1. **Purpose and Background**

This document provides guidance on procedures and responsibilities for handling herds suspected of having Senecavirus A (SVA) to ensure foreign animal disease investigations occur per Agency guidelines. 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 under Title 9, *Code of Federal Regulations* (9 CFR) Section 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 (FADDL) and authorized testing at approved National Animal Health Laboratory Network (NAHLN) laboratories. Several viral pathogens can cause vesicular lesions in swine including FMD, swine vesicular disease, and vesicular stomatitis virus. Veterinarians are unable to differentiate between these pathogens without diagnostic testing.

One virus that can cause vesicular lesions is SVA, commonly known as Seneca Valley virus. It belongs to the same family as FMD (*Picornaviridae*). Researchers have identified SVA in U.S. swine since the 1980s and the virus has been occasionally associated with sporadic outbreaks of idiopathic vesicular disease of swine. In some recent reported cases, swine herds approached 80 percent morbidity, with snout and coronary band vesicular lesions. In other cases, only 5 percent to 10 percent of animals are affected. Often veterinarians report pigs are afebrile and are bright, alert, and responsive, though some have reported mortality in pre-weaned pigs.

Accredited Veterinarians must continue to report herds with vesicular lesions to ensure rapid detection of trade-impacting FADs such as FMD to 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**


   B. This is a revised document and replaces VSG 7406.2 dated April 6, 2016, which has been rescinded.
3. **Reason for Reissuance**

VS updated this document to clarify guidance on investigations.

4. **Authority and References**

   A. **Authorities**

   - 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 Guidance:
     VSG 12000, “Foreign Animal Disease Diagnostician Certification Requirements”
     VSG 12001, “Policy for the Investigation of Potential Foreign Animal Disease/Emerging Disease Incidents (FAD/EDI)”

   - Other:
     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 must immediately report all cases exhibiting vesicular lesions to Federal or State animal health officials to ensure that FMD is not the cause (9 CFR 161.4).

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

   1) VS Guidance documents 12000 and 12001 describe how VS performs FAD investigations.

   2) VS Assistant Directors (AD) and State animal health officials will assign foreign
animal disease diagnosticians (FADDs) to each case of vesicular disease identified in pigs. Assigned staff will enter all investigation information into the USDA Emergency Management Response System (EMRS). ADs, State animal health officials, and FADDs will evaluate all information known about the case to determine FADDL submission priority. These officials will take into consideration the need to move pigs or products in prioritizing the FAD investigation and subsequent diagnostic testing.


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

1) FADDs should use 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 and supported by the State animal health official, FADDs may use NAHLN laboratories authorized by VS to conduct preliminary FMD testing.

3) If FADDs send samples to a NAHLN laboratory, a duplicate set of samples must also be collected and immediately sent to FADDL per VS Guidance 12001.

4) The AD or State animal health official will assign a priority per VS Guidance 12001 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 they suspect SVA as the etiology of the lesions.

5) The AD and State animal health official may use the clinical presentation and NAHLN FMD 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. NAHLN will report negative results per routine electronic messaging methods or as requested by the State animal health official or AD.

7) A positive FMD test result from the NAHLN laboratory will immediately elevate the investigation priority to level 1A. FADDL must confirm all NAHLN FMD lab results.

8) The AD, State animal health official, and FADDs will conduct response activities as provided in VS Guidance 12001 and outlined in the Ready Reference Guide.
D. Diagnostic Testing at NAHLN Laboratories When Samples are Received from Swine with Vesicular Lesions Not Associated with an FAD Investigation

1) Each sample submitted to a NAHLN laboratory for FMD testing must have an FAD investigation Referral Control Number (RCN), even if the samples are not associated with an FAD investigation. Laboratories will contact the State animal health official or AD of the State from which the sample originates if a veterinarian submitted samples from a vesicular case without an FAD investigation RCN. Per VS Guidance 12001, the AD or State animal health official from the State of origin will assign an FAD RCN. The AD or State animal health official of record will assign a priority per VS Guidance 12001 and notify FADDL via: FAD.Submissions@aphis.usda.gov

2) The NAHLN lab shall determine if sample size and quality is adequate for testing at both the NAHLN laboratory and at FADDL:

   a. If sample volume is insufficient, the submitting veterinarian must ship the entire sample volume to FADDL per State animal health official and/or AD instructions. The NAHLN lab should also inform the submitter and FADDL of the situation. Laboratories with questions should contact FADDL officials by calling (631) 323-3256 or (631) 375-5314 (after hours).

   b. The NAHLN laboratory may conduct the FMD PCR following reservation of materials for testing at FADDL. If sufficient sample volume remains after reservation of sample materials for FADDL and FMD testing by the authorized NAHLN lab, the lab may conduct other non-FAD testing as requested by the submitting veterinarian, including SVA PCR at the submitter’s expense.

3) In cases where an accredited veterinarian submits vesicular samples to a NAHLN laboratory without required notification, the AD or State animal health official will discuss clinical presentation and FAD reporting guidelines with the accredited veterinarian. If deemed necessary based on this discussion, the AD or State animal health official may assign an FADD to the case for further investigation and FAD sample collection if indicated.
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 of the initial date of the FADD investigation, accredited veterinarians may conduct follow-up FAD investigations only under the following conditions:

   a. An FAD investigation by an FADD has occurred within the last 14 days, at an epidemiologically linked production system, and the FAD case was FMD negative at FADDL.

   b. The accredited veterinarian (or veterinarians) agree(s) to collect, package, and send samples to FADDL and the NAHLN (if applicable) per AD and State animal health official instructions, and in accordance with VS Guidance 12001.

   c. The accredited veterinarian understands that the USDA role is to rule out FADs. Production-based disease testing may require additional tissue volume for further diagnostics at a veterinary diagnostic laboratory. USDA does not test for other diseases.

2) Accredited veterinarians will immediately contact the AD or State animal health official and report any unexpected change in morbidity, mortality, or clinical findings of vesicular disease within an epidemiologically linked production system. If necessary, the AD or State animal health official will initiate a new FAD investigation.

3) The AD or State animal health official will provide an FAD RCN for all cases. NAHLN labs cannot test for FMD without the FAD RCN.

4) The AD or State animal health official will assign a priority per VS Guidance 12001 and notify FADDL via email at: FAD.Submissions@aphis.usda.gov.

F. Critical Information for Producers and Accredited Veterinarians During and After an FAD Investigation

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

2) Communicate as provided in VS 12001 and outlined in the Ready Reference Guide.

3) Notify the AD or State animal health official when there is an unanticipated or unexpected change on the premises in morbidity or mortality associated with the vesicular lesions.

4) Ensure swine moving in non-slaughter interstate commerce meet all State and Federal animal health requirements including those set forth in 9 CFR 71.19(g). These
requirements state: “the swine must have been found free of any communicable
disease during the most recent inspection of the premises by the production system
accredited veterinarian within 30 days prior to movement.”

5) Contact the State animal health official in the receiving State when scheduling
interstate movement of non-slaughter swine from investigated premises for 30 days
following an FAD investigation. The receiving State animal health official will inform
the accredited veterinarian if any additional documentation (such as the FAD RCN) is
needed for issuance of either a certificate of veterinary inspection or other interstate
movement document, including a swine production system record summary for
movement of non-slaughter swine via interstate transit.

G. Communications Needed When Animals Destined to Slaughter Have Been Subject to a
Negative FAD Investigation and May Have Healing Vesicular Lesions (which may include
dry blisters, granulation tissue, or scabs)

1) The accredited veterinarian or producer contacts the State animal health official or AD
in the State where the premises are located to report the expected date of slaughter
and details on the establishment responsible for the slaughter.

2) The State animal health official or AD will provide official correspondence to the
USDA Food Safety Inspection Service (FSIS) District Office overseeing the
establishment to which the animals are destined for slaughter. Contact information is
found at: http://www.fsis.usda.gov/wps/portal/informational/districtoffices

This correspondence should include:

a. Documentation 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. Although documentation may vary,
any of the following documents can be used if they contain the FAD RCN
number and date of the FAD investigation:

   1. NAHLN negative test report for FMD;
   2. FADDL negative test report for FMD;
   3. State-issued certificate of veterinary inspection stating that pigs were tested
      PCR-negative for FMD, with the lab accession number included on the CVI;
   4. VS Form 1-27 (Permit for Movement of Restricted Animals), stating the pigs
      were tested for FMD and were negative; or
   5. An affidavit from the State animal health official or AD stating the pigs from the
      premises were tested and are negative. The affidavit should have letterhead
from a State animal health official or VS office.

b. A statement indicating when the animals will arrive at the slaughter establishment.

3) Accredited veterinarians and/or producers should also inform the slaughter establishment’s procurement personnel of resolved FAD investigations for the premises from which the arriving animals came.

4) If, when the shipper arrives at the slaughter plant, FSIS has not received the required documentation indicated in G.2)a, the shipper should contact the State animal health official or the AD for the required information.

H. Management of Swine Found with Vesicular Lesions in Slaughter Channels Where FSIS Was Not Notified of a Previous FAD Investigation with FMD Test Results

1) FSIS policy requires immediate notification to the AD or State animal health official when any livestock are found to have vesicular conditions at ante mortem inspection, per 9 CFR 309.15.

2) FSIS Directive 6000 provides instructions to FSIS personnel regarding FADs based on input from APHIS. FSIS will defer to State animal health official or AD recommendations.

3) If the AD determines it necessary to assign an FADD 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 FADD, State animal health official, or AD must immediately inform FSIS and the establishment of FMD test results when available.

5) The State animal health official or AD will assess the establishment’s operations and capabilities to hold product, then communicate with FSIS on how to handle animals with lesions. Subject to the AD’s or State animal health official’s discretion, containment options may include:

a. Quarantine affected animals until NAHLN or FADDL reports negative FMD PCR test results. No quarantined animals can be slaughtered until the quarantine is removed as set forth in 9 CFR 309.15(b).

b. Allow eligible animals (not quarantined and passing ante mortem inspection) to proceed to slaughter after collecting FAD samples.

1. All animals must pass FSIS ante mortem inspection procedures per FSIS requirements.
2. All FSIS postmortem regulations, including 9 CFR 311.32, apply. The establishment will hold all carcasses, processed product, and offal, including blood, from infected animals with lesions for distribution or disposal until it receives NAHLN or FADDL lab results. Rendering of affected carcasses and parts is allowed and rendered product may leave the plant.

c. Allow routine slaughter without restrictions and without testing based on FADD findings and AD or State animal health official’s recommendations.

6) Animals with vesicular lesions may not leave an establishment for another establishment until testing for FMD returns negative results. This applies to all animals, including those not presented to FSIS for ante mortem inspection (i.e., resales). Negative NAHLN FMD test results are acceptable for movement decisions by State or APHIS officials. FADDL will confirm the NAHLN results; however, FADDL confirmation is not required prior to allowing movement. Animals cleared to move from a slaughter establishment to another slaughter establishment (reshipment) must comply with all existing USDA, APHIS, and FSIS policies.

7) The FADDs should encourage establishment personnel to follow standard sanitary procedures (biosecurity) to prevent further spread of virus off the establishment.

7. Inquiries

Direct questions regarding this guidance document to the AD overseeing the State in which you are located.