Case Definition

Foot and Mouth Disease (FMD)
(Notifiable) **November 2023**

1. **Disease Information**
   - **1.1 General Disease and Pathogen Information:** Foot-and-mouth disease (FMD) is an acute, highly contagious viral disease of all cloven-hoofed animals including cattle, swine (domestic, wild, and peccaries), sheep, goats, camelids, cervids, and wild ruminants caused by the FMD virus (FMDV), of the genus *Aphthovirus* within the family *Picornaviridae*. There are seven serotypes (A, O, C, South African Territory (SAT) types SAT1, SAT2, SAT3, and Asia), and many strains within each serotype. FMD disease is endemic in parts of Asia, Africa, the Middle East, and South America; it is considered a foreign animal disease (FAD) in the United States. FMDV can be found in all secretions and excretions from acutely infected animals including expired air, saliva, milk, urine, feces, semen, amniotic fluid, and aborted fetuses, as well as in the fluid from FMD-associated vesicles. Transmission of the virus is via inhalation or ingestion of, or direct contact of skin abrasions or mucous membranes with, infectious particles. Mechanical transmission via fomites and living vectors, and windborne transmission, are also possible. In a naïve population, FMDV multiplies rapidly in multiple animals and spreads quickly throughout the population. Clinical signs usually begin 3 to 5 days after infection. In settings where there is a large amount of FMDV in the environment, or an outbreak in a naïve population, the incubation period may be as short as 24 hours. According to the World Organisation for Animal Health (WOAH), the maximum incubation period is 14 days.
   - **1.2 Clinical Signs:** Vesicles (indistinguishable from other vesicular diseases) on the oral and nasal mucosa, teats, mammary gland, coronary band, and interdigital spaces are the classic lesions associated with FMD. Lesions can cause nasal discharge, excess salivation (in cattle), anorexia, and lameness, leading to weight loss and decreased production. Fever, inappetence, lameness, and decreased milk production are generally the first signs observed, followed by shivering, lip smacking, kicking, abortion, and sudden death among young animals. The severity of clinical signs varies with animal species and virus. Cattle and pigs usually develop clinical signs more rapidly and severely. Sheep and other small ruminants rarely develop clinical signs, including vesicles, but may show signs of lameness and reproductive losses. Pigs develop severe foot lesions, which may include skin blanching, lameness, vesicular lesions on the coronary band, heels and interdigital space, and fever up to 107°F.
2. **Laboratory Criteria**
   - **2.1 Agent Isolation and Identification:** Virus isolation (VI), antigen enzyme-linked immunosorbent assays (ELISAs), and real-time reverse transcriptase polymerase chain reaction (PCR) assays are commonly used for virus detection. Samples to collect for testing include vesicular epithelium, vesicular fluid, epithelial tissues,

esophageal-pharyngeal fluid ("probang sample"), and oral and nasal swabs. VI in cell cultures and antigen ELISA are the "gold standard" tests for FMDV detection. VI is highly sensitive and specific when used with antigen ELISA or PCR. Most PCRs detect all known FMDV serotypes but cannot differentiate between serotypes.

2.2 Agent Characterization: Strain characterization is done by sequencing the P1 region of the FMDV genome or a portion of the P1 region that contains VP1 of the genome. If necessary, whole genome sequencing can be performed. Antigen ELISA is used to determine the serotype of the FMD present if sufficient sample is available.

2.3 Serology: Evaluation of antibodies to FMDV structural (SP) or non-structural viral proteins (NSP) help to discriminate vaccinated from infected animals. SP assays include the virus neutralization test (VNT) and ELISA tests which are highly sensitive, serotype-specific tests to detect FMDV antibodies. The VNT and ELISA tests may be utilized for confirmation of infection (previous or on-going) and to monitor immunity following vaccination. VNT can be used to determine the serotype subtype during vaccine matching. NSP based antibody assays include 3ABC ELISA and virus infection association antigen (VIAA) agarose immunodiffusion (AGID) tests which are not serotype-specific and are used as screening tests.

3. Case Classification

3.1 Suspect Case: An FMD-susceptible animal with:

3.1.1 clinical signs consistent with FMD; **OR**

3.1.2 epidemiological information indicative of FMD; **OR**

3.1.3 a non-negative result by a serological antibody screening assay conducted as part of a national surveillance activity.

3.2 Presumptive Positive Case: A suspect case with:

3.2.1 a non-negative test result for FMDV from a laboratory other than the National Veterinary Services Laboratories (NVSL).

3.2.1.1 identification of antibodies to NSP 3D by AGID; **OR**

3.2.1.2 identification of antibodies to 3ABC by ELISA; **OR**

3.2.1.3 identification of antibodies to structural proteins by virus neutralization for serotype identification; **OR**

3.2.1.4 identification of FMDV nucleic acid by PCR; **OR**

3.2.1.5 identification of FMDV serotype by antigen ELISA.

3.3 Confirmed Positive Case:

3.3.1 FMDV that has been isolated and sequenced at NVSL **OR**

3.3.2 An FMD susceptible animal with clinical signs consistent with FMD **or** epidemiological link to FMDV **or** cause for suspicion of previous association **or** contact with FMDV; **AND**

3.3.2.1 An FMD PCR positive result with genomic sequencing at NVSL; **OR**

3.3.2.2 Antibodies specific to FMDV are identified by 3ABC ELISA and VN at NVSL; **OR**

3.3.2.3 Antibodies specific to FMDV are identified by VIAA and virus neutralization at NVSL

4. **Reporting Criteria** FMD is a U.S. FAD that is immediately reportable under the APHIS National List of Reportable Animal Diseases (NLRAD).

4.1 NLRAD reporting in accordance with the NLRAD Standards for notifiable diseases; and by APHIS to the World Organisation for Animal Health (WOAH); **AND**

4.2 For FAD or Emerging Disease Incidents also follow standard procedures according to the Policy for the Investigation of Potential Foreign Animal Disease/Emerging Disease Incidents.