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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 78

[Docket No. 96–015–1]

Brucellosis; Approved Brucella Vaccines

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the brucellosis regulations to remove the requirement that an approved brucella vaccine be, among other things, a *Brucella abortus* Strain 19 product. This change allows for the use of vaccines that have been developed using strains of *Brucella* other than *Brucella abortus* Strain 19. Specifically, this action allows the RB51 brucella vaccine, which was licensed for use in cattle by the U.S. Department of Agriculture in February 1996, to be used in the cooperative State/Federal brucellosis eradication program.

DATES: Interim rule effective March 26, 1996. Consideration will be given only to comments received on or before May 31, 1996.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 96–015–1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 96–015–1. 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 requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Dr. M.J. Gilsdorf, National Brucellosis Epidemiologist, Cattle Diseases and Surveillance Staff, VS, APHIS, 4700 River Road Unit 36, Riverdale, MD 20737–1228, (301) 734–7708; E-mail: mgilsdorf@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Brucellosis is a contagious disease affecting animals and humans, caused by bacteria of the genus *Brucella.* In its principal animal hosts, brucellosis is characterized by abortion and impaired fertility.

The brucellosis regulations contained in 9 CFR part 78 (referred to below as the regulations) provide a system for classifying States or portions of States according to the rate of *Brucella abortus* infection present and the general effectiveness of the brucellosis control and eradication program conducted in the State or area. The classifications are Class Free, Class A, Class B, and Class C; States or areas that do not meet the minimum standards for Class C may be placed under Federal quarantine.

Through a cooperative State and Federal effort, the United States is now approaching total eradication of the field strain *Brucella abortus* in domestic cattle and bison herds. As of February 29, 1996, there were only 50 known affected cattle and bison herds, and the U.S. Department of Agriculture (USDA) had declared 34 States, Puerto Rico, and the U.S. Virgin Islands free of the disease.

One element of the cooperative State/Federal brucellosis eradication effort is the use of approved Brucella vaccines on female cattle and female bison to protect those animals against the disease. The current definition of *approved Brucella vaccine* in § 78.1 of the regulations specifies that such a vaccine must be a *Brucella abortus* Strain 19 product approved by, and produced under license of, the USDA for injection into cattle and bison to enhance their resistance to brucellosis. When that definition was written, *Brucella abortus* Strain 19 was the only strain of *Brucella* being used to produce Brucella vaccine for cattle and bison. More recently, however, research conducted by the USDA and other public and private entities has yielded promising results with vaccines that are being developed using strains of *Brucella* other than *Brucella abortus* Strain 19. In February 1996, the USDA licensed one of those new vaccines, designated RB51, for use in cattle; its licensing for use in bison is expected in the near future, pending completion of ongoing tests.

Although RB51 has been licensed and approved for use in cattle, the reference to *Brucella abortus* Strain 19 products prevents RB51, and any vaccines developed in the future from strains of *Brucella* other than *Brucella abortus* Strain 19, from meeting the definition of *approved Brucella vaccine.* Therefore, in order to eliminate that obstacle, we have removed the reference to *Brucella abortus* Strain 19 from the definition of *approved Brucella vaccine;* the regulations now require that the vaccine be a *Brucella* product without specifying a particular strain. Additionally, the definition states that an *approved Brucella vaccine* must be approved and licensed for injection into cattle and bison; as noted in the previous paragraph, RB51 has been licensed and approved for use in cattle before being licensed and approved for bison. To allow for the immediate use of RB51 in cattle, we are further amending the definition of *approved Brucella vaccine* to allow the licensing and approval to apply to a vaccine's injection into ''cattle or bison,'' rather than the more restrictive ''cattle and bison.'' Neither of these changes affects any currently licensed and approved Brucella vaccines, and the regulations still require that any *approved Brucella vaccine* must meet the USDA's approval and licensing requirements.

Brucella abortus Strain 19 Brucella vaccines cause vaccinated animals to produce antibodies that are indistinguishable on standard diagnostic tests from the antibodies produced by animals infected with brucellosis. However, the RB51 vaccine, and other vaccines produced from strains of *Brucella* other than *Brucella abortus* Strain 19 that may attain approved Brucella vaccine status in the future, do not produce those interfering antibody titers. Because of this difference, we have amended the definition of *official test* in several places to distinguish between cattle and bison vaccinated with a *Brucella abortus* Strain 19 Brucella vaccine and

cattle and bison vaccinated with approved Brucella vaccines produced from strains of *Brucella* other than *Brucella abortus* Strain 19. Specifically, in the definition of *official test* we have amended the paragraphs regarding the standard tube test or standard plate test (paragraph (a)(2)), the manual complement-fixation test (paragraph (a)(3)), the technicon automated complement-fixation test (paragraph (a)(4)), and the rivanol test (paragraph (a)(5)) by listing the agglutination reactions for classifying official vaccinates that have been vaccinated with approved Brucella vaccines produced from strains of *Brucella* other than *Brucella abortus* Strain 19. The agglutination reactions we have added are, for each test, the same as those listed for cattle and bison that are not official vaccinates, since approved Brucella vaccines produced from strains of *Brucella* other than *Brucella abortus* Strain 19 will not cause vaccinated cattle or bison to produce antibody titers. The existing agglutination reactions listed for official vaccinates have not been changed, but the regulations now specify that those reactions are for official vaccinates that have been vaccinated with a *Brucella abortus* Strain 19 approved Brucella vaccine.

To clear the way for the immediate use of RB51, we are also amending two other definitions, i.e., those for *official adult vaccinate* and *official calfhood vaccinate.* Each of those definitions contains a reference to a specific dosage of vaccine to be used in vaccinating female cattle and female bison; however, those dosages are appropriate for *Brucella abortus* Strain 19 vaccines only. Therefore, we are amending those definitions to specify that the dosage indicated is for *Brucella abortus* Strain 19 vaccines only, and that the dosage for other vaccines will be the dosage indicated on the vaccine's label instructions.

In a final rule published in the Federal Register on September 12, 1986 (51 FR 32574–32600, Docket No. 85–132), the specified dosages of Brucella vaccine for cattle and bison adults and calves were changed. To accommodate the owners of cattle and bison that had been vaccinated using the old dosage, the definitions for *official adult vaccinate* and *official calfhood vaccinate* provided that cattle or bison vaccinated prior to December 31, 1984, using the old dosage would still be considered to be official adult or calfhood vaccinates. It is unlikely that any cattle or bison herds in the United States contain cattle or bison vaccinated with the old dosage over 11 years ago, so we have removed that provision from the definitions for *official adult vaccinate* and *official calfhood vaccinate.*

Immediate Action

The Administrator of the Animal and Plant Health Inspection Service has determined that there is good cause for publishing this interim rule without prior opportunity for public comment. This rule allows the U.S. cattle industry to use the RB51 brucella vaccine, which was licensed by the USDA for use in February 1996, to vaccinate the spring crop of calves before the calves are turned out on summer pastures, which is especially important in high-risk areas where the calves may be exposed to infected animals. The U.S. cattle industry and Federal and State animal health agencies will benefit economically from using the new vaccine because the RB51 vaccine does not cause vaccinated animals to produce interfering antibody titers on diagnostic tests, so the need for traceback investigations will be significantly reduced.

Because prior notice and other public procedures with respect to this action are impracticable and contrary to the public interest under these conditions, we find good cause under 5 U.S.C. 553 to make it effective upon signature. We will consider comments that are received within 60 days of publication of this rule in the Federal Register. After the comment period closes, we will publish another document in the Federal Register. It will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required by Executive Order 12866.

Currently available *Brucella abortus* Strain 19 brucella vaccines cause vaccinated animals to produce antibodies that are indistinguishable on standard diagnostic tests from the antibodies produced by animals infected with brucellosis. Because of this, State or Federal animal health personnel must trace those animals to their herds of origin to investigate whether or not the herd is actually affected with brucellosis. This rule allows for the use of a new brucella vaccine that will not cause vaccinated cattle to produce those interfering antibody titers. This will save the cattle industry and Federal and State animal health authorities the expense of tracing animals with vaccination titers. This rule, therefore, is expected to have a favorable economic impact. The need to make this rule effective in time for U.S. cattle raisers to use RB51 to vaccinate the spring crop of calves before the calves are turned out for summer pasture makes timely compliance with sections 603 and 604 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) impracticable. The final rule for this action will include an analysis of the economic impact of this rule on small entities and will address any comments we receive on the economic impact of the rule on 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 rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 78

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

Accordingly, 9 CFR part 78 is amended to read as follows:

PART 78—BRUCELLOSIS

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

Authority: 21 U.S.C. 111–114a-1, 114g, 115, 117, 120, 121, 123–126, 134b, and 134f; 7 CFR 2.22, 2.80, and 371.2(d).

2. Section 78.1 is amended as follows:

a. By revising the definition of *Approved brucella vaccine* to read as set forth below.

b. In the definition of *official adult vaccinate,* by revising paragraph (a) to read as set forth below.

c. In the definition of *official calfhood vaccinate,* by revising paragraph (a) to read as set forth below.

d. By amending the definition of *official test* as follows:

i. In paragraph (a)(2), by revising the heading for the first table to read ''SPT OR STT CLASSIFICATION—OFFICIAL VACCINATES VACCINATED WITH A *Brucella abortus* STRAIN 19 APPROVED BRUCELLA VACCINE'' and by adding a new table immediately following the first table to read as set forth below.

ii. In paragraph (a)(3), the introductory text of paragraph (a)(3)(ii) is amended by adding the words ''vaccinated with a *Brucella abortus* Strain 19 approved brucella vaccine'' after the word ''vaccinates'', and a new paragraph (a)(3)(iii) is added to read as set forth below.

iii. In paragraph (a)(4), the introductory text of paragraph (a)(4)(ii) is amended by adding the words ''vaccinated with a *Brucella abortus* Strain 19 approved brucella vaccine'' after the word ''vaccinates'', and a new paragraph (a)(4)(iii) is added to read as set forth below.

iv. The introductory text of paragraph (a)(5)(ii) is amended by removing the words ''and official calfhood vaccinates'' and adding the words ''with a *Brucella abortus* Strain 19 approved brucella vaccine and official calfhood vaccinates vaccinated with a *Brucella abortus* Strain 19 approved brucella vaccine'' in their place.

v. The introductory text of paragraph (a)(5)(iii) is amended by adding the words ''with a *Brucella abortus* Strain 19 approved brucella vaccine'' immediately after the word ''vaccination''.

vi. A new paragraph (a)(5)(iv) is added to read as set forth below.

§ 78.1 Definitions.

* * * * *

Approved brucella vaccine. A *Brucella* product approved by and produced under license of the United States Department of Agriculture for injection into cattle or bison to enhance their resistance to brucellosis.

* * * * *

Official adult vaccinate. (a) Female cattle or female bison older than the specified ages defined for official calfhood vaccinate and vaccinated by an APHIS representative, State representative, or accredited veterinarian with a reduced dose approved brucella vaccine, diluted so as to contain at least 300 million and not more than 1 billion live cells per 2 mL dose of *Brucella abortus* Strain 19 vaccine or at the dosage indicated on the label instructions for other approved brucella vaccines, as part of a whole herd vaccination plan authorized jointly by the State animal health official and the Veterinarian in Charge; and

* * * * *

Official calfhood vaccinate. (a) Female cattle or female bison vaccinated while from 4 through 12 months of age by an APHIS representative, State representative, or accredited veterinarian with a reduced dose approved brucella vaccine containing at least 2.7 billion and not more than 10 billion live cells per 2 mL dose of *Brucella abortus* Strain 19 vaccine or at the dosage indicated on the label instructions for other approved brucella vaccines; and

* * * * *

Official test.

(a) * * *

(2) * * *

OFFICIAL VACCINATES VACCINATED WITH AN APPROVED BRUCELLA VACCINE OTHER THAN A BRUCELLA ABORTUS STRAIN 19 APPROVED BRUCELLA VACCINE

Titer			Classification
1:50	1:100	1:200	
—	—	—	Negative.
I	—	—	Suspect.
+	—	—	Do.
+	I	—	Do.
+	+	—	Reactor.
+	+	I	Do.
+	+	+	Do.

— No agglutination.
I Incomplete agglutination.
+ Complete agglutination.

* * * * *

(3) * * *

(iii) Official vaccinates vaccinated with an approved brucella vaccine other than a *Brucella abortus* Strain 19 approved brucella vaccine:

(A) Fifty percent fixation (2 plus) in a dilution of 1:20 or higher—brucellosis reactor;

(B) Fifty percent fixation (2 plus) in a dilution of 1:10 but less than 50 percent fixation (2 plus) in a dilution of 1:20—brucellosis suspect;

(C) Less than 50 percent fixation (2 plus) in a dilution of 1:10—brucellosis negative.

(4) * * *

(iv) Official vaccinates vaccinated with an approved brucella vaccine other than a *Brucella abortus* Strain 19 approved brucella vaccine:

(A) Fixation in a dilution of 1:10 or higher—brucellosis reactor;

(B) Fixation in a dilution of 1:5 but no fixation in a dilution of 1:10—brucellosis suspect;

(C) No fixation in a dilution of 1:5 or lower—brucellosis negative.

(5) * * *

(v) Official vaccinates vaccinated with an approved brucella vaccine other than a *Brucella abortus* Strain 19 approved brucella vaccine:

(A) Complete agglutination at a titer of 1:25 or higher—brucellosis reactor;

(B) Less than complete agglutination at a titer of 1:25—brucellosis negative.

* * * * *

Done in Washington, DC, this 26th day of March 1996.

Lonnie J. King,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–7837 Filed 3–29–96; 8:45 am]

BILLING CODE 3410–34–P

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9 CFR Part 92

[Docket No. 95–052–2]

Horses From Bermuda and the British Virgin Islands; Quarantine Requirements

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations regarding the importation of horses from Bermuda and the British Virgin Islands to remove the requirement that such horses be quarantined for not less than 7 days upon arrival in the United States. This action is warranted because Bermuda and the British Virgin Islands have reported no cases of Venezuelan equine encephalomyelitis (VEE), and it appears that horses imported from Bermuda and the British Virgin Islands with less than a 7-day quarantine would not pose a risk of transmitting VEE to horses in the United States.

EFFECTIVE DATE: May 1, 1996.

FOR FURTHER INFORMATION CONTACT: Dr. Joyce Bowling, Staff Veterinarian, Import/Export Animals, National Center for Import and Export, VS, APHIS, Suite 3B08, 4700 River Road Unit 39, Riverdale, MD 20737–1231, (301) 734–6479, or e-mail: jbowling@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 92, referred to below as the regulations, govern the importation into the United States of specified animals and animal products to prevent the introduction