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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 77

[Docket No. APHIS-2014-0027]

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 amending the regulations regarding official tuberculosis tests for captive cervids to remove the CervidTB Stat-Pak<sup>®</sup> as an official bovine tuberculosis test for the following species of captive cervids: Elk, red deer, white-tailed deer, fallow deer, and reindeer.

We are also amending the regulations to specify that the Dual Path Platform (DPP)<sup>®</sup> test, which was previously a supplemental test to be used in conjunction with the CervidTB Stat-Pak<sup>®</sup>, is now considered a primary test, as well. We are taking this action because the CervidTB Stat-Pak<sup>®</sup> is no longer being produced, and because we have determined that the DPP<sup>®</sup> test can reliably be used as a primary test for bovine tuberculosis in certain species of captive cervids.

This action is necessary on an immediate basis so that the regulations do not continue to authorize usage of a discontinued test, yet still provide regulated entities with 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/#!docketDetail;D=APHIS-2014-0027>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2014-0027, 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-2014-0027> 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. Owen Henderson, Senior Staff Cervid Tuberculosis Disease Specialist, Cervid Health Program, Sheep, Goat, Cervid, and Equine Health Center, Surveillance, Preparedness, and Response Services, VS, APHIS, 2150 Centre Avenue, Building B-3-123, Fort Collins, CO 80526-8117; (970) 494-7317.

#### 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, prior to issuance of this interim rule, the definition of official tuberculosis test listed the following as official tests for bovine tuberculosis in captive cervids:

- The single cervical tuberculin (SCT) test, a primary test.

- The comparative cervical tuberculin test (CCT) test, a supplemental test.
- The CervidTB Stat-Pak<sup>®</sup> test, a primary test.
- The Dual Path Platform (DPP<sup>®</sup>) test, a supplemental test.

We specified that the SCT and CCT tests were official tuberculosis tests for all species of captive cervids in a final rule published in the Federal Register on December 31, 1998 (63 FR 72104-72129, Docket No. 92-076-2). We added the CervidTB Stat-Pak<sup>®</sup> and DPP<sup>®</sup> tests as official tuberculosis tests for captive elk, red deer, white-tailed deer, fallow deer, and reindeer in an interim rule<sup>1</sup> published in the Federal Register on January 9, 2013 (78 FR 1718-1723, Docket No. APHIS-2012-0087).

We solicited comments concerning the interim rule for 60 days ending March 11, 2013. We received 11 comments by that date. They were from captive cervid producers, an organization representing captive cervid producers within the United States, and an organization representing veterinarians within the United States. All commenters supported the rule.

Since the interim rule was published, however, production of the CervidTB Stat-Pak<sup>®</sup> has been discontinued. For this reason, in this interim rule, we are amending the captive cervid regulations to remove the CervidTB Stat-Pak<sup>®</sup> from the list of official tuberculosis tests.

When we were informed that the CervidTB Stat-Pak<sup>®</sup> test would be discontinued, we began to evaluate the possible use of the DPP<sup>®</sup> test as a primary test, with the intent of determining whether the DPP<sup>®</sup> test could be used in lieu of the CervidTB Stat-Pak<sup>®</sup> test once the latter ceased to be produced. We have determined that it can be used in such a manner. Accordingly, this rule also amends the captive cervid regulations to establish a testing protocol in which the DPP<sup>®</sup> test is used as both a primary and supplemental test for bovine tuberculosis in

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<sup>1</sup> To view the interim rule, its supporting documents, or the comments that we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0087>.

elk, red deer, white-tailed deer, fallow deer, and reindeer. Below, we discuss the changes we are making to the captive cervid regulations, 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 listed the CervidTB StatPak<sup>®</sup> as an official tuberculosis test. We are amending the definition of official tuberculosis test to remove the CervidTB StatPak<sup>®</sup> from the official tuberculosis tests listed in the definition.

Section 77.20 also provides definitions of each official tuberculosis test. We are removing the definition of CervidTB Stat-Pak<sup>®</sup>.

The definition of designated accredited veterinarian in § 77.20 had stated that, among other things, a designated accredited veterinarian is an accredited veterinarian who is trained and approved to draw the blood samples needed for the CervidTB Stat-Pak<sup>®</sup> and DPP<sup>®</sup> test. (Both tests are serological.) We are amending the definition of designated accredited veterinarian to remove reference to the CervidTB Stat-Pak<sup>®</sup> test.

#### 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. We are removing references to the CervidTB Stat-Pak<sup>®</sup> test from this section. We are also updating the Web addresses provided in paragraph (d)(2) of the section in light of a recent redesign of APHIS' Web site, and replacing a reference to "local area VS offices" in the same paragraph with the term "District offices," which reflects current Agency terminology.

### 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 primary tests for tuberculosis are contained in paragraph (a) of § 77.34; requirements for supplemental tests in paragraph (b). We are amending paragraph (a) of § 77.34 to reflect the fact that the CervidTB Stat-Pak<sup>®</sup> test is discontinued, and the DPP<sup>®</sup> test may now be used as a primary test.

As amended, paragraph (a) of § 77.34 specifies that the DPP<sup>®</sup> 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 specifies that, with limited exceptions, each captive cervid that has non-negative test results to this initial DPP<sup>®</sup> test will be classified as a suspect and retested with the DPP<sup>®</sup> test no sooner than 30 days; a captive cervid that has non-negative test results to the DPP<sup>®</sup> test must not be retested using the SCT or CCT test. (We are also amending the paragraph to specify that the each captive cervid that responds to the SCT test must not be retested with the DPP<sup>®</sup> test.) Finally, it allows the DPP<sup>®</sup> 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 DPP<sup>®</sup> test will be classified as a reactor, unless APHIS determines that the captive cervid should be classified as a suspect because of possible exposure to a tuberculous animal.

With minor changes, these requirements for the use of the DPP<sup>®</sup> test as a primary test mirror the requirements that had previously been in paragraph (a) of § 77.34 regarding use of the CervidTB Stat-Pak<sup>®</sup> test as a primary test. Most of the changes are editorial; one, which removes a reference to designated tuberculosis epidemiologists, reflects an organizational restructuring in APHIS and is discussed in greater detail later in this document.

We are specifying that most captive cervids that have non-negative test results to the initial DPP<sup>®</sup> test must be classified as suspects and retested no sooner than 30 days later using the DPP<sup>®</sup> test as a supplemental test. By reduplicating the initial testing conditions to the extent practicable at such an interval, we have firm confidence in the test results provided by this second DPP<sup>®</sup> test.

As amended, paragraph (b) of § 77.34 specifies that the DPP<sup>®</sup> test may be used as a supplemental test to retest captive cervids that have been classified as suspects based on an initial DPP<sup>®</sup> test. It further specifies that this supplemental test must evaluate a serum sample drawn from the cervid no sooner than 30 days after the initial DPP<sup>®</sup> test, and that a captive cervid that has non-negative test results to two successive DPP<sup>®</sup> tests must be classified as a reactor, unless APHIS determines that another disease classification is warranted.

#### 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. We are removing references to and provisions regarding the CervidTB Stat-Pak<sup>®</sup> test from this section.

## Miscellaneous

Since the January 2013 interim rule to add the CervidTB Stat-Pak<sup>®</sup> and DPP tests to the captive cervid regulations was issued, the Office of Management and Budget (OMB) has approved the paperwork associated with that interim rule under the control number 0579-0412. We are adding a reference to this approval to § 77.33, which contains the paperwork requirements for which we sought OMB approval.

Additionally, since the interim rule was published, APHIS' Veterinary Services program has undergone a reorganization. As a result of this reorganization, APHIS has eliminated the role of designated tuberculosis epidemiologist (DTE). The functions previously reserved for DTEs are now performed by various APHIS personnel. As a result, we are removing references to DTEs from the captive cervid regulations, and are removing the definition of designated tuberculosis epidemiologist from § 77.2 of the regulations. We are replacing the references to DTEs within the captive cervid regulations with references to APHIS.

## 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 following discontinuation of the CervidTB Stat-Pak<sup>®</sup> test. 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 removes the CervidTB Stat-Pak<sup>®</sup> as an official tuberculosis test for captive cervids, and establishes a testing protocol where the DPP<sup>®</sup> test may be used in lieu of the CervidTB Stat-Pak<sup>®</sup> test.

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 DPP<sup>®</sup> test to cost approximately \$13 to \$15 per head. Owners of captive cervids will not be required to use the DPP<sup>®</sup> 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 DPP<sup>®</sup> test as official primary tuberculosis test for captive cervids. This is because of the nature of the DPP<sup>®</sup> test. As a serological test, it is relatively easy to administer, in comparison to the SCT and CCT tests, and does 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

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 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.

§ 77.2 [Amended]

2. Section 77.2 is amended by removing the definition of designated tuberculosis epidemiologist (DTE).

3. Section 77.20 is amended as follows:

a. In the definition of designated accredited veterinarian, by removing the words “CervidTB Stat-Pak<sup>®</sup> test and”;

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

c. By removing the definition of CervidTB Stat-Pak<sup>®</sup> test.

The revision reads 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.

(3) The Dual Path Platform (DPP<sup>®</sup>) test.

\* \* \* \* \*

4. Section 77.33 is amended as follows:

a. In paragraph (a)(2), by removing the words “CervidTB Stat-Pak<sup>®</sup> or”;

b. By revising paragraphs (d)(2) and (e)(3);

c. By removing paragraph (e)(4); and

d. By adding an OMB citation at the end of the section.

The addition and revisions read as follows:

§ 77.33 Testing procedures for tuberculosis in captive cervids.

\* \* \* \* \*

(d) \* \* \*

(2) DPP<sup>®</sup> 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 DPP<sup>®</sup> test on the blood sample. The form is available at the following Web site:

<http://www.aphis.usda.gov/wps/portal/footer/resources/forms>; click on the “VS forms” link on that Web page. The veterinarian must also fill out the relevant portions of a test record. This form may be obtained by contacting the local district VS office, information regarding which is available at:

[http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalhealth?1dmy&urile=wcm%3apath%3a%2Faphis\\_content\\_library%2Fsa\\_our\\_focus%2Fsa\\_animal\\_health%2Fsa\\_contact\\_us%2Fsa\\_map%2Fct\\_state\\_contacts\\_map](http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalhealth?1dmy&urile=wcm%3apath%3a%2Faphis_content_library%2Fsa_our_focus%2Fsa_animal_health%2Fsa_contact_us%2Fsa_map%2Fct_state_contacts_map). This record must be sent to the offices of the State and Federal animal health officials in the State.

(e) \* \* \*

(3) Interpretation of DPP<sup>®</sup> test results will be in accordance with the classification requirements described in § 77.34.

\* \* \* \* \*

(Approved by the Office of Management and Budget under control number 0579-0412)

5. Section 77.34 is amended as follows:

a. In paragraphs (a)(1) and (b)(1), by removing the words “the DTE” each time that they occur, and adding the word “APHIS” in their place;

b. In paragraph (a)(1), by removing the words “CervidTB Stat-Pak<sup>®</sup> or DPP<sup>®</sup> tests” and adding the words “DPP<sup>®</sup> test” in their place; and

c. By revising paragraphs (a)(2) and (b)(2).

The revisions read as follows:

§ 77.34 Official tuberculosis tests.

(a) \* \* \*

(2) DPP<sup>®</sup> test. (i) The DPP<sup>®</sup> 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 this initial DPP<sup>®</sup> test will be classified as a suspect and retested with the DPP<sup>®</sup> test. A captive cervid that has non-negative test results to the DPP<sup>®</sup> test must not be retested using the SCT or CCT test.

(ii) The DPP<sup>®</sup> 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 DPP<sup>®</sup> test will be classified as a reactor, unless APHIS determines that the captive cervid should be classified as a suspect because of possible exposure to a tuberculous animal.

(b) \* \* \*

(2) DPP<sup>®</sup> test. The DPP<sup>®</sup> test may be used as a supplemental test in order to retest captive cervids that have been classified as suspects based on an initial DPP<sup>®</sup> test. In such instances, the supplemental DPP<sup>®</sup> test must evaluate a new serum sample drawn from the cervid no sooner than 30 days after the initial DPP<sup>®</sup> test. A captive cervid that has non-negative test

results on two successive DPP<sup>®</sup> tests will be classified as a reactor, unless APHIS determines that another disease classification is warranted.

§ 77.39 [Amended]

6. Section 77.39 is amended as follows:

- a. By removing paragraph (a)(1)(iii);
- b. By redesignating paragraph (a)(1)(iv) as paragraph (a)(1)(iii);
- c. In paragraphs (b)(2)(iv) and (c), by removing the words “the DTE” and adding the word “APHIS” in their place;
- d. In paragraph (e), introductory text, by removing the words “CervidTB Stat-Pak<sup>®</sup>” each time they appear and adding the word “DPP<sup>®</sup>” in their place;
- e. In paragraph (e)(2), by removing the words “the DTE” and adding the word “APHIS” in their place;
- f. In paragraph (e)(3), by removing the words “CervidTB Stat-Pak<sup>®</sup>” each time they appear and adding the word “DPP<sup>®</sup>” in their place;

g. In paragraph (f)(1), by removing the words “CervidTB Stat-Pak<sup>®</sup>” each time they appear and adding the word “DPP<sup>®</sup>” in their place and by removing the words “the DTE” and adding the word “APHIS” in their place; and

h. In paragraph (f)(2), by removing the words “CervidTB Stat-Pak<sup>®</sup>” and adding the word “DPP<sup>®</sup>” in their place.

Done in Washington, DC, this 23<sup>rd</sup> day of July 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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