

EXPLANATION OF PROPOSED RULE

The Texas Animal Health Commission (commission) proposes amendments to Chapter 38, §§38.1, 38.2, 38.3, and 38.6, concerning “Trichomoniasis”.

The Bovine Trichomoniasis (Trich) Working Group (TWG) had an annual review on April 23, 2019, to evaluate the effectiveness of current program. The TWG discussed the program overview to date, the management of infected herds, and the need for possible revisions to the program.

The group recommends that three changes be made in the control program. The first is to ensure that samples pooled by approved laboratories are not authorized for official test purposes from Trich positive herds, herds identified as being adjacent to Trich positive herds and change of ownership. These need to be individually submitted samples so as to improve the quality of the test sample as well as to provide quicker identification for follow up on the positive animals.

The second recommendation is to limit the use of a virgin certificate as an exemption to the test requirements. The proposed rule provides that sexually intact male cattle under 18 months of age, or verified by birth date listed on the breed registry papers, must be certified by the breeder on a virgin certificate in order for the animal to be sold without a test.. Therefore, it is proposed that the use of virgin certificates be restricted to breeder animals that belong to a breed registry which maintains an official list of animals within a specific breed for which there is an association of unique identification for the cattle.

The third recommendation is that a seller must provide written disclosure for female cattle that have been exposed or potentially exposed to a Trich positive bull within the previous 6 months at the time of sale.. There is not any easy diagnostic method to disclose female cattle that are positive with Trich. This provision will allow a buyer of female cattle to take this information into account for managing the newly purchased females for breeding purposes. The commission seeks specific comments on the proposed language as to what will be most effective as a herd management tool.

FISCAL NOTE

Ms. Larissa Schmidt, Chief of Staff, Texas Animal Health Commission, has determined for the first five-year period the rules are in effect, there will be no significant additional fiscal implications for state or local government as a result of enforcing or administering the rules.

REGULATORY ANALYSIS

Public Benefit

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 more efficient rules to recognize a 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 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 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.

Economic Impact Statement The Commission has determined that the animal agricultural industries meet the statutory definition of a small or microbusiness (Government Code, Chapter 2006), and that the proposed rule would affect rural communities (as defined by Government Code, Chapter 2006); however, the Commission also has determined that the rule, as proposed, will not result in adverse economic impacts to small and microbusinesses or rural communities because the rule applies to all cattle tested for the disease and determined to be positive and the requirements are intended to prevent exposure of positive cattle to other cattle in the state, thereby protecting other microbusiness.. The rule is ensuring that bulls sold as virgins can be properly validated and that a cattle owner recognizes that pooled samples cannot be used for an official test because the test quality is more easily degraded and a positive test means that the five animals have to be retested to determine and isolate which of the five bulls was positive. The disclosure requirement just provides parties animal health information that may assist in the management of the purchased animals.

The estimated number of cattle ranchers that could be impacted by proposed the rule is 2,533. The potential economic impact is counter balanced by having great integrity in the test requirements of the control program. The test for an individual sample is estimated to cost between \$30.00 and- \$120.00. This cost is negated by the increased potential market value of the bull found test-negative for Trichomoniasis..

The Trich Control program has evolved to the point of effectively being able to identify and address Trich positive animals. The program changes will add greater integrity to the current protocols regarding qualification for virgin certificates, , ensuring that pooling of test samples does not qualify as an official test at approved laboratories, and adding a new requirement for full disclosure when selling a female animal for breeding purposes that has been exposed or potentially exposed to Trichomoniasis in the previous 6 months. There is not an alternative method of achieving the purpose of the proposed rule.

Regulatory Flexibility Analysis includes:

These proposed amendments achieve the purpose of improved quality control of a disease program to reduce risk and exposure while minimizing adverse impacts on affected small businesses and/or rural communities, if consistent with the health, safety, and environmental and economic welfare of the state. The changes proposed are intended to ensure that cattle disclosed as being Trich Positive or exposed to Trich positive animals are not sold to an unwitting purchaser and thereby creating an economic hardship on them.

Government Growth Impact Statement: In compliance with the requirements of Government Code, §2001.0221, the Commission has prepared the following Government Growth Impact Statement (GGIS). The rule as proposed, if adopted, will: (1) neither create nor eliminate a government program; (2) not result in an increase or decrease in the number of full-time equivalent employee needs; (3) not result in a need for additional General Revenue funding; (4) not affect the amount of any fee; (5) it modifies a pre-existing disease control program requirement to further reduce exposure of this disease to other cattle; (6) it does not expand an existing regulation; (7) it may increase the number of individuals subject to regulation; and (8) it will not adversely affect the state's economy.

Rule Reduction Statement: The commission has determined that the rule as proposed follows the legislative requirement that the commission shall protect all cattle within the state from diseases that pose a negative disease risk to the Texas cattle industry. It does not impose a direct cost on regulated persons within the state but rather modifies existing disease control requirements for positive cattle in order to protect the Texas Cattle industry, and therefore it is not necessary to repeal or amend any other existing rule.

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, domestic animals, domestic fowl, or exotic fowl are exposed to one of those diseases or an agency of transmission of one of those diseases.

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.

<rule>

§38.1. Definitions.

The following words and terms, when used in this chapter, shall have the defined meanings, unless the context clearly indicates otherwise:

- (1) Accredited Veterinarian--A licensed veterinarian who is approved to perform specified functions required by cooperative state-federal disease control and eradication programs pursuant to Title 9 of the Code of Federal Regulations, Parts 160 and 161.
- (2) Affected Herd--Any herd in which any cattle have been classified as *Trichomonas foetus* positive on an official test and which has not completed the requirements for elimination of the disease from the herd.
- (3) Cattle--All dairy and beef animals (genus *Bos*), excluding bison (genus *Bison*).
- (4) Certified Veterinarians--Veterinarians certified with, and approved by the commission to collect Trichomoniasis samples for official Trichomoniasis testing and to perform any other official function under the Trichomoniasis program.
- (5) Commission--The Texas Animal Health Commission.
- (6) Executive Director--The Executive Director of the Texas Animal Health Commission or his designee.
- (7) Exempt Cattle (from testing requirements)--Cattle that have been physically rendered incapable of intromission at a facility recognized by the commission.
- (8) Exposed Cattle--Cattle that are part of an affected herd or cattle that have been in contact with Trichomoniasis infected cattle.
- (9) Herd—

(A) All cattle under common ownership or supervision or cattle owned by a spouse that are on one premise; or

(B) All cattle under common ownership or supervision or cattle owned by a spouse on two or more premises that are geographically separated, but on which the cattle have been interchanged or where there has been contact among the cattle on the different premises. Contact between cattle on the different premises will be assumed unless the owner establishes otherwise and the results of the epidemiological investigation are consistent with the lack of contact between premises; or

(C) All cattle on common premises, such as community pastures or grazing association units, but owned by different persons. Other cattle owned by the persons involved which are located on other premises are considered to be part of this herd unless the epidemiological investigation establishes that cattle from the affected herd have not had the opportunity for direct or indirect contact with cattle from that specific premises. Approved feedlots and approved pastures are not considered to be herds.

(10) Herd Test--An official test of all non-virgin bulls in a herd.

(11) Hold Order--A document restricting movement of a herd, unit, or individual animal pending the determination of disease status.

(12) Infected Cattle--Any cattle determined by an official test or diagnostic procedure to be infected with Trichomoniasis or diagnosed by a veterinarian as infected.

(13) Infected Herd--The non-virgin bulls in any herd in which any cattle have been determined by an official test or diagnostic procedure to be infected with Trichomoniasis or diagnosed by a veterinarian as being infected.

(14) Movement Permit--Authorization for movement of infected or exposed cattle from the farm or ranch of origin through marketing channels to slaughter or for movement of untested animals to a location where the animals will be held under hold order until testing has been accomplished.

(15) Movement Restrictions--A "Hold Order," "Quarantine," or other written document issued or ordered by the commission to restrict the movement of livestock or exotic livestock.

(16) Negative--Cattle that have been tested with official test procedures and found to be free from infection with Trichomoniasis.

(17) Official Identification/Officially Identified--The identification of livestock by means of an official identification device, official eartag, registration tattoo, or registration brand, or any other method approved by the commission and/or Administrator of APHIS that provides unique identification for each animal. Official identification includes USDA alpha-numeric metal eartags

(silver bangs tags), 840 RFID tags, 840 bangle tags, official breed registry tattoos, and official breed registry individual animal brands.

(18) Official Trichomoniasis Test--A test for bovine Trichomoniasis, approved by the commission, applied and reported by TVMDL or any other laboratory approved as an official laboratory by the commission. The test document is valid for 60 days, provided the bull is isolated from female cattle at all times, and may be transferred within that timeframe with an original signature of the consignor.

(19) Official Laboratory Pooled Trichomoniasis test samples--Up to five samples individually collected by a veterinarian and packaged and submitted to an official laboratory which can then pool the samples.

(20) Positive--Cattle that have been tested with official test procedures and found to be infected with Trichomoniasis.

(21) Quarantine--A written commission document or a verbal order followed by a written order restricting movement of animals because of the existence of or exposure to Trichomoniasis. The commission may establish a quarantine on the affected animals or on the affected place. The quarantine of an affected place may extend to any affected area, including a county, district, pasture, lot, ranch, farm, field, range, thoroughfare, building, stable, or stockyard pen. The commission may establish a quarantine to prohibit or regulate the movement of any article or animal that the commission designates to be a carrier of Trichomoniasis and/or an animal into an affected area, including a county district, pasture, lot, ranch, farm, field, range, thoroughfare, building, stable, or stockyard pen.

(22) Registered Breeding Cattle – Cattle that belong to a breed registry, which maintains an official list of animals within a specific breed for which there is an association of unique identification for each head of cattle.

(23)[(22)] Test-Eligible Cattle--All sexually intact non-virgin male cattle and all sexually intact male cattle which have erupting or erupted permanent incisor teeth (or older), which are being sold, leased, gifted or exchanged in the state of Texas for breeding purposes.

(24)[(23)] Trichomoniasis--A venereal disease of cattle caused by the organism *Trichomonas foetus*.

(25)[(24)] TVMDL--The official laboratory for testing is the Texas A&M Veterinary Medical Diagnostic Laboratory.

(26)[(25)] Virgin Bull--Sexually intact male registered breeding cattle which have not serviced a cow and which are not more than 18 months of age as determined by the eruption of the two permanent central incisors or birth date on breed registry papers certified by the breeder; or not more than 30 months of age and certified by both the breeder based on birth date and

confirmed by his veterinarian that the bull facility is sufficient to prevent contact with female cattle. The virgin certification by the breeder is valid for 60 days, provided the bull is isolated from female cattle at all times, and may be transferred within that timeframe with an original signature of the consignor.

§38.2. General Requirements.

(a) Test Requirements. All Texas origin bulls sold, leased, gifted, exchanged or otherwise changing possession for breeding purposes in the State of Texas shall meet the following testing or certification requirements prior to sale or change of ownership in the state:

(1) Be certified as virgin, by the breeder or his representative, on and accompanied by a breeder's certificate of virgin status; or

(2) If from a herd of unknown status (a herd that has not had a whole herd test), be tested negative on three consecutive culture tests conducted not less than seven days apart or one RT-PCR test conducted within 60 days of sale or movement, be held separate from all female cattle since the test sample was collected, and be accompanied by a Trichomoniasis test record showing the negative test results.

(b) Identification of Bulls. All bulls certified as virgin bulls shall be identified by an official identification device or method on the breeder's certification of virgin status. All bulls tested for Trichomoniasis shall be officially identified at the time the initial test sample is collected. That official identification shall be recorded on the test documents prior to submittal.

(c) Confirmatory Test. The owner of any bull which tests positive for Trichomoniasis may request in writing, within five days of the positive test, that the commission allow a confirmatory test be performed on the positive bull. If the confirmatory test is positive the bull will be classified as infected with Trichomoniasis. If the confirmatory test is negative the bull shall be retested in not less than seven days to determine its disease status. If the confirmatory test reveals that the bull is only infected with fecal trichomonads, the test may be considered negative.

(d) Untested Bulls. Bulls presented for sale without a breeder's certification of virgin status for registered breeding cattle or a Trichomoniasis test record showing negative test results may:

(1) Be sold for movement only directly to slaughter; or

(2) Be sold for movement to an approved feedlot and then moved to slaughter or transported back to a livestock market under permit, issued by commission personnel, to be sold in accordance with this chapter; or

(3) Be sold and moved under a Hold Order to such place as specified by the commission for testing to change status from a slaughter bull. Such bulls shall be officially individually identified

with a permanent form of identification prior to movement, move to the designated location on a movement permit, and be held in isolation from female cattle at the designated location where the bull shall undergo three consecutive culture tests at least seven days apart or one RT-PCR test. If the results of any test are positive, all bulls in the herd of origin of the positive bull shall be placed under hold order and tested as provided by subsection (e) of this section. The positive bull shall be classified as infected and be permitted for movement only directly to slaughter or to a livestock market for sale directly to slaughter; or

(4) Be sold and moved to another physical location under permit issued by commission personnel, and then to a livestock market or location to be resold within seven days from the date of issuance. The bull cannot be commingled with female cattle during the seven days.

(e) Herd of Origin or Unit Testing.

(1) All bulls that are part of a herd of origin from which a bull is sold in accordance with subsection (d)(3) of this section and is found to be infected with Trichomoniasis shall be placed under hold order and officially tested for Trichomoniasis.

(2) All bulls that are part of a unit of origin, as epidemiologically determined by the commission, from which a bull becomes separated and that bull is found to be positive for Trichomoniasis shall be placed under a hold order and officially tested for Trichomoniasis. All bulls that are part of the unit on which the separated positive bull was located, as epidemiologically determined by the commission, shall also be placed under hold order and officially tested for Trichomoniasis.

(3) Officially tested, as used in this subsection, requires at a minimum three official culture tests conducted not less than seven days apart, or one official RT-PCR test. If the results of any test that are required by this subsection are positive, the herd shall be tested as provided by §38.3 of this chapter (relating to Infected Herds).

§38.3. Infected Herds.

(a) Bulls that have been determined to be infected by culture or by RT-PCR test and/or by confirmatory RT-PCR test shall be placed under hold order along with all other non-virgin bulls in the bull herd. Infected bulls must be isolated from all female cattle from the time of diagnosis until final disposition or as directed by the commission. Breeding bulls which have been disclosed as reactors may be retested provided: the owners, or their agents initiate a request to the TAHC Regional Director where the bull is located; that retests are conducted within 30 days after the date of the original test; test samples for retests are submitted to the TVMDL for testing; and the positive bull is held under quarantine along with all other exposed bulls on the premise. If they are retested, they must have two negative tests by RT-PCR to be released within 30 days of the initial test.

(b) Positive bulls may be moved directly to slaughter or to a livestock market for sale directly to

slaughter. In order to move, the bulls shall be individually identified by official identification device on a movement permit authorized by the commission from the ranch to the market and from the market to the slaughter facility, or from the ranch directly to the slaughter facility. Movement to slaughter shall occur within 30 days from disclosure of positive test results (or confirmatory test results) or as directed by the commission.

(c) All bulls that are part of a herd in which one or more bulls have been found to be infected shall be placed under hold order in isolation away from female cattle until they have undergone at least two additional culture tests with negative results (not less than a total of three negative culture tests or two negative RT-PCR tests) within 60 days of the initial test unless handled in accordance with subsection (d) of this section. All bulls remaining in the herd from which an infected bull(s) has been identified must be tested two more times by culture or one more time by RT-PCR test. Any bull positive on the second or third test shall be classified as positive. All bulls negative to all three culture tests or both RT-PCR tests shall be classified as negative and could be released for breeding.

(d) Breeding bulls that are part of a quarantined herd or a herd that is under a hold order and tests negative to the first official Trichomoniasis test may be maintained with the herd if the owner or caretaker of the bulls develops a Trichomoniasis herd control plan with a certified veterinarian. The Trichomoniasis herd control plan shall require all breeding bulls to be tested annually with an official Trichomoniasis test and include other best management practices to control, eliminate and prevent the spread of Trichomoniasis. The Trichomoniasis herd control plan, unless otherwise approved or disapproved by the commission, expires three years from the date the plan is signed by the herd owner or caretaker and the authorized veterinarian. Breeding bulls that are part of a Trichomoniasis herd control plan that expires or that is disapproved must be tested for Trichomoniasis as required by subsection (c) of this section.

(e) When Trichomoniasis is diagnosed in female cattle or fetal tissue, all breeding bulls associated with the herd will be restricted under a Hold Order for testing in accordance with this section.

(f) If male or female cattle are found to be infected with Trichomoniasis, then bulls that are located or were located on property adjacent to the infected animal within 30 days from the date the infected animal was removed from such property shall be officially tested for Trichomoniasis. Such bulls shall be tested within a timeframe as determined by the commission. The commission shall provide written notification to the owner or caretaker of the bulls specifying the timeframe in which the bulls must be tested. The commission may waive this testing requirement if it is epidemiologically determined by the commission that testing is not required.

(g) A seller of female cattle that were exposed or potentially exposed to a Trichomoniasis positive bull within the previous six months shall disclose, this information, in writing, prior to or at the time of sale.

§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 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, collected in an InPouch, is received in the official laboratory, in good condition, within 48 hours of collection or is incubated in an InPouch by the collecting veterinarian for 48 hours after collection, and such sample is submitted to be 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 meets the following requirements:

(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, excluding those submitted from Trichomoniasis positive herds, herds identified as being adjacent to Trichomoniasis positive herds and change of ownership. 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.