



VS Guidance 12001.4

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 of a potential Foreign Animal Disease/Emerging Disease Incident (FAD/EDI). Specific communication and operational procedures are provided in the [Foreign Animal Disease Investigation Manual](#).

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: 01/15/2024.
- B. This document replaces Veterinary Services Guidance 12001.3.

3. Reason for Reissuance

VS is reissuing this guidance to reflect changes in procedure and structure.

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](#)



VS Guidance 12001.4

- [9 CFR part 121](#)
- [9 CFR part 122](#)
- [9 CFR part 161](#)
- [49 CFR part 173](#)

B. References:

- VSG 12000.3, "Foreign Animal Disease Diagnostician Certification Requirements"
- [Foreign Animal Disease Investigation Manual](#)
- [Introduction to the FAD Preparedness and Response Plan](#)

C. Definitions:

- 1) 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 (OIE) listed terrestrial or aquatic animal disease (www.oie.int); additionally, at any time, the Secretary of Agriculture, or his or her 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 the [VS Emerging Animal Disease Preparedness and Response Plans](#). An EDI is any incident involving an emerging disease that requires field investigation. A FAD/EDI may involve livestock, poultry, other animals, or wildlife.

In the event of a FAD/EDI investigation involving wildlife, VS will work in close collaboration, communication, and coordination with State, Tribal, and Federal wildlife agencies with primary jurisdiction and subject matter expertise for wildlife.

- 2) Foreign Animal Disease Diagnostician (FADD): A Federal or State employed veterinarian who has successfully completed specialized FAD diagnostician training at the National Veterinary Services Laboratories (NVSL), as well as any other specialized training and continuing education as required and administered by VS, including requirements specified in VS Guidance Document 12000.3.

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. Area Veterinarians in Charge (AVIC) maintain a roster of currently available and equipped FADDs in the jurisdiction(s) for which they are responsible.

5. Audience

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



VS Guidance 12001.4

6. Guidance

The FAD/EDI investigation period is defined as the time from when the AVIC or his or her designee, and the State animal health official (SAHO) or his or her designee, initiate a field investigation until the time a FAD/EDI is ruled out or confirmed by a FADD field investigation, official NVSL laboratory diagnostic testing or study results, or by official VS case definitions.

A. Objectives

- 1) Provide a veterinary assessment that consists of the following:
 - a. Differential diagnosis.
 - b. Classification of investigation, which is necessary to rank and prioritize 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.
 - c. Designation of diagnostic sample priority, which is necessary to rank and prioritize the speed at which diagnostic samples are to be collected, transported, and tested; the FADD, AVIC, and SAHO must concur on the designation of diagnostic sample priority. The Diagnostic Services Section head at NVSL's Foreign Animal Disease Diagnostic Laboratory (FADDL) may also be consulted for input on priority levels.
- 2) Provide presumptive and confirmatory diagnostic testing results as rapidly as required by the designation of diagnostic sample priority to rule out or confirm a suspected FAD/EDI agent.

The FADD, as part of the required site visit or field investigation, will determine if diagnostic sample testing or studies are necessary to rule out or confirm the FAD/EDI. The AVIC and SAHO retain the right to request diagnostic sample collection during a FAD/EDI investigation. The AVIC and SAHO, along with the FADD, NVSL, and laboratory director of the State National Animal Health Laboratory Network (NAHLN) laboratory, determine a diagnostic sample submission plan that may include a duplicate set of samples being submitted to a NAHLN lab.

- 3) Ensure the appropriate veterinary medical countermeasures, regulatory actions, and communications are recommended and implemented during the investigation period, as necessary, to prevent and/or mitigate the dissemination of a FAD/EDI agent by interstate or international commerce of animals, animal products, meat, articles, or conveyances. 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



VS Guidance 12001.4

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 (such as 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 State, Federal, territory, and Tribal jurisdictions and authorities as applied to the specific situation.

B. Critical Elements

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 necropsy studies as necessary; investigating trace backs and trace forwards 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).

Critical data and information collected during an investigation includes but is not limited to: The species affected, clinical signs, lesions observed, herd/flock morbidity and mortality rates, duration of illness, vaccination history, diagnostic test history, nutritional status, premises conditions, movement history, contact history, evidence or indication of pest or vector, and evidence or indication of zoonotic disease.

C. Classification of Investigations and Correlation to Designation of Diagnostic Sample Priority

1) Classification of FAD/EDI investigations and definitions

Classification of investigation, one of the FAD/EDI investigation objectives, represents the degree of suspicion for a FAD/EDI in relation to the degree of suspicion for an endemic disease or condition. Table 1 presents the three options for classifying FAD/EDI investigations and their definitions.



VS Guidance 12001.4

Table 1: Classification of FAD/EDI Investigations and Definitions

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

2) Diagnostic sample priority designations

There are four diagnostic sample designations used during a FAD/EDI investigation. Designations take into account the magnitude of suspicion for a foreign animal disease, as well as the investigation location and consequences related to the speed of the investigation. Designations determine the speed with which sample collection, transportation, and diagnostic study are completed.

- a. Samples designated as Priority 1 are only used for investigations where there is a High Suspicion of a FAD/EDI. Complete sample collection, transportation, and diagnostic testing using rapid to extraordinarily rapid methods. NVSL and NAHLN personnel perform diagnostic testing and studies as rapidly as possible when samples arrive at the laboratory, including nights, weekends, and holidays. NVSL uses overtime as necessary to begin and complete diagnostic testing and studies.

NAHLN laboratories perform testing as requested. Payment of overtime to NAHLN laboratory personnel varies by State. Extraordinary collection and transportation methods are required when the Priority 1 investigation includes a highly contagious FAD/EDI in the differential diagnosis, or when animals, animal products, meat, articles, or conveyances are involved or engaged in interstate or international commerce. This includes but is not limited to animals, animal products, meat, articles, or conveyances currently held in slaughter or harvest facilities, processing or packing facilities, auction



U.S. DEPARTMENT OF AGRICULTURE

Marketing and Regulatory Programs
Animal and Plant Health Inspection Service
Veterinary Services

VS Guidance 12001.4

markets, exhibitions or shows, and interstate or international import-export facilities. The National Preparedness and Incident Coordination (NPIC) Center must be notified by telephone of High Suspicion classifications. NVSL must be notified as well by telephone of a Priority 1 submission.

- b. Priority 2 sample designations are used for investigations where there is an Intermediate Suspicion of a FAD/EDI. Use rapid methods to collect, transport, and study diagnostic samples. NVSL and NAHLN personnel perform diagnostic testing and studies immediately if the samples arrive at the laboratory before the close of the workday. NVSL uses overtime to complete testing and studies. NAHLN laboratories perform testing as necessary. Payment of overtime to NAHLN laboratory personnel varies by State. Diagnostic samples arriving after the close of the workday will be examined first thing the following day. Diagnostic samples received Saturday will be tested or studied on Saturday only with prior notification and discussion with NVSL and NAHLN laboratory personnel. NPIC does not require telephone notification of Intermediate Suspicion classifications.
- c. The Priority 3 designation is only used for investigations where there is a Low Suspicion of a FAD/EDI. Investigations with this designation use routine methods of collection, transport, and diagnostic study. NVSL and NAHLN personnel perform diagnostic testing and studies in accession order as received. NVSL and NAHLN overtime services will not be used for Priority 3 investigations. The Priority 3 designation is also used for routine surveillance samples. NPIC does not require telephone notification of Low Suspicion classifications.

The Priority A designation is only used for 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. It is also used when other known or potential circumstances associated with the investigation indicate it is prudent to obtain diagnostic sample testing results as rapidly as possible. NPIC requires telephone notification of Priority A designations. Use rapid to extraordinary methods to collect, transport, and study diagnostic samples. NVSL and NAHLN personnel perform diagnostic testing and studies as rapidly as possible upon sample arrival at the laboratory, including nights, weekends, and holidays. NVSL uses overtime as necessary to begin and complete diagnostic testing and studies. NAHLN laboratories perform testing as necessary. Payment of overtime to NAHLN laboratory personnel varies by State. NVSL must be notified as well by telephone of a Priority A submission.



VS Guidance 12001.4

- d. Extraordinary transportation methods include using hand carried samples, couriers, counter-to-counter services, and contracted commercial services. Rapid transportation methods include express shipping services such as FedEx® priority overnight. Routine transportation methods include express shipping services such as FedEx® priority overnight (to ensure preservation of diagnostic sample quality).

Table 2 presents the three diagnostic sample priority designations and their associated use and relative speed of sample collection, transportation, and diagnostic study.

Table 2: Diagnostic Sample Priority Designations, Correlation to Classification of Investigations, and Speed of Sample Collection, Transportation, and Diagnostic Study

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

The FADD, AVIC, and SAHO must concur on the classification of the investigation; designation of diagnostic sample priority (1, 2, 3, or A); and if a duplicate sample will be collected and sent to an approved NAHLN laboratory in addition to NVSL. If the FADD, AVIC, or SAHO have questions, concerns, or disagreements regarding the investigation classification or the designation of diagnostic sample priority, the FADD, AVIC, and SAHOs must immediately hold a conference call with the District Office, NVSL Director, and NPIC staff to resolve the issue. The NPIC staff and the District Office will host and coordinate conference calls. FADDL may also be consulted.

D. Diagnostic Case Definitions

For more information on diagnostics, please see the [Foreign Animal Disease Investigation Manual](#).

The VS Deputy Administrator classifies and designates FAD/EDI diagnostic case definitions. Examples of case definitions include “presumptive” and “confirmed” FAD/EDI cases and vary by disease. Refer to the [Animal Health Surveillance SharePoint Site](#) for disease-specific case definitions.



VS Guidance 12001.4

E. National Veterinary Services Laboratories (NVSL)

NVSL safeguards U.S. animal health and contributes to public health by ensuring its nationwide animal health diagnostic system provides timely and accurate laboratory support.

NVSL is the official reference laboratory for FAD/EDI diagnostic testing and study in the United States. NVSL must perform or officially confirm the results of all diagnostic testing and studies 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 two (2) locations for FAD/EDI diagnostic testing: Ames, Iowa (NVSL Ames) and Plum Island, New York (NVSL FADDL). The transport and shipping of FAD/EDI diagnostic samples to NVSL Ames or NVSL FADDL by species or suspected disease is found in the [Foreign Animal Disease Investigation Manual](#).

Additional information regarding [NVSL](#) can be found online.

F. National Animal Health Laboratory Network (NAHLN)

The NAHLN, created in 2002, is a comprehensive, coordinated, and modernized network of Federal and State animal health laboratories and public agricultural institutions that addresses emergency biological and chemical threats to animal agriculture and the security of the food supply. The NAHLN enhances early detection of FAD agents and newly emerging diseases and improves response to animal health emergencies (including bioterrorist events) that threaten the nation's food supply and public health.

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

A current roster of the [NAHLN laboratories](#) and the testing they are approved to perform can be found online.

G. Guidelines for Diagnostic Testing

However diagnostic testing is completed, NVSL is the official confirmatory laboratory for FAD/EDI testing in the United States unless otherwise specified by the U.S. Chief Veterinary Officer (CVO) (in other words, the VS Deputy Administrator).

- 1) At the discretion of the FADD, AVIC, and SAHO in collaboration with NVSL and NAHLN laboratory directors, two sets of diagnostic samples may be obtained.



VS Guidance 12001.4

- a. Always send the first set of diagnostic samples to the NVSL laboratory (NVSL Ames or NVSL FADDL) determined in the diagnostic sample submission plan.
 - b. Send the second set of diagnostic samples to an approved NAHLN laboratory to provide preliminary FAD/EDI diagnostic information before NVSL receives the diagnostic samples.
 - c. If a second set of diagnostic samples cannot be collected, send the samples that can be collected to the appropriate NVSL laboratory, not the NAHLN laboratory.
- 2) If an emergency situation occurs and the appropriate NVSL laboratory cannot perform FAD/EDI diagnostic testing, you may send one set of diagnostic samples to the other NVSL laboratory, and obtain a second set of samples for testing at a NAHLN Laboratory; or send the samples to another international reference laboratory as determined in the diagnostic sample submission plan. International sample shipments will require additional coordination and permitting.
 - 3) If AVIC and/or SAHO decide to submit a second set of diagnostic samples to the NAHLN laboratory, they must instruct the FADD to follow the procedures for submitting a second set of diagnostic samples to the NAHLN laboratory. The AVIC, SAHO, and/or FADD notify the NAHLN Laboratory Director if there is a change in the NAHLN laboratory submission plan after the FADD performs the investigation.

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

H. Packaging and Labeling

Packaging and labeling of 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 identification of each shipment. **Failure to follow regulations can result in substantial financial penalties.**

For more information, please refer to the [“Packing and Labeling Submissions” page](#).

I. State-Federal-Tribal Communication and Cooperation

The coordinated State-Federal-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 a FAD/EDI investigation from initiation to completion.

All FAD/EDI investigations must be initiated by the AVIC and/or the SAHO. All FAD/EDI investigations must be assigned by the AVIC and/or the SAHO to a FADD. The AVIC



VS Guidance 12001.4

and/or the SAHO must timely initiate the investigation of all credible reported or suspected FADs/EDIs, including assigning a FADD to complete a site visit or field investigation as a required part of the investigation.

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.

J. Emergency Management Response System (EMRS)

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

The AVIC, or his or her 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 by approval of the AVIC and the SAHO.

K. Requirements

Produce situation reports, spot reports, diagnostic updates, 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 to which NPIC belongs), and the VS Deputy Administrator.

Because of the rapid exchange of information required during FAD/EDI investigations, use communications such as phone calls, conference calls, email, and fax when required, in addition to the official EMRS database to record information.

7. Inquiries

Please direct any questions regarding these procedures or instructions to the NPIC staff.

Main Office: NPIC, One Health Coordination Center, FiOps Logistics Center.
Please refer to the FAD Investigation Manual for contact numbers.

Normal Business Hours: Monday – Friday 8 a.m. to 4:30 p.m. Eastern Time,



U.S. DEPARTMENT OF AGRICULTURE

Marketing and Regulatory Programs
Animal and Plant Health Inspection Service
Veterinary Services

VS Guidance 12001.4

NPIC/National Veterinary Stockpile (NVS) 24/7 Emergency Answering Service.
Foreign Animal Disease Investigations or Emerging Disease Incidents NVS Activation:
1-800-940-6524.



U.S. DEPARTMENT OF AGRICULTURE

Marketing and Regulatory Programs
Animal and Plant Health Inspection Service
Veterinary Services

VS Guidance 12001.4

Acronyms

ADA	Associate Deputy Administrator
APHIS	Animal and Plant Health Inspection Service
AVIC	Area Veterinarian in Charge
CFR	Code of Federal Regulations
CVO	Chief Veterinary Officer
EDI	Emerging disease incident
EMRS	Emergency Management Response System
FAD	Foreign animal disease
FADD	Foreign Animal Disease Diagnostician
FADDL	Foreign Animal Disease Diagnostic Laboratory
FiOps	Field Operations
NAHLN	National Animal Health Laboratory Network
NPIC	National Preparedness and Incident Coordination
NVS	National Veterinary Stockpile
NVSL	National Veterinary Services Laboratories
OIE	World Organisation for Animal Health
SAHO	State Animal Health Official
USDA	United States Department of Agriculture
VS	Veterinary Services