The Texas Animal Health Commission (commission) proposes amendments to §38.6, concerning Official Trichomoniasis Tests, in Chapter 38, which is entitled "Trichomoniasis". The purpose of the amendments is to approve a new official Trichomoniasis test.

The Bovine Trich Working Group (TWG) met on April 11, 2017, to evaluate the effectiveness of current rules. The TWG discussed the program overview to date, the management of infected herds, entry requirements, and the need for possible revisions to the program.

The TWG recommended that the commission propose rules to authorize an additional official test. Texas A&M Veterinary Medical Diagnostic Laboratory (TVMDL) is in the process of implementing an enhanced Trichomoniasis testing technology for the Polymerase Chain Reaction (PCR) test. PCR is currently accepted as an official test or an official confirmatory test for Trichomoniasis. TVMDL's Direct Sample qPCR is an enhanced testing technology using PCR. Unlike the current PCR, the qPCR test does not require the sample to be incubated or placed in an InPouch. The TWG also recommended that the deadline for submitting samples to an approved laboratory remain at 96 hours, but encouraged submission of samples to be accomplished within 48 hours.

Further, the proposal adds the term InPouch to the culture testing requirement. This proposed addition will ensure the sample is properly collected and submitted for testing.

FISCAL NOTE

Ms. Larissa Schmidt, Chief of Staff, Texas Animal Health Commission, has determined for the first five-year period the rule is in effect, there will be no significant additional fiscal implications for state or local government as a result of enforcing or administering the rule. 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 this rule poses no significant fiscal impact on small or micro-businesses, or to individuals.

PUBLIC BENEFIT NOTE

Ms. Schmidt has also determined that for each year of the first five years the rule is in effect, the public benefit anticipated as a result of enforcing the rule will be a more efficient test that is easier to collect and submit in a timely manner.

LOCAL EMPLOYMENT IMPACT STATEMENT

In accordance with Texas Government Code §2001.022, this agency has determined that the proposed rule 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 are 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 Amanda Bernhard, Texas Animal Health Commission, 2105 Kramer Lane, Austin, Texas 78758, by fax at (512) 719-0719 or by email at "comments@tahc.texas.gov".

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, through §161.041(b), to act to eradicate or control any disease or agent of transmission for any disease that affects livestock.

Pursuant to \$161.005, entitled "Commission Written Instruments", 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.

Pursuant to \$161.006, entitled "Documents to Accompany Shipment", if required that a certificate or permit accompany animals or commodities moved in this state, the document must be in the possession of the person in charge of the animals or commodities, if the movement is made by any other means.

Pursuant to §161.0417, entitled "Authorized Personnel for Disease Control", a person, including a veterinarian, must be authorized by the commission in order to engage in an activity that is part of a state or federal disease control or eradication program for animals. Section 161.0417 requires the commission to adopt necessary rules for the authorization of such persons and, after reasonable notice, to suspend or revoke a person's authorization if the commission determines that the person has substantially failed to comply with Chapter 161 or rules adopted under that chapter. Section 161.0417 does not affect the requirement for a license or an exemption under Chapter 801, Occupations Code, to practice veterinary medicine.

Pursuant to \$161.046, entitled "Rules", the commission may adopt rules as necessary for the administration and enforcement of this chapter.

Pursuant to \$161.048, entitled "Inspection of Shipment of Animals or Animal Products", the commission may require testing, vaccination, or another epidemiologically sound

procedure before or after animals are moved. 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.

Pursuant to §161.061, entitled "Establishment", if the commission determines that a disease listed in §161.041 of this code or an agency of transmission of one of those diseases exists in a place in this state or among livestock, exotic livestock, domestic animals, domestic fowl, or exotic fowl, or that a place in this state or livestock, exotic livestock, exotic livestock, domestic animals, domestic fowl, or exotic fowl, or exotic fowl are exposed to one of those diseases or an agency of transmission of one of those diseases, the commission shall establish a quarantine on the affected animals or on the affected place.

Pursuant to §161.101, entitled "Duty to Report", a veterinarian, a veterinary diagnostic laboratory, or a person having care, custody, or control of an animal shall report the existence of the diseases, if required by the commission, among livestock, exotic livestock, bison, domestic fowl, or exotic fowl to the commission within 24 hours after diagnosis of the disease.

Pursuant to §161.113, entitled "Testing or Treatment of Livestock", if the commission requires testing or vaccination under this subchapter, the testing or vaccination must be performed by an accredited veterinarian or qualified person authorized by the commission. The state may not be required to pay the cost of fees charged for the testing or vaccination. And if the commission requires the dipping of livestock under this subchapter, the livestock shall be submerged in a vat, sprayed, or treated in another sanitary manner prescribed by rule of the commission.

Pursuant to §161.114, entitled "Inspection of Livestock", an authorized inspector may examine livestock consigned to and delivered on the premises of a livestock market before the livestock are offered for sale. If the inspector considers it necessary, the inspector may have an animal tested or vaccinated. Any testing or vaccination must occur before the animal is removed from the livestock market.

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

38.6. Official Trichomoniasis Tests.

Approved Tests. Approved tests for Trichomoniasis testing within the State of Texas shall include the culture or Real Time Polymerase Chain Reaction (RT-PCR) testing of samples collected into an InPouch by certified veterinarians following approved collection, handling and shipping protocols, then tested in approved laboratories. (1) Official Culture Tests. An official test is one in which the sample, <u>collected in an InPouch</u>, is received in the official laboratory, in good condition, within 48 hours of collection <u>or is incubated in an InPouch</u> by the collecting veterinarian for 48 hours after <u>collection</u>, and such sample is <u>submitted to be</u> tested according to the "Official Protocol for Culture of Trichomoniasis." Samples in transit for more than 48 hours will not be

accepted for official culture testing. During transportation, the organisms should be protected from exposure to daylight and extremes of temperature, which should remain above 15 degrees Celsius (59 degrees Fahrenheit) and below 37 degrees Celsius (98.6 degrees Fahrenheit).

(2) Official Polymerase Chain Reaction Tests. Polymerase Chain Reaction is accepted as an official test or an official confirmatory test when completed by a qualified laboratory, approved by the Executive Director, and <u>meets the following requirements</u>: the sample is received in good condition by the laboratory within 48 hours after collection, or is Trichomoniasis samples pooled at the laboratory may qualify as official tests at a ratio of up to five individually collected samples pooled for one test. Veterinary practitioners may not submit pooled samples for an official tests.

(A) A Trichomoniasis sample submitted in an InPouch must be received in the official laboratory, in good condition, within 48 hours of collection or incubated by the collecting veterinarian for 48 hours after collection and submitted to arrive at the laboratory within 96 hours of collection. Trichomoniasis samples pooled at the laboratory may qualify as official tests at a ratio of up to five individually collected samples pooled for one test. Veterinary practitioners may not submit pooled samples for an official test.

(B) A Trichomoniasis sample submitted in phosphate buffered saline must be received in the official laboratory, in good condition, within 96 hours of collection.

(3) Other Official Tests. Other tests for Trichomoniasis may be approved by the Commission, as official tests, after the tests have been proven effective by research, have been evaluated sufficiently to determine efficacy, and a protocol for use of the test has been established.