#### EXPLANATION OF PROPOSED RULE

The Texas Animal Health Commission (TAHC) proposes a new Chapter 44 for the purpose of establishing a Bovine Viral Diarrhea Virus (BVDV) control program.

Bovine viral diarrhea (BVD) is an economically impactful disease of cattle with a worldwide prevalence that is endemic in most states. BVD is caused by the Bovine viral diarrhea virus, a Pestivirus. The major reservoir responsible for disease spread geographically is the persistent infection syndrome (BVDV-PI) seen in calves. BVDV can result in impacts to the stocker and feedlot operations by causing immunosuppression and contributing to Bovine Respiratory Disease Complex, or "Shipping Fever". This can lead to reduced feed conversion and weight gain, and increases in days on feed, morbidity, treatment cost, and mortality. In regards to cowcalf operations, all of these impacts may occur plus decreased conception rates, abortions, weak calves, and congenital defects.

The dam can be transiently infected during pregnancy and her calf become infected during development in the womb. If this infection occurs between days 40- 120 of the pregnancy, the calf's immune system may not recognize the BVD Virus as foreign, and no natural immunity is produced in the calf. The calf becomes persistently infected (PI), and produces large numbers of the virus. The calf may display a normal appearance with immunosuppression or may result in acute death, poor performance, or mucosal disease.

Texas stakeholders have indicated interest in addressing the disposition of known animals positive for BVDV. The TAHC convened a group of stakeholders to discuss the negative implications of the disease on the Texas cattle industry. Stakeholder groups represented at the meeting included Texas Southwest Cattle Raisers Association (TSCRA), Texas Cattle Feeder Association (TCFA), Livestock Marketing Association (LMA), Independent Cattlemen's Association (ICA), Texas Farm Bureau (TFB), Texas Association of Dairymen (TAD), Texas A&M AgriLife, USDA, and Texas A&M Veterinary Medical Diagnostic Laboratory (TVMDL).

The Commission can designate that specific animal diseases must be reported in order that the Commission may act as necessary to eradicate or control significant animal diseases. BVDV adversely affects both health and productivity. The losses due to transient infection are diarrhea, decreased milk production, reproductive disorders, increased occurrence of other diseases, and death. The losses from fetal infection include abortions; congenital defects; weak and abnormally small calves; unthrifty, persistently infected (PI) animals; and death among PI animals. In order to provide Texas cattle some mitigation from the risk of exposure this disease is being added as a reportable disease in Chapter 45, entitled "Reportable Diseases".

Section 44.1 is for definitions used in this chapter and contains the following definitions: (1) Accredited Veterinarian; (2) Authorized Veterinarians; (3) Bovine Viral Diarrhea virus (BVDV); (4) BVDV Approved Feedlots and Pens; (5) Cattle; (6) Commission; (7) Initial BVDV Test; (8) Executive Director; (9) Hold Order; (10) Infected Cattle; (11) Movement Permit; (12) Movement Restrictions; (13) Negative; (14) Official Identification/Officially Identified; (15) Official BVDV Retest; (16) Positive; (17) Quarantine; (18) Texas Animal Health Commission Designated Diseases; and (19) TVMDL.

Section 44.2 contains the primary elements of a BVDV Control Program. Subsection (a) provides that any veterinarian, or a veterinary diagnostic laboratory, or a person having care, custody, or control of an animal, shall report the existence of Bovine Viral Diarrhea Virus (BVDV).

Subsection (b) provides the additional information to be reported for a positive animal.

Subsection (c) provides that when BVDV is disclosed as positive using the BVDV antigen capture test (e.g., ELISA [enzyme-linked immunosorbent assay], SNAP test, or lateral flow device) or BVDV immunohistochemistry (IHC), the presumptive BVDV positive animal(s) are restricted from movement.

Subsection (d) provides that any cattle which test positive for BVDV may be retested with a confirmatory test.

Subsection (e) provides that only veterinarians authorized by the Commission's Authorized Personnel Program or TAHC staff may collect and submit samples for BVDV confirmatory retesting.

Subsection (f) provides that if the confirmatory test is positive as infected with BVDV the animal will be classified as having a persistent infection (PI) for BVDV (BVDV-PI).

Subsection (g) provides that if the confirmatory test is negative the cattle (s) shall be confirmed as negative for BVDV. If they are retested in accordance with the requirements and are test negative they will be released from the movement restrictions of the Hold Order by TAHC.

Subsection (h) provides that all cattle classified as being BVDV-PI-positive shall be identified by an official identification device.

Subsection (i) provides that the official laboratory for the confirmatory test for BVDV are the TVMDL laboratories or other laboratories approved by the Commission.

Subsection (j) provides that if cattle are confirmed positive for BVDV-PI they may only be moved under specific conditions.

Subsection (k) provides that an approved feedlot or pen(s) can accept cattle restricted for being exposed for BVDV within an area, isolating these cattle from non-exposed animals through fencing and geographic separation; official identification; biosecurity standards; and recordkeeping requirements, which include information for all animals entering and leaving a facility. Failure to meet and maintain those standards and procedures will cause a facility to have the approved status to accept these animals rescinded. It is recommended that all approved facilities be cleaned and disinfected between groups of cattle unless specifically

directed by the Commission to clean and disinfect all or portions of the pen or other parts of the facility. An approved facility shall maintain records which indicated the movement of all animals that enter and leave a facility.

Subsection (I) provides that the Commission shall establish a BVDV Program Review Working Group and there will be an annual review.

### FISCAL NOTE

Mrs. 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 because of enforcing or administering the rules.

### **REGULATORY ANALYSIS**

<u>Public Benefit</u>: Ms. Schmidt has also determined that for each year of the first five years the rules are in effect, the public benefit anticipated because of enforcing the rules will allow the agency to more effectively address the risk from cattle that have tested positive for BVDV and reduce the risk of exposure to other cattle in the state.

<u>Local Employment Impact Statement</u>: In accordance with Texas Government Code §2001.022, the Commission 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.

<u>Major Environmental Rule</u>: The Commission has determined that Government Code, §2001.0225 (Regulatory Analysis of Major Environmental Rules), does not apply to the proposed rule.

<u>Takings Assessment</u>: The Commission 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 Title 4 TAC, §59.7, and are, therefore, compliant with the Private Real Property Preservation Act in Government Code, Chapter 2007.

<u>Economic Impact Statement:</u>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 to other cattle in the state.

Regulatory Flexibility Analysis: The proposed rule does not have an adverse impact on affected

small businesses and/or rural communities located in Texas because the rule allows the Commission to identify animals that have been disclosed as being positive for a disease which negatively impacts the Texas cattle industry and to quickly and efficiently follow up on positive animals and thereby protects other similarly situated cattle from consequential disease exposure.

<u>Government Growth Impact Statement</u>: 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 provides a disease control program which supports a reporting requirement used by the agency to notify the agency of disease and thereby reduce the risk exposure to other cattle;

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.

<u>Rule Reduction Statement</u> 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 provides 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 proposed amendments may be submitted to Amanda Bernhard, Texas Animal Health Commission, 2105 Kramer Lane, Austin, Texas 78758, by fax at (512) 719-0719 or by e-mail at <u>comments@tahc.texas.gov</u>.

# 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 §161.054, and entitled "Regulation of Movement of Animals", "[t]he 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.

Pursuant to §161.048, and entitled, "Inspection of Shipment of Animals or Animal Products", "[t]he 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 §161.005, and 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 §161.044, entitled "Regulation of Livestock Movement from Stockyards or Railway Shipping Pens", "[t]he commission may regulate the movement of livestock out of stockyards or railway shipping pens and require treatment or certification of those animals as reasonably necessary to protect against communicable diseases".

Pursuant to §161.046, entitled "Rules" "[t]he commission may adopt rules as necessary for the administration and enforcement of this chapter."

Pursuant to §161.049, entitled "Dealer Records", "[t]he commission may require a livestock, exotic livestock, domestic fowl, or exotic fowl dealer to maintain records of all livestock, exotic livestock, domestic fowl, or exotic fowl bought and sold by the dealer."

Pursuant to §161.061, entitled "Establishment", "[i]f the commission determines that a disease listed in Section 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 §161.081, entitled "Importation of Animals", "[t]he commission by rule may regulate the movement, including movement by a railroad company or other common carrier, of livestock, exotic livestock, domestic animals, domestic fowl, or exotic fowl into this state from another state, territory, or country.

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

Pursuant to §161.112, entitled "Rules" the commission shall adopt rules relating to the movement of livestock, exotic livestock, and exotic fowl from livestock markets and shall require tests, immunization, and dipping of those livestock as necessary to protect against the spread of communicable diseases.

Pursuant to §161.113, entitled "Testing or Treatment of Livestock" "[i]f 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", "[a]n 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".

<rule>

CHAPTER 44 BOVINE VIRAL DIARRHEA VIRUS §44.1. 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) Authorized Veterinarians--Veterinarians certified with, and approved by the commission to perform official BVDV testing and to perform any other official function under the BVDV control program.

(3) Bovine Viral Diarrhea (BVD) – Bovine viral diarrhea is a viral disease of cattle and other ruminants that is caused by the bovine viral diarrhea virus (BVDV).

(4) BVDV Approved Feedyard/Approved Pens or other authorized locations--A confined area, either the entire feedyard or designated pens within the feedyard or at a livestock market, approved by the Executive Director of the Commission for feeding of restricted cattle for BVDV. Biosecurity standards, to include requirements for geographic separation, shall be enforced to prevent potential spread of diseases to other livestock on the premises and adjacent premises. Procedures for accountability of inventory, animal identification, and movement control shall be enforced to ensure that restricted cattle remain within approved facilities until verification of slaughter

(5) Cattle--All dairy and beef animals (genus Bos).

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

(7) Executive Director--The Executive Director of the Texas Animal Health Commission or his designee.

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

(9) Infected Cattle--Any cattle determined by an initial BVDV test or official BVDV retest procedure to be infected with BVDV.

(10) Movement Permit--Authorization for movement of infected cattle from the farm or ranch of origin to slaughter or for movement of infected animals to a location where the animals will be held under hold order until the disease issue is resolved.

(11) 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.

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

(13) 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.

(14) Official BVDV Retest--A test result for BVDV using an Antigen Capture test or IHC at TVMDL or any other laboratory approved as an official laboratory by the commission. A list of official laboratories will be published by the commission.

(15) Positive--Cattle that have been tested with official test procedures and found to be infected with BVDV and is classified as being presumptive BVDV-PI on an initial test and confirmed BVDV-PI on an official retest. NOTE: Until cleared as negative on an official retest, the animal will be managed as a BVDV-PI animal.

(16) Quarantine--A written commission document or a verbal instruction from Commission personnel followed by a written document restricting movement of animals because of the existence of or exposure to BVDV. 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 BVDV and/or an animal into an affected area, including a county district, pasture, lot, ranch, farm, field, range, thoroughfare, building, stable, or stockyard pen.

(17) Reportable BVDV Test – A positive result for a BVDV antigen capture test (e.g., ELISA [enzyme-linked immunosorbent assay], SNAP test, or lateral flow device) or BVDV immunohistochemistry (IHC). All animals receiving an initial BVDV test, must have, a minimum, a traceable local ID (e.g., alphanumeric ear tag or back tag), or official identification

(18) Texas Animal Health Commission Designated Diseases--Animal diseases that the Commission has determined must be reported in order that the Commission may act as necessary to eradicate or control significant animal diseases.

(19) TVMDL--An official laboratory for testing is the Texas A&M Veterinary Medical Diagnostic Laboratory.

§44.2. General Requirements.

(a) Any veterinarian, or a veterinary diagnostic laboratory, or a person having care, custody, or control of an animal, shall report the existence of Bovine Viral Diarrhea Virus (BVDV) to the commission within 24 hours after detection as required by §45.2 of this title, relating to "Duty to Report".

(b) In addition to reporting the existence of a disease, the reporting person or entity shall also report to the commission information relating to:

(1) any identification associated with the cattle involved;

(2) any clinical diagnosis,

(3) location of the animal; and (4) owner of the animal.

(c) When BVDV is disclosed in cattle using an initial test of BVDV antigen capture test (e.g., ELISA [enzyme-linked immunosorbent assay], SNAP test, or lateral flow device) or BVDV immunohistochemistry (IHC), the presumptive BVDV-positive animal(s) are restricted from movement unless subsequently confirmed as negative by official retesting in accordance with this section. Pooling of samples for antigen capture testing is strongly discouraged because of significantly reduced test sensitivity and challenges with managing animals that contributed to the pools. Any disclosure of BVDV in an antigen capture test pool must be reported to TAHC, to include local IDs of all animals that contributed to the pool. All animals in the BVDV-positive pool will be managed as presumptive BVDV-positive and can only be cleared by official retesting.

(d) Any cattle which test positive to BVDV may be retested with a confirmatory test performed by BVDV antigen capture ELISA or IHC at an official laboratory approved by the commission. If they are not retested for confirmation they will be classified as positive for BVDV and restricted in accordance with this section.

(e) Only veterinarians authorized by the Commission's Authorized Personnel Program or TAHC staff may collect and submit samples for BVDV confirmatory retesting.

(f) If the confirmatory test is positive indicating infection with BVDV the animal will be classified as having a persistent infection (PI) for BVDV (BVDV- PI).

(g) If the confirmatory test is negative the cattle (s) shall be confirmed as negative for BVDV. If they are retested in accordance with the requirements and are test negative they will be released from the movement restrictions of the Hold Order by TAHC.

(h) All cattle classified as being BVDV-PI-positive shall be identified by an official identification device, such as an 840 RFID or method approved by the Commission and have a brand applied on the left side of the animal near the head of the tail and with the marking of a lazy "P" with an "I" All cattle retested for BVDV shall be officially identified before or at the time the confirmation test sample is collected. That official identification shall be recorded on the test documents prior to submittal.

(i) The official laboratories for the confirmatory test for BVDV are the TVMDL laboratories or other laboratories approved by the Commission.

(i) Cattle confirmed positive for BVDV-PI may only be moved under the following conditions:

(1) Be sold or shipped directly to slaughter under permit, issued by commission personnel; or

(2) Be sold for movement to an approved feedyard or approved pens and later moved to slaughter, under permit, issued by commission personnel.

(k) BVDV Approved Feedyards/Approved Pens or other approved location: A confined area, either the entire feedyard or designated pens within the feedyard or at a livestock market, approved by the Executive Director of the Commission for holding and feeding of restricted cattle for BVDV.

(1) Designation Agreement: In order to be recognized as an approved feedyard or approved pen there shall be a signed designation agreement with TAHC indicating that the facility can meet the necessary standards to accept restricted cattle. The agreement will contain standards and procedures which the facility must meet in order to be approved. The Agreement will provide for isolation of animals, to separate and prevent contact between restricted animals and unrestricted animals through fencing and geographic separation; official identification; biosecurity standards; and recordkeeping requirements, which include information for all animals entering and leaving a facility. Failure to meet and maintain those standards and procedures will cause a facility to have the approved status rescinded. These animals will be placed under hold order and permitted out to slaughter. (2) Standards and procedures.

(A) Geographic separation: Adequate isolation of animals which separate and prevent contact with tested animals and untested animals by fencing and geographic separation. Geographic separation shall be sufficient to meet the minimum standards as to prevent potential spread of diseases to other livestock on the premises and adjacent premises.

(B) Official identification: All animals entering and leaving the facility must be officially identified and that information is to be recorded and maintained as required by subparagraph (D) of this subsection.

(C) Biosecurity standards: All approved facilities may be required to be cleaned and disinfected between groups of cattle at the direction of the Commission. Additionally, approved facilities may be required to vacate pens, that have contained BVDV infected animals, for thirty (30) days if specifically required by the Commission.

(D) Recordkeeping requirements: An approved facility shall maintain records which indicate the movement of all animals that enter and leave a facility. An approved facility must maintain the records for five (5) years.

(E) Grazing: In order for the Commission to recognize an approved facility having grazing the facility must be able to show an ability to maintain isolation of those restricted animals from unrestricted animals. An animal leaving the confined area must be destined to either another approved feedlot or approved pen, or to an approved slaughter facility.

(F) The approved status must be renewed by the operator every two years provided that the requirements specified in these regulations and the approved agreement continue to be met by the feedyard. If the Executive Director determines the feedyard's failure to comply with the Approved Pens Agreement or these regulations are grounds to rescind the agreement.

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