex viruses
10. Variola major virus (Smallpox virus)
11. Venezuelan Equine Encephalitis virus
12. Viruses causing hantavirus pulmonary syndrome
13. Yellow fever virus

Exemptions: Vaccine strains of viral agents (Junin Virus strain candid #1, Rift Valley fever virus strain MP–12, Venezuelan Equine encephalitis virus strain TC–83, Yellow fever virus strain 17–D) are exempt.

Bacteria

1. *Bacillus anthracis*
2. *Brucella abortus, B. melitensis, B. suis*
3. *Burkholderia (Pseudomonas) mallei*
4. *Burkholderia (Pseudomonas) pseudomallei*
5. *Clostridium botulinum*
6. *Francisella tularensis*

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

73.0 Applicability and related requirements.
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73.2 Purpose and scope.
73.3 General prohibition.
73.4 HHS select agents and toxins.
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73.6 Exemptions from requirements under this part.
73.7 Registration.
73.8 Security risk assessment.
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73.21 Submissions and forms.

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