VS Guidance 7406.4

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Recommendations for Swine with Potential Vesicular Disease

1. Purpose and Background

This document provides guidance for handling swine with vesicular lesions, including those suspected of having Senecavirus A (SVA), to ensure that foreign animal disease investigations occur per Animal and Plant Health Inspection Service (APHIS) 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) 161.4(f) and (g). Anyone with suspicion of such a disease is encouraged to report their suspicions to a State or Federal animal health official.

Any swine having vesicular lesions are suspects for foreign animal diseases (FADs), such as foot-and-mouth disease (FMD), until determined otherwise by Veterinary Services (VS) through authorized testing at approved National Animal Health Laboratory Network (NAHLN) laboratories with oversight and confirmatory testing, if required, by the Foreign Animal Disease Diagnostic Laboratory (FADDL). Several viral pathogens may cause vesicular lesions in swine, including FMD virus (FMDV), swine vesicular disease virus, vesicular stomatitis virus, and SVA. Veterinarians are unable to differentiate the etiology of these gross lesions without diagnostic testing.

One virus causing vesicular lesions is Senecavirus A (SVA), also known as Seneca Valley virus. It belongs to the same family as FMDV (Picornaviridae). SVA has been detected in U.S. swine for several years and the virus has been occasionally associated with sporadic outbreaks of vesicular disease of swine. In some recent reported cases, herd morbidity approaches eighty (80) percent, with snout and coronary band vesicular lesions. In other cases, only five (5) percent to ten (10) percent of animals are affected. Veterinarians often report pigs are afebrile, bright, alert, and responsive, although some have reported mortality in pre-weaned pigs.

Vesicular lesions on swine must continue to be reported by State, Federal, and accredited veterinarians to ensure rapid detection of FMD or any other FAD, if introduced. This is done to protect the health, public confidence, and marketability of our nation's livestock health, marketability of meat products, and public confidence.

This guidance document represents the Agency's position on this topic and is intended solely as guidance. It does not have the force and effect of law, does not create or confer any rights for or on any person, and does not bind the U.S. Department of Agriculture (USDA) or the public. Language suggesting that this guidance is mandatory (e.g., "shall,"

"must," "required", or "requirement") should not be construed as binding unless the terms quote from a statutory or regulatory requirement. The information this document 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 herein without appropriate justification and supervisory concurrence.

2. Document Status

A. Review date: 7/31/2024.

B. This document replaces Veterinary Services Guidance 7406.3.

3. Reason for Reissuance

VS is reissuing this guidance to reflect changes in procedure and structure, and to clarify guidance on investigations.

4. Authority and References

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

7 CFR 371.4
9 CFR 71.19
9 CFR part 53
9 CFR part 161
9 CFR 309.15
9 CFR 311.32

B. References:

- VS Guidance:
  VSG 12000.3, Foreign Animal Disease Diagnostician Certification Requirements

  VSG 12001.4, Policy for the Investigation of Potential Foreign Animal Disease/Emerging Disease Incidents (FAD/EDI)

- Other:
  Food Safety and Inspection Service Directive 6000.1, Responsibilities Related to Foreign Animal Diseases (FADs) and Reportable Conditions

  Foreign Animal Disease Investigation Manual

  Ready Reference Guide: Procedures and Policy for the Investigation of Potential Foreign Animal Disease (FAD)/Emerging Disease incidents (EDI)

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5. Audience

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

6. Guidance

A. Reporting Responsibilities of State, Federal, and Accredited Veterinarians

State, Federal, and accredited veterinarians must immediately report all swine cases exhibiting vesicular lesions to Federal or State animal health officials for further investigation to ensure that FMD or another FAD is not the cause of the lesions, per 9 CFR part 161.

B. Performing a FAD Investigation (FADI) in Swine When Vesicular Lesions are Observed

1) VS Guidance documents 12000.3 and 12001.4 describe who can perform FADIs and how VS performs FADIs.

2) VS Area Veterinarians in Charge (AVICs) and State animal health officials (SAHOs) assign foreign animal disease diagnosticians (FADDs) to oversee each case of vesicular disease identified in pigs. Assigned staff enter all investigation information into the USDA Emergency Management Response System (EMRS). AVICs, SAHOs, and FADDs evaluate all information known about the case to determine and assign the FADDL and NAHLN submission priority level. These officials prioritize the FADI and diagnostic testing for disease suspicion; however, they may consider the need to move pigs or products when designating priority.

3) The AVIC, SAHO, and FADD use VS Guidance 12001.4 and the Ready Reference Guide: Procedures and Policy for the Investigation of Potential Foreign Animal Disease (FAD)/Emerging Disease incidents (EDI) (hereinafter "Ready Reference Guide") for guidance on communications protocols. Following VS Guidance 12001.4 keeps all necessary parties aware of the investigation's progress.

4) When vesicular FADIs involve **imported** hogs (from Canada or the low-risk CSF region of the European Union), in addition to entering the FADI case records, the AVIC also notifies VS Strategy & Policy, Live Animal Imports of the investigation.

a. For imported feeding and breeding swine (Canada): The AVIC must immediately report lesions noted within the immediate post-import period (fourteen (14) days).

b. For imported breeding swine (low-risk CSF region of the EU): The AVIC must immediately report lesions noted during the entry quarantine required for these animals.

c. For immediate slaughter swine (Canada): In immediate slaughter facilities where these vesicular FADIs involving imported animals occur, the AVIC provides immediate reports (NAHLN and FADDL testing results when they become available) to VS Strategy & Policy, Live Animal Imports, for discussions with the competent authority of the country of origin.

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

1) All groups of swine identified on farm or in marketing channels exhibiting vesicular lesions compatible with a foreign animal disease must be investigated under the guidance of trained FADD investigators and be tested via approved FADDL standards.

2) FADDs should use known epidemiological information, including knowledge of SVA in the geographic area or historic incidence of SVA in the production system or market/slaughter facility associated with the current report, to assess the likelihood of SVA as a differential diagnosis for the observed vesicular lesions.

3) If supported by the AVIC and SAHO, FADDs should use VS-authorized NAHLN laboratories to conduct preliminary FMD testing if adequate sample volume remains after submitting a complete set of samples to FADDL for FADI testing per VS Guidance 12001.4. Diagnostic laboratories may subsequently conduct other non-FAD testing as requested by the submitting veterinarian, including SVA polymerase chain reaction (PCR) at the submitter's expense. USDA will pay for dual testing for FMD and SVA on samples from SVA high incidence establishments (see section I.).

4) The AVIC or SAHO assigns a priority per VS Guidance 12001.4 and notifies FADDL via e-mail at FAD.Submissions@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 the AVIC or SAHO suspect SVA as the cause of the lesions. Priority 2 or Priority 3 investigations should be upgraded to Priority A only if pigs cannot be released for movement based on NAHLN results.

5) The AVIC and SAHO may use the clinical presentation and NAHLN FMD diagnostic test result with an assessment of establishment product flow to make initial recommendations to establishment management regarding disposition and movement of the animals or carcasses after sampling.

6) The NAHLN testing laboratory immediately calls controlling State and VS animal health officials if FMD screening test results are non-negative. A non-negative FMD test result from the NAHLN laboratory immediately elevates the

investigation to Priority 1 per the guidance provided in the controlled document MAN-NAHLN-0002 "NAHLN Laboratory Guide for Foreign Animal Disease (FAD) Investigations"[1]. FADDL must confirm all non-negative NAHLN FMD lab results. NAHLN reports negative results per routine electronic messaging methods or as requested by the SAHO or AVIC.

7) The AVIC, SAHO, and FADD conduct response activities as provided in VS Guidance 12001.4 and outlined in the Ready Reference Guide.

8) When vesicular FADIs involve **imported** Canadian-origin immediate slaughter hogs, the AVIC notifies VS Strategy & Policy, Live Animal Imports of the investigation (see B.4) c. above).

D. Diagnostic Testing at NAHLN Laboratories Receiving Private Submissions from Swine with Vesicular Lesions Not Previously Associated with a FADI (no assigned Referral Control Number (RCN))

1) NAHLN laboratories should follow the guidance provided in the controlled document MAN-NAHLN-0002 "NAHLN Laboratory Guide for Foreign Animal Disease (FAD) Investigations".

2) Each sample submitted to a NAHLN laboratory for FMD testing must have a FAD RCN assigned, even if the samples are not initially associated with a FADI. If a veterinarian submitted samples from a vesicular case without a FAD RCN, the laboratory contacts its local SAHO or AVIC. Should the samples in question originate in another State, the laboratory immediately notifies the AVIC and/or SAHO of the State of origin through (or at the direction of) the local AVIC and/or SAHO associated with the testing NAHLN laboratory. Per VS Guidance 12001.4, the AVIC or SAHO ***of the State of origin*** assigns a FAD RCN and also assigns a priority per VS Guidance 12001.4 and notifies FADDL via email at FAD.Submissions@usda.gov.

3) The NAHLN laboratory determines whether sample size and quality are adequate for testing at both the NAHLN laboratory and FADDL:

a. NAHLN laboratories should follow the guidance provided in the controlled document MAN-NAHLN-0002 "NAHLN Laboratory Guide for Foreign Animal Disease (FAD) Investigations".

b. If sample volume is insufficient, the laboratory clinician in charge must ship the entire sample volume to FADDL per SAHO and/or AVIC instructions. He or she should also inform the submitter and FADDL of the lack of sufficient volume and inability to perform testing.

[1] NVSL does not post this document to a publicly available website but will provide it on request.

c. The NAHLN laboratory may conduct the FMD PCR following receipt of a FAD RCN and reservation/shipment of materials for testing at FADDL. If sufficient sample volume remains after reservation of sample materials for FADDL and for FMD testing by the authorized NAHLN laboratory, the lab may conduct other non-FAD testing as requested by the submitting veterinarian, including SVA PCR at the submitter's expense. USDA will pay for dual testing for FMD and SVA on samples from SVA high incidence establishments (see section I.).

4) In cases where an accredited veterinarian submits a case with vesicular lesions to a NAHLN laboratory without required notification, the AVIC or SAHO discuss clinical presentation and review FAD reporting guidelines with the accredited veterinarian. If deemed necessary based on this discussion, the AVIC or SAHO may assign a FADD to the case for further field investigation and FAD sample collection if indicated.

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

1) In situations where epidemiologically-linked sites (production flows) show evidence of vesicular disease and the origination site has FAD-negative results confirmed by FADDL within fourteen (14) days prior to the start date of the FADI, accredited veterinarians may conduct a follow-up FADI only under the following conditions:

a. A FADI by a FADD has been completed within the last fourteen (14) days at an epidemiologically linked production flow site, and the epidemiologically linked site has FAD-negative results confirmed by FADDL.

b. The accredited veterinarian (or veterinarians) agree(s) to collect, package, and send samples to FADDL and the NAHLN (if applicable) per AVIC and SAHO instructions, and in accordance with VS Guidance 12001.4.

c. The accredited veterinarians understand that the USDA role is to perform diagnostic testing to identify or rule out FADs. Production-based disease testing may require additional tissue volume for further diagnostics at a veterinary diagnostic laboratory following rule out of FADs at an approved NAHLN laboratory and/or FADDL. USDA does not test for other diseases.

2) Accredited veterinarians immediately contact the AVIC or SAHO and report any unexpected change in morbidity, mortality, or clinical findings of vesicular disease within epidemiologically linked production flow sites. If necessary, the AVIC or SAHO initiates a new FADI.

3) The AVIC or SAHO provides a FAD RCN for all cases. NAHLN laboratories cannot test for FMD or any other FAD without the FAD RCN unless specific and express permission is granted by the NAHLN program office and FADDL. The VS Field Operations office in the State that assigned the RCN ensures appropriate FADI data gets entered into EMRS.

4) The AVIC or SAHO assigns a priority per VS Guidance 12001.4 and notifies FADDL via email at: FAD.Submissions@usda.gov.

F. Critical Information for Producers and Accredited Veterinarians During and After a FADI

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

2) Communicate as provided for in VS Guidance 12001.4 and outlined in the Ready Reference Guide.

3) Notify the AVIC or SAHO 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 interstate commerce meet all State and Federal animal health requirements including those set forth in 9 CFR 71.19.

5) Contact the SAHO in the receiving State when scheduling interstate movement of non-slaughter swine from investigated premises for thirty (30) days following the completion of a FADI. The receiving SAHO informs the accredited veterinarian whether any additional documentation (such as the FAD RCN) is needed to issue a certificate of veterinary inspection (CVI) or other interstate movement document, including a swine production system record summary for interstate movement of non-slaughter swine.

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

1) The accredited veterinarian or producer contacts the SAHO or AVIC responsible for the State where the premises is located to report the expected date of slaughter and details on the establishment responsible for the slaughter.

2) The SAHO or AVIC provides official correspondence to the USDA Food Safety and Inspection Service (FSIS) District Office overseeing the establishment to which the animals are destined for slaughter or to the AVIC and/or SAHO in the State where the establishment is located to coordinate with FSIS.

This correspondence could include:

a. Documentation that a FADI occurred and corresponding laboratory reports indicating the animals tested from that premises are negative for FMD within the last thirty (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 FADI:

1. NAHLN negative test report for FMD.

2. FADDL negative test report for FMD.

3. State-issued CVI stating that the pigs were tested for FMD and were negative with the laboratory 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.

5. An affidavit from the SAHO or AVIC stating the pigs from the premises tested negative for FMD. The affidavit should be on letterhead from a SAHO 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 and the FSIS Public Health Veterinarian of a completed FADI in the last thirty (30) days at the arriving animals' premises of origin.

4) If the shipper arrives at the slaughter establishment without the required documentation indicated in G.2)a, the shipper should contact the SAHO or the AVIC for the required information.

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

1) FSIS policy, per FSIS Directive 6000.1, requires immediate notification to the AVIC or SAHO when any livestock are found to have vesicular conditions at antemortem inspection (per 9 CFR 309.15) through the respective FSIS District Office overseeing the establishment.

2) FSIS Directive 6000.1 provides instructions to FSIS personnel regarding FADs based on input from APHIS. FSIS defers to SAHO or AVIC recommendations.

3) If the AVIC or SAHO determines it necessary to assign a FADD to the slaughter establishment, the AVIC or SAHO follows directions as provided in the FADI Manual section 8.4 for "Slaughter Establishment FAD Investigation Process."

4) The FADD, SAHO, or AVIC immediately informs FSIS and the establishment of FMD test results when available.

5) The SAHO or AVIC assesses the establishment's operations and capabilities to hold or maintain control of product from affected swine without release into commerce, then communicates with FSIS on how to handle animals with lesions. Subject to the AVIC's or SAHO's discretion, containment options may include:

   a. Quarantining affected animals until NAHLN and/or FADDL reports negative FMD PCR NAHLN or FADDL test results at the discretion of the AVIC and SAHO. No quarantined animals are to be slaughtered until the quarantine is removed as set forth in 9 CFR 309.15(b).

   b. Allowing eligible animals (not quarantined and passing antemortem inspection) to proceed to slaughter after collecting FAD samples.

      1. All animals must pass FSIS antemortem inspection procedures per FSIS requirements.

      2. All FSIS postmortem regulations, including 9 CFR 311.32, apply.

      3. The following subparts present potential options of allowing eligible animals to proceed to slaughter. This list does not include all options, and the SAHO and AVIC should design a plan that works for each establishment's unique situation and needs.

         i. Slaughter lesioned pigs with the entire lot (no separation of lesioned vs. non-lesioned animals). The establishment must maintain control of all product and offal (no release into commerce) from the entire lot until negative FMD diagnostic results are received and State/Federal regulatory officials recommend release, unless the establishment has a robust carcass tracking system that allows for lesioned carcasses and all offal to be easily held separately from the unaffected carcasses.
         ii. Consider slaughtering lots with lesioned pigs as the last group(s) of the day to facilitate separating product and offal from unaffected lots. Establishments can choose to hold an entire day's production and offal should management deem this necessary.
         iii. Separate lesioned pigs from the non-lesioned pigs in the lot and slaughter lesioned pigs as the last lot of the day. The establishment must maintain control of all product and offal (no release into

commerce from the lesioned animals in this separated lot until receiving negative FMD diagnostic results and State/Federal regulatory officials recommend release).

iv. Hold entire lots with any lesioned pigs for slaughter until receiving negative FMD diagnostic results and State/Federal regulatory officials recommend release.

v. Test and condemn lesioned animals. Allow non-lesioned animals in the same lot to be slaughtered if they pass antemortem inspection.

4. The following subparts present potential options for holding and tracking product from affected lots or pigs. These options depend on State requirements, cold storage space availability at the slaughter facility, product and carcass tracking methods in use at the slaughter facility, and FADD suspicion of potential for FAD:

i. For an initial FADI at an establishment: The SAHO may request all carcasses and offal from the affected lot be held or tracked (without release into commerce) until negative diagnostic results are received.

ii. For repeat or regularly occurring FADIs at an establishment: The establishment and State/Federal animal health officials should work out a plan that maintains continuity of business while also allowing traceability of product without release into commerce in the event of non-negative FMD results including, but not limited to, the following examples:

- Holding affected carcasses in the retained cage.
- Storing carcasses and/or product from affected lots in a separate area of the cooler, identified as held product/quality control hold.
- Uniquely identifying each carcass, recording carcass IDs from the affected carcasses in the lot, so product can continue to be processed but can still be located.
- Offal from affected animals or lots should be held onsite, unless rendering is available onsite, until the negative FMD laboratory results become available.
- When FMD is suspected, it is the responsibility of the slaughter establishment to ensure that carcasses, product, and/or offal are appropriately controlled and not released into commerce until negative FMD laboratory results become available. Establishments that are designated as high incidence and have received specific approval may not be required to hold product.

iii. In the event of a confirmed FMD diagnosis of an investigation, segregation of lesioned lots or individual affected animals may not

prevent hold and disposition of the entire shift's kill as an additional protective measure against further spread of infection.

6) Animals with vesicular lesions and the unaffected (exposed) animals in the same lot shall 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 antemortem 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) FADDs should encourage establishment personnel to follow standard sanitary procedures (biosecurity) to prevent spread of virus off the establishment.

I. Options for SVA High Incidence Establishments

1) As SVA prevalence increases over time in slaughter channels and processing establishments, some establishments experience multiple FADIs per week, creating a large labor burden on FADDL as the reference laboratory and field personnel.

2) When processing establishments average three (3) or more days with a FADI per week over a continuous four (4) week period, the AVIC may request that the Swine Health Staff add the establishment to the high-incidence establishment list.

a. For States in which these establishments are located, AVICs may also request special permission to allow non-FADDs to collect samples from these establishments. Conditions upon which this permission is based include the potential for oversight and training of non-FADD collectors, the relationship and capabilities of the NAHLN laboratory in the State, and other factors.

b. In concurrence with the NAHLN Coordinator (or designee) and FADDL, Swine Health staff will add the establishment to the list of establishments considered high incidence, maintained by the Swine Health staff.

c. FADDs collecting samples from high incidence establishments will ship duplicate samples to the approved NAHLN laboratory. NAHLN results will be considered final, if FMD negative and SVA positive by real-time PCR.

d. FADDL will also test any FADI samples that had negative results for both FMD and SVA, or non-negative results for FMD.

e. When vesicular FADIs involve imported hogs, the AVIC will notify VS Strategy & Policy, Live Animal Imports of the investigation (emailing NAHLN and FADDL testing results when they become available).

f. Establishments will remain on the high-incidence list unless the AVIC requests their removal. AVICs and epidemiologists should monitor periodically to ensure that the establishment continues to meet the requirements to be considered a high incidence establishment.

7. Inquiries

Direct questions regarding this guidance document to the AVIC overseeing the State where you are located or national swine staff via e-mail at VS.SP.ASEP.Swine@usda.gov.