Classification

This action is taken under 50 CFR 672.20, and is in compliance with E.O. 12291.

List of Subjects in 50 CFR Part 672

Fisheries, Reporting and recordkeeping requirements.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 19, 1993.

David S. Crestin,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93–17472 Filed 7–19–93; 2:52 pm]

BILLING CODE 3510–22–M

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50 CFR Part 672

[Docket No. 921107–3068; I.D. 071993B]

Groundfish of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Closure.

SUMMARY: NMFS is closing the directed fishery for pollock in Statistical Area 63 in the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the third quarterly allowance of the total allowable catch (TAC) for pollock in this area.

EFFECTIVE DATE: 12 noon, Alaska local time (A.l.t.), July 20, 1993, through 12 noon, A.l.t., October 1, 1993.

FOR FURTHER INFORMATION CONTACT: Martin Loefflad, Resource Management Specialist, Fisheries Management Division, NMFS, (907) 586–7228.

SUPPLEMENTARY INFORMATION: The groundfish fishery in the GOA exclusive economic zone is managed by the Secretary of Commerce according to the Fishery Management Plan for Groundfish of the GOA (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson Fishery Conservation and Management Act. Fishing by U.S. vessels is governed by regulations implementing the FMP at 50 CFR parts 620 and 672.

The third quarterly allowance of pollock TAC in Statistical Area 63 is 17,257 metric tons (mt), determined in accordance with § 672.20(a)(2)(iv).

The Director of the Alaska Region, NMFS (Regional Director), has determined, in accordance with § 672.20(c)(2)(ii), that the 1993 third quarterly allowance of pollock TAC in Statistical Area 63 soon will be reached. The Regional Director established a directed fishing allowance of 16,757 mt, and has set aside the remaining 500 mt as bycatch to support other anticipated groundfish fisheries. The Regional Director has determined that the directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for pollock in Statistical Area 63, effective from 12 noon, A.l.t., July 20, 1993, through 12 noon, A.l.t., October 1, 1993.

Directed fishing standards for applicable gear types may be found in the regulations at § 672.20(g).

Classification

This action is taken under 50 CFR 672.20, and is in compliance with E.O. 12291.

List of Subjects in 50 CFR Part 672

Fisheries, Reporting and recordkeeping requirements.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 19, 1993.

Richard H. Schaefer,

Director, Office of Fisheries, Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93–17473 Filed 7–19–93; 3:14 pm]

BILLING CODE 3510–22–M

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50 CFR Part 672

[Docket No. 921107–3068; I.D. 071993A]

Groundfish of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Modification of a closure.

SUMMARY: NMFS is rescinding the closure to directed fishing for pollock in Statistical Area 62 in the Gulf of Alaska (GOA). This action is necessary to fully utilize the third quarterly allowance of the total allowable catch (TAC) for pollock in this area.

EFFECTIVE DATE: 12 noon, Alaska local time (A.l.t.), August 9, 1993, through 12 noon, A.l.t., October 1, 1993.

FOR FURTHER INFORMATION CONTACT: Andrew N. Smoker, Resource Management Specialist, NMFS, 907–586–7228.

SUPPLEMENTARY INFORMATION: The groundfish fishery in the GOA exclusive economic zone is managed by the Secretary of Commerce according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson Fishery Conservation and Management Act. Fishing by U.S. vessels is governed by regulations implementing the FMP at 50 CFR parts 620 and 672.

The directed fishery for pollock in Statistical Area 62 was prohibited from 12 noon, A.l.t., July 7, 1993, through 12 noon, A.l.t., October 1, 1993, under § 672.20(c)(2)(ii) (58 FR 37660, July 13, 1993).

The Regional Director, Alaska Region, NMFS, has determined that the third quarterly allowance of the TAC for pollock in Statistical Area 62 has not been reached. Therefore, NMFS is rescinding that closure and is reopening directed fishing for pollock in Statistical Area 62, effective at 12 noon, A.l.t., August 9, 1993, through 12 noon, A.l.t., October 1, 1993. All other closures remain in full force and effect.

Classification

This action is taken under 50 CFR 672.20, and is in compliance with E.O. 12291.

List of Subjects in 50 CFR Part 672

Fisheries, Reporting and recordkeeping requirements.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 19, 1993.

David S. Crestin,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93–17474 Filed 7–22–93; 8:45 am]

BILLING CODE 3510–22–M

Proposed Rules

Federal Register
Vol. 58, No. 140
Friday, July 23, 1993

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 3

[Docket No. 93-076-1]

Animal Welfare—Standards for Marine Mammals

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: We are considering revising the standards for the humane care and transportation of marine mammals used for exhibition and research purposes, and are soliciting comments regarding appropriate changes or additions to the present standards.

DATES: Consideration will be given only to comments received on or before October 6, 1993.

ADDRESSES: Please send an original and three copies of your comments to Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 93-076-1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are encouraged to call ahead on (202) 690-2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Dr. R. L. Crawford, Assistant Deputy Administrator, Animal Care, Regulatory Enforcement and Animal Care, APHIS, USDA, room 554, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-4981.

SUPPLEMENTARY INFORMATION:

Background

The Animal Welfare Act (the Act) (7 U.S.C. 2131 *et seq.*, enacted in 1966 and amended in 1970, 1976, 1985, and 1990) authorizes the Secretary of Agriculture to promulgate standards and other requirements governing the humane handling, housing, care, treatment, and transportation of certain animals by dealers, research facilities, exhibitors, and carriers and intermediate handlers. Regulations established under the Act are contained in 9 CFR parts 1, 2, and 3.

Under the Act, the Department established regulations in 1979 for the humane handling, housing, care, treatment, and transportation of marine mammals used for research or exhibition purposes. These standards were amended in 1984. During the 9 years since the standards were amended, advances have been made, new information has been developed, and new concepts have been implemented with regard to the housing and care of marine mammals.

We therefore consider it appropriate to review the current standards to determine what revisions, if any, are necessary. As part of our review we are requesting comments on appropriate specific standards for the humane handling, care, treatment, and transportation of marine mammals used for research or exhibition purposes. In addition, we invite responses to the following questions:

—Should ambient temperature ranges for air and water be established for each species for both indoor and outdoor facilities? If so, what should these temperature ranges be?
—Should the regulations consider the effect of noise on animals? If so, what level of noise should be allowable?
—Should public contact with marine mammals, including programs such as "Swim-with-the-Dolphins," be allowed? Under what parameters should such contact be allowed?
—Should additional recordkeeping be required in the areas of behavior, food intake, and veterinary care? If so, what recordkeeping should be required?
—Should solitary confinement of marine mammals in captivity be allowed? If so, under what conditions? Should this consideration be applied to polar bears as well?
—Is the currently required coliform test for water quality adequate? What test methods should be allowed? Should pH ranges be established by species? If so, what should these ranges be?

If we determine that the standards for marine mammals should be revised, we will publish the proposed standards for comment in the **Federal Register**.

Authority: 7 U.S.C. 2131-2157; 7 CFR 2.17, 2.51, and 371.2(g).

Done in Washington, DC, this 16th day of July 1993.

Eugene Branstool,

Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 93-17559 Filed 7-22-93; 8:45 am]

BILLING CODE 3410-34-P

9 CFR Part 78

[Docket No. 92-044-1]

Brucellosis; Interstate Movement of Swine

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the swine brucellosis regulations by standardizing and simplifying the testing requirements for States seeking validation as swine brucellosis-free, and by extending to 2 years the period during which validated brucellosis-free herds must be tested to maintain brucellosis-free status. We are also proposing to restrict the interstate movement of feral swine because of swine brucellosis. These actions appear necessary to achieve the goal of swine brucellosis eradication in the United States.

DATES: Consideration will be given only to comments received on or before September 21, 1993.

ADDRESSES: Please send an original and three copies of your comments to Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 92-044-1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are

encouraged to call ahead (202–690–2817) to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Dr. Delorias Lenard, Senior Staff Veterinarian, Swine Health Staff, VS, APHIS, USDA, room 736, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301–436–7767.

SUPPLEMENTARY INFORMATION:

Background

Brucellosis is a contagious disease affecting animals and man, caused by bacteria of the genus *Brucella*. Brucellosis in swine is characterized by abortion, infertility, orchitis, posterior paralysis, and lameness. The brucellosis regulations in 9 CFR part 78 (referred to below as the regulations) prescribe, among other things, conditions for the interstate movement of swine. Their purpose is to control, and ultimately to eradicate, brucellosis in the United States.

Under the regulations, States, herds, and individual animals are classified according to their brucellosis status. Interstate movement requirements for swine are based upon the disease status of the animal, or of the herd or State from which the animal originates. Currently, validated brucellosis-free status for a State is based on the State, among other things, having: (1) Completed surveillance, by one of several methods, during the months preceding classification, with no more than 3 percent of the tested herds having been found to have swine brucellosis, and with no diagnosed case of swine brucellosis in the State at the time of its classification; or (2) demonstrated, through a statistical analysis of the combined results of certain tests, that the testing has produced results equivalent to complete herd testing or slaughter surveillance during a 1- or 2-year period, as chosen by the State, with no diagnosed case of swine brucellosis in the 12 months preceding validation.

In recent years, considerable progress has been made toward the eradication of swine brucellosis. The incidence of swine brucellosis has declined to the point that good herd management practices have significantly reduced the risk of the disease reestablishing itself in States and herds that have been validated as free of swine brucellosis. Testing to the extent currently required no longer appears necessary to prevent the interstate spread of swine brucellosis.

We are therefore proposing to change the regulations to standardize and simplify the options regarding testing that are available to States seeking validation as swine brucellosis-free and to extend to 2 years the period during which validated brucellosis-free herds must be tested to maintain brucellosis-free status. We are also proposing to restrict the interstate movement of feral swine. We believe these changes would help us achieve the goal of eradication of brucellosis in domestic swine by the year 2000.

The proposed changes are discussed below.

Validated Brucellosis-Free State Status

We propose to reduce to three the number of surveillance options for States seeking validated brucellosis-free State status. The current definition of "Validated brucellosis-free State" in § 78.1 prescribes a range of surveillance options premised on complex time-test-traceback formulas. This diversity of options has created administrative difficulties for the Department in monitoring surveillance programs. We propose to simplify these requirements by eliminating surveillance options premised on 12- or 18-month testing regimens, and by requiring a 2-year qualification period for every State seeking validation. A State could complete required surveillance during the mandatory 2-year period by selecting one of the following options:

1. Subjecting all swine that are six months of age or older and maintained for breeding purposes to an official swine brucellosis test (complete herd testing); or

2. Market swine testing, that is, subjecting 20 percent of the State's swine that are six months of age or older and maintained for breeding purposes to an official swine brucellosis test, and demonstrating successful traceback of at least 80 percent of market swine test (MST) reactors to the herd of origin. All MST reactor herds would be subject to a complete herd test (CHT) within 30 days of the MST laboratory report date, as determined by the designated epidemiologist; or

3. Demonstrating, by a statistical analysis of all official swine brucellosis test results during the 2-year qualification period, a surveillance level equivalent or superior to the alternatives described above.

If, at any point during the 2-year qualification period, a herd were determined to be infected with swine brucellosis, depopulation of that herd would be required. A single such determination would be considered an anomaly, and would not affect the State's eligibility for validation. More than one such determination would signify the continuing presence of the disease within the State, and would therefore disqualify the State from validation as a brucellosis-free State. This proposed provision is more stringent than the currently allowed infection rate (3 percent of all herds in the State) because stakes become higher as the ambitious goal of surpassing disease control with disease eradication becomes attainable. Tolerance of multiple incidences of brucellosis-infected herds would increase the risk of disease perpetuation, jeopardizing eradication efforts.

To maintain validation, a State would be required, on an annual basis, to subject at least 5 percent of its breeding swine to an official test, and to demonstrate traceback to herd of origin of at least 80 percent of all MST reactors. Within 36–40 months of receiving validated brucellosis-free State status, the State would have to demonstrate its continuing ability to meet the criteria for initial brucellosis-free State validation, as discussed above.

For clarity, a definition of "complete herd test" would be added to the regulations to replace the current "herd blood test" provision for swine. "Complete herd test (CHT)" is the term more commonly used by producers today. The substance of the definition would not change. Similarly, a definition of "market swine test (MST) reactor" would be added to clarify that swine that react positively to a screening test, if no follow-up (confirmatory test) is conducted, are considered reactors. For information, a definition of "confirmatory test," providing a list of these tests, would also be added.

Validated Brucellosis-Free Herd Status

We are proposing to ease requirements for validated brucellosis-free herd status in validated brucellosis-free States. We would remove the requirement, in the definition of "validated brucellosis-free herd" in current § 78.1 of the regulations, that all sows and boars maintained for breeding purposes be negative to an official test. Routine testing of individual herds no longer appears warranted in validated brucellosis-free States, where the danger of the disease is remote, and where annual testing of 5 percent of breeding swine would be required for the State to maintain its validated brucellosis-free status. We therefore propose to validate as brucellosis-free any swine herd not known to be infected with swine brucellosis, located in a validated brucellosis-free State.

We are also proposing to amend the current regulations to provide a more

flexible testing regimen for a swine herd seeking, or seeking to maintain, validated brucellosis-free herd status in a State that has not been validated as brucellosis-free. The current definition of "validated brucellosis-free herd" in § 78.1 provides that for a swine herd to attain validated brucellosis-free status in any State, all sows and boars maintained for breeding purposes must first test negative to an official test. As we noted above, under this proposal, herds in a validated brucellosis-free State would not have to undergo such testing.

We are proposing a flexible testing regimen for a swine herd seeking validated brucellosis-free status in a State that is not a validated brucellosis-free State. Under the proposed provisions, the herd would qualify by testing negative to a CHT or to an incremental CHT. The incremental CHT could be conducted by testing 25 percent of all breeding swine every 80–105 days or by testing 10 percent of all breeding swine every 25–35 days, until 100 percent of these swine have been tested. If, during the course of the year, unanticipated circumstances (for example, flooding) arise, the Administrator may approve an alternative testing schedule that will achieve the purpose of the regulations. Under this alternative testing schedule, the complete herd would be tested within 365 days, with negative results. No swine could be tested twice in 1 year to comply with that year's test requirements. No further testing would be required once 100 percent of the breeding swine have been tested. After all breeding swine have tested brucellosis-negative, a herd may be validated as brucellosis-free. The herd would retain validated brucellosis-free status for a maximum of 12 months, unless it qualified for continual maintenance of validation, as described in the following paragraph.

The current definition of "validated brucellosis-free herd" provides that validation may be retained either by a negative CHT within 10 to 14 months of the last validation test date, by testing at least 20 percent of the sows and boars maintained for breeding purposes under an MST program during the year, or by testing all sows and boars maintained for breeding purposes at least once during the 1-year validation period under an approved herd plan.

Under this proposed rule, an incremental CHT would replace the MST and approved herd plan options. This change would reduce the administrative difficulties in monitoring individualized testing programs. It would introduce consistency into individual herd test schedules, without sacrificing the flexibility afforded herd owners by the current regulations. The incremental CHT could be conducted in either of the ways described above for obtaining validation, that is, 25 percent of all breeding swine would be tested, with negative results, every 80–105 days, or 10 percent of all breeding swine would be tested, with negative results, every 25–35 days, until 100 percent of these swine have been tested. If, during the course of the year, unanticipated circumstances (for example, flooding) arise, the Administrator may approve an alternative testing schedule that will achieve the purpose of the regulations. Under this alternative testing schedule, the complete herd would be tested within 365 days, with negative results. No breeding swine could be tested twice in 1 year to comply with the 25 percent requirement or the 10 percent requirement. No further testing is required once 100 percent of these swine have been tested.

The definition of "validated brucellosis-free herd" would be revised to include the proposed new provisions.

Feral Swine

In the 24 States known to have feral, or free-roaming, swine, these populations are found largely in riverine habitats and coastal swamps.

Brucellosis-infected feral swine are known to exist in at least 10 States, of which at least 3 have validated-free status, based on the incidence in domestic swine. These infected feral populations pose a danger to brucellosis-free swine in those and other States. Therefore, to protect domestic populations and expedite swine-brucellosis eradication in domestic herds throughout the United States, we propose to restrict the interstate movement of feral swine. This action would help confine brucellosis to feral populations. By reducing points of contact between feral and domestic populations, restricted interstate movement would reduce opportunities for disease transmission.

Therefore, we are proposing to introduce the following measures to restrict the interstate movement of feral swine:

1. Feral swine could be moved interstate directly to slaughter, if prevented from physical contact with any domestic swine or other livestock.

2. Feral swine from monitored-negative populations, or found negative to an official test within the 30 days prior to interstate movement, could be moved interstate, other than directly to slaughter (for example, to a hunting preserve or game farm), by permit of the APHIS representative or the State animal health official in the State of origin. A swine population may be classified by the designated epidemiologist as "monitored-negative" if the swine indicate no evidence of infection, and are from a geographically defined area: for example, a forest area, hunting preserve, or swamp.

For clarity, we propose to add definitions of "feral swine" and "monitored negative feral swine population," discussed above, to § 78.1. The definition of "feral swine" would note that previously free-roaming swine could be reclassified as domestic swine upon testing negative to an official swine brucellosis test after at least 60 days' confinement in isolation from other feral swine.

Miscellaneous

We propose to remove the redundant provision that States must have the "necessary authorities for classification as a validated brucellosis-free State for swine." This editorial change would have no substantive effect. Additionally, for informational purposes only, we propose to add a definition of "swine brucellosis" (that form of brucellosis caused by *Brucella suis* [*b. suis*] biovar 1 or 3) to § 78.1.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this proposed rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this proposed rule would have an effect on the economy of less than $100 million; would not cause a major increase in cost or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and would not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The proposed changes would result in direct benefits for producers through testing requirements either being relaxed or removed entirely, and indirect benefits through more standardized testing procedures. Fewer tests, at an estimated cost of $5 per head, would not only save herd owners money, but would also be less disruptive to normal herd operations. Similarly, savings would be realized by the removal of the requirement for

routine herd testing in validated brucellosis-free States.

The more stringent standard for validated brucellosis-free State status would disqualify any State with more than 1 confirmed herd infection. We expect that this new standard would provide States or producers with an incentive for depopulating the relatively few brucellosis-infected herds of domestic swine that, although sources of disease perpetuation and spread, are currently tolerated in some States. We therefore expect, with this provision, to expedite the eradication of swine brucellosis in domestic herds in all States in the United States. Once eradication has been achieved, as has been shown in 40 States, fewer tests must be conducted. That is, producers immediately benefit, operationally and economically, when fewer tests are required.

More than 90 percent of all domestic swine producers are small businesses. Based on the 1991 marketing year figures, sales of fewer than 4,000 head would place a producer in the "small business" category (gross receipts below $500,000). Of the 238,819 swine producers in the United States identified in the most recent Census of Agriculture, fewer than 24,000, or 10 percent, sell more than 1,000 head per year; precise figures above 1,000 are not available. We would expect large and small producers alike in States applying for validation or already validated as swine brucellosis-free to benefit to a limited extent from relaxed testing requirements. Producers in other States would be unaffected by these proposed changes to the regulations. Feral swine have a capacity for harboring and transmitting swine brucellosis to domestic herds. Feral swine moved interstate (not intended for immediate slaughter) are presumably sold to hunting preserves or at livestock auctions. However, State records indicate minimal interstate movement of feral swine. Few small entities, therefore, are likely to be affected by the proposed feral swine regulations.

We know of no other small entities that might be affected by this proposed rule.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are in conflict with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507 of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule will be submitted for approval to the Office of Management and Budget. Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please send a copy of your comments to: (1) Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, and (2) Clearance Officer, OIRM, USDA, room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250.

List of Subjects in 9 CFR Part 78

Animal diseases, Bison, Cattle, Hogs, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, 9 CFR part 78 would be amended as follows:

PART 78—BRUCELLOSIS

1. The authority citation for part 78 would continue to read as follows:

Authority: 21 U.S.C. 111–114a-1, 114g, 115, 117, 120, 121, 123–126, 134b, 134f; 7 CFR 2.17, 2.51, and 371.2(d).

2. In § 78.1, the term "herd blood test" would be revised by removing paragraph (b), and the following terms would be revised or added, in alphabetical order, as follows:

§ 78.1 Definitions.

* * * * *

Complete herd test (CHT). An official swine brucellosis test of all swine on a premises that are 6 months of age or older and maintained for breeding purposes.

Confirmatory test. A follow-up test to verify any official test results. Confirmatory tests include the standard tube test, the Rivanol test, the complement fixation test (CF), the particle concentration fluorescence immunoassay (PCFIA), the semen plasma test, and the standard plate test.

* * * * *

Feral swine. Free-roaming swine. Formerly free-roaming swine could qualify for reclassification as domestic swine upon testing negative to an official swine brucellosis test after a period of at least 60 days' confinement in isolation from other feral swine.

* * * * *

Market swine test (MST) reactor. Market swine test swine with a positive reaction to a swine brucellosis confirmatory test or other official test, if no confirmatory test is performed.

* * * * *

Monitored-negative feral swine population. Feral swine indicating no evidence of infection (indicators would include positive blood tests or clinical signs, such as abortion) and originating from a specified, geographically isolated area (a forest area, hunting preserve, or swamp, for example) may be classified by the designated epidemiologist as a monitored-negative feral swine population.

* * * * *

Swine brucellosis. The communicable disease of swine caused by *Brucella suis (B. suis)* biovar 1 or 3.

* * * * *

Validated brucellosis-free herd. (a) A swine herd not known to be infected with swine brucellosis, located in a validated brucellosis-free State; or (b) a swine herd in a State that has not been validated as brucellosis-free, provided the herd meets the conditions for validation, as follows:

(1) Validation: A swine herd may be validated as brucellosis-free if it has been found brucellosis negative after either a complete-herd test (CHT) or an incremental CHT. The incremental CHT may be conducted either by testing 25 percent of all breeding swine every 80–105 days, with negative results; or by testing 10 percent of all breeding swine every 25–35 days, with negative results, until 100 percent of these swine have been tested. The Administrator may approve an alternative testing schedule, under which the complete herd would be tested within 365 days with negative results, in cases where unforeseen circumstances warrant such action. No swine may be tested twice in 1 year to comply with the 25 percent requirement nor to comply with the 10 percent requirement. No further testing is required once 100 percent of the breeding swine have been tested. After all breeding swine have tested brucellosis negative, a herd may be

validated as brucellosis-free. A herd retains validated brucellosis-free status for a maximum of 12 months, except as provided in paragraph (2) of this definition.

(2) Validation may be continuously maintained if: (i) A complete herd test is performed once every 365 days, with negative results; or (ii) every 80–105 days, 25 percent of all breeding swine are tested, with negative results; or (iii) every 25–35 days, 10 percent of all breeding swine are tested, with negative results, until 100 percent of these swine have been tested. The Administrator may approve an alternative testing schedule, under which the complete herd would be tested within 365 days with negative results, in cases where unforeseen circumstances warrant such action. No swine may be tested twice in 1 year to comply with these requirements. No further testing is required once 100 percent of the breeding swine have been tested.

Validated brucellosis-free State. A State may apply for validated-free status when:

(a) Any herd found to have swine brucellosis during the 2-year qualification period preceding the application has been depopulated. More than one finding of a swine brucellosis-infected herd during the qualification period disqualifies the State from validation as brucellosis-free; and

(b) During the 2-year qualification period, the State has completed surveillance, annually, as follows:

(1) *Complete herd testing.* Subjecting all swine in the State that are six months of age or older and maintained for breeding purposed to an official swine brucellosis test; or

(2) *Market swine testing.* Subjecting 20 percent of the State's swine six months of age or older and maintained for breeding purposes to an official swine brucellosis test, and demonstrating successful traceback of at least 80 percent of market swine test (MST) reactors to the herd of origin. Blood samples may be collected from MST swine if the swine can be identified to their herd of origin, in accordance with § 71.19(b) of this subchapter. All MST reactor herds are subject to a CHT within 30 days of the MST laboratory report date, as determined by a designated epidemiologist; or

(3) *Statistical analysis.* Demonstrating, by a statistical analysis of all official swine brucellosis test results (including herd validation, MST, change-of-ownership, diagnostic) during the 2-year qualification period, a surveillance level equivalent or superior to CHT and MST testing programs discussed in this paragraph.

(c) To maintain validation, a State must annually survey at least 5 percent of its breeding swine, and demonstrate traceback to herd of origin of at least 80 percent of all MST reactors. A State must demonstrate its continuing ability to meet the criteria set forth in paragraph (c) of this definition within 36–40 months of receiving validated brucellosis-free State status to retain that status.

* * * * *

§ 78.30 [Amended]

3. In § 78.30, paragraph (a) would be amended by removing the words "and sows" after "brucellosis exposed swine" and adding, in their place, the words "feral swine, sows,".

4. In § 78.30, a new paragraph (c) would be added, to read as follows:

§ 78.30 General restrictions.

* * * * *

(c) (1) Feral swine may be moved interstate directly to slaughter if they do not come into physical contact with any domestic swine or other livestock.

(2) Feral swine from monitored-negative populations may be moved interstate other than directly to slaughter if accompanied by a permit issued by the APHIS representative or the State animal health official in the State of origin.

(3) Feral swine found negative to an official test within the 30 days prior to the interstate movement may be moved interstate other than directly to slaughter if accompanied by a permit issued by the APHIS representative or the State animal health official in the State of origin.

Done in Washington, DC, this 16 day of July, 1993.

Eugene Branstool,

Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 93–17556 Filed 7–22–93; 8:45 am]

BILLING CODE 3410–34–P

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9 CFR Part 113

[Docket No. 92–124–1]

Viruses, Serums, Toxins, and Analogous Products; Antibody Products

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations by: revising the designation for a group of Standard Requirements from "Blood Origin Products" to "Antibody Products;" revising five of the six existing Standard Requirements of the group; removing the sixth; and adding a new Standard Requirement for products for the treatment of failure of passive transfer. These amendments are necessary to update the standards and to provide for regulation of veterinary biological products which is more consistent with current scientific knowledge and understanding.

DATES: Consideration will be given only to comments received on or before September 21, 1993.

ADDRESSES: Send the original and three copies of your comments to Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 92–124–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. David A. Espeseth, Deputy Director, Veterinary Biologics, BBEP, APHIS, USDA, room 838, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, telephone (301) 436–8245.

SUPPLEMENTARY INFORMATION:

Background

In accordance with the regulations in 9 CFR part 113 (hereinafter referred to as "the regulations"), Standard Requirements are prescribed for the preparation of veterinary biological products. A Standard Requirement consists of specifications, procedures, and test methods which define the standards of purity, safety, potency, and efficacy for a given type of veterinary biological product. Where a Standard Requirement for a product does not exist, production procedures and specifications for purity, safety, and potency of an affected product are provided in an Outline of Production filed with the Animal and Plant Health Inspection Service (APHIS). For consistency of review and uniformity of standards, once standards for a given type of product are established, they are codified in the regulations.

In recent years the number of license applications received by APHIS for antibody products has increased substantially. A number of these products are derived from blood. However, increasing numbers have been derived from sources such as colostrum, milk, and eggs. Standard Requirements for many of these products are not

codified in the regulations, and many of them are not adequately addressed by the general requirements for blood origin products in § 113.450. For purposes of a more consistent licensing standard, more appropriate product-indication statements, greater guidance to manufacturers, and more reliable products, we propose to amend the regulations in the following manner.

First, it is proposed that the title "Blood Origin Products" be changed to "Antibody Products." The reason for this is that the revised standards would be applicable to more than just blood origin products. In addition, the proposed rule would revise the Standard Requirements in §§ 113.450, 113.451, 113.452, 113.454, and 113.455, and remove the Standard Requirement in § 113.453. The most significant revisions involve § 113.450. The proposed revisions to § 113.450 would provide definitions for some of the terms used in the regulations pertaining to antibody products, and present the new nomenclature devised for these products. Additionally, the revisions would provide more specific requirements for assessing the health of animals supplying source materials. For example, horses used to supply blood would be required to be tested for specific infectious diseases, including equine infectious anemia and piroplasmosis. Current regulations do not specify the diseases. They would also allow for alternative methods of handling and processing of source materials. Current regulations only allow for the use of one type of treatment (conventional heating) to inactivate contaminants. The revised regulations would allow for the treatment regimen to involve conventional heating or the use of ionizing radiation. Based on available data, the radiation dose specified should prove at least as effective at inactivating contaminants as the specific heat treatment regimens described in the current and revised regulations. The proposal also provides special purity standards for dried antibody products administered orally. Some of these products contain nonpathogenic bacteria deliberately introduced during the production process. Regular purity standards allow for presence of no bacteria. The proposed revisions to § 113.450 would also remove provisions pertaining to minimum globulin content and minimum protein content. These measurements are specified in the current regulations primarily to ensure that the serum from donor animals used to treat cases of failure of passive transfer is not abnormally low with respect to globulin and overall protein content. The proposed changes to the regulations make these measurements partially inapplicable, since antibodies from sources other than serum are allowed. In addition, the measurement specified in the new § 113.449 for products for the treatment of failure of passive transfer (see below) is more related to product efficacy.

The Standard Requirement in § 113.453 would be removed because no applicable licensed product exists for this section and because the potency tests described are obsolete. The proposed revisions to the remaining Standard Requirements (§§ 113.451, 113.452, 113.454, and 113.455) would: (1) Apply the new nomenclature devised for veterinary antibody products; (2) remove the limitation that the source material for a veterinary antibody product be the blood of hyperimmunized animals; restrictions on the nature of the source material associated with the proposed standards would be limited to those involving animals, collection procedures, and handling and processing methods (e.g., milk from a cow with brucellosis and/or that is simply filtered rather than irradiated or conventionally heat treated would not be an acceptable source material); (3) remove references to purity and safety testing, since purity and safety testing of antibody products would be addressed in § 113.450 and need only be referenced in these and subsequent Standard Requirements for the various veterinary antibody product types.

In addition, the proposed rule would establish a new Standard Requirement in § 113.499 for products used in the treatment of a condition of neonatal animals characterized by an abnormally low concentration of circulating maternal immunoglobulin. This condition is commonly referred to as "failure of passive transfer." It should be mentioned that the new Standard Requirement would permit failure of passive transfer (FPT) products to be recommended for use only in neonates of the same species as that which supplies the component material. For example, An FPT product of bovine origin could not be recommended for use in foals. For an FPT product, it is accepted that sufficient antibodies are contained therein to provide the neonate with some degree of protection against infectious disease. In most cases, however, the protective capacity of an FPT product is not as well defined as that for an antibody product intended for protection against a specific infectious disease, even when the product is for use in neonates of the same species. Due to this fact, and because of considerations such as spectrum of antibody, antibody half-life, and antibody functionality, APHIS believes that recommendations for cross-species use of these products should not be allowed. It should also be mentioned that the proposed Standard Requirement for FPT products provides that such products, if for oral administration, be recommended for administration within 24 hours of birth and for parenteral administration be recommended for administration within 120 hours of birth. The 24-hour limit is set with the understanding that the ability of the neonate gut to absorb large molecules such as immunoglobulins is very transient, and is lost or very reduced by 24 hours after birth, particularly if the animal has previously suckled. The 120-hour limit, while somewhat arbitrary, is set with the understanding that a diagnosis of failure of passive transfer is reserved for a very young animal, an animal that has not had sufficient time to mount an effective, active immune response against whatever microbial pathogens exist in its environment.

As noted above, the proposed rule would establish a new, more uniform nomenclature for veterinary antibody products. The term "antibody" would be used to describe a specific antibody product that contains antibodies directed against a nontoxin antigen, and the term "antitoxin" would be used to describe a specific antibody product that contains antibodies directed against toxin. If the antibodies are monoclonal, the term "monoclonal" would be included. For consistency with current naming practices for veterinary vaccines, the name of a virus-specific product would include the name of the disease the virus causes, while the name of a bacterium-specific product would include the scientific name of the bacterium. The true name of a specific antibody product would also indicate the type of animal from which the component antibodies originate. The following are examples of true names for specific antibody products: "Escherichia Coli Monoclonal Antibody, Murine Origin;" "Clostridium Perfringens Type C Antitoxin, Equine Origin;" "Duck Virus Hepatitis Antibody, Duck Origin."

The term "IgG" (immunoglobulin G) would be used to describe a product for the treatment of failure of passive transfer. The true name for such a product would also specify the species of origin of the IgG. The following are examples of true names for products for the treatment of failure of passive transfer: "Equine IgG," "Bovin IgG."

This nomenclature reflects the fact that IgG is the component of an FPT product measured in the efficacy study and in the serial-release potency test in accordance with § 113.499. The rationale for measuring IgG is founded on two main points. First, the condition known as failure of passive transfer has been most often defined in the scientific literature as an abnormally low level of IgG in the serum of a neonate. Second, IgG is the predominant immunoglobulin class in virtually all materials from which the FPT product antibodies would be derived. A product for which claims can be made for both the prevention and/or alleviation of a specific infectious disease and the treatment of failure of passive transfer would be named according to the guidelines for a product used for a specific infectious disease.

Executive Orders 12291 and Regulatory Flexibility Act

We are issuing this proposed rule in conformance with Executive Order 12291 and Departmental Regulation 1512–1 and have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this proposed rule, if implemented, would have an effect on the economy of less that $100 million; would not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions, and would not have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The proposed amendments to the regulations should, in most instances, either have no significant economic impact on the entities noted above or have a positive economic impact. For example, as proposed, manufacturers would not be restricted to pasteurization for the treatment of source materials and would not be restricted to the use of blood from hyperimmunized horses for the manufacture of veterinary antibody products for the prevention and/or alleviation of specific infectious diseases. Where the proposal may have a negative economic impact on manufacturing, such impact should be minimal. The negative impact may arise because the proposed rule would prohibit recommendations for cross-species use of FPT products. However, notification that such a proposal was being considered was given by APHIS over 4 years ago.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. It is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. There are no administrative proceedings which must be exhausted prior to any judicial challenge to the regulations under this rule.

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 113

Animal biologics, Export, Imports, Reporting and recordkeeping requirements.

Accordingly, 9 CFR part 113 would be amended as follows:

PART 113—STANDARD REQUIREMENTS

1. The authority citation for part 113 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.17, 2.51, and 371.2(d).

2. The undesignated center heading preceding § 113.450 would be revised to read "Antibody Products."

3. Section 113.450 would be revised to read as follows:

§ 113.450 General requirements for antibody products.

Unless otherwise prescribed in a Standard Requirement or in a filed Outline of Production, all antibody products shall meet the applicable requirements of this section.

(a) *Terminology.* The following terms in the regulations and standards concerning antibody products shall mean:

Antibody. An immunoglobulin molecule, having a precise glycoprotein structure, produced by certain cells of the B lymphocyte lineage in response to antigenic stimulation, and functioning to specifically bind and influence the antigens that induced its synthesis.

IgG (Immunoglobulin G). One of the several recognized classes of structurally related glycoproteins whose representatives include all known antibodies.

Monoclonal. Produced by, or derived from, the offspring of a single common progenitor cell.

Failure of passive transfer. A condition of neonates characterized by an abnormally low concentration of circulating maternal IgG.

(b) *Nomenclature.* Antibody products shall be named as follows:

(1) *Virus-specific products.* The true name of a virus-specific product shall: include the term "antibody," specify the disease for which the product is intended, and indicate the type of animal that supplied the component antibodies. If the antibodies are monoclonal, the term "monoclonal" shall be used. Example: "Duck Virus Hepatitis Antibody, Duck Origin."

(2) *Bacterium-specific products.* The true name of a bacterium-specific product shall: include the term "antibody" if the component antibodies are directed against a nontoxin antigen or the term "antitoxin" if the component antibodies are directed against toxin, specify the organism against which the product is intended, and indicate the type of animal that supplied the component antibodies. If the antibodies are monoclonal, the term "monoclonal" shall be used. Example: "Escherichia Coli Monoclonal Antibody, Murine Origin."

(3) *Failure of passive transfer products.* The true name of a product for treatment of failure of passive transfer shall: include the term "IgG" and indicate the type of animal that supplied the component IgG. Example: "Bovine IgG."

(4) *Combination products.* The true name of a product for treatment of failure of passive transfer as well as for the prevention and/or alleviation of a specific viral or bacterial disease shall be named according to the nomenclature prescribed above for virus-specific or bacterium-specific products.

(c) *Animals.* All animals used in the production of antibody products shall be healthy. Their health status shall be determined by physical examination by, or under the direct supervision of, a licensed veterinarian and by tests for infectious diseases. Such animals shall be maintained at licensed establishments: *Provided,* That cows maintained at Grade A dairies (or the equivalent) that are not injected with antigens for the purpose of stimulating the production of specific antibodies and that are used only for the purpose of supplying lacteal secretions are exempt from being maintained at a licensed establishment.

(1) No animal shall be used while showing clinical signs of disease. The

presence of minor localized injuries or lesions (contusions, lacerations, burns, etc.) without body temperature elevation and without significant pain and distress shall not be construed as clinical evidence of disease.

(2) Before first use and on a regular basis, all animals used in the manufacture of antibody products shall be individually subjected to applicable tests for infectious diseases. Records of all test results shall be maintained. An animal which tests positive for an infectious disease shall not be used in the manufacture of antibody products. Retests shall be conducted as deemed necessary by the Administrator.

(i) Before first use, horses shall be tested as follows for:

(A) Equine infectious anemia (EIA) at a laboratory approved by APHIS.

(B) Piroplasmosis, dourine, and glanders at the National Veterinary Services Laboratories.

(C) Brucellosis at a laboratory approved by APHIS. Horses with standard agglutination titers of 1:50 or less can be used for production. Horses with standard agglutination titers equal to or greater than 1:100 may be tested by the Rivanol or card tests. Reactors to these supplemental tests shall not be used for production. Nonreactors to the supplemental tests shall be retested after 30 days. If the supplemental tests are negative and the agglutination titer has not increased, the animal may be used for production. Otherwise, the animal is unsatisfactory for this purpose.

(ii) Horses shall be retested annually for EIA and, if housed or pastured with any other species, shall be retested annually for brucellosis.

(iii) Before first use, cattle shall be tested as follows for:

(A) Tuberculosis by an accredited veterinarian: *Provided*, That cattle at Grade A dairies supplying lacteal secretions only need only be tested for tuberculosis in accordance with applicable Milk Ordinances or similar laws or regulations.

(B) Brucellosis at a laboratory approved by APHIS. Cattle with standard agglutination titers of 1:50 or less can be used for production. Cattle with standard agglutination titers equal to or greater than 1:100 may be tested by the Rivanol or card tests. Reactors to these supplemental tests shall not be used for production. Nonreactors to the supplemental tests shall be retested after 30 days. If the supplemental tests are negative and the agglutination titer has not increased, the animal may be used for production; otherwise, the animal is unsatisfactory for this purpose. Cattle at Grade A dairies supplying lacteal secretions only need not be tested individually for brucellosis if a portion of their secretions contribute to the herd milk pool tested as required by the brucellosis ring test. An animal of a herd testing positive by this test shall be used in production.

(iv) Cattle shall be retested annually for both tuberculosis and brucellosis. Cattle at Grade A dairies supplying lacteal secretions only need only be tested for tuberculosis in accordance with applicable Milk Ordinances or similar laws or regulations. Cattle at Grade A dairies supplying lacteal secretions only need not be tested individually for brucellosis if a portion of their secretions contribute to the herd milk pool tested as required by the brucellosis ring test. An animal of a herd testing positive by this test shall not be used in production.

(v) For other species, appropriate tests and the frequency with which they are applied shall be specified in the filed Outline of Production for the product.

(vi) If a positive result is obtained on any prescribed test, the positive animal(s) shall be removed from the herd and the remaining animals retested. Production shall not be renewed until a negative herd test is obtained not less than 28 days following removal of the positive animal(s).

(vii) Negative animals shall be maintained separate and apart from untested or positive animals of any species. Production animals shall not be used for any other purpose, such as testing, work, or recreation.

(d) *Collection procedures.* Blood, lacteal secretions, and egg material shall be collected as described in the filed Outline of Production for the product.

(e) *Ingredient handling and processing.* Blood derivatives (serum, plasma, etc.), lacteal secretions, and egg material used in the production of antibody products shall be subjected to an appropriate procedure for the inactivation of potential contaminating microorganism. The procedure employed shall be specified in the filed Outline of Production for the product.

(1) Blood derivatives of equine origin shall be heated at 58.0–59.0 °C for 60 minutes, and blood derivatives of bovine, porcine, or other origin shall be heated at 58.0–59.0 °C for 30 minutes. In lieu of heat treatment, blood derivatives of any origin may be treated with three megarads of ionizing radiation.

(2) Lacteal secretions shall be heated as described in paragraph (c)(1) of this section, or shall be pasteurized at either 72 °C for 15 seconds or 89 °C for 1 second using appropriate equipment. In lieu of the heat treatment regimens prescribed, lacteal secretions may be treated with three megarads of ionizing radiation.

(3) Egg material shall be heated at 58.0–59.0 °C for 30 minutes or treated with three megarads of ionizing radiation.

(4) Blood derivatives, lacteal secretions, and egg material shall not contain preservatives at the time of treatment, and immediately after treatment shall be cooled to 7 °C or lower.

(5) Licensees shall keep detailed records as to each batch treated and each serial of product prepared for marketing. Recording charts shall bear full information concerning the material treated and tests made of the equipment used for treatment.

(f) *Preservatives.* Liquid antibody products, except those immediately frozen following preparation and maintained in a frozen state, shall contain at least one preservative from the following list, within the range of concentration set forth:

(1) Phenol 0.25 to 0.55 percent, or

(2) Cresol 0.10 to 0.30 percent, and/or

(3) Thimerosal 0.01 to 0.03 percent, or

(4) Other preservative(s) specified in the filed Outline of Production for the product.

(g) *Antigens for hyperimmunization.* If animals are hyperimmunized to generate antibodies for a product for the prevention and/or alleviation of a specific infectious disease, and a USDA-licensed veterinary biological product is not employed for this purpose, the following shall apply:

(1) For each antigen, a Master Seed shall be established.

(i) Bacterial Master Seeds shall be tested for purity and identity as prescribed for live bacterial vaccines in § 113.64.

(ii) Viral Master Seeds shall be tested for purity and identity as prescribed for live virus vaccines in § 113.300.

(2) The maximum allowable passage level of the hyperimmunizing antigen shall be the passage level of the antigen used to generate product shown to be efficacious and shall not exceed 10 passages from the Master Seed.

(h) *Purity tests.* Final container samples of each serial and each subserial shall be tested for viable bacteria and fungi as follows:

(1) Dried products for parenteral administration and liquid products shall be tested as prescribed in § 113.26.

(2) For dried products for oral administration, 10 final container samples shall be reconstituted with sterile water at the volume recommended on the label and tested for the following contaminants:

(i) *Coliforms.* One milliliter of each rehydrated sample shall be pipetted into a 100×15 mm petri dish and 10–15 ml of violet red bile agar at 45–50 °C added. The plate shall be manipulated to coat its entirety with the agar-sample mixture and allowed to stand until the mixture solidifies. The plate shall then be incubated at 35 °C for 24 hours. A positive control plate and a negative control plate shall be prepared at the same time and in the same manner as the plates containing samples of the serial. All plates shall be examined at the end of the incubation period. If growth is observed on the negative control plate, or no growth is observed on the positive control plate, the test shall be considered inconclusive and may be repeated. If growth is observed on any of the 10 plates containing samples of the serial, one retest to rule out faulty technique may be conducted on samples from 20 final containers. If growth is observed on any of the retest plates, or if a retest is not initiated within 21 days of the completion of the original test, the serial or subserial is unsatisfactory.

(ii) *Salmonellae.* One milliliter of each rehydrated sample shall be pipetted into a 100×15 mm petri dish and 10–15 ml of brilliant green agar at 45–50 °C added. The dish shall be manipulated to coat its entirety with the agar-sample mixture and allowed to stand until the mixture solidifies. The plate shall then be incubated at 35 °C for 24 hours. A positive control plate and a negative control plate shall be prepared at the same time and in the same manner as the plates containing samples of the serial. All plates shall be examined at the end of the incubation period. If growth is observed on the negative control plate, or no growth is observed on the positive control plate, the test shall be considered inconclusive and may be repeated. If growth is observed on any of the 10 plates containing samples of the serial, one retest to rule out faulty technique may be conducted on samples from 20 final containers. If growth is observed on any of the retest plates, or if a retest is not initiated within 21 days of the completion of the original test, the serial or subserial is unsatisfactory.

(iii) *Fungi.* One milliliter of each rehydrated sample shall be pipetted into a 100×15 mm petri dish and 10–15 ml of appropriately acidified potato dextrose agar at 45–50 °C added. The plate shall be manipulated to coat its entirety with the agar-sample mixture and allowed to stand until the mixture solidifies. The plate shall then be incubated at 20–25 °C for 5 days. A positive control plate and a negative control plate shall be prepared at the same time and in the same manner as the plates containing samples of the serial. All plates shall be examined at the end of the incubation period. If growth is observed on the negative control plate, or no growth is observed on the positive control plate, the test shall be considered inconclusive and may be repeated. If growth is observed on any of the 10 plates containing samples of the serial, one retest to rule out faulty technique may be conducted on samples from 20 final containers. If growth is observed on any of the retest plates, or if a retest is not initiated within 21 days of the completion of the original test, the serial or subserial is unsatisfactory.

(iv) *Total bacterial count.* One milliliter of each rehydrated sample shall be pipetted into a 100×15 mm petri dish and 10–15 ml of tryptone glucose extract agar at 45–5 °C added. The plate shall be manipulated to coat its entirety with the agar-sample mixture and allowed to stand until the mixture solidifies. The plate shall then be incubated at 35 °C for 48 hours. A positive control plate and a negative control plate shall be prepared at the same time and in the same manner as the plates containing samples of the serial. All plates shall be examined at the end of the incubation period. If growth is observed on the negative control plate, or no growth is observed on the positive control plate, the test shall be considered inconclusive and may be repeated. If the average number of bacterial colonies on the 10 plates containing samples of the serial exceeds that specified in the filed Outline of Production for the product, one retest to rule out faulty technique may be conducted on samples from 20 final containers. If the average number of bacterial colonies on the retest plates exceeds that specified in the filed Outline of Production for the product, or if a retest is not initiated within 21 days of the completion of the original test, the serial or subserial is unsatisfactory.

(i) *Safety tests.* Bulk of final container samples of each serial shall be tested as prescribed in § 113.33(b). Dried product shall be reconstituted as indicated on the label and 0.5 ml injected per mouse.

§ 113.451 [Amended]

4. In § 113.451, paragraphs (b) and (c) would be removed, paragraph (d) would be redesignated paragraph (b), and the introductory text to the section would be revised to read as follows:

113.451 Tetanus Antitoxin.

Tetanus Antitoxin is a specific antibody product containing antibodies directed against the toxin of *Clostridium tetani.* Each serial shall meet the applicable general requirements provided in § 113.450 and paragraph (a) of this section, and be tested for potency as provided in paragraph (b) of this section. Any serial found unsatisfactory by a prescribed test shall not be released.

* * * * *

5. In § 113.452, the section heading, introductory text of the section, and paragraph (a) would be revised; paragraph (b) would be removed; paragraph (c) would be redesignated as new paragraph (b); and newly redesignated paragraph (b) introductory text, (b)(1), and (b)(3) would be revised to read as follows:

§ 113.452 Erysipelothrix Rhusiopathiae Antibody.

Erysipelothrix Rhusiopathiae Antibody is a specific antibody product containing antibodies directed against one or more somatic antigens of *Erysipelothrix rhusiopathiae.* Each serial shall be tested as provided in this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) Each serial shall meet the applicable general requirements provided in § 113.450.

(b) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested using the two-stage test provided in this section.

(1) In the first stage, each of 40 Swiss mice, each weighing 16 to 20 grams, shall be injected subcutaneously with 0.1 ml of product (dried product shall be rehydrated according to label directions). Twenty-four hours postinjection, the injected mice and 10 additional mice designated controls shall be challenged subcutaneously with the same culture of *Erysipelothrix rhusiopathiae.*

* * * * *

(3) The mice injected with product shall be observed for 10 days postchallenge and all deaths recorded. The second stage shall be required when 7–10 of the mice injected with product die in the first stage. The second stage shall be conducted in a manner identical to the first stage.

* * * * *

§ 113.453 [Removed]

6. Section 113.453 would be removed and reserved.

§ 113.454 [Amended]

7. In § 113.454, the introductory text of the section and paragraph (a) would be revised; paragraph (b) would be removed; paragraph (c) would be redesignated as new paragraph (b) and the introductory text of paragraph (b) would be revised to read as follows:

§ 113.454 Clostridium Perfringens Type C Antitoxin.

Clostridium Perfringens Type C Antitoxin is a specific antibody product containing antibodies directed against the toxin of *Clostridium perfringens* Type C. Each serial shall be tested as provided in this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) Each serial shall meet the applicable general requirements provided in § 113.450.

(b) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested using the toxin-neutralization test for Beta Antitoxin provided in this section. Dried products shall be rehydrated according to label directions.

8. In § 113.455, the introductory text of the section and paragraph (a) would be revised; paragraph (b) would be removed; paragraph (c) would redesignated as new paragraph (b) and the introductory test of paragraph (b) would be revised to read as follows:

§ 113.455 Clostridium Perfringens Type D Antitoxin.

Clostridium Perfringens Type D Antitoxin is a specific antibody product containing antibodies directed against the toxin of *Clostridium perfringens* Type D. Each serial shall be tested as provided in this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) Each serial shall meet the applicable general requirements provided in § 113.450.

(b) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested using the toxin-neutralization test for Epsilon Antitoxin provided in this section. Dried products shall be rehydrated according to label directions.

* * * * *

§§ 113.456 through 113.498 [Reserved]

9. New §§ 113.456 through 113.498 would be added and reserved.

10. Section 113.499 would be added to read as follows:

§ 113.499 Products for treatment of failure of passive transfer.

A product for the treatment of failure of passive transfer shall contain a specified minimum quantity of IgG per dose and shall be recommended for use only in neonates of the same species as that of antibody origin. A product for oral administration shall not be recommended for use in animals more than 24 hours of age, while one for parenteral administration shall not be recommended for use in animals more than 120 hours of age. Each serial shall meet the applicable general requirements provided in § 113.450 and be tested for potency as provided in this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) *Establishment of an IgG Reference Product.* An IgG Reference Product shall be established as follows:

(1) At least 20 newborn, colostrum-deprived animals of the species for which the product is recommended shall be randomly selected.

(2) Blood samples shall be taken from each animal.

(3) Each animal shall be administered one dose of product by the recommended route and shall be observed for 24 hours.

(i) Any adverse reactions shall be recorded.

(ii) The dosage of product administered to each animal shall be based on the weight of the animal, in accordance with label directions.

(4) After 24 hours, blood samples shall be taken from each animal.

(5) Pretreatment and post treatment serum IgG concentrations shall be concurrently determined for each animal by five replicate tests using a radial immunodiffusion (RID) method acceptable to APHIS and described in the filed Outline of Production for the product.

(6) Using the same method, five replicate tests shall be conducted concurrently on an IgG Species Standard supplied or approved by APHIS.

(7) For an IgG Reference Product to be satisfactory, all animals used to establish the reference must remain free of unfavorable product-related reactions and at least 90 percent of the paired serum samples must reflect an increase in IgG concentration equal to or greater than the IgG concentration of the IgG Species Standard.

(b) *Antibody functionality.* Prior to licensure, the prospective licensee shall perform a neutralization study, or another type of study acceptable to APHIS, to demonstrate functionality of product antibody.

(c) *Potency.* Bulk or final container samples of completed product from each serial shall be tested for IgG content as provided in this paragraph. Samples of the test serial and of an IgG Reference Product established in accordance with paragraph (a) of this section shall be concurrently tested for IgG content by the RID method referred to in paragraph (a)(5) of this section. Five replicate tests shall be conducted on each. If the IgG level per dose of the test serial does not meet or exceed that of the IgG Reference Product, one complete retest (involving five replicate IgG determinations on both the test serial and the IgG Reference Product) to rule out faulty technique may be conducted. If, upon retest, the IgG level per dose of the test serial does not meet or exceed that of the IgG Reference Product, or if a retest is not conducted, the serial is unsatisfactory.

Done in Washington, DC, this 6th day of July 1993.

Eugene Branstool,

Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 93-17608 Filed 7-22-93; 8:45 am]

BILLING CODE 3410-34-P

Animal and Plant Health Inspection Service

9 CFR Part 113

[Docket No. 92-132-1]

Viruses, Serums, Toxins, and Analogous Products; Revision of Standard Requirements

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Standard Requirements concerning the Dog Safety Tests; Canine Distemper Vaccine, Killed Virus; Canine Hepatitis Vaccine, Killed Virus; Canine Adenovirus Type 2 Vaccine, Killed Virus; Mink Enteritis Vaccine, Killed Virus; Canine Hepatitis Vaccine, Live Virus; Canine Adenovirus Type 2 Vaccine, Live Virus; and Canine Distemper Vaccine, Live Virus. The proposed rule is necessary because new test methods and procedures have been developed that would replace current test requirements and increase the validity of test results. The effect of the proposed amendments would be to allow the use of these new test methods and procedures and to relax some of the restrictions currently in effect. Also, the section containing the Standard Requirement for Canine Distemper Vaccine (Ferret Virulent) would be removed because this vaccine is no longer manufactured.