Surveillance Guidance to Support the Secure Milk Supply (SMS) Continuity of Business Plan during an FMD Outbreak

April 2018

I. Purpose
This surveillance guidance supports continuity of business for dairy cattle operations located in a Control Area during an FMD outbreak and are referred to in the USDA FAD PReP Foot-and-Mouth Disease Response Plan, The Red Book; Appendix F: FMD Outbreak Surveillance Guidance and Rationale, September 2014.

II. Introduction
In an FMD outbreak, Responsible Regulatory Officials (local, state, tribal, and federal officials, as appropriate) have the authority and responsibility to establish Control Areas around FMD infected premises and to manage animal and animal product movement within, into, and out of the Control Area. Dairy premises in an FMD Control Area must be designated as Monitored Premises to be eligible to request a permit for movement of animals and perhaps for animal products. Monitored Premises must meet a set of defined criteria, such as having a valid National Premises Identification Number (PIN) and having implemented biosecurity measures and surveillance. Obtaining a movement permit for animals may also require meeting additional biosecurity measures and surveillance (inspection, diagnostics) on the animals to be moved. This document only addresses surveillance guidance.

The Secure Milk Supply (SMS) Plan recommends surveillance of all susceptible animals on a premises within a Control Area to demonstrate a lack of evidence of FMD infection in order to be designated as a Monitored Premises. Additional surveillance is recommended for issuing movement permits for animals and some animal products within or outside of a Control Area. This surveillance should provide the highest degree of confidence possible that animal and/or animal product movement can occur to support business continuity without spreading infection. The ability to provide a very high degree of confidence that animals are negative for FMD virus using currently available, validated laboratory testing methods, and sample collection protocols for large groups or certain types of animals is limited at this time. These surveillance methods cannot prove freedom from infection, they can only establish lack of evidence of infection. This document does not review sample sizes or frequencies which are dependent upon outbreak or virus strain related factors and the surveillance plan factors. These are guidelines only; decisions will be made by the Responsible Regulatory Officials based on the unique characteristics of each outbreak. FMD virus diagnostic tests can only be conducted at approved National Animal Health Laboratory Network (NAHLN) labs, listed here: https://www.aphis.usda.gov/animal_health/nahln/downloads/fmd_lab_list.pdf.

III. Potential Surveillance Methods for Evidence of FMD Virus Infection on Dairy Premises in an FMD Control Area
The potential surveillance approaches for dairy premises in an FMD Control Area include:

1. **Submission of a completed epidemiologic questionnaire** to the Responsible Regulatory Officials at the beginning of an outbreak, and as new Infected Premises, which the dairy may have contact with, are identified.

2. **Serological surveillance** measures antibody against FMD virus. Serum antibodies are not detectable until several days after infection and typically after cattle develop clinical signs. Therefore, serological surveillance is not useful for providing a high degree of confidence that cattle are not in an early stage of infection at the time of movement. Serologic surveillance can provide a high degree of confidence that the animal or herd were/was not infected 14 days previously. This can be useful for issuing movement permits for animal products that can be stored for 14 days (e.g., semen and embryos).
Diagnostic testing availability at NAHLN labs

- There is not a validated serologic test for FMD virus at NAHLN labs at this time (April 2018).

3. Virological surveillance analyzes specimens for the presence of FMD virus. NAHLN laboratories are approved to conduct real-time reverse transcription polymerase chain reaction (rRT-PCR) assays for FMDV.

Diagnostic testing availability at NAHLN labs

- **Oral Swabs:** The FMD rRT-PCR test for oral swabs is available, has a sensitivity of 94% and specificity of 99%, and takes approximately four hours to run. [1]

- **Milk:** The FMD rRT-PCR test for milk is available at some NAHLN laboratories and takes approximately four hours to run. The conclusion of assay performance characteristics from testing at USDA Plum Island Animal Disease Center was that, at least early during the onset of infection when virus shedding in milk is greatest, the test can reasonably detect FMDv from a bulk tank in which a single infected dairy cow is shedding virus out of a herd size of 100-1000. [2] More information is available in the USDA document, “Potential Uses of a rRT-PCR Assay for FMD in Bulk-Tank Milk in the United States” at: https://www.aphis.usda.gov/animal_health/downloads/CEAH%20BTM%20Evaluation%20for%20FMD_Sept%2029_2017%20POSTED.pdf.

Virological Surveillance Limitations

- Cattle may be in an early stage of infection before FMD virus can be detected in oral swabs or milk.

- **Oral Swabs:** Collecting individual oral swab samples daily would be very labor intensive and require extensive laboratory testing. Pooling of individual swabs for testing would reduce the amount of testing required, however, pooling of oral swabs from cattle has not been validated. Future development and validation of a pen-level test, such as the use of ropes to collect oral fluid samples, would provide a pooled sample without the need to restrain animals.

- **Milk:** Not all animals will be lactating and represented in the milk sample, however, the sample is representative of the lactating herd and other animals in contact with them; test results may be delayed if the number of samples exceeds the laboratory capacity to process submitted samples in a timely manner; not all NAHLN labs are currently (April 2018) proficiency tested to perform the milk rRT-PCR test. The milk rRT-PCR test could be used for surveillance for lactating animals in an FMD outbreak once NAHLN labs achieve proficiency for milk rRT-PCR testing.

4. Periodic inspection of cattle for evidence of FMD virus infection under the authority of the Responsible Regulatory Officials. The Responsible Regulatory Officials could designate an Accredited Veterinarian as part of the Unified Incident Command to periodically inspect cattle for evidence of FMD virus infection. Any suspicious clinical signs in animals could be investigated with laboratory testing.

Limitations of Inspection by Accredited Veterinarians

- The frequency of inspection may be limited by the number of Accredited Veterinarians available and the number of premises needing inspection. The frequency of inspection will be determined by the Responsible Regulatory Officials. Subclinical infections will not be detected through visual examination.

5. Active Observational Surveillance (AOS) conducted daily by trained Cattle Health Monitors employed by the premises could supplement the periodic inspections by an Accredited Veterinarian. AOS is a systematic method for routinely monitoring livestock (cattle, pigs) for potential signs of early FMD virus infection during an outbreak. AOS is possible for cattle in all production phases (housed in pens, dry lots, barns or on pasture). The Secure Milk Supply Plan includes AOS materials for training on-farm observers, including recognition of abnormal health events and clinical signs that may indicate early FMD infection. There are also materials that visually depict FMD lesions in cattle and a record keeping system to
track health observations, milk production and feed consumption data [3] for producers who do not already use a record keeping system for that information.

**Active Observational Surveillance (AOS) includes:**

- **Daily visual observation** of cattle by trained, farm-based observers (referred to as Cattle Health Monitors) who are familiar with the health status of the livestock and able to recognize abnormal findings (clinical signs and/or changes in productions parameters) that may be an early indicator of FMD virus infection;
- **Daily documentation** of health normal or abnormal findings (referred to as AOS records) by Cattle Health Monitors;
  - Data may include clinical signs or the lack of (e.g., fever, nasal discharge, lameness), health events (e.g., death loss), or production data (e.g., no changes, decreased milk production, decreased feed consumption).
- **Prompt reporting** of abnormal findings to Responsible Regulatory Officials with a follow up examination of animals by them or their designee (Accredited Veterinarian). The Responsible Regulatory Officials may decide to conduct laboratory testing on any suspicious cases.

**AOS Limitations**

- Ensuring personnel are adequately trained to recognize and accurately document increased frequency of signs potentially suggestive of FMD and are motivated to report them
- Basing animal movement decisions on subjective observations
- Limited numbers of Accredited Veterinarians for follow up inspections
- Not all animals will be lactating and represented in the milk production records; however, this is representative of the lactating herd and other animals in contact with them
- Daily feed consumption data may not be possible under certain management conditions, such as cattle with free-choice feed access.

**IV. Surveillance for Designation as a Monitored Premises**

The surveillance guidance for premises in a Control Area to become designated as a Monitored Premises could include:

- Completion and updating of an epidemiologic questionnaire
- Conducting AOS daily by trained Cattle Health Monitors employed by the premises
- Periodic inspection of animals and daily AOS records by Accredited Veterinarians under the authority of the Responsible Regulatory Officials
- Follow-up laboratory testing for animals with any suspicious clinical signs

**V. Surveillance for Animal Movement Permits**

Dairy premises meeting the requirements to be designated as a Monitored Premises, including the surveillance guidance described above, would be eligible to request animal movement permits. Additional surveillance to increase the confidence that the movement will not spread FMD virus is recommended. The additional surveillance guidance for requesting an animal movement permit could include:

- Documentation of AOS (described above) **for at least 7 days** prior to the proposed animal movement demonstrating no evidence of FMD virus infection of susceptible animals on the premises.
  - For cattle destined for slaughter, AOS is documented in **that population** of animals
  - For animals moving to another production site, AOS is documented in **all susceptible animals** on the premises
- Negative diagnostic tests (oral swab rRT-PCR) of representative individual animals that can be safely handled and restrained within 24 or 48 hours of proposed movement. The requirement of laboratory testing may depend on the laboratory capacity and the nature of the animal movement. For example, the requirement for laboratory testing for animals moving to a production site outside of the Control Area may be more stringent as compared to animals moving directly to slaughter within the Control Area.
• Visual inspection of animals to be moved, and of relevant AOS documentation by Responsible Regulatory Officials or their designees (Accredited Veterinarian) when cattle are loaded for movement off-site.

VI. Surveillance for Semen/Embryo Movement Permits
Premises meeting the described biosecurity and surveillance criteria to be a Monitored Premises would be eligible to request semen/embryo movement permits with additional surveillance to increase the confidence that the movement will not spread FMD virus. Semen and embryos originating from within a Control Area should be held, frozen at the source herd for 14 days after collection. Serologic evidence of negative antibody status for the donor animal(s) would provide assurance that the semen or embryos collected 14 days or more previously are negative for FMD virus. However, since serologic testing is not available at NAHLN labs, continuous Active Observational Surveillance and periodic inspection by an Accredited Veterinarian demonstrating no evidence of FMD virus infection (required to be a Monitored Premises) will also provide a high degree of confidence that the semen and embryos collected 14 days or more previously are negative for FMD virus.

VII. Surveillance for Milk Movement
The Secure Milk Supply (SMS) Plan for Continuity of Business, available at [www.securemilksupply.org](http://www.securemilksupply.org), describes two options for dairy premises in any FMD Control Area that are NOT designated as Infected, Suspect, or Contact Premises to move milk. It provides Regulatory Officials with the flexibility to manage milk movement, which may or may not involve surveillance testing at the beginning of an outbreak.

If surveillance is required, it may be via testing bulk tank milk using real-time reverse transcriptase-polymerase chain reaction (rRT-PCR) assay for FMD virus. The potential use of this assay during an FMD outbreak is described in “Potential Uses of a rRT-PCR Assay for FMD in Bulk-Tank Milk in the United States”, available at: [https://www.aphis.usda.gov/animal_health/downloads/CEAH%20BTM%20Evaluation%20for%20FMD_Sept%2029_2017%20POSTED.pdf](https://www.aphis.usda.gov/animal_health/downloads/CEAH%20BTM%20Evaluation%20for%20FMD_Sept%2029_2017%20POSTED.pdf)

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Comments
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References
[1] Personal communication, Fawzi Mohamed, Foreign Animal Diseases Diagnostic Laboratory, National Veterinary Services Laboratories, USDA; September 23, 2016