

The Texas Animal Health Commission (commission) proposes amendments to §43.20, concerning Definitions, and §43.21, concerning General Requirements, in Chapter 43, Subchapter C, which is entitled “Eradication of Tuberculosis in Cervidae”. The purpose of the amendments is to include new types of tuberculosis tests for captive cervids.

Historically, the single cervical tuberculin skin test (SCT) and the comparative cervical tuberculin skin test (CCT) have been the only approved official tests for *Mycobacterium bovis* in captive cervids. Recently, the United States Department of Agriculture, Veterinary Services, approved the Stat-Pak<sup>®</sup> as a primary test and the DPP test as a secondary test for official program testing to diagnose TB in captive elk, red deer, white-tailed deer, fallow deer, and reindeer when the test is conducted at an approved laboratory. Both of these tests offer the advantage of decreased handling of animals when compared to skin testing.

### **FISCAL NOTE**

Ms. Larissa Schmidt, Director of Administration, Texas Animal Health Commission, has determined for the first five-year period the rules are in effect, there will be no additional fiscal implications for state or local government as a result of enforcing or administering the rules. An Economic Impact Statement (EIS) is required if the proposed rule has an adverse economic effect on small businesses. The agency has evaluated the requirements and determined that there is not an adverse economic impact and, therefore, there is no need to do an EIS. Implementation of the rules poses no significant fiscal impact on small or micro-businesses.

### **PUBLIC BENEFIT NOTE**

Ms. Schmidt has also determined that for each year of the first five years the rules are in effect, the public benefit anticipated as a result of enforcing the rules will be that the state requirements will conform to the federal standard.

### **LOCAL EMPLOYMENT IMPACT STATEMENT**

In accordance with Texas Government Code §2001.022, this agency has determined that the proposed rules will not impact local economies and, therefore, did not file a request for a local employment impact statement with the Texas Workforce Commission.

### **TAKINGS ASSESSMENT**

The agency has determined that the proposed governmental action will not affect private real property. The proposed amendments address an activity related to the handling of animals, including requirements for testing, movement, inspection, identification, reporting of disease, and treatment in accordance with 4 TAC §59.7, and are, therefore, compliant with the Private Real Property Preservation Act in Government Code, Chapter 2007.

### **REQUEST FOR COMMENT**

Comments regarding the proposal may be submitted to Carol Pivonka, Texas Animal Health

Commission, 2105 Kramer Lane, Austin, Texas 78758, by fax at (512) 719-0721 or by e-mail at “comments@tahc.state.tx.us”.

## **STATUTORY AUTHORITY**

The amendments are proposed under the following statutory authority as found in Chapter 161 of the Texas Agriculture Code. The commission is vested by statute, §161.041(a), with the requirement to protect all livestock, domestic animals, and domestic fowl from disease. The commission is authorized, by §161.041(b), to act to eradicate or control any disease or agent of transmission for any disease that affects livestock. If the commission determines that a disease listed in §161.041 of this code or an agent of transmission of one of those diseases exists in a place in this state among livestock, or that livestock are exposed to one of those diseases or an agent of transmission of one of those diseases, the commission shall establish a quarantine on the affected animals or on the affected place. That is found in §161.061.

As a control measure, the commission by rule may regulate the movement of animals. The commission may restrict the intrastate movement of animals even though the movement of the animals is unrestricted in interstate or international commerce. The commission may require testing, vaccination, or another epidemiologically sound procedure before or after animals are moved. That is found in §161.054. An agent of the Commission is entitled to stop and inspect a shipment of animals or animal products being transported in this state in order to determine if the shipment originated from a quarantined area or herd; or determine if the shipment presents a danger to the public health or livestock industry through insect infestation or through a communicable or noncommunicable disease. That authority is found in §161.048. A person is presumed to control the animal if the person is the owner or lessee of the pen, pasture, or other place in which the animal is located and has control of that place; or exercises care or control over the animal. That is under §161.002.

Section 161.007 provides that if a veterinarian employed by the commission determines that a communicable disease exists among livestock, domestic animals, or domestic fowl or on certain premises or that livestock, domestic animals, or domestic fowl have been exposed to the agency of transmission of a communicable disease, the exposure or infection is considered to continue until the commission determines that the exposure or infection has been eradicated through methods prescribed by rule of the commission. Section 161.005 provides that the commission may authorize the executive director or another employee to sign written instruments on behalf of the commission. A written instrument, including a quarantine or written notice, signed under that authority has the same force and effect as if signed by the entire commission.

No other statutes, articles or codes are affected by the amendments.

### **43.20. Definitions.**

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Accredited Herd--A herd that has passed at least two consecutive official tuberculosis tests of all eligible animals conducted at nine to 15 month intervals, has no evidence of bovine

tuberculosis, and meets the requirements of the UM&R.

(2) Affected herd--A herd that contains or has recently contained one or more animals infected with *Mycobacterium bovis* and has not passed the required tests for release from quarantine.

(3) Approved laboratory--A State/Federal Veterinary Diagnostic laboratory. The primary laboratory for tuberculosis histopathology and bacteriology culture and Cervid TB Stat-Pak Antibody Testing shall be the National Veterinary Services Laboratory, Ames, Iowa. Food Safety Inspection Service, Field Service Laboratories, may be utilized for histopathology.

(4) Cervid TB Stat-Pak Antibody Test--A primary supplemental serologic test used to screen for bovine tuberculosis in elk, red deer, white-tailed deer, fallow deer, and reindeer only. Samples for this test shall only be collected by state and federal animal health officials or designated accredited veterinarians.

~~(4) Blood Tuberculosis Test (BTB)– The BTB test is a supplemental test for bovine tuberculosis in Cervidae. The BTB test may be used, at no expense to the Commission, as a supplemental test to establish the disease status of a herd or to retest suspects. Samples for this test shall only be collected by state, federal, or accredited veterinarians.~~

(5) Cervidae--All species of deer, elk, and moose raised under agricultural conditions for the production of meat, the production of other agricultural products, sport, or exhibition.

(6) Commission--The Texas Animal Health Commission.

(7) Comparative Cervical Tuberculin (CCT) Test--The intradermal injection of biologically balanced bovine Purified Protein Derivative (PPD) PPD tuberculin and avian PPD tuberculin at separate sites in the mid-cervical area to determine the probable presence of bovine tuberculosis (*Mycobacterium bovis*) by comparing the response of the two tuberculins 72 hours (plus or minus six hours) following injection. This test may be used for retesting Single Cervical Tuberculin Test (SCT) suspects and shall be administered only by an approved state or federal veterinarian.

(8) Designated Accredited Veterinarian (DAV)--An accredited veterinarian trained and approved to conduct the Single Cervical Test for tuberculosis on Cervids and the Cervid TB Stat-Pak Antibody Test for tuberculosis on elk, red deer, white-tailed deer, fallow deer, and reindeer.

(9) Designated Tuberculosis Epidemiologist (DTE)--An epidemiologist who has demonstrated the knowledge and ability to perform the functions specified by the Bovine Tuberculosis Eradication Uniform Methods and Rules. The DTE must be selected jointly by the cooperating State Animal Health Official, the Area Veterinarian in Charge, and the Regional Epidemiologist. The National Animal Health Programs staff must concur in the appointment. The DTE has the responsibility to determine the scope of epidemiological investigations, assist in development of individual herd plans, and to coordinate disease surveillance and eradication programs within their geographic area of responsibility. The DTE has authority to make independent decisions concerning the use and interpretation of diagnostic tests and management of affected herds when those actions are supported by sound disease eradication principles.

(10) Direct shipment to slaughter--The shipment of tuberculosis reactors and suspects and tuberculosis-exposed cervids from the premises of origin, by permit, directly to a slaughtering establishment operating under state or federal inspection, without diversion to assembly points of any type.

(11) Dual-Path Platform Test (DPP)--A secondary more specific serologic test used when animals have non-negative results on the Stat-Pak test. The initial DPP is run on the non-negative blood submitted for the Stat-Pak test.

(11) ~~ELISA Test--The enzyme linked immunosorbant assay component of the BTB Test is recognized as a presumptive test for Bovine Tuberculosis in Cervidae. The ELISA test may be used to meet intrastate change of ownership test requirements.~~

(12) Herd--A group of cervids and other hoof stock maintained on common ground or two or more groups of cervids and other hoof stock under common ownership or supervision that are geographically separated but can have an interchange or movement without regard to health status. (A group is construed to mean one or more animals.)

(13) Individual Herd Plan--A written disease management plan that is designed by the herd owner and/or other herd representative and a State or Federal veterinarian to eradicate tuberculosis from an affected herd while reducing human exposure to the disease. The herd plan will include appropriate herd test frequencies, tests to be employed, and any additional disease or herd management practices deemed necessary to eradicate tuberculosis from the herd in an efficient and effective manner. The plan must be approved by the State Animal Health Official and the Area Veterinarian in Charge, and have the concurrence of the Regional or Designated Tuberculosis Epidemiologist.

(14) Monitored Herd--A herd on which identification records are maintained on animals over one year of age slaughtered and inspected for tuberculosis at an approved State/Federal slaughter facility or an approved laboratory, and animals tested negative for tuberculosis in accordance with the requirements for interstate movement specified in the Tuberculosis Eradication in Cervidae Uniform Methods and Rules. The initial qualifying total herd size is the annual average of animals one year of age or older during the initial qualifying period, which period shall not exceed three years. The combined number of slaughtered or tested animals in the sample must be evenly distributed over a three year period, and no less than half of the qualifying animals must be slaughter inspected. The rate to detect infection at a 2.0% prevalence level with 95% confidence would require a maximum number of 178 animals.

#### Attached Graphic

(15) Negative animals--Cervids that show no response to a Single Cervical Tuberculin tuberculosis test or elk, red deer, white-tailed deer, fallow deer or reindeer that test negative on the Stat-Pak test . Animals that show a non-negative response on the Single Cervical Tuberculin Test or the Stat-Pak test may be and have been classified negative by the testing veterinarian DTE based upon history, secondary supplemental tests (CTT or DPP) or; examination of carcasses ~~or laboratory results.~~

(16) No gross lesion (NGL) animals--Cervids that do not reveal a lesion(s) of bovine tuberculosis upon necropsy.

(17) Official eartag--An identification eartag that provides unique identification for each individual animal by conforming to the alpha-numeric National Uniform Eartagging System.

(18) Official tuberculosis test--A test for bovine tuberculosis applied and reported by approved personnel. The official tests for cervidae are the single cervical test and; the comparative cervical test, ~~and the blood tuberculosis test.~~ The Stat-Pak test and the DPP test are considered official tests for elk, red deer, white-tailed deer, fallow deer or reindeer only.

(19) Permit--An official document issued by a representative of the Commission, USDA APHIS-VS, or an accredited veterinarian that is required to accompany reactor, suspect or exposed cervids to slaughter. The permit will list the reactor tag number or official eartag number in the case of suspect and exposed cervids; the owner's name and address; origin and destination; number of cervids included; and the purpose of the movement. If a change in

destination becomes necessary, a new permit must be issued by authorized personnel. No diversion from the destination of the permit is allowed.

(20) Qualified herd--A cervid herd that has undergone at least one complete official negative test of all eligible animals within the past 12 months and is not classified as an accredited herd, has no evidence of bovine tuberculosis, and meets the standards of the UM&Rs.

(21) Reactor--Any cervid that shows a response to an official tuberculosis test and is classified a reactor by the DTE testing veterinarian.

(22) Single Cervical Tuberculin Test (SCT)--The intradermal injection of 0.1 mL (5,000 tuberculin units) of USDA PPD Bovis tuberculin in the mid-cervical region with reading by visual observation and palpation in 72 hours (plus or minus six hours) following injection. This test shall be administered only by a state, federal, or designated accredited veterinarian.

(23) Surveyed Herd--A cervid herd in which surveillance records are maintained on all animals over one year of age that are surveyed for evidence of bovine tuberculosis by routine post mortem inspection at an approved state/federal slaughter facility, or approved diagnostic laboratory, or routine tuberculosis tests performed by a designated accredited veterinarian or by other appropriate surveillance methods approved by a representative of the TAHC.

(24) Suspect--Any cervid that shows a response to the single cervical tuberculin test or any elk, red deer, white-tailed deer, fallow deer or reindeer that test non-negative on the Stat-Pak test and is not classified a reactor, or is classified suspect by a supplemental tuberculosis test.

(25) Tuberculin--A product that is approved by and produced under USDA license for the intradermal injection of cervids for the purpose of detecting bovine tuberculosis.

(26) Tuberculosis--A disease in Cervidae caused by *Mycobacterium bovis* (M. bovis).

### 43.21. General Requirements.

~~(a) Change of ownership requirements effective September 1, 1996, unless prior to that date sufficient information is obtained pursuant to §43.22(d)(1) of this title (relating to Herd Status Plans for Cervidae) to allow an epidemiological evaluation as to the necessity for change of ownership testing.~~

~~(1) Animal identification. All animals shall be individually identified by an official eartag or other approved identification device.~~

~~(2) Testing. All cervidae sold through auction markets shall be tested negative to a tuberculosis test within 90 days prior to sale, except:~~

~~(A) Animals originating from an accredited, qualified, monitored or surveyed herd.~~

~~(B) Animals consigned to an approved state/federal inspected slaughter facility.~~

~~(3) Recordkeeping requirements. Records documenting the sale of animals shall be maintained by the seller for a minimum period of five years.~~

~~(a) (b) Reporting of tests. All cervidae tested shall be officially individually identified by an official eartag at the time of an official test. A report of all tuberculosis tests, including the official identification of each animal by eartag number, age, sex, and breed, and a record of the size of the response, of the Single Cervical Tuberculin Test or the result of the TB Cervid Stat Pak Antibody Testing where indicated, and test interpretation shall be submitted in accordance with the requirements of the cooperating state and federal officials.~~

~~(b) (e) Classification of cervidae tested.~~

(1) Single cervical tuberculin test.

(A) Herds of unknown status. All SCT responses shall be recorded and the animals classified as suspects and quarantined for retest with the CCT ~~or BTB~~, unless in the judgment of the testing veterinarian the reactor classification is indicated.

(B) Known infected herds. All responses shall be recorded and the animals classified as reactors.

(2) Comparative cervical test--All responses are to be measured to the nearest 0.5mm.

(A) Animals having a response to bovine PPD of less than 1mm should be classified negative.

(B) Animals having a response to bovine PPD from 1mm through 2mm that is equal to or greater than the avian PPD response shall be classified as suspects.

(C) Animals having a response to bovine PPD greater than 2.0mm but equal to the avian response shall be classified as suspects, except when in the judgment of the testing veterinarian the reactor classification is indicated.

(D) Animals meeting the criteria for suspect classification on two successive CCTs shall be classified as reactors.

(E) Animals having a response to bovine PPD which is greater than 2.0mm and is 0.5mm greater than the avian PPD response shall be classified as reactors.

(3) Suspect SCT cervids may be retested by ~~either~~ the CCT only ~~or the BTB~~. The CCT may be applied within ten days following the SCT injection or after 90 days. If the CCT is applied within ten days of the SCT, the opposite side of the neck shall be used. ~~The sample for the BTB shall be taken 13-30 days after the SCT injection.~~ Animals positive to the CCT ~~or the BTB~~ shall be classified as reactors.

(4) Suspects may be necropsied in lieu of retesting, and, if found without evidence of *M. bovis* infection by histopathology and culture (including selected NGL specimens submitted from animals having no gross lesions indicative of tuberculosis), shall be considered negative for tuberculosis.

~~(5) Elisa Test--Animals positive to the Elisa test shall be classified as suspects and quarantined for retest with an official TB test.~~

(c) Classification of captive elk, red deer, white-tailed deer, fallow deer or reindeer tested.

(1) Cervid TB Stat Pak antibody test.

(A) Herds of unknown status. All Stat Pak non-negative responses shall be recorded and the animals classified as suspects and quarantined for retest with the DPP unless in the judgment of the DTE the reactor classification is indicated.

(B) Known infected herds. All non-negative responses shall be recorded and the animals classified as reactors.

(2) Dual-Path Platform Test shall be performed on all non-negatives samples submitted for Stat Pak Testing. Animals non-negative on the Stat-Pak test and non-negative on a single DPP test should be classified as suspect unless the DTE determines that a reactor classification is warranted.

(3) Animals classified as suspect by a single DPP test may be retested with the DPP test only with a new blood sample drawn no sooner than 30 days after the initial sample was obtained.

(4) Animals that are non-negative on two successive DPP tests should be classified as reactor.

(5) Suspects may be necropsied in lieu of retesting, and, if found without evidence of *M. bovis* infection by histopathology and culture (including selected NGL specimens submitted from animals having no gross lesions indicative of tuberculosis), shall be considered negative for tuberculosis.

(d) Disposition of Tuberculin-Responding Cervidae.

(1) Reactors shall remain on the premises where they were disclosed until a state or federal permit for movement has been obtained. Movement for immediate slaughter will be within 15 days of classification directly to a slaughter establishment where approved state or federal inspection is maintained. Alternatively, the animals may be destroyed and necropsy conducted by or under the supervision of a state or federal regulatory veterinarian that has been trained in tuberculosis necropsy procedures.

(2) Herds containing suspects to the SCT shall be quarantined until the suspect animals are:

(A) retested by the CCT within ten days of the SCT injection; or

(B) retested by the CCT after 90 days; or

~~(C) retested by the BTB test between 13 and 30 days after the SCT injection; or~~

~~(C)~~ ~~(D)~~ shipped under permit directly to a slaughter facility under state or federal inspection, or necropsied. If such animals are found without evidence of *M. bovis* infection by histopathology and culture (including selected NGL specimens submitted from animals having no gross lesions indicative of tuberculosis), they shall be considered negative for tuberculosis.

(3) Suspects to the CCT comparative cervical test or equivocal to the BTB shall remain under quarantine until:

(A) comparative cervical suspects are retested by the CCT after 90 days; or

~~(B) BTB equivocal animals are retested by the BTB test optimally before 60 days following the SCT injection; or~~

~~(B)~~ ~~(C)~~ such animals are shipped under permit directly to a slaughter facility under state or federal inspection, or necropsied. If such animals are found without evidence of *M. bovis* infection by histopathology and cultured (including selected NGL specimens submitted from animals having no gross lesions indicative of tuberculosis), they shall be considered negative for tuberculosis.

(4) An animal meeting the suspect criteria on two successive CCT ~~or two BTB equivocal tests~~ followed by one suspect CCT test shall be classified as a reactor and be identified as such. The testing veterinarian must justify exceptions in writing and have the concurrence of State or Federal animal health personnel.

(e) Identification of Reactors. Reactor cervids shall be identified by branding with the letter "T" at least two by two inches in size, high on the left hip near the tailhead, and by tagging with an official eartag bearing a serial number and inscription "U.S. Reactor" attached to the left ear of each reactor animal.

(f) Disposition of elk, red deer, white-tailed deer, fallow deer or reindeer that are non-negative on the Stat-Pak test and non-negative on a single DPP test.

(1) Reactors shall remain on the premises where they were disclosed until a state or federal permit for movement has been obtained. Movement for immediate slaughter will be within 15 days of classification directly to a slaughter establishment where approved state or federal inspection is maintained. Alternatively, the animals may be destroyed and necropsy conducted by or under the supervision of a state or federal regulatory veterinarian that has been trained in tuberculosis necropsy procedures.

(2) Herds containing suspects to the Stat-Pak test and a single DPP test shall be quarantined until the suspect animals are:

(A) retested by the DPP test only with a new blood sample drawn no sooner than 30 days after the initial sample was obtained; or

(B) shipped under permit directly to a slaughter facility under state or federal inspection, or

necropsied. If such animals are found without evidence of M. bovis infection by histopathology and culture (including selected NGL specimens submitted from animals having no gross lesions indicative of tuberculosis), they shall be considered negative for tuberculosis.

(3) Animals that are non-negative on two successive DPP tests should be classified as reactor. Any exceptions to reactor classification must be justified by the designated TB epidemiologist in writing and have the concurrence of the regional TB epidemiologist.

(g) ~~(f)~~ Quarantine procedures.

(1) All herds in which reactor animals are disclosed shall be quarantined. Exposed animals must remain on the premises where disclosed unless a state or federal permit for movement to slaughter has been obtained. Movement for immediate slaughter must be directly to a slaughter establishment where approved state or federal inspection is administered. Animals must be identified by official eartag. Use of "S" brand is required, or animals must be shipped in an official sealed vehicle. The "S" brand shall be applied to either the left jaw or the tailhead.

(2) Cervidae herds in which M. bovis is confirmed shall remain under quarantine if not depopulated, and must pass three consecutive official tuberculosis tests of all animals. The first test must be conducted 90 days or more after the last test yielding a positive animal, with two additional tests at 180-day minimum intervals. Five annual complete herd tests of all animals shall be given following the release from quarantine.

(3) Cervidae herds that have had a test of all eligible animals with NGL reactors only and no evidence of tuberculosis infection is found by histopathology and culture of M. bovis (including selected NGL specimens submitted from animals having no gross lesions indicative of tuberculosis) may be released without further restrictions.

(4) Cervidae herds in which compatible or suggestive lesions are found by histopathology without the isolation of M. bovis may be released from quarantine following a negative 90-day retest of the entire herd, provided there is no known association with M. bovis.

(5) Cervidae herds that exhibit NGL reactors in which no evidence of tuberculosis infection is found by histopathology and culture of M. bovis and are unable to conduct a test of all eligible animals, shall be evaluated by the state and/or regional tuberculosis epidemiologist for possible release of quarantine.

(h) ~~(g)~~ Procedures in affected herds. Disclosure of tuberculosis in any herd shall be followed by a complete epidemiological investigation. All cervids in herds from which tuberculosis animals originate, and all cervids that are known to have associated with affected cervids or other affected animals, shall be tested promptly. These procedures shall apply to adjacent and contact herds as well as to the evaluation and testing of possible source herds for the affected herd. Herds that have received exposed animals shall be tested following the slaughter or testing of the exposed animals. Every effort shall be made to ensure the immediate elimination of the disease from all species of animals on the premises. The herd shall be handled as outlined under subsection (e) of this section, Quarantine Procedures.

(i) ~~(h)~~ Retest Schedules for High Risk Herds.

(1) In herds with a history of lesions compatible or suggestive for tuberculosis by histopathology, two complete annual herd tests shall be given after release from quarantine. Herds with a bacteriologic isolation of a Mycobacteria species other than M. bovis should be considered negative for bovine tuberculosis with no further testing requirements.

(2) In a newly assembled herd on premises where a tuberculosis herd has been depopulated, two annual herd tests shall be applied to all animals. The first test must be approximately six months after assembly of the new herd. If the premises are vacated for over one year, these requirements

may be waived.

(3) Exposed animals previously sold from known infected herds shall be depopulated if possible, or tested with the SCT or Stat Pak/DPP by State or Federal veterinarians. ~~The BTB test may be used simultaneously with the SCT as an additional diagnostic test.~~ All animals non-negative ~~positive~~ to either test shall be classified as reactors.

(A) If bovine tuberculosis is confirmed in the exposed animal(s), the remainder of the receiving herd shall be classified as an infected herd and handled according to subsection (f)(2) of this section.

(B) If negative to the test, the exposed animal(s) will subsequently be handled as if a part of the infected herd of origin for purposes of testing, quarantine release, and the five annual high-risk tests. The remainder of the herd shall be tested at the time of the initial investigation and retested in one year with the SCT or Stat Pak/DPP. Supplemental diagnostic tests may be used if needed.

(4) Herds indicated as the source(s) of animals in slaughter traceback investigations shall be placed under quarantine within 30 days of notification to the area office, and a herd test scheduled. Testing of source herds of slaughter animals having lesions of tuberculosis shall be done by state or federal regulatory veterinarians using the SCT or Stat Pak/DPP.

(A) If the herd of origin is positively identified and *M. bovis* has been confirmed by bacterial isolation from the slaughter animal, all animals responding to the SCT or Stat Pak/DPP shall be classified as reactors. In all other cases, supplemental diagnostic tests may be used.

(B) In herds identified as the source of culture negative lesioned animals, responding animals may be classified as reactors or suspects. If classified as suspects, they may be retested by supplemental diagnostic tests.

(j) ~~(i)~~ Cleaning and disinfection of premises, conveyances, and materials. All premises--including all structures, holding facilities, conveyances, and materials--that are determined by program officials to constitute a health hazard to humans or animals because of tuberculosis, shall be properly cleaned and disinfected. This shall be done within 15 days after the removal of tuberculosis-affected or exposed cervids in accordance with approved procedures. However, these officials may extend the time limit for disinfection to 30 days when a request for such extension is received prior to the expiration date of the original 15-day period allowed.