

TITLE 4.AGRICULTURE

Part 2. TEXAS ANIMAL HEALTH COMMISSION

Chapter 38. TRICHOMONIASIS

4 TAC §§38.1 - 38.7

The Texas Animal Health Commission (Commission) adopts a new Chapter 38, entitled "Trichomoniasis", §§38.1 - 38.7. Sections 38.1 - 38.4 and 38.6 - 38.7 are adopted with changes to the proposed text as published in the November 28, 2008, issue of the Texas Register (33 TexReg 9615). The text of the rules will be republished. Section 38.5 is adopted without changes to the proposed text as published in the November 28, 2008, issue of the *Texas Register* (33 TexReg 9615) and will not be republished.

Bovine Trichomoniasis (aka trichomoniasis or trich) is a venereal disease of cattle caused by the protozoa *Tritrichomonas foetus* (*T. foetus*). The organism lives in the folds of the prepuce and internal sheath in bulls, and colonizes the vagina, cervix, uterus and oviducts of cows. It causes early embryonic death, abortion and extended calving seasons. Bulls will remain persistently infected and spread infection from cow to cow during natural service; however, cows generally clear infection after three to four heat cycles. Bulls over four years old are typically the main reservoir of infection in a herd; this is because older bulls often have deeper preputial folds (crypts), making for a more hospitable environment for trich to live.

Certain herd management practices are risk factors for infection--commingled grazing or fence-line contact, where fences are not well maintained, with other herds is one documented risk factor, as is purchase of bulls of unknown disease status. Control of *T. foetus* in an infected herd includes testing bulls and culling those infected. Although use of younger bulls has been recommended as a control strategy because they have a lower prevalence of infection than older bulls, such use will not eliminate the possibility of infection. Artificial insemination is considered the classic method for controlling venereal diseases of cattle. However, this is often impractical in range cattle operations due to lack of facilities, expertise or management practices. Additionally, annual pregnancy testing and culling of non-pregnant cows can help control herd infection. Also, vaccination of females can decrease duration and severity of infection. If exposure to other risk factors cannot be avoided, vaccination is believed to help reduce economic loss.

The Commission convened a Trichomoniasis (Trich) Working Group (TWG) which met on September 26, 2008, in Austin, Texas. Eighteen members were present. Trich Working Group Chairman Coleman Locke, Beef Cattle Commissioner, led a discussion of objectives. The goal of the group was to provide recommendations to the Texas Animal Health Commission on the components and implementation strategy for a Trichomoniasis Control Program for the State of Texas. The members were in agreement with the goal.

The first point of discussion was relative to the type of bulls to be tested. Should Texas accept "virgin" bulls without a negative test? After discussion, members agreed that we should accept bulls as virgin, with a breeder's certification of virginity, up to the loss of the first two incisor teeth. Bulls would be approximately 18 months of age at time of loss of first two incisors. Bulls with erupting incisors would have to be tested prior to entry into Texas or sale as breeding bulls in Texas. Also it was discussed whether the rules

should be applied to cows and heifers as well as bulls. Some members expressed concerns over early bred cows and heifers and open cows and noted that these animals, if from an infected herd, could spread the disease into a buyer's herd. A number of states include cows and heifers in their regulations. After discussion, the TWG agreed that our program should only impact bulls, but that there should be an education component to educate producers about the dangers posed by purchased cows of unknown status.

The members expressed concerns about having another long, drawn out regulatory program such as the cattle brucellosis program. The TWG supported the inclusion in the rules of a requirement for a program review group that would meet annually to evaluate progress of the program and make recommendations relative to sunsetting the program or for improvement to the program.

Group Recommendations for the Initial Rule Proposal

Approved Tests. Which Trichomoniasis tests should be approved to test bulls for importation or for sale in the state? Culture of Trich organisms is the gold standard test for the disease. The recommendation is to collect the test sample in an InPouch and incubate the sample in the same pouch. Microscopic evaluation and identification of the organism in the pouch denotes a positive test. The other test approved for use in most other states is the Real Time Polymerase Chain Reaction test (RT-PCR) which is performed on a sample collected and incubated in an InPouch. The TWG recommended that culture in an InPouch followed by microscopic identification of the cultured organism, and the RT-PCR test performed on InPouch samples be classified as official approved tests for the Texas Trichomoniasis Program. The estimated laboratory costs (does not include veterinary collection or sample shipping costs) for culture tests is \$5.00 per culture, and for RT-PCR tests is \$25.00 per sample.

The group also discussed how many tests are needed to determine the status of an animal. It was recommended that a single test of all non-virgin bulls in the herd, in which all of the bulls were negative, would be sufficient for movement or sale for breeding of any tested bull in the bull herd. It was recommended that bulls of unknown status or non-virgin bulls from a herd that is Trich infected be tested negative on three culture tests performed not less than 7 days apart or be negative to at least two RT-PCR tests performed not less than 7 days apart.

Approved Labs. Currently many veterinary practitioners culture and examine Trich samples in their clinic laboratories. A number of states approve veterinary practitioner labs as official laboratories. However, neither TVMDL nor TAHC have the personnel or resources to conduct the training, check testing and certification necessary to establish practitioner labs as approved labs. The TWG recommended, at least as a place to start, that the TVMDL laboratories be classified as the official Trich laboratories for Texas. TVMDL has the staff and laboratory capacity to perform the tests for the program. Members agreed that if additional laboratories are needed, or logistic challenges (i.e. too far from an approved lab, inadequate mail service, etc.) TAHC labs and private practitioner labs could be considered at a later time.

Certification of veterinarians. Almost all states have some degree of required training or certification of veterinarians for collection of samples, handling and processing of samples for shipment to laboratories, reporting of results and handling of positive animals and herds. It was suggested and the TWG members agreed that TAHC would evaluate the certification programs of other states and identify the most appropriate components

for inclusion in our program. The Commission will work with representatives from TVMA and from Texas AgriLife Extension Service to develop and deliver a veterinary Trichomoniasis certification program.

Identification of bulls. The TWG concurred that bulls tested for Trich would be identified by an official identification device or method at the time the initial test sample is collected. Official identification would include: Official Alpha-numerical USDA metal eartags (bangs tags), Official 840 RFID tags, Official 840 flap or bangle tags, and Official individual animal breed registry tattoo or breed registry individual animal brands.

What happens when a bull is found to be infected? Many states have provisions for evaluation of culture positive bulls by means of a confirmatory RT-PCR test. The TWG recommended that a provision to petition for a confirmatory RT-PCR test be included in the Texas program. Bulls that have been determined to be infected by culture and/or confirmatory RT-PCR would be placed under hold order along with all other non-virgin bulls in the bull herd. Positive bulls could only be sold for slaughter. Movement to slaughter should occur within 30 days from disclosure of positive test results (or confirmatory test results). Positive bulls could be moved to markets for sale only directly to slaughter or from the ranch directly to slaughter. Infected bulls would be individually identified by official identification device on a VS 1-27 movement permit from the ranch to the market and from the market to the slaughter facility, or from the ranch directly to the slaughter facility. Infected bulls must be isolated from all female cattle from the time of diagnosis until final disposition. All bulls remaining in the herd from which an infected bull(s) has been identified would have to be tested two more times. Any bull positive on the second or third test would be classified as infected. All bulls negative to all three tests would be classified as negative and could be released for breeding.

Reporting of Trich test results. After discussion of the issue the TWG recommended that all Trich tests performed--both positive and negative--be reported to TAHC. Results should be reported within 48 hours following completion of the test. At the present time the prevalence and distribution of Trich in Texas is not well identified. The reporting of all tests would enable development of prevalence and distribution data for the state and may help in the future to determine the most appropriate direction for the program.

Validity of test results. The group also discussed how long a negative test would be valid. The TWG agreed that imported breeding bulls have a negative test that was conducted within 30 days of importation into Texas. The TWG concurred that for sale of breeding bulls raised, tested and sold in Texas, that the negative test would in actuality be valid until the bull was exposed to a cow. From a practical and workable standpoint, members agreed that the negative status of tested bulls would be valid for 150 days from the test date so long as the bull had been maintained in isolation from any contact with female cattle from the time of Trich sample collection.

Chapter 38 contains the following sections:

Section 38.1 is entitled "Definitions" and provides definitions for terms utilized in this chapter.

Section 38.2 is entitled "General Requirements" and contains test and identification for bulls as well as contains the standards for a confirmatory test.

Section 38.3 is entitled "Infected Bulls and Herds" and describes how infected bulls and their associated herds are handled.

Section 38.4 is entitled "Certified Veterinary Practitioners" and provides that only veterinarians certified through the Commission shall collect samples for official tests for Trichomoniasis within the state of Texas.

Section 38.5 is entitled "Official Laboratories" and provides that the Texas Veterinary Medical Diagnostic Laboratory is the official laboratory to conduct testing for Trichomoniasis.

Section 38.6 is entitled "Official Trichomoniasis Tests" and recognizes which test are official test for Trichomoniasis.

Section 38.7 is entitled "Review of the Program" and establishes that the program will be reviewed in order to determine the effectiveness of this control program and make recommendations to the Commission whether the program should be continued or sunsetted.

Response to Comments and Changes to Proposal:

The rules were published for a sixty (60) day comment period.

The Commission received seventy-four (74) comments on the proposed disease control program for trichomoniasis. Those comments ran a broad spectrum from unequivocal support for a trichomoniasis control program to the other end of the spectrum with some feeling that the program is not needed or it will be costly and ineffective. A large number of the comments provided a variety of specific suggestions or recommendations for how the program should either be modified, strengthened, weakened or delayed. The Commission appreciates all the comments and through this document provides a response to all the comments with justification for changes made to the proposal in response to the comments.

The specific requirement that engendered the largest number of comments was regarding the age for certifying a breeding bull as having "virgin" status and therefore not have to be tested for Trichomoniasis prior to sale. Under the proposed rules, breeding bulls could be certified as virgin only up to approximately 18 months of age. The status, under the proposal, was for any "(s)exually intact male cattle which have not serviced a cow and which are young enough that neither of the first two incisor teeth have been lost" would be considered virgin. Obtaining that status would allow a breeding bull to be sold without test. The written comments that the Commission received covered the spectrum of recommendations. Several commenters requested that all breeding bulls be tested and remove the untested status for virgin bulls. A couple of other commenters felt like the "virgin" status should be offered or extended through thirty-six (36) months of age. Various other commenters have offered different age options ranging from less than eighteen (18) months to twenty-four (24) months, with twenty-four (24) months receiving the most comments. Also the Commission looked at the other states to see what age they established for virgin status and a majority of other states which have a Trich program allow classification of breeding bulls as virgin up to twenty-four (24) months of age.

The range of comments were varied for a variety of reasons. The most common reason was the fact that various breeds reach sexual maturity at different ages. While some

breeds are sexually mature at eighteen (18) months, others may not reach sexual maturity until approximately thirty-six (36) months of age. There was also concern expressed through the comments that many producers did not have the facilities to maintain isolation of young bulls to ensure virgin status. Also some folks wanted a veterinarian to be able to certify the virgin status. Because a veterinarian provides services to a client on his cattle he could provide an additional level of certification. Since a veterinarian is licensed by the state and has a veterinary-client-patient relationship, with knowledge about the capability and management practices of the client to manage young bulls in isolation from female cattle, this is a viable suggestion as another level of certification of virgin status.

In response to the comments on virgin status the Commission is modifying the proposed rule to allow classification of bulls up to twenty-four (24) months of age as virgin, with the age being determined by the bull having the central permanent incisor teeth in wear or by a breeder's registry certificate of age. Additionally, the rules will be modified to allow a breeder and his veterinarian to certify bulls as virgin up to thirty (30) months of age. The veterinarian's certification would verify that the facilities and management practices are sufficient to maintain the bulls in isolation from female cattle.

The second area where there were a large number of specific comments was regarding number and kinds of tests that are to be utilized in the program. The proposal provided for two tests to be recognized by the Commission. The first is the "Culture Test" which is designed to identify live trich organisms in a culture media and requires that a sample be received in the official laboratory, in good condition, within forty-eight (48) hours of collection. For the Culture test, ambient conditions in shipment are critical as the organisms should be protected from exposure to daylight and extremes of temperature.

This Culture test required three different tests which engendered a lot of concern about cost and efficiency. In trying to create an effective control program the Commission realizes that there is not a singularly 100% effective test that can be relied upon by all. The costs for multiple culture testing and veterinary visits were of concern throughout a number of the comments submitted. Because three culture tests conducted a week apart are necessary to provide a high degree of confidence that the bull being tested by the culture method is truly negative, there would be an increased cost to the owner of the bull. A number of commenters suggested that the culture test not be approved for use in the program. There were several reasons for retaining the culture test as an official or approved test. The Culture test is considered the "Gold Standard" test for the disease. It is a valid test for Trich and is continually being utilized in many states to diagnose the disease. While not a part of the proposed rule, the test could be utilized as a tool for herd diagnostic testing.

The other recognized test for Trich is the Polymerase Chain Reaction (PCR) test. The PCR tests can identify either live or dead trich organisms in a test sample. Many states recognize the regular PCR test as official. Others require the Real-Time (RT) PCR test. The proposed rule recognizes the RT-PCR test as an official test on samples tested in Texas and would have required two RT-PCR tests to classify a bull as negative. The sample for RT-PCR testing is the identical to the sample that is needed for culture. It is collected in the same manner as the culture sample. However, the RT-PCR test is not so sensitive to environmental conditions as the culture test. It will give positive test results so long as there is trich DNA present in the sample. The sample would not have to arrive at the laboratory within 48 hours of collection to be a valid sample, as is required for culture.

Many commenters believed that multiple RT-PCR tests are not necessary to classify a bull as negative. They urged that the proposed rule be amended to allow sale of bulls based on one negative RT-PCR rather than two. After evaluating the comments, engaging in discussion with the trichomoniasis work group and in review of test protocols for other states, it was determined that one negative PCR test should suffice for bulls from herds not known to be infected. The proposed rule will be amended to require only one PCR test.

As part of these comments regarding the cost and efficiency of testing for trichomoniasis a couple of commenters requested that the agency should allow for a lay person, such as an employee or the cattle owner, working under the direction of their veterinarian, to collect the samples for trich testing. The Commission understands that such an option might incur some cost savings for a producer but ultimately the credibility of the program is dependent upon sampling and certification by qualified veterinarians.

As part of the comments and discussion on testing, several commenters also raised the issue of laboratory capacity and availability. Several veterinarians mentioned in their comments that restrictions on the lab availability and shipping requirements would prohibit them from collecting samples for culture tests on Friday and Saturday. The majority of these comments were made to the proposed rule requirements for a whole herd negative test on all breeding bulls as condition for sale of any breeding bulls from the herd. Based on comments received the commission is modifying the proposed rule to eliminate the requirement for a test of all non-virgin breeding bulls in the herd as a condition for sale of any breeding bull from the herd. Under the amended provisions any non-virgin breeding bull would be allowed to sell for breeding purposes if the bull was negative on three consecutive culture tests conducted not less than one week apart or negative on one PCR test. As result of these changes and after discussion with the Texas Veterinary Medical Diagnostic Laboratory (TVMDL) the Commission believes that TVMDL has the capacity and can handle the test demands for the Texas trichomoniasis control program. Also it needs to be noted that we learned from TVMDL that the actual temperature range referenced in the rule under §38.6 for appropriate ambient conditions was incorrect. We have corrected that range to reflect the appropriate temperature range under the test protocols.

Also in response to comments, discussion with laboratory personnel and discussion at the working group meeting regarding the timeframes for submission of samples and the impact of these timeframes on the days each week a veterinarian could collect trich samples, the Commission is amending the timeframes for submission of samples by the collecting veterinarian, handling of samples and receipt of samples by the laboratory. The requirement for receipt of samples for culture testing at the laboratory will remain as written in the proposed rule--the samples must be received in good condition by the laboratory within forty-eight (48) hours of collection. However, for samples being submitted for RT-PCR testing, the samples are to be submitted to arrive at the laboratory within forty-eight (48) hours of collection, or be incubated by the collecting veterinarian for forty-eight (48) hours following collection, then submitted to arrive at the laboratory within ninety-six (96) hours of collection. The Commission believes that these amendments to the proposed rule will effectively address the concerns about sample collection and laboratory issues.

Pooling samples was also a topic of a couple of comment letters. These commenters requested that pooling of samples be allowed on tests of bull herds. Pooling of samples is a sampling technique in which samples from several bulls are placed in the same culture

media pouch. Pooling of samples has been utilized effectively by a number of veterinary practitioners to diagnose trich in infected cattle herds. If a pooled sample is positive, each individual bull included in the pooled sample would have to be retested to determine which individual animals were actually positive for the disease. Pooling could significantly reduce laboratory costs to the producer. Discussion at the working group meeting disclosed that test processes for pooled samples had not been validated. Additionally, there was a strong belief that bulls being tested for sale as breeding bulls should have individual tests. The working group urged that a test procedure for pooled samples be validated. Additionally, the working group noted that the proposed trich rules apply to bulls being sold for breeding purposes, they do not apply to bulls on farms and ranches that are not being offered for sale. Therefore, the rules do not prohibit a veterinarian from pooling samples taken as part of herd diagnostic tests. The Commission will not recognize pooling of samples as a procedure for testing of bulls for sale or importation.

The third area that received a number of comments were requests for the Commission to focus effort on education and information, with implementation of a control program held to a later date. Throughout a large number of comments submitted to the Commission the issue of awareness of the effects of Trich was widely varied. There were a number of comments that expressed or indicated a lack of first hand knowledge of the disease or how great an impact it might have on the cattle producers in this state. At the other end of the spectrum there were a number of comments that specifically represented first hand experience with the disease getting into their herd and the great cost and effort to test and eradicate the disease from their herd. There was also a number of commenters who wanted to know why the Commission would try and create a control program for a disease that did not have a human impact.

These issues were discussed at length by the working group. Ultimately a majority of the working group expressed the belief that Texas needs to move forward in development and implementation of a Trich program. They noted that the disease is having a very significant impact on cattle producers and breeders in the state and that it was the cattle and agriculture organizations and individual producers who requested development of the program. Both commenters and working group members stressed the necessity for an extensive information and educational effort by the industry organizations, extension, veterinary association, university and agency on the disease and its impacts on the cattle industry of the state. The Commission fully believes that education is an essential part of an effective disease control effort and has already developed and distributed some informational materials. The agency is also working with Agrilife Extension, Texas Veterinary Medical Association, TVMDL and the cattle industry organizations in the state to develop and deliver effective information and educational components of the trich program. While informational and educational efforts are critical to successful program, these efforts alone will not effectively address the disease situation. Based on a majority of comments received and a majority response from the working group, the Commission should proceed with implementation of the trich program as modified by comments received. However, in recognition of the need for an extensive information and education program and the time needed for certification of veterinarians, the working group recommended and the Commission supports delaying the implementation date for the provisions of Chapter 38 from September 1, 2009 until January 1, 2010 to provide time for information, education and certification efforts.

Another area of concern that a number of commenters raised is that the proposed trich control program does not address the disease in female cattle. The program as proposed is

currently focused only on breeding bulls. The Commission recognizes that female cattle play a significant role in the disease process and that infected female cattle are the source of disease for breeding bulls. However, unlike bulls, female cattle have the ability to clear themselves from the disease. Almost all female cattle that are given 120 - 150 days of sexual rest will clear the organism from their reproductive systems. Additionally, most initial programs in other states did not include regulatory requirements for the cow herd. After discussion of this issue and the comments received relative to it at the working group meeting, the recommendation to the Commission is that the rules continue to be focused on the breeding bull and that the disease in the cow herd be addressed through information and education efforts.

Several commenters suggested that the agency conduct slaughter surveillance to determine the prevalence of Trich before implementing a trich program in the state. They note that without prevalence data, the Commission would have insufficient information on which to develop a program. The Commission appreciates this concern but must note that available data, while not sufficient to determine prevalence of the disease, does show that trich is widely distributed throughout the state. Additionally, the Commission lacks the resources to conduct a slaughter surveillance effort. It was noted at the working group meeting that a study could take considerable time during which the disease continues to spread. The majority of commenters urged that the Commission proceed with implementation of a trich program because of the disease impact on our cattle industry.

A couple commenters wanted to know what consisted of a bull herd. As a practical matter one bull used for breeding constitutes a herd. The definition used for herd is one used by the Commission for a variety of other disease control or eradication programs. It starts with one bull and can expand to any size for all cattle under common ownership or supervision or herds which have cattle that have been interchanged or where there has been contact among the cattle on the different premises.

Some commenters wanted to know how a positive bull would be handled. Under the proposed rules a bull(s) that tests positive on any test is classified as a positive or infected bull. It is possible that a young bull can test positive on a culture test and not be infected with *Tritrichomonas foetus*. Such bulls are typically infected with *Trichomonas intestinalis* which does not cause infertility in cattle. For this reason the proposed rules include a provision whereby the owner of a bull which tested positive could be retested by RT-PCR test. The RT-PCR test can differentiate infection caused by *Tritrichomonas foetus* from *Trichomonas intestinalis*. Bulls positive on a PCR confirmatory test are classified as trich infected animals. A positive animal is required to go to slaughter and they would be moved to slaughter under a VS 1-27 permit, which provides for accountability and can be verified.

There were a couple of requests from producers that move cattle back and forth among neighboring states as part of their normal ranching operations. They requested that the current commuter herd program utilized for TB and Brucellosis be expanded to include Trich. A commuter herd program basically would allow a cattle herd owner to perform a test for Trichomoniasis on the bull herd and allow movement between the states without having to have a test prior to each movement. Commission staff will work with neighboring states to address this issue.

A number of commenters also question the appropriate timeframe that a test be valid after a bull is tested. The proposed regulations would allow tests to remain valid for 150 days on Texas bulls kept apart from females. However several commenters believe that this

timeframe is too long and could allow for a greater risk that the animal had been exposed and become positive for Trich. This issue was discussed at the working group meeting. Members believe that the amendments incorporated into the proposed rule which provide that a bull could be classified as a virgin up to the age of 24 or 30 months and the amendments to allow individual bulls to sell on three negative culture tests or a single PCR test effectively eliminate the need for the test to be valid for an extended time. Therefore the recommendation is to reduce the test validity to 30 days following the test. This recommendation is incorporated into the adopted rule.

Some commenters asked what the impact of the proposed rule would be on exhibition or competition bulls. Unless these animals enter the state for the purpose of breeding or are sold, leased or exchanged for breeding purposes, these bulls would be allowed to enter without a test under the current provisions for exhibition cattle.

Some commenters noted that the proposed rule does not address the problem of a neighbor's animal getting into their pastures and commingling with their cattle herd, possibly spreading trich. Some working group members suggested that when animals get into neighboring herds that the animals be required to test for trich. The current proposed rules do not impact neighboring herds even though they may be exposed, and in some cases may have been the source of the disease. As proposed the rules only address bulls being sold for breeding purposes and bulls in herds found to be infected as result of testing for change of ownership or interstate movement. After discussion of this issue, the working group recommended that this issue be addressed through information and education efforts and not be included in the proposed rules.

Several commenters also raised concern about the Commission's enforcement of the program. The Commission realizes that the validity of the program depends on effective enforcement. The Commission takes enforcement as an important part of the agency mission. Under our statutory authority the Commission has an ability to issue administrative penalty for violations of agency regulations. The Commission will utilize all efforts to make sure compliance is effectively employed for this program.

There was a comment made regarding the use of the drug Dimetridazole as an effective treatment option. The commenter noted that at one time this was used for treatment of Trichomoniasis. The Commission appreciates the comment but would note that currently there are no effective treatment products that are labeled for treatment of trich and there are no effective treatment products that can be legally prescribed by a veterinarian for treatment of trich infected animals.

At the working group meeting, members discussed proposed implementation dates for the intrastate program. The proposed rule sets the implementation date as "not before September 1, 2009". After discussion, the working group recommended implementation for the intrastate program begin on January 1, 2010.

STATUTORY AUTHORITY

Chapter 38 is adopted 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 authority 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 authority 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.

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.

§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 *Trichostrongylus axei* 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) and 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 sterile for breeding.
- (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 Restrictions--A "Hold Order," "Quarantine," or other written document issued or ordered by the Commission to restrict the movement of livestock or exotic livestock.

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

(16) 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 included USDA alpha-numeric metal eartags (silver bangs tags), 840 RFID tags, 840 bangle tags, official breed registry tattoos, official breed registry individual animal brands, and official Trich tags issued by the animal health official of the state of origin of imported bulls.

(17) Official Trichomoniasis test--A test for bovine trichomoniasis, approved by the Commission, applied and reported by TVMDL or any other laboratory classified as an official laboratory by the Commission.

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

(19) Permit--(VS 1-27)--A premovement 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.

(20) 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.

(21) 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 imported into the state of Texas or is being sold, leased, gifted or exchanged in the state of Texas for breeding purposes.

(22) Trichomoniasis--A venereal disease of cattle caused by the organism *Tritrichomonas foetus*.

(23) TVMDL--The official laboratory for testing is the Texas Veterinary Medical Diagnostic Laboratory.

(24) Virgin Bull--Sexually intact male cattle which have not serviced a cow and which are not more than 24 months of age as determined by the presence of the two permanent central incisors in wear 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.

§38.2. General Requirements.

(a) Test Requirements: All Texas origin bulls sold, leased, gifted, exchanged or otherwise change 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), or a Trich infected herd, be tested negative on three consecutive culture tests conducted not less than seven days apart or one RT-PCR test conducted within 30 days of sale or movement, be held separate from all female cattle since the test, sample was collected, and be accompanied by a Trich 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 identified by an official identification device or method at the time the initial test sample is collected. Official identification includes: Official Alpha-numerical USDA metal ear tags (bangs tags), Official 840 RFID tags, Official 840 flap or bangle tags, and Official individual animal breed registry tattoo or breed registry individual animal brands. That 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 (5) 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 or a Trich test record showing negative test results may:

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

(2) 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 to a breeding bull. Such bulls shall be officially individually identified with a permanent form of identification prior to movement, move to the designated location on a VS1-27 permit, be held in isolation from female cattle at the designated location for not less than 21 days where the bull shall undergo three culture tests or for not less than 7 days where the bull shall undergo one RT-PCR test. If the results of any test are positive the bull shall be classified as infected and be permitted for movement only directly to slaughter or to a market for sale directly to slaughter.

§38.3. Infected Bulls and 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.

(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 VS-1-27 movement permit 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).

(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). All bulls remaining in the herd from which an infected bull(s) has been identified would have to be tested two more times by culture or one more time by RT-PCR test. Any bull positive on the second

or third test would be classified as positive. All bulls negative to all three culture tests or both RT-PCR tests would be classified as negative and could be released for breeding.

§38.4. Certified Veterinary Practitioners.

(a) Only veterinarians certified through the Commission may perform Trichomoniasis program procedures, including but not limited to, collection of samples for official tests for Trichomoniasis within the state of Texas, submission of samples to official laboratories, identification of tested bulls and virgin bulls, management of Trichomoniasis infected bull herds, movement of infected bulls, and reporting of test results. In order to collect and submit Trichomoniasis samples a veterinary practitioner shall be certified to perform Trichomoniasis program procedures. In order to be certified, a veterinarian shall also be licensed to practice veterinary medicine in the state of Texas and be accredited through USDA.

(b) All veterinarians desiring to perform Trichomoniasis program functions shall participate in a certification program on Trichomoniasis program requirements and procedures before performing any Trichomoniasis program functions, including but not limited to review of the disease, proper sample collection techniques, sample preservation and laboratory submission, identification of animals, management of infected herds and shipment of infected or exposed animals to slaughter. The official certification program shall be conducted by or under the auspices of the Commission. Certified veterinarians shall be recertified every three years.

(c) Certified veterinarians shall utilize approved procedures for collection of samples, identification of animals and submission of samples to laboratories.

(d) Certified veterinarians shall only utilize the official laboratories for culture of Trichomoniasis samples.

(e) Certified veterinarians shall submit all Trichomoniasis samples including all official identification on official Trichomoniasis test and report forms to the TVMDL within the following time lines: Samples submitted for culture tests shall be submitted to arrive at the laboratory within forty-eight hours of collection of the samples. Samples submitted for RT-PCR tests shall be submitted to arrive at the laboratory within 48 hours of collection or be incubated by the collecting veterinarian for 48 hours, then be submitted to arrive at the laboratory within 96 hours of collection.

§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 is received in the official laboratory, in good condition, within forty-eight (48) hours of collection and such sample is tested according to the "Official Protocol for Culture of Trichomoniasis." Samples in transit for more than forty-eight (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 the sample is received in good condition by the laboratory within forty-eight (48) hours after collection, or is incubated by the collecting veterinarian for 48 hours after collection, then submitted to arrive at the laboratory 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.

§38.7. Review of the Program.

The Commission shall establish a Trichomoniasis Program Review Working Group consisting of members from the cattle industry, veterinary profession, veterinary diagnostic laboratory, veterinary college, extension service and agency representatives which shall annually review the Trichomoniasis program and make recommendations to the Commission on amendments to program components or operation, or whether or not the program should be continued.

This agency hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

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Texas Animal Health Commission

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