Surveillance Guidance to Support the SPS Continuity of Business Plan during an FMD, CSF, or ASF Outbreak  
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Purpose
This surveillance guidance supports continuity of business for swine operations located in a Control Area during a foreign animal disease (FAD) outbreak and are referred to in the following documents:

- USDA FAD PReP African Swine Fever Disease Response Strategy (there is limited information available for ASF surveillance)

Foot and mouth disease (FMD), classical swine fever (CSF), and African swine fever (ASF) are the highly contagious FADs addressed in the Secure Pork Supply Plan.

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

The Secure Pork Supply (SPS) Plan recommends surveillance of all susceptible animals on a premises within a Control Area to demonstrate a lack of evidence of FAD infection in order to be designated as a Monitored Premises. Additional surveillance is recommended for issuing movement permits for animals within or outside of a Control Area. This surveillance should provide the highest degree of confidence possible that animal 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 the FAD 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, CSF, and ASF virus diagnostic tests can only be conducted at approved National Animal Health Laboratory Network (NAHLN) labs, listed here:

Potential Surveillance Methods for Evidence of FMD, CSF, or ASF Virus Infection on Pork Production Sites in a Control Area

The potential surveillance approaches for pigs in an FMD, CSF, or ASF Control Area include:

1. **Submission of a completed epidemiological questionnaire** to the Responsible Regulatory Officials at the beginning of the Control Area designation and when new Infected Premises are identified. The answers to the questions will help determine if the premises has had any contact with an infected premises via animals, animal products, feed, fomites, or people.

2. **Serological surveillance** measures antibody against FMD, CSF, or ASF virus. Serum antibodies are not detectable until several days after infection and typically after pigs develop clinical signs. Therefore, serological surveillance is not useful for providing a high degree of confidence that pigs 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 information can be useful for monitoring a premises over time and when issuing movement permits for animal products that can be stored for 14 days (e.g., frozen semen).

**Diagnostic testing availability at NAHLN labs**
- There is not a validated serologic test for FMD, CSF, or ASF virus at NAHLN labs at this time (June 2017).

3. **Virological surveillance** analyzes specimens for the presence of FMD, CSF, or ASF virus. NAHLN laboratories are approved to conduct real-time reverse transcription polymerase chain reaction (rRT-PCR) assays for FMDV, CSFV, and ASFV. Other diagnostic tests will be included in the Plan as they are approved. Collecting samples such as tonsils from dead animals would increase likelihood of detection of an FAD.

**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]
- **Oral Fluid Samples Collected with Ropes**: A proof-of-concept study conducted at the Foreign Animal Disease Diagnostic Laboratory (FADDL) testing for FMDv, CSFv, and ASFv and utilizing a Multiplex RT-qPCR demonstrated 83.9–98.3% efficiency and 100% specificity under the conditions used in the study. [2]
- **Tonsil/Tonsil Scrapings/Nasal Swabs**: One rRT-PCR test for CSF demonstrated 100% specificity and can be run in 2 hours or less. In this study, virus was detected in the oronasal samples 3 to 5 days before clinical signs were evident. [3] The probe and primer sequences used in this study have minor modifications from those used in the NAHLN labs. In another study, ASFv was detected in tonsil scrapings 2 to 4 days before clinical signs were observed, with a sensitivity of 95.4% and 100% specificity. ASFv was also detected in nasal swabs with 100% specificity and 92.8% sensitivity. [4]
- **Whole Blood**: The ASF rRT-PCR test on whole blood is available, has a sensitivity of 89.7% and specificity of 100%, and takes less than 2 hours to run. [4] Utilizing an rRT-PCR test, CSF virus was detected 0 to 3 days in blood samples before clinical signs appeared. [3]

**Virological Surveillance Limitations**
- Pigs may be in an early stage of infection before FMD, CSF, or ASF virus can be detected in oral swabs, oral fluid samples collected with ropes, tonsils, tonsil scrapings, nasal swabs, or whole blood. Sampling all pigs that are observed with non-specific signs
of an early stage of a potential infectious disease (lethargy, loss of appetite, huddling) may increase the likelihood of early detection of an FAD.

- **Oral Swabs for FMD testing:** Collecting individual oral swab samples daily would be very labor intensive and require extensive laboratory testing. It can be difficult to safely restrain and collect oral swabs from finished-weight pigs, sows, and boars; and this could result in injury to the animal and handler. Pooling of individual swabs for testing would reduce the amount of testing required; however, pooling of oral swabs from pigs has not been validated.

- **Oral Fluid Samples Collected with Ropes:** Once pigs become febrile, they may be less likely to chew on the cotton ropes as they are feeling sick and may be less active.

- **Tonsil/Tonsil scrapings/nasal swabs for CSF testing:** Tonsils are a reliable sample to test pigs for CSF. However, tonsil are collected during necropsy which can limit the number of animals to be tested. Tonsil scraping and nasal swab collection both require individual animal restraint which can be more difficult in finish-weight animals as well as sows and boars. Collecting tonsillar scrapings can also be more difficult to perform in very young piglets.

- **Whole Blood for ASF testing:** As with collecting oral swabs, nasal swabs, and tonsillar scrapings, collection of whole blood requires animals be individually restrained which again can be more difficult in finish-weight animals as well as sows and boars.

**Sample Collection**

For all three diseases, 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. In addition, pig producers routinely utilize oral fluid samples to test for endemic diseases in their herds, so they are trained in hanging ropes in pens and collecting samples. During a large outbreak when resources are being stretched, having producers collect their own samples would be necessary.

**Sample Collection Training**

Animal caretakers trained in collecting tonsil, oral fluid, or nasal swab samples can collect samples for submission during a large outbreak when the resources of the Responsible Regulatory Officials are limited. Accredited veterinarians who oversee the herd should lead sample collection training and determine which individuals are capable of doing it correctly.

4. **Periodic inspection of pigs for evidence of FMD, CSF, or ASF 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 the pigs for evidence of FMD, CSF, or ASF virus infection. Any suspicious clinical signs in animals could be investigated with laboratory testing. Inspection of pigs at load-out would provide an extra degree of confidence that clinical signs are not apparent in the animals being moved. This approach may be discontinued if the extent of the outbreak stretches beyond available resources.

**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. Accredited Veterinarians would need to use proper biosecurity between sites, which may limit the number of sites they can visit per day.

5. **Active Observational Surveillance (AOS) conducted daily by trained Swine Health Monitors employed by the production site 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, CSF, or ASF infection during an outbreak. AOS is possible for pigs in all production phases. The Secure Pork Supply Plan includes AOS materials for training on-farm
observers, including recognition of abnormal health events and clinical signs that may indicate early FMD, CSF, or ASF virus infection. There are also materials that visually depict FMD, CSF, or ASF lesions in pigs and a record-keeping system to track health observations, death loss and those treated by injection [5] for pork production sites who do not already use a record keeping system for that information.

**AOS includes:**
- **Daily visual observation** of pigs by trained farm employees called Swine Health Monitors who are familiar with the health status of the livestock on the site and able to recognize abnormal findings (clinical signs and/or changes in production parameters) that may be an early indicator of FMD, CSF, or ASF virus infection;
- **Daily documentation** of normal or abnormal findings (referred to as AOS records) by Swine Health Monitors;
  - Data may include clinical signs or the lack of (e.g., fever, lameness, lethargy), health events (e.g., death loss, animals treated by injection), or production data (decrease water or feed intake).
- **Promptly reporting** 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, CSF, or ASF and are motivated to report them
- Basing animal movement decisions on subjective observations.
- Limited numbers of Accredited Veterinarians for follow up inspections
- Daily feed or water consumption data may not be possible under certain management conditions.

**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 epidemiology questionnaire
- Conducting AOS daily by trained Swine 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

**Surveillance for Animal Movement Permits**
Pork production sites 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, CSF, or ASF 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 FAD virus infection of animals on the premises.
- For animals 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 (rRT-PCR) of representative individual animals that can be safely handled and restrained within 24 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. When tests are validated, oral fluid sample collection from groups of animals using cotton ropes would allow for a larger number of animals to be tested without risk to the animals or handlers which occurs during individual animal restraint.
• Visual inspection of animals to be moved, and of relevant AOS documentation by Responsible Regulatory Officials or their designees (Accredited Veterinarian) when pigs are loaded for movement off-site.

**Surveillance for Semen Movement Permits**

Premises meeting the described biosecurity and surveillance criteria to be a Monitored Premises would be eligible to request semen movement permits with additional surveillance to increase the confidence that the movement will not spread FMD, CSF, or ASF virus. Frozen or fresh semen originating from within a Control Area may be shipped once the semen tests negative for FMD, CSF, or ASF virus.

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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; January 27, 2017