

recordkeeping requirements, comes from sections 114(a) and 301(a) of the CAA.

List of Subjects in 40 CFR Part 80

Environmental protection, Administrative practice and procedure, Air pollution control, Confidential business information, Fuel additives, Gasoline, Imports, Labeling, Motor vehicle fuel, Motor vehicle pollution, Penalties, Reporting and recordkeeping requirements.

Dated: October 9, 2008.

Stephen L. Johnson,
Administrator.

■ For the reasons set forth in the preamble, 40 CFR part 80 is amended as set forth below:

PART 80—REGULATION OF FUELS AND FUEL ADDITIVES

■ 1. The authority citation for part 80 continues to read as follows:

Authority: 42 U.S.C. 7414, 7542, 7545 and 7601(a).

■ 2. Section 80.1275 is amended as follows:

- a. By adding paragraph (d)(1)(v).
- b. By redesignating paragraph (d)(2) as paragraph (d)(3).
- c. By adding paragraph (d)(2).

§ 80.1275 How are early benzene credits generated?

* * * * *

(d) * * *

(1) * * *

(v) Providing for benzene alkylation.

(2)(i) A refiner may petition EPA to approve, for purposes of paragraph (d)(1) of this section, the use of operational changes and/or improvements in benzene control technology that are not listed in paragraph (d)(1) of this section to reduce gasoline benzene levels at a refinery.

(ii) The petition specified in paragraph (d)(2)(i) of this section must be sent to: U.S. EPA, NVFEL-ASD, Attn: MSAT2 Early Credit Benzene Reduction Technology, 2000 Traverwood Dr., Ann Arbor, MI 48105.

(iii) The petition specified in paragraph (d)(2)(i) of this section must show how the benzene control technology improvement or operational change results in a net reduction in the refinery's average gasoline benzene level, exclusive of benzene reductions due simply to blending practices.

(iv) The petition specified in paragraph (d)(2)(i) of this section must be submitted to EPA prior to the start of the first averaging period in which the refinery plans to generate early credits.

(v) The refiner must provide additional information as requested by EPA.

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[FR Doc. E8-24591 Filed 10-15-08; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

42 CFR Part 73

RIN 0920-AA09

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: Final rule.

SUMMARY: This document completes the biennial review and republication of the lists of biological agents and toxins regulated by the U.S. Department of Health and Human Services (HHS), as well as those biological agents and toxins regulated by both HHS and the U.S. Department of Agriculture (USDA). Because USDA has chosen to no longer regulate ten biological agents and toxins which HHS still believes have the potential to pose a severe threat to public health and safety, we have moved those ten biological agents and toxins from the overlap select agents and toxins section to the HHS select agents and toxins section of the select agent regulations.

In a companion document published in this issue of the **Federal Register**, the USDA has established corresponding final rules regarding the select agents and toxins regulated only by the USDA, as well as those overlap select agents and toxins regulated by both agencies.

DATES: The final rule is effective November 17, 2008.

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)*, requires 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 considers the effect on human health of exposure to an agent or toxin; the degree of contagiousness of the agent 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. 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 lists in a final rule, published on March 18, 2005, and made effective on April 18, 2005. The select agents and toxins lists found in Part 73 are found in two sections. The biological agents and toxins listed in section 73.3 (HHS select agents and toxins) are those biological agents and toxins regulated only by HHS. The biological agents and toxins listed in section 73.4 (Overlap select agents and toxins) are those biological agents and toxins regulated both 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 considers 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.

To assist with the biennial review, HHS reviewed recommendations provided by subject matter experts and the Intragovernmental Select Agents and

Toxins Technical 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).

HHS completed its biennial review on February 22, 2007 and on August 28, 2007, we published in the **Federal Register** (72 FR 49244) a proposal to neither add nor remove any agents or toxins from our select agents and toxins lists. However, we did advise that HHS intended to continue to regulate ten biological agents and toxins that USDA was proposing to no longer regulate.

After conducting its biennial review, on August, 28, 2007 (72 FR 49231) USDA proposed that it would no longer regulate ten of the biological agents and toxins currently listed by them as "overlap" select agents and toxins. Published in today's **Federal Register** is USDA's final rule that removes 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.

For the proposed rule, we provided for a 60-day comment period for written comments that ended October 29, 2007. Relevant issues raised by the comments are discussed below. Based on the rationale set forth in the proposed rule, we are affirming the provisions of the proposed rule as a final rule.

Commenters recommended that the following biological agents and toxins be removed from the HHS list to mirror their removal by USDA: (1) Botulinum neurotoxin producing species of *Clostridium*, (2) Eastern equine encephalitis virus, (3) Botulinum neurotoxins; and (4) *Clostridium perfringens* epsilon toxin because "they are found naturally in the U.S. and most are ubiquitous and the proposed rule does not give the basis for maintaining these naturally occurring agents." One commenter further argued that *Clostridium perfringens* epsilon toxin should be removed because "the use of this toxin as a bioterrorism weapon is highly unlikely due to several factors including the method and effectiveness of administration, the lack of potential secondary transmission to uninfected

individuals." We made no changes based on these comments. The potential negative impact of exposure to a select agent or toxin to the public health may be different from its impact on agriculture. As a part of its review using subject matter experts, HHS determines whether a select agent or toxin has the potential to pose a significant public health threat based on the effect of the exposure to the agent or toxin to humans, the degree of contagiousness that an agent will have with respect to humans, availability of treatments for humans, and the susceptibility by vulnerable human populations. Based on these criteria, HHS confirmed its prior determination that these agents and toxins have the potential to pose a significant public health threat because they have acute toxicity, have lethality in humans, can easily be produced in large quantities, and can be transferred by an aerosol method. In contrast, USDA's evaluations and determinations that it would remove these agents and toxins from its regulation is detailed in their **Federal Register** notice published on August 28, 2007 (See 72 FR 49231) and today's **Federal Register** that:

- Botulinum neurotoxin producing species of *Clostridium* (i.e., *C. botulinum*, *C. butyricum* and *C. baratii*) are widely distributed in soil, sediments of lakes and ponds, and decaying vegetation. The species may be found in any region of the world and some species may occasionally colonize the intestinal tract of birds and mammals under natural conditions. The neurotoxins produced by these agents produce the infectious toxicosis of botulism. There is a well known and established history of infection and toxicosis in agricultural species associated with *C. botulinum* in the United States, and USDA concluded that Botulinum neurotoxin producing species do not pose a serious threat to American agriculture.

- Based on evidence that transmissibility from animal to animal is negligible and that, historically, outbreaks of botulism occur periodically in the United States, USDA determined that botulinum neurotoxins are a poor agroterrorism weapon, and USDA should therefore remove Botulinum neurotoxins and Botulinum neurotoxin producing species of *Clostridium* from the list of overlap select agents in its regulations in § 121.4(b).

- Eastern equine encephalitis virus has been recognized as an important veterinary pathogen that infects equines and birds during sporadic outbreaks. Infection results in central nervous system dysfunction and may result in moderate to high morbidity and

mortality. The virus is maintained naturally in nature in marshes and swamps in an enzootic bird-mosquito-bird cycle, and is endemic in the United States along the Atlantic and Gulf coasts. Eastern equine encephalitis virus does not play a major role in agricultural species of concern, and equine species are considered a dead-end host of the virus.

- Additionally, the working group concluded that because the following overlap select agents and toxins are naturally found in the United States, do not pose a significant impact to animal health, and are not likely candidates for use in an agroterrorism event directed toward animal health, these select agents and toxins would have a limited socio-economic impact on American agriculture, and thus should be removed from the list: Botulinum neurotoxin producing species of *Clostridium*, *Clostridium perfringens* epsilon toxin, *Francisella tularensis*, Staphylococcal enterotoxin, shigatoxin, and T-2 toxin.

One commenter further proposed that (1) "CDC provides an exemption for the use of the agents noted above in the manufacture of veterinary biologics in facilities licensed by the USDA's Center for Veterinary Biologics (CVB) or their investigational use by biologics firms under CVB supervision," (2) "that they remain on the overlap list" or (3) "if they remain on the CDC Select Agent list and are removed from the Overlap list that CDC utilize the CVB for oversight and inspection of CVB licensed firms." We made no changes based on these comments. The regulations currently provide that products that are, bear, or contain listed select agents or toxins that are cleared, approved, licensed, or registered under the Virus-Serum-Toxin Act (21 U.S.C. 151-159) are exempt from the provisions of this part insofar as their use meets the requirements of that Act. Veterinary biologics licensed by USDA's Center for Veterinary Biologics are licensed under the authority of the Virus-Serum-Toxin Act. The regulations also provide that on a case-by-case basis the HHS Secretary may exempt from the requirements of the part 73 regulations an investigational product that is, bears, or contains a select agent or toxin, when such product is being used in an investigation authorized under any Federal Act and additional regulation under part 73 is not necessary to protect public health and safety. See 42 CFR 73.5(d). While we and USDA do everything we can to minimize disruption due to select agent oversight, CDC has determined that it would not be appropriate to utilize CVB for oversight and inspection of registered

entities that only have select agents and toxins on the HHS list.

Several commenters noted a typographical error on page 49245 that listed the aggregate amount for Botulinum neurotoxins as "05. mg." This was a typographical error and we were not proposing to change the aggregate amount for Botulinum neurotoxins under the control of a principal investigator, a treating physician or veterinarian, or a commercial manufacturer or distributor that would meet the exclusion provisions for part 73. The maximum aggregate amount of Botulinum neurotoxins under the control of a principal investigator, a treating physician or veterinarian, or a commercial manufacturer or distributor that meets the requirement for exclusion under 42 CFR 73.4 will continue to be 0.5 mg.

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 final rule has been reviewed under Executive Order 12866, and has been determined not to be significant. For this action, the Office of Management and Budget has waived its review under Executive Order 12866.

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 Final Rule 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 Final Rule 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: September 22, 2008.

Michael O. Leavitt,
Secretary.

■ For the reasons stated in the preamble, we have amended 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 107–188, 116 Stat. 637 (42 U.S.C. 262a).

■ 2. In § 73.3, revise paragraphs (b), (d)(3), and (f)(3)(i) to read as follows:

§ 73.3 HHS select agents and toxins.

* * * * *

(b) HHS select agents and toxins:

- Abrin
- Botulinum neurotoxins
- Botulinum neurotoxin producing species of *Clostridium*
- Cercopithecine herpesvirus 1 (Herpes B virus)
- Clostridium perfringens* epsilon toxin
- Coccidioides posadasii/Coccidioides immitis*
- Conotoxins

- Coxiella burnetii*
- Crimean-Congo haemorrhagic fever virus
- Diacetoxyscirpenol
- Eastern Equine Encephalitis virus
- Ebola viruses
- Francisella tularensis*
- Lassa fever virus
- Marburg virus
- Monkeypox virus
- Ricin
- Rickettsia prowazekii*
- Rickettsia rickettsii*
- Saxitoxin
- Shiga-like ribosome inactivating proteins
- Shigatoxin
- South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
- Staphylococcal enterotoxins
- T–2 toxin
- Tetrodotoxin
- Tick-borne encephalitis complex (flavi) viruses (Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis [Russian Spring and Summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever])
- Variola major virus (Smallpox virus) and Variola minor virus (Alastrim)
- Yersinia pestis*

* * * * *
(d) * * *

(3) HHS toxins under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor, if the aggregate amount does not, at any time, exceed the following amounts: 100 mg of Abrin; 0.5 mg of Botulinum neurotoxins; 100 mg of *Clostridium perfringens* epsilon toxin; 100 mg of Conotoxins; 1,000 mg of Diacetoxyscirpenol; 100 mg of Ricin; 100 mg of Saxitoxin; 100 mg of Shiga-like ribosome inactivating proteins; 100 mg of Shigatoxin; 5 mg of Staphylococcal enterotoxins; 1,000 mg of T–2 toxin; or 100 mg of Tetrodotoxin.

* * * * *
(f) * * *
(3) * * *

(i) The seizure of Botulinum neurotoxins, Ebola viruses, *Francisella tularensis*, Lassa fever virus, Marburg virus, South American Haemorrhagic Fever virus (Junin, Machupo, Sabia, Flexal, Guanarito), Variola major virus (Smallpox virus), Variola minor (Alastrim), or *Yersinia pestis* must be reported within 24 hours by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after seizure of the select agent or toxin.

* * * * *

■ 3. In § 73.4, revise paragraphs (b) and (f)(3)(i), and remove paragraph (d)(3) to read as follows:

§ 73.4 Overlap select agents and toxins.

* * * * *

(b) Overlap select agents and toxins:

- Bacillus anthracis*
- Brucella abortus*
- Brucella melitensis*
- Brucella suis*
- Burkholderia mallei* (formerly *Pseudomonas mallei*)
- Burkholderia pseudomallei* (formerly *Pseudomonas pseudomallei*)
- Hendra virus
- Nipah virus
- Rift Valley fever virus
- Venezuelan Equine Encephalitis virus

* * * * *

(f) * * *

(3) * * *

(i) The seizure of *Bacillus anthracis*, *Brucella melitensis*, Hendra virus, Nipah virus, Rift Valley fever virus, or Venezuelan equine encephalitis virus must be reported within 24 hours by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after seizure of the select agent or toxin.

* * * * *

■ 4. In § 73.5 revise paragraph (a)(3)(i) to read as follows:

§ 73.5 Exemptions for HHS select agents and toxins.

(a) * * *

(3) * * *

(i) The identification of any of the following HHS select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: Botulinum neurotoxins, Ebola viruses, *Francisella tularensis*, Lassa fever virus, Marburg virus, South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito), Variola major virus (Smallpox virus), Variola minor (Alastrim), or *Yersinia pestis*. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after identification.

* * * * *

■ 5. In § 73.6, revise paragraph (a)(3)(i) to read as follows:

§ 73.6 Exemptions for overlap select agents and toxins.

(a) * * *

(3) * * *

(i) The identification of any of the following overlap select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: *Bacillus anthracis*, *Brucella melitensis*, Hendra

virus, Nipah virus, Rift Valley fever virus, or Venezuelan equine encephalitis virus. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after identification.

* * * * *

[FR Doc. E8-24623 Filed 10-15-08; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 071106673-8011-02]

[ID 101008A]

Fisheries of the Exclusive Economic Zone Off Alaska; Atka Mackerel in the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; modification of a closure.

SUMMARY: NMFS is opening directed fishing for Atka mackerel in the Eastern Aleutian District and the Bering Sea subarea of the Bering Sea and Aleutian Islands management area (BSAI) by vessels participating in the BSAI trawl limited access fishery. This action is necessary to fully use the 2008 total allowable catch (TAC) of Atka mackerel in these areas specified for vessels participating in the BSAI trawl limited access fishery.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), October 10, 2008, through 1200 hrs, A.l.t., October 13, 2008. Comments must be received at the following address no later than 4:30 p.m., A.l.t., October 27, 2008.

ADDRESSES: Send comments to Sue Salveson, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, Attn: Ellen Sebastian. You may submit comments, identified by "ID 101008A," by any one of the following methods:

- Electronic Submissions: Submit all electronic public comments via the Federal eRulemaking Portal website at <http://www.regulations.gov>.
- Mail: P. O. Box 21668, Juneau, AK 99802.
- Fax: (907) 586-7557.
- Hand delivery to the Federal Building: 709 West 9th Street, Room 420A, Juneau, AK.

All comments received are a part of the public record and will generally be posted to <http://www.regulations.gov> without change. All Personal Identifying Information (e.g., name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter N/A in the required fields, if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe portable document file (pdf) formats only.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907-586-7269.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

NMFS closed the directed fishery for Atka mackerel by vessels participating in the BSAI trawl limited access fishery in the Eastern Aleutian District and the Bering Sea subarea on September 1, 2008 (73 FR 51242, September 2, 2008).

NMFS has determined that approximately 152 mt of the 2008 Atka mackerel TAC specified for vessels participating in the BSAI trawl limited access fishery in the Eastern Aleutian District and the Bering Sea subarea remain in the directed fishing allowance. Therefore, in accordance with § 679.25(a)(1)(i), (a)(2)(i)(C), and (a)(2)(iii)(D), and to fully utilize the 2008 TAC of Atka mackerel in these areas specified for vessels participating in the BSAI trawl limited access fishery, NMFS is terminating the previous closure and is opening directed fishing for Atka mackerel by vessels participating in the BSAI trawl limited access fishery in the Eastern Aleutian District and the Bering Sea subarea. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance will be reached after 72 hours. Consequently, NMFS is prohibiting directed fishing for the 2008 TAC of Atka mackerel in these areas specified for vessels participating in the BSAI trawl limited access fishery