

VS Guidance 12001.5

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

1. Purpose and Background

This document provides Veterinary Services (VS) policy for field investigation and communication regarding a potential Foreign Animal Disease/Emerging Disease Incident (FAD/EDI). The [Foreign Animal Disease Investigation Manual](#) provides specific communication and operational procedures.

FAD/EDI investigations provide a veterinary assessment that consists of the following:

- Differential diagnosis.
- Investigation classification ranks and prioritizes the differential diagnosis in terms of the magnitude of suspicion for a FAD in relation to the magnitude of suspicion for an endemic disease or condition.
- Designation of diagnostic sample priority ranks and prioritizes the speed at which diagnostic samples are collected, transported, and tested. The Foreign Animal Disease Diagnostician (FADD), Area Veterinarian in Charge (AVIC), and state animal health official (SAHO) must concur on the designation of diagnostic sample priority. These individuals may also consult the National Veterinary Services Laboratories (NVSL) on priority levels.

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: 5/30/2027.
- B. This document replaces Veterinary Services Guidance 12001.4.

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3. Reason for Reissuance

VS is reissuing the document to update internal references and links.

4. Authority and References

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

- [7 CFR part 331](#)
- [7 CFR 371.4](#)
- [9 CFR part 53](#)
- [9 CFR part 71](#)
- [9 CFR part 82](#)
- [9 CFR part 94](#)
- [9 CFR part 121](#)
- [9 CFR part 122](#)
- [9 CFR part 161](#)
- [49 CFR part 173](#)

B. References:

- [VSG 12000.4, Foreign Animal Disease Diagnostician Certification Requirements](#)
- [Ready Reference Guide: VSG 12001.5](#)
- [Foreign Animal Disease Investigation Manual](#)
- [Introduction to the FAD Preparedness and Response Plan](#)
- [VS Emerging Animal Disease Preparedness and Response Plan](#)

C. Definitions:

- 1) Foreign Animal Disease (FAD): A terrestrial animal disease or pest, or an aquatic animal disease or pest, not known to exist in the United States or its territories. A FAD may be a World Organisation for Animal Health (WOAH) listed terrestrial or aquatic animal disease (woah.org); additionally, at any time, the Secretary of Agriculture, or their designee, may designate a disease or pest as a FAD. Occasionally, "FAD" may be used interchangeably with Transboundary Animal Disease (TAD). An emerging disease is defined in the [VS Emerging Animal Disease Preparedness and Response Plan](#). An Emerging Disease Incident (EDI) is any incident involving an emerging disease that requires field investigation. An FAD/EDI may involve livestock, poultry, other animals, or wildlife. In the event of an FAD/EDI investigation involving wildlife, VS will work in close collaboration, communication, and coordination with state, tribal, and federal wildlife agencies with primary wildlife jurisdiction and subject matter expertise.

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- 2) Foreign Animal Disease Diagnostician (FADD): A federal- or state-employed veterinarian who has successfully completed specialized FAD diagnostician training at the NVSL, as well as any other specialized training and continuing education as required and administered by VS, including requirements specified in VS Guidance 12000.4.

VS Professional People Training (PPT) maintains a national roster of currently available or active FADDs. VS District Directors or designees maintain District rosters of currently available and equipped FADDs. AVICs maintain a roster of currently available and equipped FADDs in the jurisdiction(s) for which they are responsible.

- 3) USDA Case Definition: The VS Deputy Administrator is responsible for FAD/EDI diagnostic case definitions. Criteria to meet “presumptive” and “confirmed” FAD/EDI infections vary by disease. Refer to the Animal Health Surveillance SharePoint Site for disease-specific case definitions.

5. Audience

VS employees, state and local cooperators, and accredited veterinarians.

6. Guidance

VS defines the FAD/EDI investigation period as the time from when the AVIC , or their designee, and the SAHO, or their designee, initiate a field investigation until the time a FAD/EDI is ruled out or confirmed per the appropriate case definition by a FADD field investigation and official NVSL diagnostic test results, as applicable.

A. FAD/EDI Investigation

Critical elements of an investigation include but are not limited to:

Interviewing persons for incident history; observing clinical signs; physically examining animals; collecting and analyzing epidemiological information; collecting diagnostic samples as necessary; performing necropsies as necessary; investigating traces of animals, animal products, meat, articles, or conveyances as necessary; recommending and establishing intrastate quarantine as necessary (under the SAHO’s authority); and recommending and establishing interstate quarantines during the investigation period as necessary (under the Secretary of Agriculture’s authority).

Data and information collected during an investigation includes but is not limited to:

Species affected, duration of illness, clinical signs and lesions observed, herd/flock morbidity and mortality rates, vaccination history, diagnostic test history, nutritional

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status, premises conditions, movement history, contact history, evidence or indication of pest or vector, and evidence or indication of zoonotic disease.

B. Veterinary Assessment

- 1) Identify and rank the differential diagnoses and determine the level of suspicion for an FAD versus an endemic disease or condition.
 - a. The FADD, as part of the required field investigation, will determine whether sample collection for diagnostic testing is necessary to rule out or confirm the FAD/EDI. However, the AVIC and SAHO retain the right to request diagnostic sample collection during an FAD/EDI investigation.
 - b. The FADD, AVIC, and SAHO should concur on the designation of the VS diagnostic priority (see Section 6.C). These officials may also consult NVSL regarding questions about priority levels.
 - c. Where needed, the AVIC and SAHO, with the FADD, NVSL, and director of the state's National Animal Health Laboratory Network (NAHLN) laboratory, can quickly consult to determine a diagnostic sample submission plan that may include a duplicate set of samples being sent to a NAHLN Laboratory (refer to Section 6.B.2)).
 - d. Packaging and labeling biological substances for shipment requires familiarity with and training in current rules and regulations, which frequently change. Shippers are responsible for proper packaging, marking, labeling, documentation, classification, and shipment identification. Failure to follow regulations can result in substantial financial penalties. For more information, please refer to "[Packaging and Labeling Submissions to the NVSL.](#)"
- 2) Provide official diagnostic test results according to the assigned VS diagnostic priority to rule out or confirm a suspected FAD/EDI agent.
 - a. Collectors may collect duplicate samples at the discretion of the FADD, AVIC, and SAHO in coordination with NVSL and the NAHLN laboratory director.
 - b. If the FADD can collect only one set of samples, they must send them to the appropriate NVSL Laboratory, not the NAHLN laboratory.
 - c. Send one set of diagnostic samples to the appropriate NVSL laboratory. For more information, refer to the [General NVSL Information](#) webpage for the appropriate NVSL laboratory.

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- d. Send the second set to the appropriate NAHLN laboratory (refer to list of [NAHLN Laboratories](#)); due to geographic proximity, the NAHLN Laboratory may receive and test samples for approved FADs before NVSL receives them. Testing for endemic diseases should start only after FADs are ruled out.
- 3) Recommend and implement the appropriate veterinary medical countermeasures, regulatory actions, and communications during the investigation period as necessary to prevent and/or mitigate the dissemination of an FAD/EDI agent by interstate or international commerce of animals, animal products, meat, articles, or conveyances.

This includes state or interstate quarantines as necessary (under the SAHO's authority) during the investigation period. Examples of interstate or international commerce include but are not limited to slaughter or harvest facilities, processing or packing facilities, auction markets, exhibitions or shows, and interstate or international import-export-facilities. The appropriate veterinary medical countermeasures, regulatory actions, and communications will depend on factors such as:

- a) The epidemiology of the suspected FAD/EDI agent (e.g., a highly contagious disease).
 - b) The clinical and epidemiological findings obtained during the investigation as they correspond to the case definition for the suspected FAD/EDI disease agent (before obtaining presumptive or confirmatory diagnostic testing results).
 - c) The federal, state, territory, and tribal jurisdictions and authorities as applied to the specific situation.
- C. Investigation Classification and VS Diagnostic Priority
- 1) VS classifies FAD/EDI investigations by level of suspicion (Table 1) and defines four diagnostic priorities (Table 2). The diagnostic priority should be consistent with the level of FAD/EDI suspicion, and consider the location of the investigation, density of susceptible species, and potential onward consequences. The diagnostic priority assigned determines the expediency of the investigation from collection of samples to test results.

Table 1: Classification of FAD/EDI Investigations and Definitions

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Classification of Investigations	Definition
High Suspicion	The veterinary medical and regulatory assessments conducted are consistent with an FAD/EDI and are generally inconsistent with an endemic disease/condition.
Intermediate Suspicion	The veterinary medical and regulatory assessments conducted are consistent with an FAD/EDI but are also consistent with an endemic disease/condition.
Low Suspicion	The veterinary medical and regulatory assessments conducted are generally inconsistent with an FAD/EDI and are consistent with an endemic disease/condition.

2) VS diagnostic priority designations

- a. VS Priority 1 is only applied to investigations where there is a High Suspicion of a FAD/EDI. For these investigations, VS emphasizes obtaining confirmatory test result(s) as soon as possible and expects sample collection, transportation, and diagnostic testing to be conducted safely and quickly. This may require extraordinary measures.

Extraordinary transportation methods include hand-carried samples, couriers, counter-to-counter services, and contracted commercial air/land services. Overnight transportation methods include courier services such as FedEx® and UPS® with delivery options that can be tailored appropriately.

Priority 1 investigations may require night, weekend, or holiday work to complete the diagnostic testing on the day of sample receipt; NVSL applies overtime as needed. NAHLN laboratories are also expected to perform testing as requested on the day of receipt; payment of overtime to NAHLN laboratory personnel varies by state.

Required notifications for incoming Priority 1 submissions:

- 1. Email (confirmed) and verbal notification to the receiving NAHLN and/or NVSL laboratory and the NAHLN Coordinator(s), including sample submission form(s) and shipment tracking/courier information.

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2. Email (confirmed) and verbal notification of the National Preparedness and Incident Coordination (NPIC) Center.
- b. Priority A designation is only used for an Intermediate Suspicion of a FAD/EDI classification or Low Suspicion of a FAD/EDI classification when animals, animal products, meat, articles, or conveyances in interstate or international commerce are involved and/or are potentially held, delayed, or quarantined pending the results of diagnostic testing or studies for a FAD. Priority A investigations may also require extraordinary transportation measures, and overtime work to complete the diagnostic testing on the day of sample receipt as with Priority 1 submissions.
- Required notifications for Priority A submissions:
1. Email (confirmed) and verbal notification to the receiving NAHLN and/or NVSL Laboratory and the NAHLN Coordinator(s), including sample submission form(s) and shipment tracking/courier information.
 2. Email (confirmed) and verbal notification of NPIC.
- c. VS Priority 2 is used for investigations where there is an Intermediate Suspicion of an FAD/EDI. The timeline from sample collection to test results should be no more than two (2) business days. NVSL and NAHLN laboratory personnel are expected to perform same day testing during their normal business hours. The labs will test diagnostic samples arriving after the close of business the following business day. Saturday testing only occurs with prior notification and agreement among state, federal, and NVSL and/or NAHLN laboratory personnel. Payment of overtime to NAHLN laboratory personnel varies by state.
- Required notifications for Priority 2 submissions:
- Verbal or email notification to the receiving NAHLN and/or NVSL laboratory and the NAHLN Coordinator(s) including sample submission form(s) and shipment tracking/courier information.
- d. VS Priority 3 is applied where there is Low Suspicion of an FAD/EDI or samples are collected for routine surveillance. Investigations with this designation use routine methods and turnaround times for sample collection, transport, and diagnostic testing. NVSL and NAHLN laboratory personnel perform diagnostic testing in routine accession order as received and without overtime.

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Email notifications for incoming Priority 3 submissions are recommended to the receiving NAHLN and/or NVSL laboratory and the NAHLN Coordinator(s), including sample submission form(s) and shipment tracking/ courier information.

Table 1: VS Diagnostic Priorities by Investigation Classification

Diagnostic Priority	Investigation Classification	Urgency of Sample Collection, Transportation, and Testing	Speed and Type of Contact Needed
Priority 1	High Suspicion	Rapid to extraordinary methods	Immediate notification of NPIC, NVSL, and NAHLN by phone
Priority A	Intermediate or Low Suspicion	Rapid to extraordinary methods	
Priority 2	Intermediate Suspicion	Rapid methods	Timely notification of NVSL and NAHLN by phone or email
Priority 3	Low Suspicion	Routine methods	

Refer to [Ready Reference Guide 12001.5](#) for the step-by-step process and procedures for conducting FAD/EDI investigations.

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D. Official Testing Laboratories

1) National Veterinary Services Laboratories (NVSL)

NVSL is the official reference laboratory for FAD/EDI diagnostic testing in the United States. NVSL conducts all confirmatory testing related to FAD/EDI investigations in the United States unless otherwise specified by the Animal and Plant Health Inspection Service (APHIS) Administrator, or as delegated to the VS Deputy Administrator.

NVSL has multiple laboratories and locations for FAD/EDI diagnostic testing: Consult the [NVSL website](#) or call NVSL at (515) 337-7601 for the appropriate location to send samples if there are questions. In general, the reference laboratory will accept the samples at their primary location, but in certain cases, testing may be available at alternative locations.

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Table 3. NVSL laboratories and abbreviated list of species/syndromes tested.

NVSL Lab	Abbreviated list of species/syndromes*	Location
NVSL-Diagnostic Virology Laboratory	FAD/EDIs viral diseases for avian, aquaculture, equine, companion animals, congenital malformations due to Orthobunyaviruses (Akabane, Schmallenberg, Aino), Heartwater, porcine Teschovirus encephalomyelitis (unless hemorrhagic rule-out), influenza in any species	National Center for Animal Health (NCAH)- Ames, IA
NVSL-Diagnostic Bacteriology and Pathology Laboratory	FAD/EDIs -Bacterial diseases for all species, with emphasis on the bacterial tier one agents and Brucellosis, and transmissible spongiform encephalopathies (i.e., BSE).	NCAH- Ames, IA
NVSL-Diagnostic, Bioanalytical, and Reagent Laboratory	FAD/EDI's for entomologic conditions (i.e., ticks, haemoparasites, maggots, screwworms)	NCAH- Ames, IA
NVSL-Foreign Animal Disease Diagnostic Laboratory	FAD/EDIs for ruminant and swine (including vesicular and hemorrhagic fever rule-outs), rabbits	Plum Island Animal Disease Center, NY or National Bio-and Agro Defense Facility, Manhattan, KS

*For further information of testing at NVSL Laboratories by species or suspected disease please refer to the [Foreign Animal Disease Investigation Manual](#).

Users can find additional information regarding NVSL on the [General NVSL Information](#) web page.

2) National Animal Health Laboratory Network (NAHLN)

The NAHLN, created in 2002, is a comprehensive, coordinated, and modernized network of federal, state, and university-associated animal health laboratories that provide animal health diagnostic testing to detect biological threats to animal agriculture, thus protecting animal health, public health, and the nation's food supply. The NAHLN enhances early detection, rapid response, and appropriate recovery from high-consequence animal diseases, including FAD agents and

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emerging diseases, including the potential for bioterrorist events or intentionally introduced agents.

VS trains, proficiency tests, and approves NAHLN laboratory personnel to conduct testing for several high-consequence FADs. With the approval of the SAHO and AVIC, FADDs can collect FAD samples in duplicate to send one set to the local NAHLN laboratory and the other to NVSL.

If an FAD/EDI outbreak occurs, VS provides further guidance on diagnostic sample submissions to NAHLN laboratories.

Users can find a current roster of the NAHLN laboratories and the testing they are approved to perform on the [NAHLN Laboratories](#) web page.

- 3) In the rare occurrence of an emergent situation involving testing that is not offered by NVSL, arrange an immediate conference call with the AVIC, SAHO, and the NVSL Director to determine the disposition of the samples.

E. Communication and Reporting

1) Federal-state-tribal communication and cooperation

The coordinated federal-state-tribal response to a potential FAD/EDI requires close communication and cooperation among all stakeholders and jurisdictions. The AVIC and the SAHO (or designee) must closely communicate and cooperate on all aspects of an FAD/EDI investigation from initiation to completion.

The AVIC and/or SAHO must initiate all FAD/EDI investigations. The AVIC and/or the SAHO must assign all FAD/EDI investigations to an FADD. The AVIC and/or the SAHO must initiate the investigation of all credible reported or suspected FADs/EDIs timely, including assigning a FADD to complete a site visit or field investigation as a required part of the investigation. Refer to the [Ready Reference Guide 12001.5](#) for the step-by-step process and procedures for conducting FAD/EDI investigations.

Timely communication within the state and tribal communities should include the VS District Director, AVIC, and SAHO.

The FADD, AVIC, and SAHO must concur on the classification of the investigation and the diagnostic priority and determine whether collectors should send duplicate samples to a NAHLN Laboratory and NVSL. If officials do not concur, or have questions or concerns, the AVIC should contact NPIC staff to host and

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coordinate an immediate conference call to include the SAHO and NVSL Director to resolve the issue quickly.

The AVIC and/or SAHO assigns a FAD/EDI Case Coordinator to assist with investigation support, communications, and Emergency Management Response System (EMRS) data entry, as required by the location, scale, complexity, or urgency of the investigation.

2) Emergency Management Response System (EMRS)

The EMRS “Routine FAD/EDI Reporting” is the official APHIS web-enabled database recording all FAD/EDI investigations. The EMRS database automatically sends email notices to selected VS personnel when VS initiates FAD/EDI investigations in the system. This capability enables the field office and NPIC to monitor potential national “clusters” of FAD/EDI investigations in real-time.

The AVIC, or their designee, ensures the EMRS Referral Control Number is assigned and transmitted to the FADD and the SAHO. EMRS must be used for all FAD/EDI investigations.

[EMRS](#) is accessed through the internet and permits approved state, VS, and NAHLN Laboratory personnel access to enter and view investigations from their state or territory. All entries are confidential. EMRS database access at the state or territory level is controlled and maintained with AVIC and SAHO approval.

3) Reporting

The AVIC and SAHO produce situation reports and diagnostic updates based on NAHLN and NVSL official test results and regulatory assessments as required by the urgency or complexity of the investigation or at intervals requested by the Field Office, the VS Associate Deputy Administrator for Strategy and Policy (the VS unit in which NPIC resides), and/or the VS Deputy Administrator.

Because of the rapid exchange of information required during FAD/EDI investigations, call, email, and/or fax information when needed, in addition to recording information in EMRS.

7. Inquiries

Please send all inquiries regarding these procedures or instructions to the NPIC staff:

Main Office: NPIC, Strategy and Policy. Please refer to the [Foreign Animal Disease Investigation Manual](#) for contact numbers.

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Business Hours: Monday – Friday 8 a.m. to 4:30 p.m. Eastern Time, NPIC/National Veterinary Stockpile (NVS) 24/7 Emergency Answering Service.

Foreign Animal Disease Investigations or Emerging Disease Incidents National Veterinary Stockpile Activation: 1-800-940-6524.