**RESOLUTION NUMBER: 2 Combined with 14, 28 and 33 Approved as Amended**

**SOURCE:** **COMMITTEE ON NATIONAL ANIMAL HEALTH LABORATORY NETWORK (NAHLN)**
**COMMITTEE ON ANIMAL EMERGENCY MANAGEMENT**
**COMMITTEE ON DISEASES OF CATTLE AND BISON**
**COMMITTEE ON FOREIGN AND EMERGING ANIMAL DISEASES**

**SUBJECT MATTER:** **Foot-and-Mouth Disease Diagnostics – Oral Swab Deviation for a New Population of Animals**

**BACKGROUND INFORMATION:**

A stakeholder group comprising bovine germplasm industry members, state and federal animal health officials and veterinary diagnostic laboratory representatives are collaborating to create guidance criteria to allow domestic movement of bovine germplasm and high genomic merit animals located in a regulatory control area during a foot-and-mouth disease (FMD) outbreak in the United States (US). The Bovine Germplasm Movement Plan is a guidance document being developed utilizing funding provided by the United States Department of Agriculture (USDA) National Animal Disease Preparedness and Response Program. Maintaining safe domestic movement of germplasm and high genomic merit animals from their birth location into the genetic system is the focus of this guidance. This provides business continuity opportunities for the cattle industry and preservation of genetic material.

Heifer and bull calves from embryos have their deoxyribonucleic acid (DNA) tested. Young heifers and bulls (from 35 to 120 days of age) that meet or exceed genomic testing expectations are frequently moved intra- and interstate from their origin herds to semen production centers or donor facilities where they are raised. An estimated 30,000 implanted embryos will result in approximately 10,000 calves from which nearly 220 bulls enter semen production for artificial insemination.

Young female calves with high genomic merit may be moved once or twice from their origin recipient herds or private cattle operations to the oocyte collection facility. Adult female donors could be moved to satellite centers, usually within 2–3 hours of their origin, on the day of oocyte collection and return home the same day. They could also remain at centers and be collected a few times every 14 days. Female donors on a long-term in vitro

fertilization program will usually move to donor facilities and stay for several months before returning to their herd of origin.

Bulls used for semen collection may enter production centers as young calves (from dairy or embryo recipient herds) or as older bulls purchased or leased from private seedstock producers. Most bulls are examined, tested for endemic diseases and moved to isolation facilities for further testing before moving into the resident herds at production centers. Semen collected from these bulls is sold internationally and domestically.

Movement of these high genomic merit animals from FMD control areas will require a movement permits and is based on risk. Diagnostic testing coupled with active observational surveillance (AOS) records could increase the confidence of state animal health officials reviewing business continuity permit requests that the target population movement within or out of an FMD control area will not spread FMD virus. The target population would be high genomic merit animals (bulls, heifers, cows) that have no evidence of FMD infection based on AOS data for at least 14 days needing to move from their origin premises in FMD control areas to enter semen/embryo systems (maintaining genetic supply chain) within or outside of control areas. Additionally, source herds requesting movement permits should be designated at-risk or monitored premises and would need to meet state generate and Secure Food Supply Plan criteria:

- Traceability information is available (Premises Identification Number, Global Positioning System coordinates, and information on type and number of animals moved)
- Biosecurity measures listed in the biosecurity checklist are in place and acceptable to responsible regulatory officials
- Trace back/forward information is acceptable; premises is not infected, suspect or contact
- Destination premises and states are willing to accept the cattle
- No evidence of infection based on disease monitoring (surveillance)

Additionally, destination premises should have the ability to quarantine animals upon arrival and conduct AOS for 14 days

The oral swab real-time reverse transcriptase polymerase chain reaction (rRT-PCR) test is a validated sample type for use in animals with clinical signs of FMD and a validated test with known specificity (99%) and sensitivity (94%) for use by the USDA, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), National Veterinary Services Laboratory (NVSL), Foreign Animal Disease Diagnostic Laboratory. The National Animal Health Laboratory Network (NAHLN) labs are proficiency tested for the rRT-PCR FMD assay but are not approved to test oral swabs on non-clinical animals. This test has not been validated for use in animals with no clinical signs of FMD - new target population. Therefore, a NAHLN laboratory would need to request a deviation from the NAHLN program office for Emergency Use Approval (EUA) of this test on non-clinical animals.

The process for NAHLN EUA involves the NAHLN program office collaborating with the USDA-APHIS-VS-NVSL Director, the National Preparedness and Incident Coordination Center, state animal health officials, the USDA-APHIS-VS Area Veterinarian-in-Charge and USDA-APHIS Emergency Coordinator for that/those state(s) to come up with a plan. The plan will need to address the logistics for sample collection, timing of collection, number of animals to be tested, frequency of testing (single or serial testing) and result interpretation. This process usually happens at the time of an outbreak when the need arises. It can be established pre-outbreak if the need has been identified. That time is now – to meet the business continuity opportunities for the movement of high genomic merit animals into the germplasm industry, contributing to cattle reproduction and preservation of genetic material.

There are gaps in scientific data to determine the sample collection and testing logistics. For instance, oral swab rRT-PCR testing can be used sooner than a serology assay to detect FMD infection but may still produce false negative results during an early stage of pre-clinical infection. The window of the early infection stage when the FMD virus will be undetectable by the rRT-PCR test is unknown.

During an outbreak, time and resources will be limited for the stakeholders described above to request and secure the deviation. Being able to define this process pre-outbreak benefits all parties so sample collection and testing can be promptly implemented during an FMD outbreak.

The number of animals tested would only be a portion of the high genomic population born each year and female ovum donors (assuming the entire US is not a control area). Average yearly data from 4 commercial semen production centers across the 48 contiguous states are approximately 2,350 bull calves, 3,800 heifer calves, and 400-500 female ovum donors. The cost of testing oral swabs for business continuity will be the responsibility of the submitter (owner, business, etc.) not the state and federal agencies managing the response.

**RESOLUTION:**

The United States Animal Health Association urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service, National Veterinary Services Laboratory, Foreign Animal Disease Diagnostic Laboratory to determine the sensitivity of an oral swab real-time reverse transcriptase polymerase chain reaction test for foot-and-mouth disease. Additionally, the testing frequency and interval should be developed through input from the Center for Epidemiology and Animal Health Surveillance Design and Analysis Group.

A policy that describes test result interpretation and reporting protocols should also be developed under the guidance of the National Preparedness and Incident Coordination Center.

Lastly, based on the data collected, the National Animal Health Laboratory Network (NAHLN) program office should define guidelines for a pre-outbreak deviation process that can be initiated by a NAHLN laboratory interested in requesting this Emergency Use Approval.

The USDA should prioritize defining guidelines for a pre-outbreak oral swab deviation process and test evaluation on a new population of animals, policy development for results interpretation and reporting protocols and testing frequency. USAHA urges Congress to appropriate additional funding for NAHLN to support this work.