Animal and Plant Health Inspection Service

9 CFR Part 77

[Docket No. 96–092–1]

Tuberculosis in Cattle and Bison; State Designation

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the tuberculosis regulations concerning the interstate movement of cattle and bison by raising the designation of Oklahoma from a modified accredited State to an accredited-free State. We have determined that Oklahoma meets the criteria for designation as an accredited-free State.

DATES: Interim rule effective December 26, 1996. Consideration will be given only to comments received on or before February 24, 1997.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 96–092–1, 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. 96–092–1. 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. Mitchell A. Essey, Senior Staff Veterinarian, National Animal Health Programs, VS, APHIS, 4700 River Road Unit 36, Riverdale, MD 20737–1231, (301) 734–7727; or e-mail: messey@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The ''Tuberculosis'' regulations, contained in 9 CFR part 77 (referred to below as ''the regulations''), regulate the interstate movement of cattle and bison because of tuberculosis. Bovine tuberculosis is the contagious, infectious, and communicable disease caused by *Mycobacterium bovis.* The requirements of the regulations concerning the interstate movement of cattle and bison not known to be affected with, or exposed to, tuberculosis are based on whether the cattle and bison are moved from jurisdictions designated as accredited-free States, modified accredited States, or nonmodified accredited States.

The criteria for determining the status of States (the term ''State'' is defined to mean any State, territory, the District of Columbia, or Puerto Rico) are contained in a document captioned Uniform Methods and Rules—Bovine Tuberculosis Eradication,'' which has been made part of the regulations via incorporation by reference. The status of States is based on the rate of tuberculosis infection present and the effectiveness of a tuberculosis eradication program. A State must have no findings of tuberculosis in any cattle or bison in the State for at least 5 years to be designated as an accredited-free State.

Before publication of this interim rule, Oklahoma was designated in § 77.1 of the regulations as a modified accredited State. However, Oklahoma now meets the requirements for designation as an accredited-free State. Therefore, we are amending the regulations by removing Oklahoma from the list of modified accredited States in § 77.1 and adding it to the list of accredited-free States in that section.

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. Immediate action is warranted to change the regulations so that they accurately reflect the current tuberculosis status of Oklahoma as an accredited-free State. This will provide prospective cattle and bison buyers with accurate and up-to-date information, which may affect the marketability of cattle and bison since some prospective buyers prefer to buy cattle and bison from accredited-free States.

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 publication in the Federal Register. 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.

Cattle and bison are moved interstate for slaughter, for use as breeding stock, or for feeding. Oklahoma has approximately 62,000 cattle herds with a combined total of 5,800,000 cattle. Approximately 95 percent of herd owners would be considered small businesses. Changing the status of Oklahoma may affect the marketability of cattle and bison from the State, since some prospective cattle and bison buyers prefer to buy cattle and bison from accredited-free States. This may result in some beneficial economic impact on some small entities. However, based on our experience in similar designations of other States, the impact should not be significant.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will 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 12988

This rule has been reviewed under Executive Order 12988, 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 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 77

Animal diseases, Bison, Cattle, Reporting and recordkeeping requirements, Transportation, Tuberculosis.

Accordingly, 9 CFR part 77 is amended as follows:

PART 77—TUBERCULOSIS

1. The authority citation for part 77 continues to read as follows:

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

§ 77.1 [Amended]

2. In § 77.1, in the definition for ''Modified accredited state'', paragraph (2) is amended by removing ''Oklahoma,''.

3. In § 77.1, in the definition for ''Accredited-free state'', paragraph (2) is amended by adding ''Oklahoma,'' immediately before ''Oregon,''.

Done in Washington, DC, this 16th day of December 1996.

A. Strating,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–32724 Filed 12–24–96; 8:45 am]

BILLING CODE 3410–34–P

9 CFR Part 113

[Docket No. 93–128–2]

Viruses, Serums, Toxins, and Analogous Products; Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the standard requirement for Encephalomyelitis Vaccine, Eastern and Western, Killed Virus, by specifying requirements for killed Venezuelan equine encephalomyelitis vaccines and revising the standard potency test for Eastern and Western equine encephalomyelitis vaccines. The amendments require the use of Vero 76 cells in the test to evaluate the potency of Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus, and establish minimum antibody titers which must be elicited by each of the indicated fractions, as determined by a plaque reduction, serum neutralization assay in which Vero 76 cells are used.

EFFECTIVE DATE: January 27, 1997.

FOR FURTHER INFORMATION CONTACT: Dr. David A. Espeseth, Director, Licensing and Policy Development, Center for Veterinary Biologics, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1237, (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

In accordance with the regulations in 9 CFR part 113, standard requirements are prescribed for the preparation of veterinary biological products. A standard requirement consists of specifications, procedures, and test methods that define the standards of purity, safety, potency, and efficacy for a veterinary biological product. Where a standard requirement for a product has not been established, production procedures and specifications for purity, safety, and potency of a biological product are provided in an Outline of Production filed with the Animal and Plant Health Inspection Service (APHIS).

On November 27, 1995, we published in the Federal Register (60 FR 58255–58256, Docket No. 93–128–1) a proposed rule to amend the regulations in § 113.207 by providing requirements for killed Venezuelan equine encephalomyelitis vaccines and amending the potency test provisions for killed Eastern and Western equine encephalomyelitis vaccines. The proposed amendments required the use of Vero 76 cells in the test to evaluate the potency of Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus and establish minimum antibody titers which must be elicited by each of the indicated fractions, as determined by a plaque reduction, serum neutralization assay in which Vero 76 cells are used.

We solicited comments concerning our proposal for 60 days ending January 26, 1996. We received two comments by that date from a manufacturer of veterinary biological products and a veterinary biologics industry consultant. They are discussed below.

One commenter expressed support for the rule provided adequate data are available to justify the proposed revisions. Adequate data are available to support the revisions. Antibody titers in guinea pigs, as measured by duck embryo fibroblasts, were correlated with protection in horses. Antibody titers in guinea pigs measured by Vero 76 cells were, in turn, correlated with those measured by duck embryo fibroblasts. Therefore, the Agency believes that there is justification for the proposed revisions. No changes to the regulations are made in response to this comment.

The other commenter, who claimed to have considerable experience with the plaque reduction, serum neutralization assay in which Vero cells are used, stated that ''less than 1:10'' rather than ''less than 1:4'' should be set as the acceptable titer for control guinea pigs in the tests for the Eastern and Western type fractions because nonspecific titers up to 1:10 are commonly encountered. In response to the commenter, the Agency notes that the correlative studies to support the rule were conducted with guinea pigs with prevaccination titers of less than 1:4. APHIS believes that extrapolation of the results of the studies to a situation where the sera of test animals prior to vaccination are negative at a 1:10 dilution but positive at a 1:4 dilution is inappropriate. No change to the regulations is made in response to this comment.

The second commenter also requested that, in proposed § 113.207(b)(4), ''three or four vaccinate serum samples'' instead of ''two or three vaccinate serum samples'' be specified to ''be consistent with the initial tests being satisfactory if 80 percent of the vaccinates show protective titers.'' In response to the commenter, APHIS notes that the proposed ''two or three vaccinate serum samples'' does not differ from the requirement specified under the current regulations. Moreover, paragraph (b)(6) of § 113.207 of the current regulations not proposed for amendment specifies that four or more failures is a basis for an unsatisfactory test, and that for a given fraction, at least 9 of the 10 vaccinated guinea pigs, or 90 percent, must have an acceptable titer for a satisfactory first-stage test. Therefore, ''three or four vaccinate serum samples'' and ''80 percent of the vaccinates show[ing] protective titers'' would be inconsistent with current regulations. No change to the regulations is made in response to this comment.

Therefore, based on the rationale set forth in the proposed rule and in this document, we are adopting the provisions of the proposed rule as a final rule without change.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This rule revises the standard requirement in § 113.207 for Encephalomyelitis Vaccine, Eastern and Western, Killed Virus, by specifying a different cell type for use in the potency test assay and specifying different minimum specific antibody titers that must be achieved for a satisfactory test. In addition, the rule revises the standard requirement so that it would also apply to Encephalomyelitis Vaccine, Venezuelan, Killed Virus. The Agency believes the titers given in the standard requirement are adequately correlated with claimed efficacy and that they would be readily obtained by all relevant vaccines currently licensed. We do not expect any increase in cost to the biologics manufacturers affected by this rule. The changes should actually decrease costs for most impacted manufacturers, since fewer repeat tests will be needed and obtaining Vero 76 cells should prove less expensive than procuring primary DEF.