Recommendations for Swine with Potential Vesicular Disease

1. Purpose and Background

Accredited veterinarians must immediately report all diagnosed or suspected cases of animal diseases not known to exist in the United States to State or Federal animal health officials and take precautions to prevent the spread of communicable diseases as per Title 9, Code of Federal Regulations (9 CFR) 161.4(f) and (g). Any swine having vesicular lesions are suspects for foreign animal diseases (FAD), such as foot-and-mouth disease (FMD), until determined otherwise by Veterinary Services (VS) via the Foreign Animal Disease Diagnostic Laboratory and through authorized testing at approved National Animal Health Laboratory Network (NAHLN) laboratories. Vesicular lesions in swine are caused by several viral pathogens, including FMD, swine vesicular disease, and vesicular stomatitis virus. They cannot be differentiated without diagnostic testing.

One virus that can cause vesicular lesions is senecavirus A (SVA), commonly known as Seneca Valley virus. It belongs to the same family FMD (Picornaviridae). SVA has been identified in U.S. swine since the 1980s and has been occasionally associated with sporadic outbreaks of idiopathic vesicular disease of swine. In some reported cases, swine herds approach 80 percent morbidity, with snout and coronary band vesicular lesions. In other cases only 5 to 10% of animals are affected. Often pigs are reported to be afebrile and are bright, alert, and responsive. Mortality in preweaned pigs has also been reported.

This document provides guidance on procedures and responsibilities for handling herds suspected of having SVA to ensure that foreign animal disease investigations occur per agency guidelines. Reporting of herds with vesicular lesions must continue to ensure rapid detection of trade impacting foreign animal vesicular diseases (FAD) such as FMD, safeguard American agriculture, and protect the health, quality, public confidence, and marketability of our nation’s livestock and products.

This guidance document represents the Agency’s position on handling cases of swine exhibiting vesicular lesions. The information it contains may be made available to the public. While this document provides guidance for users outside VS, VS employees may not deviate from the directions provided without appropriate justification and supervisory concurrence.

2. Document Status

A. Valid through April 6, 2019.

B. This is a revised document and replaces VSG 7406.1 dated 10/19/15, which is cancelled.
3. **Reason for Reissuance**

Modifications were made to clarify guidance on investigations.

4. **Authority and References**

   A. **Authority** (*Code of Federal Regulations* (CFR)):

      - 7 CFR 371.4
      - 9 CFR part 53
      - 9 CFR part 161
      - 9 CFR 309.15
      - 9 CFR 311.32

   B. **References**:

      - VS 12000.1, *Foreign Animal Disease Diagnostician Certification Requirements*
      - VS 12001.2, *Policy for the Investigation of Potential Foreign Animal Disease/Emerging Disease Incidents (FAD/EDI)*
      - *Food Safety Inspection Service Directive 6000.1, Responsibilities Related to Foreign Animal Diseases and Reportable Conditions*
      - *Foreign Animal Disease Investigation Manual*

5. **Audience**

VS employees, other Federal and State agencies, accredited veterinarians, and members of the public.

6. **Guidance**

   A. **Reporting Responsibilities of Accredited Veterinarians**

      Accredited veterinarians are to immediately report all cases of vesicular disease to Federal or State animal health officials. The reporting of all vesicular diseases is necessary to ensure that FMD is ruled out. (9 CFR 161.4.)

   B. **Performing a FAD Investigation in Swine when Vesicular Lesions are Observed**

      1) Foreign animal disease investigations are to be performed in accordance to VS Guidance documents 12000.1 and 12001.2.

      2) VS Assistant Directors (AD) and State animal health officials (SAHO) will assign foreign animal disease diagnosticians (FADD) to each case of vesicular disease identified in pigs and ensure the investigation and all information is entered into the USDA Emergency Management Response System (EMRS). ADs, SAHOs and FADDs will use professional judgment to evaluate each case for submission to FADDL and NAHLN laboratories that are authorized by Veterinary Services for FMD.
testing. Prioritization of the FAD investigation and subsequent diagnostic testing will take into consideration the need to move pigs or products.

3) Communication by the AD, SAHO, and FADD regarding investigation activities will be conducted per established policies as provided in VS guidance 12001.2 and outlined in the Ready Reference Guide: Procedures and Policy for the investigation of potential Foreign Animal Disease (FAD)/Emerging Disease incidents (EDI). This guide is found online at: https://www.aphis.usda.gov/animal_health/emergency_management/downloads/documents_manuals/rrg_fadd_manual.pdf. It is important to communicate per this protocol so that all necessary parties are kept aware of the progress of the investigation.

C. FADD Investigations for Swine that are Suspected to Have SVA Based on Epidemiological Data

1) FADD should use professional judgment and known epidemiological information including knowledge of SVA in the geographic area or historic incidence of SVA in the production system associated with the current report.

2) Where appropriate, NAHLN laboratories that are authorized by VS to conduct FMD testing can be utilized (see attachment A.)

3) If samples are sent to the NAHLN laboratory, a duplicate set of samples must concurrently be collected and immediately sent to FADDL per VS Guidance document 12001.2.

4) The AD or SAHO will assign a priority per VS Guidance Document 12001.2 and notify FADDL via email at: FAD.Submissions@aphis.usda.gov. The prioritization level assigned to the FAD investigation will take into consideration the need to move pigs or products. The priority should be no higher than a Priority 2 when SVA is suspected.

5) The AD and SAHO may use the clinical presentation and NAHLN diagnostic test result to make initial decisions regarding disposition and movement of the animals.

6) The NAHLN testing laboratory will immediately call State and VS officials in the State where the animals are located if FMD screening tests are positive. Negative results will be reported per routine electronic messaging methods or as requested by the SAHO or AD.

7) A positive test result for FMD from the NAHLN laboratory will immediately elevate the investigation priority level previously established. FADDL must confirm all FMD NAHLN lab results.

8) Communication by the AD, SAHO, and FADD regarding response activities will be conducted per established policies provided in VS Guidance 12001.2 and outlined in the Ready Reference Guide: Procedures and Policy for the investigation of potential
D. Diagnostic Testing at NAHLN Laboratories When Samples are Received from Swine with Vesicular Lesions That Are Not Associated with a FAD Investigation

1) Every sample must have a FAD investigation Referral Control Number (RCN) to be tested for FMD at a NAHLN laboratory, even if no investigation is launched. Laboratories will contact the SAHO or AD of the State from which the sample originates if samples are submitted from a vesicular case without a FAD investigation RCN. Per VS Guidance 12001.2, the AD or SAHO from the State of origin will assign a FAD RCN.

2) The AD or SAHO of record will assign a priority per VS Guidance Document 12001.2 and notify FADDL via FAD.Submissions@aphis.usda.gov

3) The NAHLN lab shall determine if sample size and quality is adequate for testing at both the NAHLN laboratory and at FADDL. If not, shipment of samples to FADDL must be done the same day or first thing the next day. The submitter and FADDL should be informed of the situation as well. Laboratories with questions should contact FADDL officials by calling (631) 323-3256 or (631) 375-5314 (after hours).

4) After the NAHLN laboratory has received the FAD RCN, the FMD PCR may be conducted at the NAHLN lab if there is sufficient volume. Only if there is sufficient sample volume remaining after FMD testing by the authorized NAHLN lab, the lab may conduct other non-FAD testing as ordered by the submitting veterinarian, including SVA PCR at the submitter’s expense. FMD testing is the top priority.

5) In cases where an accredited veterinarian submits samples, the AD or SAHO will discuss clinical presentation and FAD reporting guidelines with the accredited veterinarian. If deemed necessary based on this discussion, a FADD may be assigned to the case and FAD sample collection and investigation procedures will be followed.

E. Collection of Samples by Accredited Veterinarians in Swine Production Systems Previously Investigated and Tested Negative for FADs

1) In situations where epidemiologically linked production sites show evidence of vesicular disease and the origination site has FAD-negative results confirmed by FADDL within 14 days from date of FADD investigation, accredited veterinarians may conduct follow-up FAD investigations only under the following conditions:

   a. A FAD investigation by an FADD has occurred within the last 14 days, at an epidemiologically linked production system, and the FAD case was found FMD negative at FADDL.
b. The accredited veterinarian(s) agrees to collect, package, and send samples to FADDL and the NAHLN (if applicable) per AD and SAHO instructions, and in accordance with VS Guidance 12001.2.

c. The accredited veterinarian understands that the USDA role is to rule out FADs. Production-based disease testing may require additional diagnostics at a veterinary diagnostic laboratory. Testing for other diseases is not necessarily part of the USDA testing repertoire or reimbursable by USDA.

2) Accredited veterinarians will immediately contact the AD or SAHO and report any unexpected change in morbidity, mortality, or clinical findings of vesicular disease within an epidemiologically linked production system. A new FAD investigation may be initiated if determined necessary.

3) The AD or SAHO will provide a FAD RCN for all cases. NAHLN labs cannot test for FMD without the FAD RCN.

4) The AD or SAHO will assign a priority per VS Guidance Document 12001.2 and notify FADDL via email at: FAD.Submissions@aphis.usda.gov.

F. Critical information for producers and accredited veterinarians during and after a FAD investigation

1) Follow strict biosecurity to prevent spread between sites and production systems.


3) Notify the AD or SAHO when there is an unanticipated/unexpected change on the premises in morbidity/morality associated with the vesicular lesions.

4) Accredited veterinarians must ensure that swine moving in interstate commerce meet all State and Federal animal health requirements including those set forth in 9 CFR 71.19(g) and 161.4. These requirements include ensuring that the animals moving interstate are healthy, have no clinical signs of disease, are fit for travel, properly identified etc., before issuing certificates of veterinary inspection.

5) The accredited veterinarian will contact the SAHO in the receiving State when interstate movement of non-slaughter swine is scheduled from investigated premises for 30 days following an FAD investigation. The receiving State SAHO will inform the accredited veterinarian if any additional documentation (such as the FAD RCN) necessary for issuance of either a certificate of veterinary inspection or other interstate movement document, including a swine production system record.
G. The following communications are needed when animals destined to slaughter have been subject to a negative FAD investigation and have healed vesicular lesions:

1) The accredited veterinarian contacts the SAHO or AD in the State of where the premises are located and provides detailed information on when and where the animals are expected to be slaughtered.

2) The SAHO or AD will assist by providing official correspondence to the USDA Food Safety Inspection Service (FSIS) office overseeing the establishment where the animals are destined to be slaughtered. This correspondence could include:

   a. Information that an FAD investigation occurred and corresponding laboratory reports indicating the animals tested from that premises are negative for FMD within the last 30 days.

   b. Detailed information on when the animals are expected to arrive at the slaughter establishment.

3) Lists of FSIS District Office contact information can be found at: [http://www.fsis.usda.gov/wps/portal/informational/districtoffices](http://www.fsis.usda.gov/wps/portal/informational/districtoffices)

4) Accredited veterinarians and/or producers should also inform the slaughter establishment’s procurement personnel of resolved FAD investigations that have occurred on the originating premises for the loads of animals being sent to the establishment.

H. Management of swine found with vesicular lesions in slaughter channels where FSIS was not notified of a previous FAD investigation

1) FSIS policy requires immediate notification to the AD or SAHO when any livestock are found to have vesicular conditions at ante mortem inspection, per 9 CFR 310.15.

2) [FSIS Directive 6000.1](http://www.fsis.usda.gov/wps/portal/informational/districtoffices) provides instructions to FSIS personnel regarding FADs based on input from APHIS. FSIS will defer to SAHO or AD recommendations after notification by FSIS.

3) If it is determined that a FADD will be assigned to the slaughter establishment, the AD will follow directions as provided in the FAD Investigation Manual section 8-5 for “Slaughter Establishment FAD Investigation Process.”

4) The SAHO or AD will need to communicate with FSIS on how to further process affected animals eligible for slaughter at the official establishment. Establishment operations and capabilities to hold product may need to be assessed. Subject to FADD observations, containment options may include:
a. Quarantining and holding the lot of animals until they receive NAHLN or FADDL results, or at the AD’s or SAHO’s discretion. No quarantined animals can be slaughtered until the quarantine is removed as set forth in 9 CFR 309.15(b).

b. Allowing eligible animals (animals passing ante mortem inspection) to be slaughtered after collecting FAD samples.

   1. All animals would need to pass FSIS ante mortem inspection procedures (i.e., no swine with acute systemic disease, typically indicated by acute or active vesicular lesions, fever, or other systemic clinical signs per 9 CFR 309.15(b), will pass inspection)

   2. All FSIS post mortem regulations apply.

   3. All carcasses, processed product, and offal, including blood, from all animals in the lot will be held for distribution or disposal until NAHLN or FADDL lab results are received. Onsite rendering is acceptable.

c. Allowing routine slaughter without restrictions and without testing based on FADD findings and AD or SAHO recommendations.

d. Animals with vesicular lesions will not leave an establishment for another establishment until testing has been completed by a NAHLN laboratory. FADDL will confirm the NAHLN results; however, FADDL confirmation is not required prior to movement. Animals moving from a slaughter establishment to another slaughter establishment must comply with all existing USDA and FSIS policies.

7. Inquiries

Questions regarding this guidance document should be directed to AD overseeing the State in which you are located.