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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 77

[Docket No. 04–094–2]

Tuberculosis in Captive Cervids; Extend Interval for Conducting Reaccreditation Test

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations regarding tuberculosis in captive cervids by extending, from 2 years to 3, the term for which accredited herd status is valid and increasing by 12 months the interval for conducting the reaccreditation test required to maintain the accredited tuberculosis-free status of cervid herds. We are also reducing, from three tests to two, the number of consecutive negative official tuberculosis tests required of all eligible captive cervids in a herd before a herd can be eligible for recognition as an accredited herd. These actions will reduce testing costs for herd owners, lessen the potential for animal injury or death during testing, and lower administrative costs for State and Federal regulatory agencies. In addition, we are amending the regulations by removing references to the blood tuberculosis test for captive cervids, as that test is no longer used in the tuberculosis eradication program for captive cervids. This change updates the regulations so that they refer only to those official tests currently in use.

DATES: *Effective Date:* April 21, 2006.

FOR FURTHER INFORMATION CONTACT: Dr. Michael Dutcher, Senior Staff Veterinarian, National Tuberculosis Eradication Program, Eradication and Surveillance Team, National Center for Animal Health Programs, VS, APHIS,

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SUPPLEMENTARY INFORMATION:

Background

Through the National Cooperative State/Federal Bovine Tuberculosis Eradication Program, the Animal and Plant Health Inspection Service (APHIS) works cooperatively with the Nation's livestock industry and State animal health agencies to eradicate bovine tuberculosis from domestic livestock in the United States and prevent its recurrence.

Federal regulations implementing this program are contained in 9 CFR part 77, "Tuberculosis" (referred to below as the regulations), and in the "Uniform Methods and Rules—Bovine Tuberculosis Eradication" (UMR), which is incorporated by reference into the regulations. The regulations restrict the interstate movement of cattle, bison, and captive cervids to prevent the spread of tuberculosis. Subpart C of the regulations (§§ 77.20 to 77.41) addresses captive cervids.

On January 12, 2006, we published in the *Federal Register* (71 FR 1985–1988, Docket No. 04–094–1) a proposal¹ to amend the regulations regarding tuberculosis in captive cervids by extending, from 2 years to 3, the term for which accredited herd status is valid and increasing by 12 months the interval for conducting the reaccreditation test required to maintain the accredited tuberculosis-free status of cervid herds. We also proposed to reduce, from three tests to two, the number of consecutive negative official tuberculosis tests required of all eligible captive cervids in a herd before a herd can be eligible for recognition as an accredited herd. We proposed these actions to reduce testing costs for herd owners, lessen the potential for animal injury or death during testing, and lower administrative costs for State and Federal regulatory agencies. In addition, we proposed to amend the regulations by removing references to the blood tuberculosis test for captive cervids, as that test is no longer used in the tuberculosis eradication program for

captive cervids. We proposed this change to update the regulations so that they refer only to those official tests currently in use.

We solicited comments on our proposal for 60 days ending on March 13, 2006. We received 32 comments by that date, from producers, industry group representatives, private citizens, and one State agency. In all, 30 of the 32 commenters supported the rule, although three of these commenters had questions or suggestions regarding the proposed rule. The two remaining commenters were opposed to the proposed rule. The issues raised by the commenters are discussed below.

Two commenters opposed the change to the current testing requirements. One of these commenters was concerned that the proposed rule would not protect the health of Americans or the health of America's livestock industry. The commenter stated that by allowing cervid producers to obtain accredited tuberculosis-free status with fewer consecutive negative tests, as well as allowing these same herds to retain that status for longer periods without required re-testing, the U.S. food supply will be endangered. This commenter also stated that the U.S. Animal Health Association's (USAHA) Committee on Tuberculosis noted that "there is continuing concern that the level of surveillance for TB in captive cervids may be inadequate."

We do not believe the changes in this rule will reduce the effectiveness of our tuberculosis surveillance and eradication program, nor will they increase the risk of captive herds endangering the U.S. food supply. Further, the proposed rule was prepared in an effort to directly address the concerns of the USAHA Committee on Tuberculosis regarding surveillance for tuberculosis in captive cervids, and has been endorsed by that committee. By reducing testing costs for herd owners and lessening the potential for animal injury or death during testing, we are making the program more accessible to cervid producers. This will result in better surveillance for tuberculosis due to greater participation by cervid producers in the eradication program. Experience has shown that careful management in accredited herds of captive cervids in accordance with the regulations and the UMR virtually eliminates the already low probability of

¹To view the proposed rule and the comments we received, go to <http://www.regulations.gov>, click on the "Advanced Search" tab, and select "Docket Search." In the Docket ID field, enter APHIS–2004–0119, then click on "Submit." Clicking on the Docket ID link in the search results page will produce a list of all documents in the docket.

introducing tuberculosis into a herd from outside sources. Because of this, it is also our belief that the greater producer participation and the resulting improved surveillance will address, in part, the concerns over the level of surveillance in cervids as reported in the aforementioned 2005 Report from the USAHA Committee on Tuberculosis. Additionally, continued participation by owners in this program will yield monitoring and surveillance data on cervids that is extremely important to our efforts to detect and eliminate tuberculosis-affected herds in the United States. With respect to the food safety issue raised by the commenter, the Centers for Disease Control and Prevention reports that, while rare, humans can become infected with *Mycobacterium bovis*, but that the most common cause of such infection is through the consumption of unpasteurized milk products from infected cows. The consumption of meat is not considered to present a risk of transmitting *M. bovis* to humans. We are not making any changes to the final rule as a result of this comment.

Two of the commenters who supported the rule suggested we add additional blood tests—one specifically suggested Cervigam and/or the Rapid Test—to the list of official tests for tuberculosis in cervids.

Because we recognize the need for more modern and practical tests for tuberculosis in captive cervids, we plan to conduct validation studies of both the Cervigam test and the Rapid Test. If the studies demonstrate that these two tests are acceptable, we will initiate the process of making the Cervigam and the Rapid Test official tests for tuberculosis in captive cervids. At this time, however, we are not making any changes to the regulations as a result of this comment.

Another commenter who supported the rule questioned whether or not he would have to retest his cervids for tuberculosis if he sold deer and needed to move them across State lines. This commenter also suggested that certification should be “federally sponsored.”

Under the regulations as amended by this rule, animals moving interstate from an accredited tuberculosis-free herd would not require testing as long as the herd’s most recent test was within the past 36 months. The regulations in part 77 and the specific requirements regarding the interstate movement of cervids from accredited herds are administered by APHIS and thus do provide the Federal “sponsorship” suggested by the commenter.

Another commenter who supported the rule stated that the tuberculosis testing costs and high and low ranges of animal values presented in the proposed rule’s economic analysis were too low. The commenter stated that the average cost of tuberculosis testing is “significantly higher” than \$10 to \$15 a head, and that the high/low ranges of animal values were likewise too low.

We acknowledge that our estimates of testing costs, which we acknowledged were preliminary, and animal values, which were based on limited industry information, may be too low in some cases. Higher costs and values would, however, further emphasize the economic benefits of adopting this rule, insofar as the savings to producers would be even higher than estimated. We will continue to seek additional information that will allow us to more accurately estimate the costs of testing and the value of animals.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, without change.

Effective Date

This is a substantive rule that relieves restrictions and, pursuant to the provisions of 5 U.S.C. 553, may be made effective less than 30 days after publication in the **Federal Register**.

This final rule extends the term for which accredited herd status is valid, increases the interval for conducting reaccreditation tests, and reduces the number of consecutive negative official tuberculosis tests required of all eligible captive cervids in a herd before a herd can be eligible for recognition as an accredited herd. Making this rule effective immediately will reduce testing costs for herd owners, lessen the potential for animal injury or death during testing, and lower administrative costs for State and Federal regulatory agencies. Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined that this rule should be effective upon signature.

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.

We are amending the regulations regarding tuberculosis in captive cervids by extending, from 2 years to 3, the term for which accredited herd status is valid and increasing by 12 months the interval for conducting the

reaccreditation test required to maintain the accredited tuberculosis-free status of cervid herds. We are also reducing, from three tests to two, the number of consecutive negative official tuberculosis tests required of all eligible captive cervids in a herd before a herd can be eligible for recognition as an accredited herd. These actions will reduce testing costs for herd owners, lessen the potential for animal injury or death during testing, and lower administrative costs for State and Federal regulatory agencies. In addition, we are amending the regulations by removing references to the blood tuberculosis test for captive cervids, as that test is no longer used in the tuberculosis eradication program for captive cervids. This change will update the regulations so that they refer only to those official tests currently in use.

Of primary importance among captive cervids are deer and elk, which are farmed for breeding stock, velvet antler, meat, and sales to game parks and exhibits. This is a relatively small industry, and as such was not tracked as a separate line item in census data before the 2002 Census of Agriculture. The 2002 Census estimates there are 286,863 deer being raised on 4,901 farms, and 97,901 elk on 2,371 farms in the United States. Due to the devastating effects of chronic wasting disease in captive cervids, these numbers are largely believed to be an overstatement of current market conditions. Unfortunately, the census data do not consider the per head value of deer or elk. However, limited data are collected by the two major cervid industry associations, the North American Elk Breeders Association (NAEBA) and the North American Deer Farmers Association (NADeFA). Membership in the above associations is estimated to constitute 60 percent of the farmed cervid industry. Attempts to get current information on deer and elk industries and corresponding values were unsuccessful. However, we previously gathered information from the above major industry associations in connection with another rulemaking related to deer and elk,² and have used that information as the source of the estimates in this analysis.

NAEBA estimates about 75 percent of its members have 100 or fewer animals, 15 percent have more than 100 but fewer than 500, and the remaining 10 percent have more than 500 elk. Numbers of elk per farm vary depending on the farm classification, commercial

² See Docket No. 00-108-2, published in the **Federal Register** on December 24, 2003 (68 FR 74513-74529).

or hobby. The value per elk also varies, depending on type of animal (e.g., bull, calf) and market conditions, ranging from a high of \$5,000 for superior animals to a low of \$500 for non-pedigree animals. In 2002, NAEBA estimated the average value per head of elk was \$2,000; using this figure, we can approximate the value of the 97,901 elk on U.S. farms to be \$195.8 million. In 2001, gross receipts for members in NAEBA (velvet antler, breeding stock, and meat) totaled \$44.3 million.

NADeFA estimates there are an average of 50 deer per farm. The actual number of deer per farm varies, depending on usage, from a high of 3,000 for commercial farms to a low of 5 for hobby farms. The value of each deer also varies depending on the type of animal (e.g., wapiti, white-tail, fallow) and market conditions. NADeFA estimates the average value per animal to be \$1,687, with wapiti deer at the high end at \$4,000 each, and fallow deer at the low end at \$375 each. Using this average per head value of \$1,687, the value of the 286,863 deer on U.S. farms can be approximated at \$483.9 million.

This final rule amends the regulations by extending the term for which accredited herd status is valid, increasing the interval for conducting reaccreditation tests, and reducing the number of consecutive negative official tuberculosis tests required of all eligible captive cervids in a herd before a herd can be eligible for recognition as an accredited herd. We expect these changes will encourage producers already participating in this voluntary program to maintain accredited herds, as they will reduce testing costs. Continued participation in this program is important to bovine tuberculosis eradication efforts, as accreditation testing yields monitoring and surveillance data on cervids which greatly assist in our efforts to detect and eliminate tuberculosis-affected herds in the United States.

The potential benefits of this final rule are fairly clear, the most obvious being decreased testing costs for those producers maintaining accredited herds. Furthermore, reducing testing requirements would lower administrative costs for State and Federal regulatory agencies. In addition, by extending the interval between reaccreditation tests and reducing the number of qualifying tests, the need to round up deer and elk for testing, and the potential for animal injury or death during that process, will be reduced.

Currently, APHIS records indicate there are 1,024 accredited herds of captive cervids in the United States. APHIS is currently in the process of

researching the average cost to producers of identifying animals and testing them for tuberculosis. Our preliminary research indicates the average cost of tuberculosis testing ranges from \$10 to \$15 per head. Thus, in a 6-year period, the changes in the regulations will translate to a cost savings of \$20 to \$30 per head, as there will be only two tests required for reaccreditation and two tests required to qualify for initial accreditation instead of three in each case. If we were to assume each of the 1,024 accredited herds had an average of 50 animals, the longer interval between reaccreditation tests and the reduction in the number of qualifying tests will result in a total cost savings to the domestic industry of approximately \$1,024,000 to \$1,536,000 over a 6-year period.³

According to the two major cervid associations, the majority of their members would be classified as small entities by U.S. Small Business Administration standards.⁴ For producers wishing to maintain accredited status, considering that the estimated average value per head is \$2,000 and \$1,687 for elk and deer, respectively, the cost savings of reduced testing represent less than 2 percent of the per head value. In general practice, we assume a regulation that has compliance costs which equal a small business' profit margin, or 5 to 10 percent of annual sales, pose an impact which can be considered "significant."⁵ For the purposes of illustration and analysis of potential effects on small entities, if we assume a cervid producer owns only a single average herd of 50 deer, with annual sales or value of approximately \$84,350, compliance costs totaling between \$4,218 and \$8,435 would qualify as posing a "significant" economic impact on this entity. In this case, the average compliance costs of tuberculosis testing for an entire herd would be \$750, using the high-end average cost per head of \$15, which would not qualify as monetarily significant. Thus, for those producers participating in the voluntary cervid accreditation program, the cost

³ Calculation: 1,024 herds × 50 animals per herd × \$10 (or \$15 for high-end estimate) × 2 tests.

⁴ NAEBA estimates 75 percent of its members have 100 or fewer animals, which translates to an average value per elk farm of \$200,000 (100 animals × \$2,000). NADeFA estimates there are an average of 50 deer per farm, which translates into an average total value per deer farm of \$84,350 (50 animals × \$1,687). A small cervid operation is one having \$750,000 or less in annual receipts. Table of Size Standards based on NAICS 2002. Washington, DC: U.S. Small Business Administration, 2004.

⁵ Verkuil, Paul R. "A Critical Guide to the Regulatory Flexibility Act," *Duke Law Journal*, Apr. 1982: 928.

savings from the elimination of two tests, while beneficial, would not represent a significant monetary savings.

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 final 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 final 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 77

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

■ Accordingly, we are amending 9 CFR part 77 as follows:

PART 77—TUBERCULOSIS

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

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 77.20 is amended as follows:

- a. In the definition for *accredited herd*, by removing the word "three" and adding the word "two" in its place.
- b. By removing the definition for *blood tuberculosis* (BTB) test.
- c. In the definition for *negative*, by removing the words "classified by the testing laboratory as "avian" or "negative" on the BTB test,".
- d. By revising the definition for *official tuberculosis test* to read as set forth below.
- e. In the definition for *reactor*, by removing the words " , or is classified by

the testing laboratory as “*M. bovis* positive” on the BTB test.”.

■ f. In the definition for *suspect*, by removing the words “, or that is classified by the testing laboratory as equivocal on the BTB test,”.

The revisions read as follows:

§ 77.20 Definitions.

* * * * *

Official tuberculosis test. Any of the following tests for bovine tuberculosis in captive cervids, applied and reported in accordance with this part:

(1) The single cervical tuberculin (SCT) test.

(2) The comparative cervical tuberculin test (CCT) test.

* * * * *

§ 77.33 [Amended]

■ 3. Section 77.33 is amended as follows:

■ a. In paragraph (a) introductory text, by removing the words “in paragraphs (a)(1) and (a)(2)” and adding the words “in paragraph (a)(1)” in their place.

■ b. By removing and reserving paragraphs (a)(2), (b)(2), (d)(2), and (e)(3).

§ 77.34 [Amended]

■ 4. Section 77.34 is amended as follows:

■ a. In paragraph (a)(1), by removing the words “either the CCT test or the BTB test” and adding the words “the CCT test” in their place.

■ b. By removing paragraph (c).

■ 5. Section 77.35 is amended as follows:

■ a. In paragraph (a)(1), by removing the word “three” in the first sentence and adding the word “two” in its place.

■ b. By revising paragraph (d) to read as set forth below.

§ 77.35 Interstate movement from accredited herds.

* * * * *

(d) *Maintenance of accredited herd status.* To maintain status as an accredited herd, the herd must test negative to an official tuberculosis test within 33–39 months from the anniversary date of the second consecutive test with no evidence of tuberculosis disclosed (that is, the test on which the herd was recognized as accredited or the accrediting test). Each time the herd is tested for reaccreditation, it must be tested 33–39 months from the anniversary date of the accrediting test, not from the last date of reaccreditation (for example, if a herd is accredited on January 1 of a given year, the anniversary date will be January 1 of every third year). Accredited herd status is valid for 36 months (1,095

days) from the anniversary date of the accrediting test. If the herd is tested between 36 and 39 months after the anniversary date, its accredited herd status will be suspended for the interim between the anniversary date and the reaccreditation test. During the suspension period, the herd will be considered “unclassified” and captive cervids may be moved interstate from the herd only in accordance with the movement requirements for the State or zone in which the herd is located.

§ 77.37 [Amended]

■ 6. In § 77.37, paragraph (a)(2), footnote 3 is redesignated as footnote 2.

■ 7. In § 77.39, paragraph (a) is amended as follows:

■ a. In paragraph (a)(1)(i) introductory text, by removing the words “or the BTB test”.

■ b. By removing and reserving paragraph (a)(1)(i)(B).

■ c. In paragraph (a)(1)(ii) introductory text, by removing the words “or the first BTB test”.

■ d. In paragraph (a)(1)(ii)(A), by removing the word “; or” and adding a period in its place.

■ e. By removing and reserving paragraph (a)(1)(ii)(B).

■ f. In paragraph (e) introductory text, by removing the fourth sentence after the paragraph heading and revising the last two sentences of the paragraph to read as set forth below.

§ 77.39 Other interstate movements.

* * * * *

(e) *Herds that have received captive cervids from an affected herd.* * * * Any exposed captive cervid that responds to the SCT test must be classified as a reactor and must be slaughter inspected or necropsied. Any exposed captive cervid that tests negative to the SCT test will be considered as part of the affected herd of origin for purposes of testing, quarantine, and the five annual whole herd tests required for affected herds in paragraph (d) of this section.

* * * * *

Done in Washington, DC, this 21st day of April 2006.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 06–3984 Filed 4–26–06; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 93

[Docket No. APHIS–2006–0020]

States Approved To Receive Stallions and Mares From CEM-Affected Regions; Indiana

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Direct final rule.

SUMMARY: We are amending the animal importation regulations by adding Indiana to the lists of States approved to receive certain stallions and mares imported into the United States from regions affected with contagious equine metritis (CEM). We are taking this action because Indiana has entered into an agreement with the Administrator of the Animal and Plant Health Inspection Service to enforce its State laws and regulations to control CEM and to require inspection, treatment, and testing of horses, as required by Federal regulations, to further ensure the horses’ freedom from CEM. This action relieves unnecessary restrictions on the importation of mares and stallions from regions where CEM exists.

DATES: This rule will be effective on June 26, 2006, unless we receive written adverse comments or written notice of intent to submit adverse comments on or before May 30, 2006. If we receive written adverse comments or written notice of intent to submit adverse comments, we will publish a document in the **Federal Register** withdrawing this rule before the effective date.

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov> and, in the lower “Search Regulations and Federal Actions” box, select “Animal and Plant Health Inspection Service” from the agency drop-down menu, then click on “Submit.” In the Docket ID column, select APHIS–2006–0020 to submit or view public comments and to view supporting and related materials available electronically. Information on using [Regulations.gov](http://www.regulations.gov), including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site’s “User Tips” link.

- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. APHIS–2006–0020,