severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

For additional information, see the direct final rule which is located in the rules section of this **Federal Register**.

Dated: August 16, 2007.

Richard E. Greene,

Regional Administrator, Region 6.

[FR Doc. E7–16830 Filed 8–27–07; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 73

Possession, Use, and Transfer of Select Agents and Toxins

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: The select agents and toxins listed in 42 CFR part 73 include those regulated only by the U.S. Department of Health and Human Services (HHS) (42 CFR 73.3), as well as those overlap select agents and toxins regulated by both HHS and the U.S. Department of Agriculture (USDA) (42 CFR 73.4). In response to USDA's proposal to no longer regulate ten select agents and toxins currently listed as ''overlap'' agents and toxins, we are proposing to move those ten select agents and toxins from the overlap select agents and toxins section to the HHS select agents and toxins section.

DATES: Written comments must be received on or before October 29, 2007. Comments received after October 29, 2007 will be considered to the extent practicable.

ADDRESSES: Comments on the changes to the list of select agents and toxins should be marked ''Comments on the changes to the list of select agents and toxins'' and mailed to: Centers for Disease Control and Prevention, Division of Select Agents and Toxins, 1600 Clifton Road, MS A–46, Atlanta, GA 30333. Comments may be e-mailed to: *SAPcomments@cdc.gov.*

FOR FURTHER INFORMATION CONTACT: Robbin Weyant, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Rd., MS A–46, Atlanta, GA 30333. Telephone: (404) 718–2000.

SUPPLEMENTARY INFORMATION: The *Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Subtitle A of Public Law 107–188 (42 U.S.C. 262a) (the Bioterrorism Preparedness Act),* required the HHS Secretary to establish by regulation a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety. In determining whether to include an agent or toxin on the list, the HHS Secretary considered the effect on human health of exposure to an agent or toxin; the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans; the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent illnesses resulting from an agent or toxin; the potential for an agent or toxin to be used as a biological weapon; and the needs of children and other vulnerable populations. Once established, the Bioterrorism Preparedness Act requires that the HHS Secretary review and republish the list of select agents and toxins on at least a biennial basis.

The HHS Secretary promulgated the current select agents and toxins list in a final rule amending Part 73 of title 42 of the Code of Federal Regulations, published on March 18, 2005, and made effective on April 18, 2005. The select agents and toxins list found in Part 73 is divided into two sections. The select agents and toxins listed in section 73.3 (HHS select agents and toxins) are those select agents and toxins regulated only by HHS. The select agents and toxins listed in section 73.4 (Overlap select agents and toxins) are those select agents and toxins regulated by HHS and USDA under the provisions of the Agricultural Bioterrorism Protection Act of 2002.

The Agricultural Bioterrorism Protection Act of 2002, Subtitle B of Public Law 107–188 (7 U.S.C. 8401) (the Agricultural Bioterrorism Protection Act), requires the USDA Secretary to establish by regulation a list of each biological agent and each toxin that the Secretary determines has the potential to pose a severe threat to animal or plant health or animal or plant products. In determining whether to include an agent or toxin on the list, the USDA Secretary considered the effect of exposure to the agent or toxin on animal or plant health, and on the production and marketability of animal or plant products; the pathogenicity of the agent or the toxicity of the toxin and the methods by which the agent or toxin is transferred to animals and plants; the availability and effectiveness of pharmacotherapies and prophylaxis to treat and prevent any illness caused by the agent or toxin; and the potential of an agent or toxin for use as a biological weapon. The USDA Secretary is also required to conduct a biennial review of the USDA select agents and toxins list.

HHS completed its biennial review on February 22, 2007 and determined that it would neither add nor remove any agents or toxins from its select agents and toxins list. To assist with the biennial review, HHS reviewed recommendations provided by subject matter experts and the Intragovernmental Select Agents and Toxins Advisory Committee (ISATTAC). The ISATTAC is comprised of Federal government employees from the CDC, the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the USDA/Animal and Plant Health Inspection Service (APHIS), USDA/Agricultural Research Service (ARS), USDA/CVB (Center for Veterinary Biologics) and the Department of Defense (DOD).

After conducting its biennial review, USDA has proposed that it will no longer regulate ten of the select agents and toxins currently listed as ''overlap'' select agents and toxins in section 73.4. If their decision becomes final, HHS will move those ten select agents and toxins from section 73.4 to section 73.3. Published in today's **Federal Register** is USDA's proposal to remove from Part 121 of Title 9 of the Code of Federal Regulations the following agents and toxins: Botulinum neurotoxins; Botulinum neurotoxin producing species of *Clostridium, Coxiella burnetti, Francisella tularensis, Coccidioides immitis,* Eastern equine encephalitis virus, T–2 toxin, Staphylococcal enterotoxins, Shigatoxin, and *Clostridium perfringens* epsilon toxin. Comments regarding USDA's proposal to no longer regulate ten select agents and toxins currently listed as ''overlap'' agents and toxins should be sent to USDA.

Regulatory Analyses

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), requires that the HHS consider the impact of paperwork and other information collection burdens imposed on the public. We have determined no new information collection requirements are associated with this proposed rule.

Executive Order 12866 and Regulatory Flexibility Act

This action has been determined not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget. The Regulatory Flexibility Act (5 U.S.C. 601

et seq.) requires an agency to review regulations to assess their impact on small entities unless the agency determines that a rule is not expected to have a significant impact on a substantial number of small entities. This rule will have no costs because it merely changes the designation of ten select agents and toxins from being regulated by both HHS and USDA to being regulated solely by HHS. We hereby certify this proposed rule will not have a significant economic impact on a substantial number of small businesses.

Unfunded Mandates

The Unfunded Mandates Reform Act at 2 U.S.C. 1532 requires that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of $100 million or more (adjusted for inflation) in any given year. This proposed rule is not expected to result in any one-year expenditure that would exceed this amount.

Executive Order 12988

This Notice of Proposed Rulemaking has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Would preempt all State and local laws and regulations that are inconsistent with this rule; (2) would have no retroactive effect; and (3) would not require administrative proceedings before parties may file suit in court challenging this rule.

Executive Order 13132

This Notice of Proposed Rulemaking has been reviewed under Executive Order 13132, Federalism. The notice does not propose any regulation that would preempt State, local, and Indian tribe requirements, or that would have any substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

List of Subjects in 42 CFR Part 73

Biologics, Incorporation by reference, Packaging and containers, Penalties, Reporting and Recordkeeping requirements, Transportation.

Dated: August 17, 2007.

Michael O. Leavitt,

Secretary.

For the reasons stated in the preamble, we are proposing to amend 42 CFR part 73 as follows:

PART 73—SELECT AGENTS AND TOXINS

1. The authority citation for part 73 continues to read as follows:

Authority: 42 U.S.C. 262a; sections 201–204, 221 and 231 of Title II of Public Law No. 107–188, 116 Stat. 637 (42 U.S.C. 262a).

2. Amend paragraph (b) of § 73.3 by adding the following entries in alphabetical order and revising the entry for *Coccidioides posadasii* to read as follows:

§ 73.3 HHS select agents and toxins.

* * * * *

(b) * * *

Botulinum neurotoxins

Botulinum neurotoxin producing species of *Clostridium*

* * * * *

Clostridium perfringens epsilon toxin

Coccidioides posadasii/Coccidioides immitis

* * * * *

Coxiella burnetii

* * * * *

Eastern Equine Encephalitis virus

* * * * *

Francisella tularensis

* * * * *

Shigatoxin

* * * * *

Staphylococcal enterotoxins

T–2 toxin

* * * * *

3. Amend paragraph (d)(3) of § 73.3 by adding the following entries in alphabetical order: 05. mg of Botulinum neurotoxins; 100 mg of *Clostridium perfringens* epsilon toxin; 100 mg of Shigatoxin; 5 mg of Staphylococcal enterotoxins; or 1,000 mg of T–2 toxin.

4. Amend paragraph (f)(3)(i) of § 73.3 by adding the following entries in alphabetical order: Botulinum neurotoxins and *Francisella tularensis.*

§ 73.5 [Amended]

5. Amend paragraph (a)(3)(i) of § 73.5 by adding the following entries in alphabetical order: Botulinum neurotoxins and *Francisella tularensis.*

§ 73.4 [Amended]

6. Amend paragraph (b) of § 73.4 by removing the entries for Botulinum neurotoxins, Botulinum neurotoxin producing species of *Clostridium, Clostridium perfringens* epsilon toxin, *Coccidioides immitis, Coxiella burnetii,* Eastern Equine Encephalitis virus, *Francisella tularensis,* Shigatoxin, Staphylococcal enterotoxins, and T–2 toxin.

7. Remove paragraph (d)(3) of § 73.4.

8. Amend paragraph (f)(3)(i) of § 73.4 by removing the following entries: Botulinum neurotoxins and *Francisella tularensis.*

§ 73.6 [Amended]

9. Amend paragraph (a)(3)(i) of § 73.6 by removing the following entries: Botulinum neurotoxins and *Francisella tularensis.*

[FR Doc. 07–4233 Filed 8–27–07; 8:45 am]

BILLING CODE 4163–18–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; 12-Month Finding on a Petition To List the Gunnison's Prairie Dog as Threatened or Endangered

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; initiation of status review and request for new information.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the opening of a public comment period regarding the status of the Gunnison's prairie dog (*Cynomys gunnisoni*) in the contiguous United States. We are initiating this status review under a July 2, 2007, court-approved settlement agreement, in which we agreed to prepare a 12-month finding on a petition to list the species as threatened or endangered under the Endangered Species Act of 1973, as amended (Act). Through this action, we encourage all interested parties to provide us information regarding the status of, and any potential threats to, the Gunnison's prairie dog.

DATES: To be considered in the 12-month finding, comments must be received on or before October 29, 2007. However, we will accept new scientific and commercial information on the Gunnison's prairie dog after the official comment period closes.

ADDRESSES: If you wish to provide new information, you may submit your comments and materials by any one of the following methods:

(1) You may mail or hand-deliver written comments and information to Gunnison's Prairie Dog Comments, U.S. Fish and Wildlife Service, 764 Horizon Drive, Building B, Grand Junction, Colorado 81506–3946.

(2) You may electronic mail (e-mail) your comments to *FW6_Gunnison's_prairie_dog@fws.gov*. For directions on how to submit comments by e-mail, see the ''Public