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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 77

[Docket No. APHIS-2012-0087]

Approved Tests for Bovine Tuberculosis in Cervids

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are adding the CervidTB Stat-Pak[®] and DPP[®] tests as official tuberculosis tests for the following species of captive cervids: Elk, red deer, white-tailed deer, fallow deer, and reindeer. We are taking this action because we have determined that the tests can reliably detect the presence or absence of antibodies to bovine tuberculosis in certain species of captive cervids. This action is necessary on an immediate basis in order to provide regulated entities with more options in order to meet the testing requirements for captive cervids within the regulations.

DATES: This interim rule is effective [Insert date of publication in the Federal Register]. We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the Federal Register].

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

- Federal eRulemaking Portal: Go to:

<http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0087-0001>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2012-0087, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0087> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. C. William Hench, Senior Staff Veterinarian, Eradication and Surveillance Team, National Center for Animal Health Programs, VS, APHIS, 2150 Centre Avenue, Building B-3E20, Fort Collins, CO 80526-8117; (970) 494-7378.

SUPPLEMENTARY INFORMATION:

Background

Bovine tuberculosis is a contagious and infectious granulomatous disease caused by the bacterium Mycobacterium bovis. Although commonly defined as a chronic debilitating disease, bovine tuberculosis can occasionally assume an acute, rapidly progressive course. While any body tissue can be affected, lesions are most frequently observed in the lymph nodes, lungs, intestines, liver, spleen, pleura, and peritoneum. Although cattle are considered to be the true hosts of M. bovis, the disease has been reported in several other species of livestock, most notably bison and captive cervids. There have also been instances of infection in other domestic and nondomestic animals, as well as in humans.

Through the National Cooperative State/Federal Bovine Tuberculosis Eradication Program, the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) 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,” which is incorporated by reference within the regulations. The regulations restrict the interstate movement of cattle, bison, and captive cervids to prevent the spread of bovine tuberculosis. Subpart C of the regulations (§§ 77.20 to 77.41, referred to below as the captive cervid regulations) addresses captive cervids.

Currently, in the captive cervid regulations, there are several instances in which we require captive cervids to be tested with an official tuberculosis test. For example, in § 77.35, in order for a herd of captive cervids to be recognized as accredited, all cervids in the herd must have tested negative to at least two consecutive official tuberculosis tests, conducted at 9 to 15 month intervals, with certain, limited exceptions.

In § 77.20 of the captive cervid regulations, the definition of official tuberculosis test has provided that the single cervical tuberculin (SCT) test, a primary test, and comparative cervical tuberculin (CCT) test, a supplemental test, are recognized by APHIS as official tuberculosis tests, provided that they are applied and reported in accordance with the captive cervid regulations.

In the same section, the definitions of single cervical tuberculin (SCT) test and comparative cervical tuberculin (CCT) test provide how to apply each test; the sequence in

which the tests should be administered and the manner in which test results should be interpreted are specified in § 77.34. The individuals who may administer each test and the reporting requirements for each test are found in § 77.33.

We recently received a request to evaluate the CervidTB Stat-Pak[®] test, a primary test, and Dual Path Platform (DPP)[®] test, a supplemental test, as official tests for bovine tuberculosis in the following species of captive cervids: Elk, red deer, white-tailed deer, fallow deer, and reindeer. Based on our evaluation, we have determined that the tests can reliably detect the presence or absence of antibodies to bovine tuberculosis in these species of captive cervids. Accordingly, we are amending the captive cervid regulations to recognize these two tests as official tuberculosis tests. We discuss these amendments immediately below, by section.

Definitions (§ 77.20)

As we mentioned previously, prior to issuance of this interim rule, the definition of official tuberculosis test in § 77.20 of the captive cervid regulations specified that only the SCT and CCT tests are official tuberculosis tests. We are amending the definition of official tuberculosis test so that it specifies that the CervidTB Stat-Pak[®] and DPP[®] tests are also official tuberculosis tests.

We are also adding definitions of CervidTB Stat-Pak[®] test and Dual Path Platform (DPP[®]) test to § 77.20. We are defining CervidTB Stat-Pak[®] test as: “A serological assay to determine the presence of antibodies to bovine tuberculosis (M. bovis) in elk, red deer, white-tailed deer, fallow deer, and reindeer, in which a blood sample taken from a captive cervid is placed on a strip containing an antibody-detecting reagent. The sample is then diluted by using a buffer solution. Once sufficient time has elapsed, the strip indicates if antibodies are present in the sample.” We are defining Dual Path Platform (DPP[®]) test as: “A serological

assay to determine the presence of antibodies to bovine tuberculosis (M. bovis) in elk, red deer, white-tailed deer, fallow deer, and reindeer, in which a blood sample taken from a captive cervid and a buffer solution are placed on a strip. The diluted sample then migrates to another strip, which contains an antibody-detecting reagent. This latter strip indicates if antibodies are present in the sample.”

The definition of designated accredited veterinarian in § 77.20 has stated that a designated accredited veterinarian is an accredited veterinarian who is trained and approved by cooperating State and Federal animal health officials to conduct the SCT test on captive cervids. As we discuss at greater length below, we are also allowing designated accredited veterinarians to draw the blood samples needed for the CervidTB Stat-Pak[®] and DPP[®] tests. Accordingly, we are amending the definition of designated accredited veterinarian to specify that designated accredited veterinarians may draw such samples.

Finally, prior to issuance of this interim rule, the definitions of negative, reactor, and suspect in § 77.20 presupposed that only the SCT and CCT tests are official tuberculosis tests for purposes of classifying captive cervids according to these classifications. We are amending these definitions to reflect that the CervidTB Stat-Pak[®] and DPP[®] tests are now also considered official tuberculosis tests for such purposes.

Testing procedures for tuberculosis in captive cervids (§ 77.33)

Section 77.33 of the captive cervid regulations specifies, among other things, who may administer official tuberculosis tests, which diagnostic laboratories have been approved by APHIS, the reporting requirements for each test, and how the tests will be interpreted.

Paragraph (a) of § 77.33 provides the approved testers for each official tuberculosis test. Prior to issuance of this interim rule, the section had specified that official tuberculosis tests may

only be given by a veterinarian employed by the State in which the test is administered or by a veterinarian employed by USDA, except that designated accredited veterinarians, for whom correct application of the SCT test is part of their accreditation training, could conduct the SCT test. Because collecting blood samples is also part of such training, and because both the CervidTB Stat-Pak[®] and DPP[®] test are serological assays that rely on blood samples, we are amending paragraph (a) of § 77.33 to specify that designated accredited veterinarians may also draw blood for the CervidTB Stat-Pak[®] or DPP[®] test. The veterinarian who draws the sample will then ship it to the National Veterinary Services Laboratories (NVSL) in Ames, IA, for testing using these tests.

(Paragraph (b) of § 77.33 specifies that, with one, limited exception, histopathology and culture results for all tuberculosis diagnoses will only be accepted from NVSL. While we recognize that both the CervidTB Stat-Pak[®] and DPP[®] tests could be administered outside of NVSL, we would need to evaluate any use of the tests outside of NVSL at length in order to assess the likely reliability of test results for tests administered in such a manner. Pending the conclusion of such evaluations, we will require the tests to be administered by NVSL.)

Paragraph (d) of § 77.33 provides reporting requirements for the various official tuberculosis tests for captive cervids. Paragraph (d)(1) of § 77.33 contains reporting requirements for the SCT and CCT tests. A number of these reporting requirements pertain only to tests that are intradermally administered and require interpretation of palpation at the injection site, as both the SCT and CCT tests are, and are thus not applicable to the CervidTB Stat-Pak[®] and DPP[®] tests.

Accordingly, we are adding a paragraph (d)(2) to § 77.33. This paragraph provides that, for the CervidTB Stat-Pak[®] and DPP[®] tests, the veterinarian who draws blood from the captive

cervid must submit a request to NVSL to perform the CervidTB Stat-Pak[®] and, if necessary, the DPP[®] test on the blood sample.

The request must be on a form specified by APHIS for such requests. The form, currently Veterinary Services (VS) form 10-4, "Specimen Submission," is available at: <http://www.aphis.usda.gov/library/forms/#vs>. The completed form, including appendices, must be sent along with the blood samples to the address provided by NVSL on their Web site, http://www.aphis.usda.gov/animal_health/lab_info_services/about_nvsl.shtml. The veterinarian must also fill out the relevant portions of a test record; this record is currently VS form 6-22, "Tuberculosis Test Record." The form may be obtained by contacting the local area VS office, information regarding which is available at http://www.aphis.usda.gov/animal_health/area_offices/. This record must be sent to the offices of the State and Federal animal health officials in the State.

Paragraph (e) of § 77.33 contains information regarding interpretation of test results. We are amending paragraph (e) to specify that interpretation of CervidTB Stat-Pak[®] and DPP[®] test results will be in accordance with the relevant paragraphs of § 77.34.

Official tuberculosis tests (§ 77.34)

As we mentioned previously, § 77.34 of the captive cervid regulations contains requirements regarding the sequence in which official tuberculosis tests should be administered and the manner in which test results should be interpreted for purposes of the captive cervid regulations. Requirements regarding the SCT test, a primary test for tuberculosis, are contained in paragraph (a) of § 77.34; requirements regarding the CCT, a supplemental test, are in paragraph (b). We are adding requirements regarding the CervidTB Stat-Pak[®] test, a primary

test, to paragraph (a) of § 77.34, and requirements regarding the DPP[®] test, a supplemental test, to paragraph (b).

As amended, paragraph (a) of § 77.34 specifies that the CervidTB Stat-Pak[®] test is a primary test that may be used in individual captive elk, red deer, white-tailed deer, fallow deer, and reindeer, and in herds of these species that are of unknown tuberculous status. It further requires, with limited exceptions, that each captive cervid that has non-negative test results to the CervidTB Stat-Pak[®] test must be classified as a suspect and retested with the DPP[®] test; a captive cervid that has non-negative test results to the CervidTB Stat-Pak[®] test must not be retested using the SCT or CCT test. (We are also adding reciprocal language to the paragraph to specify that the each captive cervid that responds to the SCT test must not be retested with the CervidTB Stat-Pak[®] or DPP[®] tests.) Finally, it allows the CervidTB Stat-Pak[®] test to be used in affected herds of captive elk, red deer, white-tailed deer, fallow deer, and reindeer, and in herds of these species that have received captive cervids from an affected herd; in such instances, each captive cervid that has non-negative test results to the CervidTB Stat-Pak[®] test must be classified as a reactor, unless the designated tuberculosis epidemiologist (DTE), the State or Federal epidemiologist designated by the Administrator of APHIS to make decisions concerning the interpretation of diagnostic tests in a State, determines that the captive cervid should be classified as a suspect because of possible exposure to a tuberculous animal. This is consistent with our current protocol for interpretation of test results for SCT tests administered to captive cervids from such herds.

We are specifying that most captive cervids that have non-negative test results to the CervidTB Stat-Pak[®] test must be classified as suspects and retested using the DPP[®] test. This is because of the nature of the CervidTB Stat-Pak[®] test. The CervidTB Stat-Pak[®] test produces

results that indicate the presence or absence of antibodies for bovine tuberculosis in blood drawn from a captive cervid. It does not, however, indicate the level at which these antibodies have been determined to be present in the blood. Moreover, because the CervidTB Stat-Pak[®] test does not have a specificity level of 100 percent, there is a degree of uncertainty regarding non-negative test results provided by the test.

We are requiring that this corroboratory testing use the DPP[®] test because both the CervidTB Stat-Pak[®] and the DPP[®] are serological tests that can be conducted in succession within a laboratory environment, and because the specificity of the DPP[®] test, in conjunction with the sensitivity of the CervidTB Stat-Pak[®], gives us a high degree of confidence regarding our ultimate determination of the tested cervid's disease status.

As amended, paragraph (b) of § 77.34 specifies that the DPP[®] test is a supplemental test that may only be used in order to retest captive cervids that have been classified as suspects after being tested with the CervidTB Stat-Pak[®] test, and may not be used as a primary test. It further specifies that a captive cervid that has non-negative test results to its first DPP[®] test must be classified as a suspect, unless the DTE determines, based on epidemiological evidence, that the captive cervid should be classified as a reactor.

A captive cervid classified as a suspect on its first DPP[®] test may be retested using the DPP[®] test to evaluate a new blood sample drawn from the cervid no less than 30 days after this first DPP[®] test. A captive cervid that has non-negative test results on two successive DPP[®] tests must be classified as a reactor.

If a captive cervid has non-negative test results to its first DPP[®] test and is classified as a suspect, the owner of the cervid will have the option of having the cervid taken for slaughter or necropsy for a final determination of status or of having the cervid retested, using the DPP[®] test,

no less than 30 days later. (In the intervening period, a quarantine of the herd will remain in effect prohibiting the interstate movement of captive cervids from the herd. We discuss this at greater length later in this document.) If the cervid again has non-negative test results to the DPP[®] test after 30 days, it is reasonable to classify the cervid as a reactor. This is consistent with our current policy for captive cervids that have non-negative test results to the CCT test.

Interstate movements (§ 77.39)

Section 77.39 of the captive cervid regulations contains restrictions on the interstate movement of captive cervid herds involved in an epidemiological investigation or subject to affected herd management.

Paragraph (a) of § 77.39 contains restrictions on the interstate movement of herds containing a cervid classified as a suspect. Paragraph (a)(1) of § 77.39 contains restrictions on the movement of the suspect itself. We are amending paragraph (a)(1) to specify that, if a captive cervid is classified as a suspect on the CervidTB Stat-Pak[®] test, it must be quarantined until it is slaughtered or retested and found negative for tuberculosis based on the DPP[®] test. It further specifies that, if a captive cervid is classified as a suspect on an initial DPP[®] test, it must be slaughtered or quarantined for no less than 30 days and retested using the DPP[®] test. If it has non-negative test results to this second DPP[®] test, it must be classified as a reactor, with the attendant movement restrictions of such a classification.

We are requiring cervids classified as suspects to be quarantined because any cervid classified as a suspect may potentially be infected with bovine tuberculosis. Allowing its interstate movement other than directly to slaughter or necropsy may contribute to the spread of tuberculosis.

Paragraph (a)(2) of § 77.39 contains restrictions on the interstate movement of all other cervids in a herd that contains a suspect. Prior to issuance of this interim rule, the paragraph had specified that a herd containing a suspect must remain under quarantine until the suspect is retested using a supplemental test or is inspected at slaughter or necropsied and found negative. However, it did not specify that the DPP[®] test is one of the supplemental tests that may be administered to the animal. We are amending paragraph (a)(2) accordingly.

Paragraph (e) of § 77.39 contains restrictions on the interstate movement of herds that have received captive cervids from an affected herd. Prior to issuance of this interim rule, the introductory text of the paragraph had specified that if a herd receives captive cervids from an affected herd, the receiving herd must be placed under quarantine, and the captive cervids from the affected herd of origin must be considered exposed to tuberculosis, and must be slaughtered, necropsied, or tested with the SCT test. We are amending the paragraph so that it provides that the exposed cervids may also be tested using the CervidTB Stat-Pak[®] test.

Paragraph (e)(3) of § 77.39 has provided that, if all these exposed captive cervids test negative for tuberculosis, the receiving herd may be released from quarantine, but must be retested with the SCT test 1 year after release from quarantine in order for captive cervids from the herd to continue to be moved interstate. We are amending the paragraph so that it also allows the cervids to be retested using the CervidTB Stat-Pak[®] test.

Paragraph (f) of § 77.39 contains restrictions on the movement of captive cervids from herds suspected of being the source of tuberculosis. Prior to issuance of this interim rule, the paragraph had specified the restrictions that must be placed on the herd if any of the captive cervids in the herd respond to the SCT test. The paragraph now also specifies the restrictions

that must be placed on the herd if any of the animals in the herd have non-negative test results to the CervidTB Stat-Pak[®] test.

Immediate Action

Immediate action is warranted to provide regulated entities who must have their captive cervids tested in order to comply with the captive cervid regulations with additional testing options. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the Federal Register.

We will consider comments we receive during the comment period for this interim rule (see DATES above). After the comment period closes, we will publish another document in the Federal Register in which we will respond to the comments we receive and finalize or, as necessary, revise the provisions of this interim rule.

Executive Order 12866 and Regulatory Flexibility Act

This interim rule is subject to Executive Order 12866. However, for this action, the Office of Management and Budget has waived its review under Executive Order 12866.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities.

This rule adds the CervidTB Stat-Pak[®] and DPP[®] tests as official tuberculosis tests for captive cervids. The current official tuberculosis tests are the SCT and CCT tests. It is APHIS policy that owners are responsible for assuming the costs associated with primary official tuberculosis tests for bovine tuberculosis in captive cervids; the Agency assumes the cost of corroboratory testing. Bovine tuberculosis testing using the SCT test, including veterinary fees,

costs about \$10 to \$15 per head. We have estimated bovine tuberculosis testing using the CervidTB Stat-Pak[®] test, including veterinary fees, to cost approximately \$13 to \$15 per head. Owners of captive cervids will not be required to now use the CervidTB Stat-Pak[®] test instead of the SCT test, but may choose to do so if they determine such use to be cost-effective for their operations.

That being said, we do anticipate that producers may, in certain instances, experience benefits because of the availability of the CervidTB Stat-Pak[®] and DPP[®] tests as official tuberculosis tests for captive cervids. This is because of the nature of the CervidTB Stat-Pak[®] and DPP[®] tests. As serological tests, they are relatively easy to administer, in comparison to the SCT and CCT tests, and do not require the animals to be held for a significant period of time while the test is applied. There is thus a lower risk of misapplication of the tests and morbidity due to handling of the animals during application.

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. It has no preemptive effect.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection or recordkeeping requirements included in this rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS-2012-0087. Please send a copy of your comments to: (1) Docket No. APHIS-2012-0087, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238, and (2) Clearance Officer, OCIO, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this rule.

This rule requires individuals who wish to have their cervids tested to fill out an application.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological

collection techniques or other forms of information technology; e.g., permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 0.13 hours per response.

Respondents: Captive cervid producers.

Estimated annual number of respondents: 975.

Estimated annual number of responses per respondent: 2.

Estimated annual number of responses: 1,950.

Estimated total annual burden on respondents: 253 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

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 of designated accredited veterinarian, by adding the words “or draw blood for the CervidTB Stat-Pak[®] test and DPP[®] test” after the words “(SCT) test”;

b. In the definitions of negative, reactor, and suspect, by removing the words “the SCT test or the CCT test,” and adding the words “an official tuberculosis test” in their place;

c. By revising the definition of official tuberculosis test; and

d. By adding, in alphabetical order, definitions of CervidTB Stat-Pak[®] test and Dual Path Platform (DPP[®]) test.

The revision and additions read as follows:

§ 77.20 Definitions.

* * * * *

CervidTB Stat-Pak[®] test. A serological assay to determine the presence of antibodies to bovine tuberculosis (M. bovis) in elk, red deer, white-tailed deer, fallow deer, and reindeer, in which a blood sample taken from a captive cervid is placed on a strip containing an antibody-detecting reagent. The sample is then diluted by using a buffer solution. Once sufficient time has elapsed, the strip indicates if antibodies are present in the sample.

* * * * *

Dual Path Platform (DPP[®]) test. A serological assay to determine the presence of antibodies to bovine tuberculosis (M. bovis) in elk, red deer, white-tailed deer, fallow deer, and

reindeer, in which a blood sample taken from a captive cervid and a buffer solution are placed on a strip. The diluted sample then migrates to another strip, which contains an antibody-detecting reagent. This latter strip indicates if antibodies are present in the sample.

* * * * *

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.
- (3) The CervidTB Stat-Pak[®] test.
- (4) The Dual Path Platform (DPP[®]) test.

* * * * *

3. Section 77.33 is amended as follows:

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

b. In paragraph (a)(1), by removing the words “in § 77.34(a)(2)” and adding the words “in § 77.34(a)(1)(ii)” in their place;

c. By adding a new paragraph (a)(2);

d. By adding a new paragraph (d)(2); and

e. By adding new paragraphs (e)(3) and (e)(4).

The additions read as follows:

§ 77.33 Testing procedures for tuberculosis in captive cervids.

(a) * * *

(2) A designated accredited veterinarian may draw blood for the CervidTB Stat-Pak[®] or DPP[®] test.

* * * * *

(d) * * *

(2) CervidTB Stat-Pak[®] and DPP[®] test. For the CervidTB Stat-Pak[®] and DPP[®] test, the veterinarian who draws blood from the captive cervid must submit a form specified by APHIS for such requests to NVSL to perform the CervidTB Stat-Pak[®] and, if necessary, DPP[®] test on the blood sample. The form is available at <http://www.aphis.usda.gov/library/forms/#vs>. The completed form, including any appendices, must be sent along with the blood samples to the address provided at the following Web site:

http://www.aphis.usda.gov/animal_health/lab_info_services/about_nvsl.shtml. The veterinarian must also fill out the relevant portions of a test record. This form may be obtained by contacting the local area VS office, information regarding which is available at http://www.aphis.usda.gov/animal_health/area_offices/. This record must be sent to the offices of the State and Federal animal health officials in the State.

(e) * * *

(3) Interpretation of CervidTB Stat-Pak[®] test results will be in accordance with the classification requirements described in § 77.34(a).

(4) Interpretation of DPP[®] test results will be in accordance with the classification requirements described in § 77.34(b).

* * * * *

4. Section 77.34 is revised to read as follows:

§ 77.34 Official tuberculosis tests.

(a) Primary tests. (1) Single cervical tuberculin (SCT) test. (i) The SCT test is a primary test that may be used in individual captive cervids and in herds of unknown tuberculous status. Each captive cervid that responds to the SCT test must be classified as a suspect until it is retested with the CCT test and is either found negative for tuberculosis or is classified as a reactor, unless, with exception of a designated accredited veterinarian, the testing veterinarian determines that the captive cervid should be classified as a reactor based on its response to the SCT test. A designated accredited veterinarian must classify a responding captive cervid as a suspect, unless the DTE determines, based on epidemiological evidence, that the captive cervid should be classified as a reactor. A captive cervid that responds to the SCT test must not be retested using the CervidTB Stat-Pak[®] or DPP[®] tests.

(ii) The SCT test is a primary test that may be used in affected herds and in herds that have received captive cervids from an affected herd. When used with affected herds or in herds that have received a captive cervid from an affected herd, the SCT test may only be administered by a veterinarian employed by the State in which the test is administered or employed by USDA. In affected herds or herds that have received captive cervids from an affected herd, each captive cervid that responds to the SCT test must be classified as a reactor, unless the DTE determines, based on epidemiological evidence, that the cervid should be classified as a suspect because of possible exposure to a tuberculous animal.

(2) CervidTB Stat-Pak[®] test. (i) The CervidTB Stat-Pak[®] test is a primary test that may be used in individual captive elk, red deer, white-tailed deer, fallow deer, and reindeer, and in herds of these species that are of unknown tuberculous status. Except as specified in paragraph (a)(2)(ii) of this section, each captive cervid that has non-negative test results to the CervidTB Stat-Pak[®] test must be classified as a suspect and retested with the DPP[®] test. A captive cervid

that has non-negative test results to the CervidTB Stat-Pak[®] test must not be retested using the SCT or CCT test.

(ii) The CervidTB Stat-Pak[®] test is a primary test that may be used in affected herds of captive elk, red deer, white-tailed deer, fallow deer, and reindeer, and in herds of these species that have received captive cervids from an affected herd. In such herds, each captive cervid that has non-negative test results to the CervidTB Stat-Pak[®] test must be classified as a reactor, unless the DTE determines that the captive cervid should be classified as a suspect because of possible exposure to a tuberculous animal.

(b) Supplemental tests. (1) Comparative cervical tuberculin (CCT) test.

(i) The CCT test is a supplemental test that may only be used in order to retest captive cervids that have been classified as suspects after being tested with the SCT test. The CCT test may be used in affected herds only after the herd has tested negative to at least two whole herd SCT tests and only with the prior written consent of the DTE. The CCT test may not be used as a primary test.

(ii) A captive cervid tested with the CCT test must be classified as negative if it has a response to the bovine PPD tuberculin that is less than 1 mm.

(iii) Unless the testing veterinarian determines that the captive cervid should be classified as a reactor because of possible exposure to a tuberculous animal, a captive cervid tested with the CCT test must be classified as a suspect if:

(A) It has a response to the bovine PPD tuberculin that is greater than 2 mm and that is equal to the response to the avian PPD tuberculin; or

(B) It has a response to the bovine PPD tuberculin that is equal to or greater than 1 mm and equal to or less than 2 mm and that is equal to or greater than the response to the avian PPD tuberculin.

(iv) A captive cervid tested with the CCT test must be classified as a reactor if:

(A) It has a response to the bovine PPD tuberculin that is greater than 2 mm and that is at least 0.5 mm greater than the response to the avian PPD tuberculin; or

(B) It has been classified as a suspect on two successive CCT tests.

(C) Any exceptions to the reactor classification under the conditions in paragraph (b)(1)(iv) of this section must be justified by the testing veterinarian in writing and have the concurrence of the DTE.

(2) Dual Path Platform (DPP[®]) test. (i) The DPP[®] test is a supplemental test that may only be used in order to retest captive cervids that have been classified as suspects after being tested with the CervidTB Stat-Pak[®] test. The DPP[®] test may not be used as a primary test.

(ii) A captive cervid that has non-negative test results to its first DPP[®] test must be classified as a suspect, unless the DTE determines, based on epidemiological evidence, that the captive cervid should be classified as a reactor. A captive cervid classified as a suspect on its first DPP[®] test may be retested using the DPP[®] test to evaluate a new blood sample drawn from the cervid no less than 30 days after this first DPP[®] test.

(iii) A captive cervid that has non-negative test results on two successive DPP[®] tests must be classified as a reactor.

5. Section 77.39 is amended as follows:

a. By adding new paragraphs (a)(1)(iii) and (a)(1)(iv);

- b. In paragraph (a)(2), by removing the words “CCT test or the BTB test” and adding the words “CCT test, DPP[®] test, or the BTB test” in their place;
- c. By revising paragraph (e), introductory text;
- d. By revising paragraph (e)(3);
- e. By revising paragraph (f)(1); and
- f. In paragraph (f)(2), by adding the words “or the CervidTB Stat-Pak[®] test” after the words “SCT test”.

The revisions and additions read as follows:

§ 77.39 Other interstate movements.

(a) * * *

(1) * * *

(iii) A captive cervid classified as a suspect on the CervidTB Stat-Pak[®] test must be quarantined until it is slaughtered or retested using the DPP[®] test and found negative for tuberculosis based on the DPP[®] test.

(iv) A captive cervid classified as a suspect on an initial DPP[®] test must be slaughtered or otherwise must be quarantined until it is retested using the DPP[®] test. A captive cervid that has negative test results to this second DPP[®] test may be released from quarantine. A captive cervid that has non-negative test results to this second DPP[®] test must be classified as a reactor and may only be moved in accordance with paragraph (b) of this section.

* * * * *

(e) Herds that have received captive cervids from an affected herd. If a herd has received captive cervids from an affected herd, the captive cervids from the affected herd of origin will be considered exposed to tuberculosis. The exposed captive cervids and the receiving herd must be

quarantined. The exposed captive cervids must be slaughtered, necropsied, or tested with the SCT test by a veterinarian employed by the State in which the test is administered or employed by USDA, or tested with the CervidTB Stat-Pak[®] test. Any exposed captive cervid that responds to the SCT test must be classified as a reactor and must be inspected at slaughter or necropsied. Any exposed captive cervid that has non-negative test results to the CervidTB Stat-Pak[®] test must be classified as a reactor and must be inspected at slaughter or necropsied. Any exposed captive cervid that tests negative to the SCT or CervidTB Stat-Pak[®] 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.

* * * * *

(3) If all the exposed captive cervids test negative for tuberculosis, the receiving herd will be released from quarantine if it is given a whole herd test and is found negative for tuberculosis and will return to the herd classification in effect before the herd was quarantined. In addition, the receiving herd will must be retested with the SCT or CervidTB Stat-Pak[®] test 1 year after release from quarantine in order for captive cervids from the herd to continue to be moved interstate. Supplemental diagnostic tests may be used if any captive cervids in the herd show a response to the SCT test or have non-negative test results to the CervidTB Stat-Pak[®] test.

(f) * * *

(1) If the herd is identified as the source of captive cervids having lesions of tuberculosis and M. bovis has been confirmed by bacterial isolation from the slaughter animal, all captive cervids in the herd that respond to the SCT must be classified as reactors. All captive cervids in the herd that respond to the CervidTB Stat-Pak[®] test must be classified as reactors. If none respond to the SCT test or have non-negative test results to the CervidTB Stat-Pak[®] test, the herd

may be released from quarantine and will return to the herd classification status in effect before the herd was quarantined, unless the DTE determines that additional testing is appropriate to ensure the herd's freedom from tuberculosis.

* * * * *

Done in Washington, DC, this 2nd day of January, 2013 .

Kevin Shea

Acting Administrator, Animal and Plant Health Inspection Service.

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