NAHEMS GUIDELINES:
SURVEILLANCE, EPIDEMIOLOGY, AND TRACING

FAD PReP
Foreign Animal Disease Preparedness & Response Plan

NAHEMS
National Animal Health Emergency Management System

USDA

APHIS

the Center for Food Security & Public Health
Iowa State University®

United States Department of Agriculture • Animal and Plant Health Inspection Service • Veterinary Services

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The Foreign Animal Disease Preparedness and Response Plan (FAD PReP)/National Animal Health Emergency Management System (NAHEMS) Guidelines provide a framework for use in dealing with an animal health emergency in the United States.

This FAD PReP/NAHEMS Guidelines was produced by the Center for Food Security and Public Health, Iowa State University of Science and Technology, College of Veterinary Medicine, in collaboration with the U.S. Department of Agriculture Animal and Plant Health Inspection Service through a cooperative agreement.

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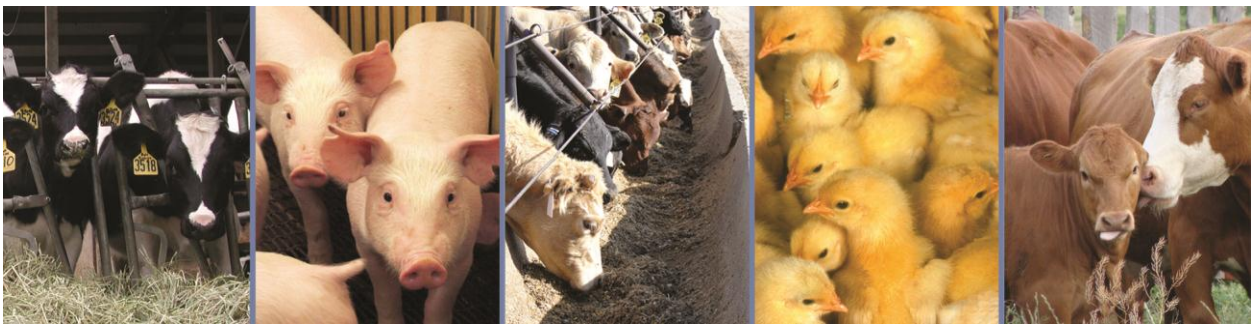
THE IMPERATIVE FOR FOREIGN ANIMAL DISEASE PREPAREDNESS AND RESPONSE

Why Foreign Animal Diseases Matter

Preparing for and responding to foreign animal diseases (FADs), like highly pathogenic avian influenza (HPAI) and foot-and-mouth disease (FMD), are critical measures to safeguard our nation's animal health, public health, and food supply.

There are significant potential consequences of an FAD outbreak in the United States. For example, the 2001 FMD outbreak in the United Kingdom cost an estimated £8 billion ($13 billion) and reduced the British gross domestic product by 0.2 percent. Studies have projected a likely cost of between $6 billion and $14 billion for a U.S. outbreak contained to California. In addition to the economic impact, the social and psychological impact on both producers and consumers would be severe.



Challenges of Responding to an FAD Event

An FAD outbreak will be challenging to all stakeholders. For example, there will be disruptions to interstate commerce and international trade. Response activities are complex, and significant planning and preparation must be conducted before an outbreak. Outbreaks can become large and widespread. Large, geographically dispersed and diverse teams will need to be assembled rapidly and must react quickly. The response effort must have the capability to be rapidly scaled up, involving many times more resources, personnel, and countermeasures. As such, responding to an FAD—large or small—may be a very complex and difficult effort.

Lessons Learned from Past FAD Outbreaks

Past outbreaks both in the United States and other countries have allowed us to learn important lessons that can be applied to preparedness and response efforts. To achieve successful outcomes in future FAD outbreaks, it is vital to identify, understand, and apply these lessons learned:

- Provide a unified State-Federal-Tribal-industry planning process that respects local knowledge
- Ensure the unified command sets clearly defined and obtainable goals
- Have a unified command that acts with speed and certainty to achieve united goals
- Employ science-based and risk-management approaches that protect public health and animal health, stabilize animal agriculture, the food supply, and the economy
- Ensure guidelines, strategies, and procedures are communicated and understood by responders and stakeholders

- Acknowledge that high expectations for timely and successful outcomes require the:
  – Rapid scale-up of resources and trained personnel for veterinary activities and countermeasures
  – Capability to quickly address competing interests before or during an outbreak
- Ensure rapid detection and FAD tracing, essential for timely control of FAD outbreaks

FAD PReP Mission and Goals

The significant threat and potential consequences of FADs and the challenges and lessons-learned of effective and rapid FAD response have led to the development of the Foreign Animal Disease Preparedness and Response Plan, also known as "FAD PReP." The mission of FAD PReP is to raise awareness, expectations, and develop capabilities surrounding FAD preparedness and response. The goal of FAD PReP is to integrate, synchronize, and de-conflict preparedness and response capabilities as much as possible before an outbreak, by providing goals, guidelines, strategies, and procedures that are clear, comprehensive, easily readable, easily updated, and that comply with the National Incident Management System.

In the event of an FAD outbreak, the three key response goals are to: *(1) detect, control, and contain the FAD in animals as quickly as possible; (2) eradicate the FAD using strategies that seek to stabilize animal agriculture, the food supply, the economy, and protect public health; and (3) provide science- and risk-based approaches and systems to facilitate continuity of business for non-infected animals and non-contaminated animal products.*

FAD PReP Documents and Materials

FAD PReP is not just one, standalone FAD plan. Instead, it is a comprehensive U.S. preparedness and response strategy for FAD threats. This strategy is provided and explained in a series of different types of integrated documents, as illustrated and described below.

FAD PReP Suite of Documents and Materials

Note: APHIS=Animal and Plant Health Inspection Service, NAHEMS = National Animal Health Emergency Management System, SOP = standard operating procedures.

- Strategic Plans—Concept of Operations
  - *APHIS Framework for Foreign Animal Disease Preparedness and Response:* This document provides an overall concept of operations for FAD preparedness and response for APHIS, explaining the framework of existing approaches, systems, and relationships.
  - *National Center for Animal Health Emergency Management (NCAHEM) Stakeholder Coordination and Collaboration Plan*: This plan describes NCAHEM strategy for enhancing stakeholder collaboration and identifies key stakeholders.
  - *NCAHEM Incident Coordination Group Plan:* This document explains how APHIS headquarters will organize in the event of an animal health emergency.
- NAHEMS Guidelines
  - These documents describe many of the critical preparedness and response activities, and can be considered as a competent veterinary authority for responders, planners, and policy-makers.
- Industry Manuals
  - These manuals describe the complexity of industry to emergency planners and responders and provide industry a window into emergency response.
- Disease Response Plans
  - Response plans are intended to provide disease-specific information about response strategies. These documents offer guidance to all stakeholders on capabilities and critical activities that would be required to respond to an FAD outbreak.
- Critical Activity Standard Operating Procedures (SOPs)
  - For planners and responders, these SOPs provide details for conducting 23 critical activities such as disposal, depopulation, cleaning and disinfection, and biosecurity that are essential to effective preparedness and response to an FAD outbreak. These SOPs provide operational details that are not discussed in depth in strategic documents or disease-specific response plans.
- Continuity of Business Plans (Developed by public-private-academic partnerships)
  - *Secure Egg Supply (SES) Plan:* The SES Plan uses proactive risk assessments, surveillance, biosecurity, and other requirements to facilitate the market continuity and movement of eggs and egg products during an HPAI outbreak.
  - *Secure Milk Supply (SMS) Plan:* Currently under development, the SMS plan will help facilitate market continuity for milk and milk products during an FMD outbreak.
- Outbreak Response Tools
  - Case definitions, appraisal and compensation guidelines and formulas, and specific surveillance guidance are examples of important outbreak response tools.
- State/Tribal Planning
  - State and Tribal planning is essential for an effective FAD response. These plans are tailored to the particular requirements and environments of the State or Tribal area, taking into account animal populations, industry, and population needs.
- Industry, Academic, and Extension Planning
  - Industry, academia, and extension stakeholder planning is critical and essential: emergency management is not just a Federal or State activity.
- APHIS Emergency Management
  - APHIS directives and Veterinary Services Memorandums provide critical emergency management policy. APHIS Emergency Management documents provide guidance on topics ranging from emergency mobilization, to the steps in investigating a potential FAD, to protecting personnel from highly pathogenic avian influenza.

These documents are available on the FAD PReP collaboration website: https://fadprep.lmi.org. For those who have access to the APHIS intranet, these documents are available on the internal APHIS FAD PReP website: http://inside.aphis.usda.gov/vs/em/fadprep.shtml.

PREFACE

The Foreign Animal Disease Preparedness and Response Plan (FAD PReP)/National Animal Health Emergency Response System (NAHEMS) Guidelines provide the foundation for a coordinated national, regional, state and local response in an emergency. As such, they are meant to complement non-Federal preparedness activities. These guidelines may be integrated into the preparedness plans of other Federal agencies, State and local agencies, Tribal Nations, and additional groups involved in animal health emergency management activities.

The Surveillance, Epidemiology, and Tracing Guidelines are a component of APHIS' FAD PReP/NAHEMS Guideline Series, and are designed for use by APHIS Veterinary Services (VS), and other official response personnel in the event of an animal health emergency, such as the natural occurrence or intentional introduction of a highly contagious foreign animal disease in the United States.

The Surveillance, Epidemiology, and Tracing Guidelines provide guidance for USDA employees, including National Animal Health Emergency Response Corps (NAHERC) members, on surveillance, epidemiology, and tracing principles for animal health emergency deployments. This Guidelines document provides information for responders in the Disease Surveillance Branch and the Situation Unit and other personnel associated with surveillance, epidemiology, and tracing activities. The general principles discussed in this document are intended to serve as a basis for understanding and making sound decisions regarding surveillance, epidemiology, and tracing. As always, it is important to evaluate each situation and adjust procedures to the risks present in the situation.

The FAD PReP/NAHEMS Guidelines are designed for use as a preparedness resource rather than as a comprehensive response document. For more detailed response information, see plans developed specifically for the incident and consult the FAD PReP Standard Operating Procedures (SOP): 3. Surveillance. Additional surveillance, epidemiology, and tracing resources are included in the Appendix and in the references at the end of this document.

APHIS DOCUMENTS

This "FAD PReP/NAHEMS Guidelines: Surveillance, Epidemiology, and Tracing" has corresponding disease-specific FAD PReP Standard Operating Procedures (SOP): 3. Surveillance.

Several key APHIS documents complement this "FAD PReP/NAHEMS Guidelines: Surveillance, Epidemiology, and Tracing" and provide further details when necessary. This document references the following APHIS documents:

- FAD PReP/NAHEMS Guidelines:
  - Biosecurity (2011)
  - Cleaning and Disinfection (2011)
  - Health and Safety (2011)
  - Personal Protective Equipment (2011)
  - Quarantine and Movement Control (2011)
  - Vaccination for Contagious Diseases (2011)
  - Wildlife Management and Vector Control (2011)

- FAD PReP Standard Operating Procedures (SOP):
  - 3. Surveillance
  - 2b. Case Definition Development Process

- Veterinary Services Memorandum No. 580.4

Many of these documents are available on the FAD PReP collaboration website at: https://fadprep.lmi.org Username and password can be requested.

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Guidelines: Surveillance, Epidemiology, and Tracing

1. INTRODUCTION

A foreign animal disease (FAD) is a terrestrial animal disease or pest, or an aquatic animal disease or pest, not known to exist in the United States (U.S.) or its territories. Some examples of FADs include: foot-and-mouth disease (FMD), high pathogenicity avian influenza (HPAI), classical swine fever, and Nipah. The U.S. keeps FAD agents out of our susceptible animal populations through preventive measures such as import restrictions, exclusion activities at borders and ports of entry, and public education programs.

If an FAD outbreak is suspected, the initial site investigation is conducted by a Foreign Animal Disease Diagnostician. Instructions for investigating a potential FAD are provided by U.S. Department of Agriculture (USDA) Animal Plant Health Inspection Service (APHIS) Veterinary Services (VS) *Memo 580.4: Procedures for the Investigation of Potential Foreign Animal Disease/Emerging Disease Incidents.* This document is available at the FAD PReP collaboration website: https://fadprep.lmi.org. Username and password can be requested. It is also publicly available at: http://www.aphis.usda.gov/animal_health/lab_info_services/downloads/VS_Memo580_4.pdf.

Once an animal is presumed positive for an FAD, or an FAD agent has been isolated and identified, appropriate national measures will be mobilized in support of the local response. Surveillance, epidemiology, and tracing components of an FAD response must be implemented quickly. They provide a real-time understanding of the situation and enable the earliest possible and most appropriate intervention strategies to be implemented (e.g., quarantine, movement control, vaccination, stamping-out, etc.).

Surveillance, epidemiology, and tracing techniques will be employed in an FAD outbreak to:

- Detect new and existing cases (animals or premises).
- Understand characteristics of the disease (e.g., clinical signs, incubation period, populations affected) and outbreak characteristics (e.g., sources, disease incidence patterns, geographic distribution, transmission dynamics, and reservoirs) and how they affect specific populations.
- Identify risk factors associated with disease occurrence (e.g., age, production practices, species, wildlife, vectors).
- Provide information for decision-making to design and implement control measures against the disease being targeted, such as designation of zones for disease control procedures.
- Evaluate the effectiveness of the control measures implemented and adjust them as the situation dictates.

1.1 The Surveillance, Epidemiology, and Tracing Guidelines

Veterinary responders, animal health technicians, and other trained personnel may assist with surveillance, epidemiology, and tracing activities. In order to perform these job duties, a broad understanding of surveillance and epidemiological concepts is required. These guidelines provide an overview of surveillance, epidemiology, and tracing principles and procedures that may be employed in an FAD response. Surveillance, epidemiology, and tracing activities are presented sequentially in this

manual; however, these activities may occur simultaneously. Additional operational procedures for disease control and eradication (e.g., biosecurity, cleaning and disinfection, and quarantine and movement control, etc.) will also be necessary during an FAD response and are briefly covered in these guidelines.

1.2 Definitions

The terms surveillance, epidemiology, and tracing are interrelated. There are many definitions for each term that vary slightly; in these guidelines they are defined as follows.

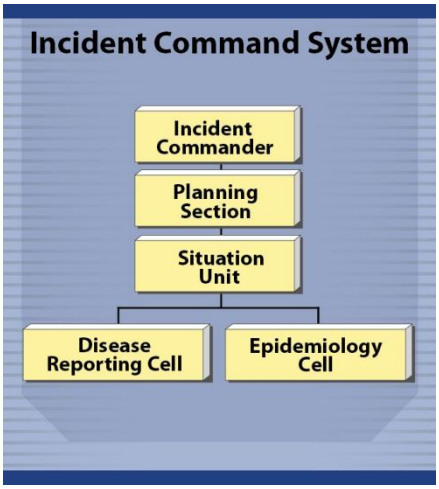
- **Surveillance** – an intensive form of data recording that encompasses gathering, documenting, and analyzing data. Information is then disseminated so that action can be taken to evaluate disease status and eradicate or control a disease.
- **Epidemiology** – the study of the distribution of disease in populations and of factors that determine its occurrence. Investigations involve observing animal populations and making inferences from data and observations.
- **Tracing** – information gathering on recent movements (during a defined time period) of animals, personnel, vehicles, and fomites (both to and from affected premises) to identify potential spread of disease to other livestock premises and to detect a putative source of infection for the affected farm.

Additional terms used in these guidelines can be found in the Glossary at the end of this document.

2. SURVEILLANCE, EPIDEMIOLOGY, AND TRACING PERSONNEL

An Incident Command System (ICS) will be implemented during an animal health emergency. The ICS structure is flexible—the exact number and names of groups may vary according to the circumstances of the FAD event. All FAD response efforts will incorporate surveillance, epidemiology, and tracing activities in some way. Appendix A shows a sample ICS structure and highlights entities with roles in surveillance, epidemiology, and tracing; however, alternate structures are acceptable.

2.1 Planning Section



2.1.1 Situation Unit

The Situation Unit is responsible for the administrative components of surveillance. This includes planning and analysis of surveillance information.

2.1.1.1 Disease Reporting Cell

Within the Situation Unit, the Disease Reporting Cell formulates daily surveillance activities and analyzes surveillance data. Duties of the Disease Reporting Cell include but are not limited to the following:

- Accumulates, enters, checks, and reports disease data
- Assists epidemiology personnel in investigations by summarizing and organizing epidemiological information and graphics

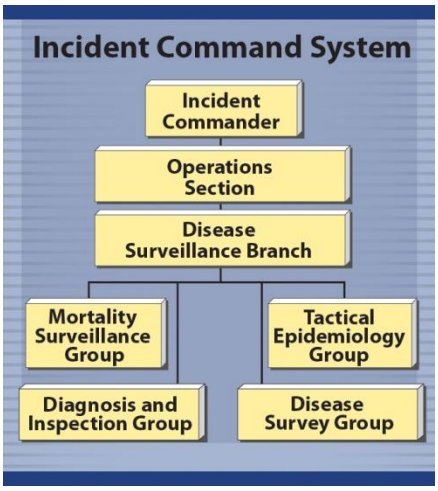
These duties are listed only as an example. For more information on specific duties, see the disease-specific *FAD PReP Standard Operating Procedure (SOP): Surveillance.*

2.1.1.2 Epidemiology Cell

The Epidemiology Cell is responsible for the administrative components of epidemiology. Duties of the Epidemiology Cell include but are not limited to:

- Plans outbreak response based on surveillance reports and other data
- Collects and analyzes case data reported by the Disease Reporting Officer (Disease Reporting Cell)

2.2 Operations Section



2.2.1 Disease Surveillance Branch

The Disease Surveillance Branch is responsible for field duties involving surveillance and epidemiology; this includes collecting, tabulating, and reporting surveillance information. There are four groups within the Disease Surveillance Branch that accomplish surveillance and epidemiology fieldwork. They include the Disease Survey Group, the Diagnosis and Inspection Group, the Mortality Surveillance Group, and the Tactical Epidemiology Group. Duties of these groups include but are not limited to the following:

2.2.1.1 Disease Survey Group

- Determines which farms and backyards within the control area have susceptible species
- Collects global positioning system (GPS) information for each premises

2.2.1.2 Diagnosis and Inspection Group

- Conducts investigations and sampling to survey for the presence of the disease agent

2.2.1.3 Mortality Surveillance Group

- Collects and samples dead animals from farms to survey for presence of the disease agent

2.2.1.4 Tactical Epidemiology Group

- Conducts field investigations to assist in the classification of premises
- Conducts tracing activities
- Inputs and extracts outbreak-associated data from the electronic database (for information on the currently used Emergency Management Response System [EMRS] see section 9)
- Guides management of FAD outbreaks in conjunction with the Situation Unit (Planning Section)

These duties are listed only as an example. For more information on specific duties for these groups, see the disease-specific *FAD PReP SOP: Surveillance.*

3. ZONES, AREAS, AND PREMISES DESIGNATIONS IN AN FAD OUTBREAK

The Disease Surveillance Branch and the Situation Unit have the responsibility to identify disease control zones and determine premises classifications, among other things. They work together to ensure adequate surveillance to support information-based decisions and to regain disease-free status as soon as possible in an FAD outbreak. Table 1 summarizes the premises designations that would be employed in an FAD outbreak response.

Table 1: Summary of Premises Designations

Premises	Definitions	Zone
Infected Premises (IP)	Premises where a presumptive positive case or confirmed positive case exists based on laboratory results, compatible clinical signs, case definition, and international standards.	Infected Zone
Contact Premises (CP)	Premises with susceptible animals that may have been exposed to the Foreign Animal Disease (FAD) agent, either directly or indirectly, including but not limited to exposure to animals, animal products, fomites, or people from Infected Premises.	Infected Zone, Buffer Zone
Suspect Premises (SP)	Premises under investigation due to the presence of susceptible animals reported to have clinical signs compatible with the FAD. This is intended to be a short-term premises designation.	Infected Zone, Buffer Zone, Surveillance Zone, Vaccination Zone
At-Risk Premises (ARP)	Premises with susceptible animals, but none have clinical signs compatible with the FAD. Premises objectively demonstrates that it is not an Infected Premises, Contact Premises or Suspect Premises. At-Risk Premises seek to move susceptible animals or products within the Control Area by permit. Only At-Risk Premises are eligible to be Monitored Premises.	Infected Zone, Buffer Zone
Monitored Premises (MP)	Premises objectively demonstrates that it is not an Infected Premises, Contact Premises, or Suspect Premises. Only At-Risk Premises are eligible to become Monitored Premises. Monitored Premises meet a set of defined criteria in seeking to move susceptible animals or products out of the Control Area by permit.	Infected Zone, Buffer Zone
Free Premises (FP)	Premises outside of a Control Area and not a Contact or Suspect Premises.	Surveillance Zone, Free Area
Vaccinated Premises (VP)	Premises where emergency vaccination has been performed. This may be a secondary premises designation.	Containment Vaccination Zone, Protection Vaccination Zone

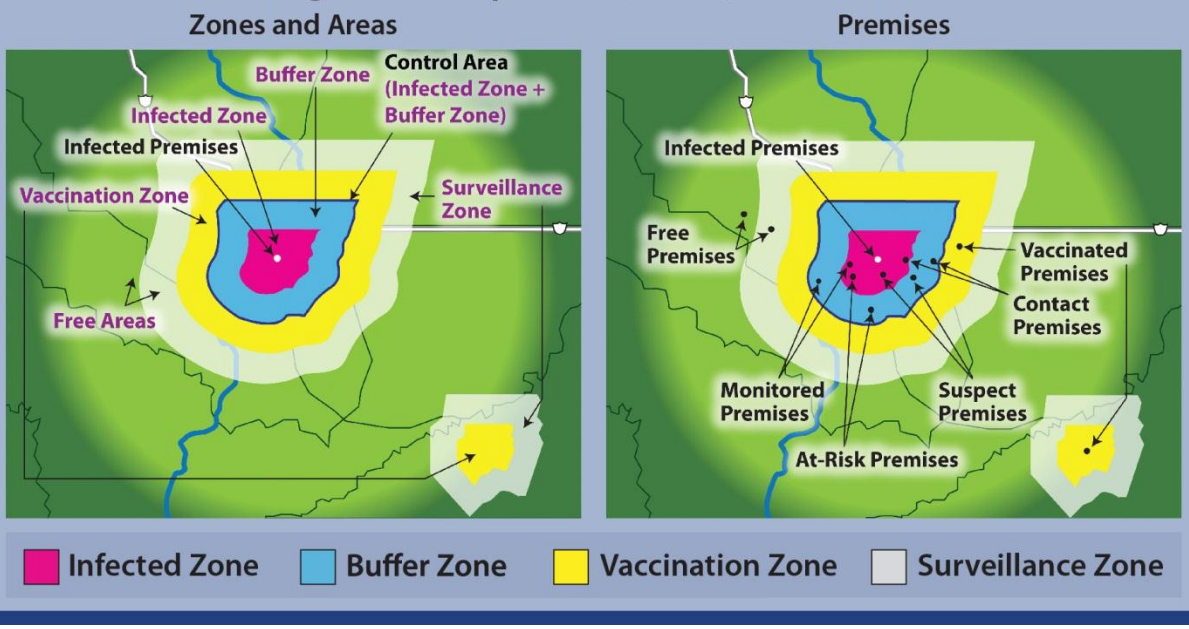
Table 2 summarizes the zone and area designations that would be used in an FAD outbreak response.

Table 2: Summary of Zone and Area Designations

Zone	Definition
Infected Zone (IZ)	Zone that immediately surrounds an Infected Premises.
Buffer Zone (BZ)	Zone that immediately surrounds an Infected Zone or a Contact Premises.
Control Area (CA)	Consists of an Infected Zone and a Buffer Zone.
Surveillance Zone (SZ)	Zone outside and along the border of a Control Area.
Free Area (FA)	Area not included in any Control Area.
Vaccination Zone (VZ)	Emergency Vaccination Zone classified as either Containment Vaccination Zone (typically inside the Control Area) or Protection Vaccination Zone (typically outside Control Area). This may be a secondary zone designation.

Figure 1 illustrates all the zones and premises.

Figure 1: Example Zones, Areas, and Premises



Note: Figures are not to scale. The Vaccination Zone can be either a Protection Vaccination Zone or Containment Vaccination Zone.

Table 3 lists the factors that are used to determine the size of the CA.

Table 3: Factors Used to Determine Control Area Size

Factors	Additional Details
Jurisdictional areas	• Effectiveness and efficiency of administration • Multi-jurisdictional considerations: local, State, Tribal, and multistate
Physical boundaries	• Areas defined by geography • Areas defined by distance between premises
Disease epidemiology	• Reproductive rate • Incubation period • Ease of transmission • Infectious dose • Species susceptibility • Modes of transmission (fecal-oral, droplet, aerosol, vectors) • Survivability in the environment • Ease of diagnosis (for example, no pathognomonic signs; requires diagnostic laboratory testing) • Age of lesions
Infected Premises characteristics	• Number of contacts • Transmission pathways and transmission risk » Extent of animal movement » Number of animals » Species of animals » Age of animals » Movement of traffic and personnel to and from premises (fomite spread) » Biosecurity measures in place at time of outbreak
Contact or contiguous Premises characteristics	• Number and types of premises • Susceptible animal populations and population density • Animal movements • Movement of traffic (fomites) and personnel to and from premises (fomite spread) • Biosecurity measures in place prior to outbreak
Environment	• Types of premises in area or region • Land use in area or region • Susceptible wildlife and population density • Wildlife as biological or mechanical vectors
Climate (for aerosol spread diseases)	• Prevailing winds • Humidity
General area, region, or agricultural sector biosecurity	• Biosecurity practices in place prior to outbreak • Biosecurity practices implemented once outbreak detected
Number of backyard or transitional premises	• Types of premises, animal movements, and network of animal and fomite movements
Continuity of business	• Continuity of business plans and processes in place or activated at beginning of outbreak (such as surveillance, negative diagnostic tests, premises biosecurity, and risk assessments) • Permit processes, memorandums of understanding, and information management systems in place or activated at beginning of outbreak

The size of the CA depends upon the FAD agent and circumstances of the outbreak. The radius of the CA may be as small as 6.2 miles (10 kilometers) beyond the perimeter of the closest IP. Table 4 shows the minimum sizes of areas and zones that have been established for CA, IZ, BZ, and SZ.

Table 4: Minimum Sizes of Areas and Zones

Zone or Area	Minimum Size and Details
Infected Zone	• Perimeter should be at least 3 km (~1.86 miles) beyond perimeters of presumptive or confirmed Infected Premises. Will depend on disease agent and epidemiological circumstances. This zone may be redefined as the outbreak continues.
Buffer Zone	• Perimeter should be at least 7 km (~4.35 miles) beyond the perimeter of the Infected Zone. Width is generally not less than the minimum radius of the associated Infected Zone, but may be much larger. This zone may be redefined as the outbreak continues.
Control Area	• Perimeter should be at least 10 km (~6.21 miles) beyond the perimeter of the closest Infected Premises. Please see previous table for factors that influence the size of the Control Area. This area may be redefined as the outbreak continues.
Surveillance Zone	• Width should be at least 10 km (~6.21 miles), but may be much larger.

For details on the zones, areas, and premises, see the *APHIS Framework for Foreign Animal Disease Preparedness and Response*. For additional information integrating the zones, areas, and premises designations with specific FAD response strategies, see the disease-specific response plans, such as the *FMD Response Plan: The Red Book* and the *HPAI Response Plan: The Red Book*. These documents are available on the following sites: FAD PReP collaboration website at: https://fadprep.lmi.org.and the APHIS FAD PReP website (for APHIS employees) at: http://inside.aphis.usda.gov/vs/em/fadprep.shtml.

4. ROUTINE ANIMAL HEALTH SURVEILLANCE

Many Federal and State organizations perform routine surveillance for both endemic and FAD agents. Surveillance programs are in place for a number of animal diseases of significance—including HPAI, bovine spongiform encephalopathy, brucellosis, classical swine fever, pseudorabies, scrapie, vesicular stomatitis, and viral hemorrhagic septicemia.

Detailed information about ongoing animal health and productivity surveillance activities in the U.S. (for both endemic and FADs) is provided by the U.S. Animal Health and Productivity Surveillance Inventory and can be found at http://nsu.aphis.usda.gov/inventory/index.faces.

5. SURVEILLANCE IN AN FAD OUTBREAK

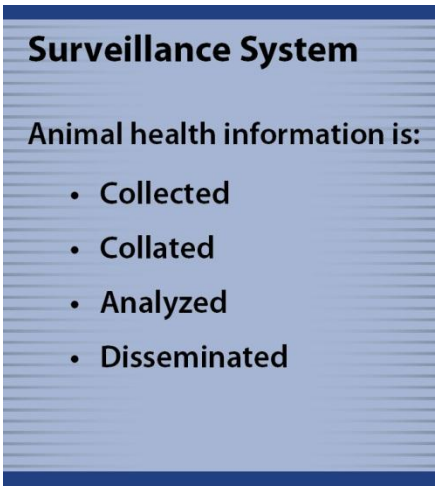
5.1 Developing a Surveillance Plan

Surveillance activities begin with the development of a surveillance plan. The Disease Surveillance Branch, in collaboration with the Situation Unit, is responsible for developing the surveillance plan. A surveillance plan is a documented framework that systematically describes the components of a surveillance system that will be put into place during an FAD response. A surveillance plan includes:

- The purpose, rationale, objectives, and desired outcome of surveillance activities
- Stakeholders and responsible parties
- Population to be sampled, sampling methods, and diagnostic testing considerations
- Performance metrics (i.e., adequate sampling techniques)
- Plans for data analysis, reporting, and presentation
- Expected implementation, budgeting, and evaluation plans

For some high-consequence FADs (e.g., FMD, HPAI), detailed surveillance planning has been conducted to prepare for future outbreaks. More information can be found in the disease-specific *FAD PReP SOP: Surveillance*. In other cases, surveillance plans must be composed in real-time. The Outbreak Response Toolbox is a USDA-designed resource to assist surveillance planning in an FAD response; see section 5.6.1 for more information.

A surveillance plan must address the purpose, scope, audience, and roles and responsibilities of personnel in the surveillance system to be developed. A surveillance system is designed to collect, collate, analyze, and disseminate animal health data.



Purpose of a surveillance system – describes why the system is needed and how the system components will be used. The purpose may change or evolve over time; for example, early in an FAD response an important purpose of surveillance is to detect new cases or clusters of disease. Later, surveillance data may be used to evaluate disease control measures and intervention efforts or to prove freedom from disease.

Scope of the surveillance system – describes what the surveillance system will and will not include (i.e., disease agent, population, geographic location, etc.). In an FAD outbreak, the surveillance system will likely be targeted towards a specific disease agent (e.g., FMD, HPAI).

Audience for the surveillance system – describes who will use the surveillance system and the data that are collected from the surveillance system. In an FAD response, personnel with surveillance and epidemiology duties in the ICS will be the primary audience for surveillance information.

Roles and responsibilities of surveillance team members – describes the composition and organization of the surveillance team, as well as tasks to be performed. Individuals involved in surveillance planning and field activities are included. In an FAD response, the surveillance team may include infectious disease experts, species experts, risk analysis experts, technical writers, and others.

5.2 Elements of a Surveillance Plan

It is important to decide how and when surveillance will be conducted prior to the commencement of surveillance activities. The actions and information needed for outbreak management changes throughout the course of the outbreak. Surveillance will be ongoing during the outbreak (a continuous activity) until last the area/zone is proven disease free. The following factors must be taken into account during surveillance planning:

- Disease description
- Surveillance objectives
- Stakeholders and responsible parties
- Population description
- Case definitions
- Data sources
- Sampling methods
- Diagnostic tests

5.2.1 Disease Description

Supporting information about the FAD agent under surveillance should be gathered from existing sources (e.g., scientific literature, government databases). Much of this information will be used by epidemiologists to develop the case definition to be used for the outbreak (see section 5.2.5). The following information should be included in the disease description section of a surveillance plan: etiologic agent, geographic distribution, clinical signs, pathological findings, available laboratory tests, epidemiology, economic impact, and methods of control.

5.2.2 Surveillance Objectives

Surveillance objectives must be specifically described in a surveillance plan; they identify goals that when accomplished will achieve the purpose(s) of the surveillance system. There may be multiple objectives. The disease-specific *FAD PReP SOP: Surveillance* (e.g., FMD, HPAI) contain surveillance objectives for individual pathogens. For example, Table 5 shows the surveillance objectives that have been developed for HPAI.

Table 5. Surveillance Objectives by Time Period for HPAI

Time Period	Objective
The initial 72 hours post-HPAI outbreak declaration	Detect existing infected flocks and premises as quickly as possible.
The control and eradication period (from initial 72-hour period until the last case is detected and eradicated)	Detect IP, new or existing, so that control measures can be put in place. Provide evidence that premises are free of HPAI, thereby permitting poultry and poultry product movements in the CA. Evaluate the outbreak management control activities. Provide evidence that the FA is free of disease, thereby enabling unrestricted poultry and poultry product movement.
The post-eradication (quarantine) period	Prove that the CA and FA are free of disease (using World Organization for Animal Health [OIE] recommendations on surveillance).

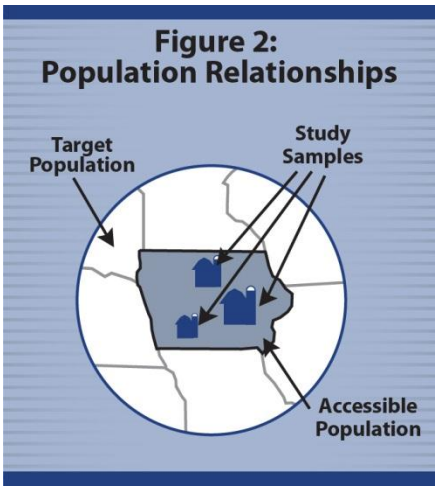
5.2.3 Stakeholders and Responsible Parties

There are multiple stakeholders (i.e., groups or organizations with an interest in surveillance activities or outcomes) and individuals responsible for designing, implementing, and managing the surveillance system; they must be clearly identified. The ICS structure contains personnel with surveillance

responsibilities. However, in some situations, industry stakeholders may be included in surveillance planning and data collection. Any participating personnel must be trained to be successfully integrated into a response. In addition, involved industry stakeholders must embrace the importance of cooperation with other groups and units.

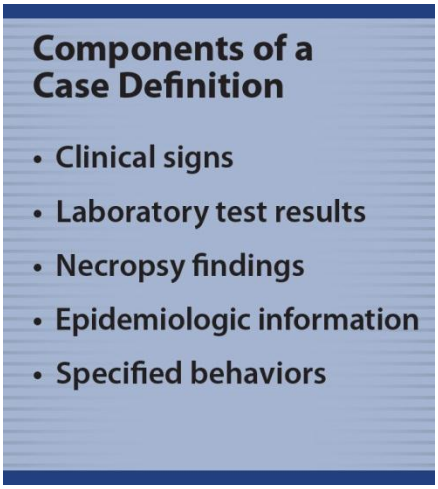
5.2.4 Population Description

The study population is a subset of the target population (Figure 2). In other words, the study population is derived from the larger target population. For example, in an FAD outbreak, the entire livestock population in the Midwest may be the target population. However, livestock in the state of Iowa may be most accessible. Within the state of Iowa, a subset of livestock (and premises) may be chosen for FAD testing. These animals, and premises, become the study population.



The study population, or the population to be sampled, must be described by the surveillance plan. In an FAD outbreak, the study population contains animals at risk of infection with the FAD. The study population may contain animals of a certain species, breed or type; age; or production phase. Geographic location may also be a defining factor. For FADs that infect multiple species (e.g., FMD) more than one study population may be identified for surveillance. For more information on selection of study samples (i.e., animals/premises to be sampled) see section 5.2.7.

5.2.5 Case Definitions



Clear case definitions must be developed for FAD agents under investigation. Case definitions must be consistent and specific so that all individuals who identify and report cases are able to properly count/categorize cases; this will reduce confusion between various surveillance participants. The components of a case definition include: general disease and pathogen information (e.g., etiologic agent, distribution, clinical signs, incubation period, differential diagnosis, transmission and reservoir, and epidemiology), laboratory criteria, reporting criteria, and control and surveillance procedures. For many high-consequence FADs, case definitions have been developed by the National Surveillance Unit (NSU). See https://fadprep.lmi.org for more information. The *FAD PReP SOP: Case Definition Development Process* provides additional information on how case definitions are derived.

At least three case definitions are developed during an FAD outbreak. They include:

- **Suspect case** – includes animals (or premises) with clinical signs compatible with the FAD that private practitioners and people in daily contact with livestock would see in the field and report. Information is provided on how to report their findings.
- **Presumptive positive case** – includes clinical signs consistent with the FAD, epidemiological links, and laboratory test(s) that would support current infection or exposure to the disease of concern.
- **Confirmed positive case** – indicates what tests are required to unequivocally determine the presence of the FAD agent.

5.2.6 Data Sources

Data are essentially facts (i.e., observations, clinical signs, and laboratory test results) that are collected by the surveillance system. Surveillance systems rely on data from multiple sources. These include but are not limited to the following:

- Livestock producers/farm records
- Veterinarians
- Livestock organizations
- Slaughter plants
- Auction/market records
- Disease reporting (or notification) systems and control programs
- Targeted testing/screening
- Post mortem diagnostic specimen collection
- Wildlife data
- Sentinel units

5.2.6.1 Livestock Producers/Farm Records

Livestock producers are likely to be the first to notice sick animals and are therefore an important part of a surveillance system. In addition to reporting suspect cases, producers may provide livestock records that contain information during an FAD outbreak. Production data is likely to be available for some livestock, especially for dairy cattle and swine. The type, format, and quality of farm record data may be highly variable. Additionally, there may be confidentiality issues with farm record access.

5.2.6.2 Veterinarians

Veterinarians often have early contact with sick animals, including livestock and wildlife, during routine veterinary activities (i.e., herd reproductive exams, etc.). They may also be called to examine animals that are clinically ill. It may be possible to collect medical records from veterinarians in an FAD outbreak. However, similar to farm production records, the type, format, and quality of information contained in veterinary records is likely to vary greatly. There may also be confidentiality issues with medical record collection.

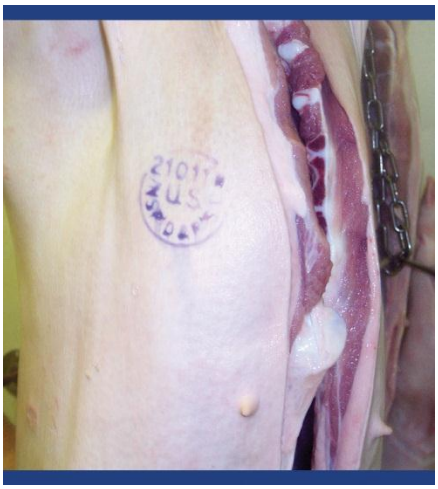
5.2.6.3 Livestock Organizations

Livestock organizations may provide data and function as a conduit for FAD information from the response effort to their group members. Although livestock organizations will not have data on individual animals, they may provide information on the composition and distribution of species-specific groups in the U.S. Information collected by livestock organizations is likely similar to that collected by the Census of Agriculture. However, livestock organizations may have more current information and be able to identify individual livestock producers.

5.2.6.4 Slaughter Plants

Only clinically healthy animals are intended for slaughter. However, infected animals may be slaughtered prior to the development of clinical signs, or animals may be subclinically ill. All livestock must undergo ante mortem inspection on the day of slaughter (in both federally and state inspected plants); animals may be condemned based on inspection results. No further diagnostic inspection is performed on condemned animals, with the exception of testing for bovine spongiform encephalopathy in cattle with central nervous system signs. All slaughtered livestock are inspected post mortem. Examination results are

recorded only for animals requiring disposition by a Food Safety and Inspection Service (FSIS) veterinarian. The amount of information recorded varies widely and may only include notation of significant clinical lesions (e.g., peritonitis, pneumonia). As such, disposition records are not diagnostic reports or medical records; however, they may provide information in an FAD outbreak. They may also be subject to confidentiality rules. For more information on livestock slaughter and inspection procedures refer to the USDA FSIS website at: http://www.fsis.usda.gov/regulations_&_policies/regulations_directives_&_notices/index.asp.



5.2.6.5 Auction/Market Records

Records from livestock auctions or markets may help identify animal movements. This may be particularly helpful during tracing activities that occur in an FAD response. See section 8.1.2 for more information on tracing information sources.

5.2.6.6 Disease Reporting (or Notification) Systems and Control Programs

Information collected during routine surveillance programs may be useful in the event of an FAD outbreak. For example, the U.S. conducts regular surveillance for classical swine fever. Information collected from this program may help determine the potential distribution and severity of disease in a U.S. classical swine fever outbreak.

5.2.6.7 Targeted Testing/Screening

Targeted testing/screening involves testing of animals with clinical signs similar to the suspected FAD or populations with risk factors for disease. Depending on the FAD agent, different types of testing may be conducted. Blood or swabs are common ante mortem samples. These samples can be tested in a diagnostic laboratory for evidence of infection by bacteriological, virological or serological techniques.

5.2.6.8 Post Mortem Diagnostic Specimen Collection

Post mortem inspections involve the collection of diagnostic specimens. Tissues, or other specimens, can be submitted for diagnostic testing, which varies according to the FAD agent suspected. Diagnostic laboratories collect information about diagnostic specimens that are submitted, including owner information (name, address, etc.) and animal information (age, species, etc.). These records may be accessible; however, access may be hampered by confidentiality issues as with veterinary medical records.

5.2.6.9 Wildlife Data

Data on wildlife populations may be more difficult to collect compared to livestock. Potential data sources include ground surveys, aerial surveys, local reports from wildlife biologists and hunters, carcasses, and live animal capture. For more information on wildlife surveillance, including data sources, see the *FAD PReP/NAHEMS Guidelines: Wildlife Management and Vector Control (2011).*

5.2.6.10 Sentinel Units

When it is desirable to assess the health status of a population periodically, sentinel surveillance may be utilized. Although the term "sentinel" can be applied to populations, farms, or animals, it generally involves repeated sampling of a group that is representative of those that are highly at-risk.

There are a number of important considerations for establishing a sentinel surveillance program. They include: herd or site selection, animal selection, frequency of sampling, and testing protocol. In the past, sentinel surveillance has been used for HPAI in the U.S. Sentinel bird programs have also been employed to show that premises are free of disease after depopulation, cleaning, and disinfection for other diseases. See the *FAD PReP SOP: Surveillance* for more detailed information on the use of sentinels for a specific FAD.

5.2.7 Sampling Methods

Sampling methods for a surveillance system must be described in detail for in FAD outbreak. Data collection methods must be determined and statistical concerns must also be addressed. This section describes considerations for developing accurate and practical sampling methods including:

- Sample type
- Sample size (number of samples)
- Random sampling
- Targeted (non-random) sampling
- Sampling duration and frequency
- Sample areas/locations
- Diagnostic test availability
- Pooled testing (combining samples from multiple animals)

5.2.7.1 Sample Type

The type of sample collected varies depending on the FAD agent, test availability, laboratory capabilities and/or preferences, and resources (both personnel and financial). Information can be collected via surveys, questionnaires, visual inspections, and collection of diagnostic specimens (ante or post mortem).

5.2.7.2 Sample Size

Rarely is it feasible to test all susceptible animals in an FAD outbreak. Instead, a subset of the herd or group must be selected. Sample size, or the number of animals to be sampled, is affected by the following factors:

- **Population size** – the size of the specific animal population*
- **Disease prevalence** – the total number of cases of a disease in a given population at a specific time (for more information, see section 6.4.1)
- **Diagnostic test sensitivity** – the likelihood of the test to accurately identify infected animals (for more information, see section 5.2.8)
- **Confidence level** – the degree of certainty that the test results reflect the true disease status of the specific animal population (95 percent is commonly used)

*Note: sample size calculations can be adapted for animals on single premises or herds/flocks/premises in a defined area.

Sample sizes can be calculated using mathematical formulas or by calculators provided by the VS Outbreak Surveillance Toolbox (see section 5.6.1). However, some generalities about sample sizes exist.

- The larger the proportion of animals sampled relative to the total population, the greater the likelihood of detecting disease if it is present in the population.
- The higher the prevalence of disease in the herd or flock, the smaller the sample size that is required to detect an infected animal.
- The larger the sample selected, the greater the confidence that can be placed in the results.

5.2.7.3 Random Sampling

Random sampling occurs when every animal in the target population has an equal probability of being selected for testing. To determine the prevalence or incidence of disease, random samples are generally preferred over non-random samples because results can be better extrapolated to the population at risk (for more information, see section 6.4.1). For example, assume that 50 dairy cows per day are sampled (examined) to determine the incidence of lameness in the herd. If the first 50 cows in the milk string are examined (a non-random sample) the sample may be skewed; cows with lameness would likely be at the end of the string and would be missed. Instead, if every n^{th} cow in the string is examined, the sample is more likely to represent the whole group.

5.2.7.4 Targeted (Non-Random) Sampling

Non-random samples may be chosen because of convenience (i.e., samples are easy to obtain) or because a certain group is known to have a specific risk factor or a higher prevalence of disease. During a disease outbreak, non-random samples are often preferred because the primary objective of surveillance is to identify cases of disease. Targeted sampling may be used to select and test animals that have clinical signs consistent with the disease agent or other risk factors for infection. This increases the probability of detecting a diseased animal. Targeted surveillance is cost effective and increases the likelihood of finding new cases. For example, if a dairy is under surveillance for FMD, cows with lameness should be identified. In contrast to the example above, the last 50 cows in the milk string may be sampled, because they are the most likely to be lame and have lesions consistent with FMD.

5.2.7.5 Sampling Duration and Frequency

Surveillance begins as soon as possible in an FAD response. In general, a minimum of three inspections (of susceptible animals) per maximum incubation period for the disease under investigation is required. The intervals between samples (i.e., inspections, surveys) will depend on the maximum incubation period of the disease. However, in most cases, susceptible animals will be placed under surveillance for at least two maximum incubation periods. The sampling frequency of animals, herds, or premises is chosen based on a number of factors. They include the following:

- **Latent period** – period of time between host infection and the ability to infect others
- **Incubation period** – period of time between infection and development of clinical signs
- **Infectious period** – period of time that an infected animal can transmit the pathogen to another susceptible animal

Maximum Incubation Period

The longest period that elapses between the introduction of the FAD agent into a susceptible animal and the occurrence of the first clinical signs compatible with the FAD agent.

Rapidity and ease of disease transmission between animals or premises, and likelihood of disease spread also affect sampling frequency. In addition, sampling duration and frequency can be affected by the type of premises (e.g., At-Risk vs. Suspect vs. Contact) and the location of the premises (e.g., IZ, BZ, SZ).

Repeated testing of animals or premises is often necessary. When repeated testing is conducted, a previous negative test result can strengthen information gained from a subsequent negative test result (when the time between samplings is short). In other words, if an animal or premises tests negative twice in succession, the validity of the negative test result is strengthened. In addition, the value of a previous negative test result decreases as the interval between sampling increases. Consequently, two negative test results that occur within days of each other are more reliable than two negative test results that occur within weeks of each other.

5.2.7.6 Sample Areas/Locations

In an FAD outbreak, the target population may be selected based on areas/locations. For example, an FAD agent capable of long-range aerosol transmission (e.g., FMD) could place livestock within miles of an infected premises under surveillance. The process of premises/zone classifications is very important for determining surveillance needs by location. Surveillance needs may vary within the control area (e.g., detecting new cases) compared to the free area (e.g., determining freedom from infection). Refer to the disease-specific *FAD PReP SOP: Surveillance* for more information.

Surveillance involving wildlife is difficult since wildlife populations move at-will within the control area and other zones. The density and distribution of wildlife, their movement patterns, home ranges, and behavior should be considered when developing a surveillance plan. For guidance on wildlife surveillance, refer to the *FAD PReP/NAHEMS Guidelines: Wildlife Management and Vector Control (2011).*

5.2.7.7 Diagnostic Test Availability

The chosen sampling methods for an FAD outbreak will consider the laboratory tests that are validated, approved, and available for the disease agent. Test availability may be affected by manufacturer capacity, reagent availability, etc. There may be some commercially manufactured diagnostic tests for a given FAD agent that are available in other countries but not approved for use in the U.S. For more information on diagnostic tests, see section 5.2.8.

5.2.7.8 Pooled Testing

In some instances, it is desirable to test diagnostic specimens from multiple animals that are combined. This is known as pooled testing. Pooled testing is a cost-effective approach that is especially useful when time and resources are limited. Many different diagnostic specimens can be pooled; for example, a bulk milk tank sample contains milk from multiple cows. The disease-specific *FAD PReP SOP: Surveillance* contains information about pooled testing for specific FADs. For example, HPAI surveillance utilizes the five-bird pool, which combines samples taken from five dead or euthanized sick birds from the poultry house's (flock's) daily dead birds into one sample. Pooled testing is not appropriate for all sample types or pathogens. In some cases, it may increase the likelihood of false negative results.

5.2.8 Diagnostic Tests

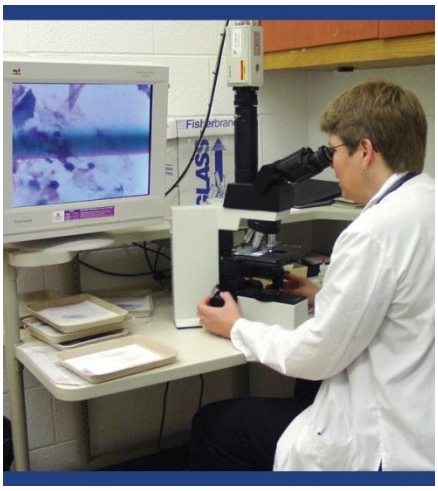
5.2.8.1 Choosing a Diagnostic Test

The diagnostic tests to be used in an FAD outbreak will be determined by the National Veterinary Services Laboratories (NVSL). When choosing a diagnostic test, NVSL will consider the speed, reliability, reproducibility, precision, accuracy, ease of use, and cost for each available diagnostic test.

5.2.8.2 Sensitivity and Specificity

Sensitivity and specificity are important criteria to consider when choosing a diagnostic test. A variety of diagnostic tests may be available for a given FAD. Each diagnostic test has a different ability to correctly identify diseased and non-diseased animals. Sensitivity is the ability of a test to correctly classify a percentage of diseased animals as positive. For example, if the test sensitivity is 95 percent, 95 out of 100 sick animals will be detected. Specificity is the ability of a test to correctly classify non-diseased animals as disease negative.

5.2.8.3 Laboratory Capacity



As previously mentioned, multiple factors will affect diagnostic test availability. Laboratory capacity, or the ability of a laboratory to complete necessary FAD testing, may also be a limiting factor. In an FAD response, samples will be sent to the Foreign Animal Disease Diagnostic Laboratory (FADDL) in Plum Island, NY or the NVSL in Ames, IA. Alternatively, the National Animal Health Laboratory Network (NAHLN), a network of State, university, and other approved laboratories, maintains the capacity and capability to provide laboratory services in support of FAD outbreaks. A NAHLN laboratory may also be selected per *VS Memo 580.4*.

5.3 Data Analysis and Interpretation

Methods to be used in summarizing, analyzing, and interpreting data should be described in the surveillance plan. In the ICS, epidemiologists are responsible for data analysis. When complex data analysis is required, the methods and results should be discussed in such a way that non-epidemiologists can understand them.

Data interpretation is the process by which the analyst translates findings from the data into language useful for decision-making and policy development. Data interpretation should be sensitive to the political environment, but the results should not be biased by political pressures. This is especially important in an FAD response, where disease control options may include potentially unpopular solutions such as mass depopulation and euthanasia. Ideally, the interpretation of the analysis should provide options for decision-makers to consider.

5.4 Diagnostic Specimen Collection

5.4.1 Diagnostic Specimen Types

The number and type of diagnostic specimens to be collected in an FAD outbreak will be determined by surveillance personnel. The following diagnostic specimens may be collected:

- Blood or serum
- Skin or vesicular lesions (epithelial tissue or vesicular fluid)
- Feces, rectal swabs, cloacal swabs, or genital tract swabs
- Semen samples
- Nasal, oral, or oropharyngeal swabs
- Nasal discharge, saliva, tears
- Tissues (e.g., tonsil, spleen, kidney, liver, lymph node, lung, brain, etc.)
- Milk
- Other environmental samples

5.4.2 Submission of Diagnostic Specimens

Before diagnostic specimen collection begins, personnel should understand which specimens are to be collected and how they should be obtained and packaged. Personnel should also be instructed on biosecurity procedures because sample takers could inadvertently transmit the disease agent. The type of specimen to be collected will be influenced by the disease of concern, the diagnostic tests available, and the ability to obtain the sample from the targeted species. However, the final decision on specimen collection will be made by Incident Command. All supplies and materials required for sample collection should be obtained and gathered prior to entering the sampling area.

Samples should be collected in a manner to prevent cross contamination and sample degradation. Once samples are obtained, they should be clearly and legibly labeled with permanent, waterproof ink. Label all specimens in a manner that allows identification of the specimen (e.g., animal, location, date, type, etc.). Samples should be packaged accordingly in selective or transport media, properly cooled (i.e., with ice packs or dry ice), or in formalin as required. Sample containers should be padded to prevent breakage or spillage.

Shipping and transport requirements of the specimen should also be considered as they can affect the quality/preservation of a sample. This differs depending on the sample collected and information desired from the sample. Packaging and shipping requirements as set by the diagnostic lab, shipping company, and the U.S. Department of Transportation must be followed. For more information on packaging and labeling diagnostic specimens, see:
http://www.aphis.usda.gov/animal_health/lab_info_services/packaging_labeling.shtml

5.5 Demonstrating Freedom from Infection

Surveillance plans to demonstrate freedom from infection must be developed for each FAD agent. Freedom from infection implies the absence of the pathogenic agent in a country, zone, or compartment. In practice, it is not possible to prove (i.e., be 100 percent confident) that a population is free from infection (unless every member of the population is examined simultaneously with a perfect test with both sensitivity and specificity equal to 100 percent). Instead, the aim is to provide adequate evidence (to an acceptable level of confidence), that infection, if present, is present in less than a specified proportion of the population.

The U.S. is a member of the World Organization for Animal Health (OIE); as such, it makes every effort to demonstrate freedom from infection to a level of confidence acceptable to OIE Members. For example, with *x* number of negative test results in a given population, the U.S. can state that the prevalence of disease is less than the threshold prevalence (1/1000, 1/10,000, 1/100,000 etc.) used to calculate the sample size with 95 percent confidence.

Any self-declaration of freedom from infection should contain evidence demonstrating that the requirements for the disease status have been met in accordance with the OIE standards. These standards are outlined in Chapter 1.4 of the *OIE Terrestrial Animal Health Code (2011).* A proof of disease freedom surveillance scheme has been developed for HPAI; see the *HPAI Surveillance SOP* for additional information.

5.6 Surveillance Planning Resources

5.6.1 National Surveillance Unit

The NSU provides resources for surveillance planning and may participate in surveillance planning during an FAD outbreak. The NSU Outbreak Surveillance Toolbox, available on the APHIS Intranet or on CD, is designed to assist in developing a surveillance plan.

The Toolbox provides information and resources to establish:

- Case definitions (based on epidemiologic, clinical, diagnostic, and exclusion criterion) for the disease in question
- Case classifications (suspect case, presumptive positive case, confirmed positive case)
- Premises classifications (infected, suspect, contact, etc.) Note: premises definitions are the same as those given by the *APHIS Framework for Foreign Animal Disease Preparedness and Response*
- Disease control zones (Infected Zone, Buffer Zone, Surveillance Zone, etc.) Note: zone definitions are the same as those given by the *APHIS Framework for Foreign Animal Disease Preparedness and Response*
- Sampling plans within each disease control zone (or free area) to detect disease, if present, within individual herds and "prove" disease freedom in these herds

The Toolbox relies heavily on the premises/zones classifications. These classifications are essential to an FAD response because they relate to surveillance, epidemiology, and tracing; quarantine and movement control; biosecurity; and other components of the response. For more information on premises/zone classifications, refer to section 3 of this document: Zones, Areas, and Premises Designations in an FAD Outbreak.

For individuals who have access to the APHIS intranet, the Toolbox is available on the internal APHIS FAD PReP website: http://inside.aphis.usda.gov/vs/em/fadprep.shtml. For individuals who do not have access to the APHIS intranet, toolbox access can be requested at: national.surveillance.unit@aphis.usda.gov. For more information on the toolbox see Appendix B.

5.6.2 FAD PReP Standard Operating Procedures

For some high-consequence FADs detailed surveillance plans have been developed. Refer to the disease-specific *FAD PReP SOP: Surveillance* for more information. These documents also contain additional information on the surveillance concepts that have been discussed in section 5 of these Guidelines. For examples of surveillance parameters to consider during an FAD outbreak, see Appendix C.

6. PRINCIPLES OF EPIDEMIOLOGY

6.1 Functions of Epidemiology

Epidemiology is the study of disease in populations and of factors that determine its occurrence. There are four core functions of epidemiology:

- Surveillance
- Field investigation
- Analytic studies
- Evaluation

6.1.1 Surveillance

As discussed in section 5, surveillance involves ongoing collection, analysis, interpretation, and dissemination of data related to disease. This information is used to determine specific actions for FAD mitigation (e.g., quarantine, vaccination, depopulation, etc.) Surveillance is conducted to monitor a population for the presence, or absence, of disease.

6.1.2 Field Investigation

Surveillance provides information for action. In an FAD outbreak, surveillance will be used to detect cases or clusters of disease cases in the field. Epidemiologists will then collect additional information regarding the disease outbreak. This may include identifying the disease source, determining if other animals have been exposed, and learning more about the history of disease.

6.1.3 Analytic Studies

In an FAD response, information gleaned from surveillance activities and field investigations will be used in analytic studies. Disease rates will be calculated, and parts of the animal population that may be at higher risk than others will be described. This will aid in identification of risk factors for disease, and determination of the source of disease. Many epidemiologic studies will require advanced analytic techniques.

6.1.4 Evaluation

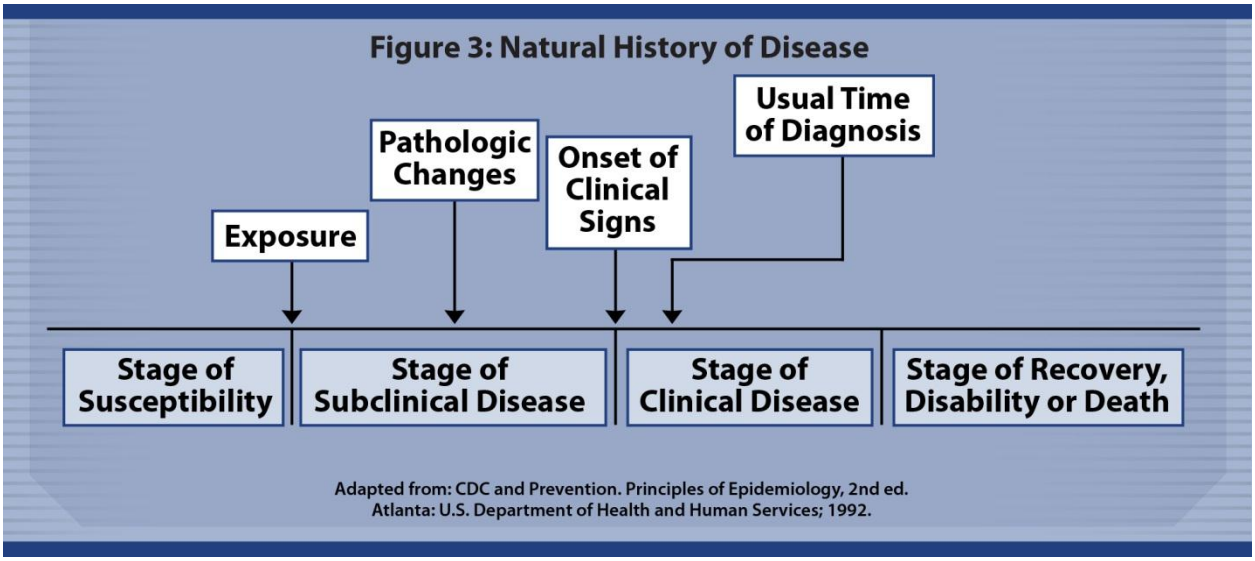
Evaluation is the process of determining the effectiveness, efficiency, and impact of activities with respect to established goals. In an FAD response, strategies to contain, control, and/or eradicate a contagious FAD must be constantly evaluated to ensure that appropriate actions are undertaken.

6.2 Disease Characteristics

In an FAD outbreak, information collected via surveillance will be utilized by epidemiologists in a number of ways. One of the first tasks of epidemiologists is to describe the characteristics of disease. In some instances, such as a novel FAD outbreak, limited information may be available. Characteristics of disease include the history/spectrum of disease and disease transmission mode(s).

6.2.1 History/Spectrum of Disease

For most infectious diseases, the course of disease progression is predictable (when treatment does not occur). Known as the natural history of disease (Figure 3), the process begins with exposure to a pathogen. The onset of clinical signs marks the transition from subclinical to clinical disease. Most diagnoses are made during the stage of clinical disease. In some animals disease does not progress to clinically apparent illness (known as subclinical disease); animals may be infectious nonetheless. These animals are known as carriers. Ultimately, the disease process ends either in recovery, disability, or death.



6.2.2 Disease Transmission Modes

Every pathogen lives, grows, and multiplies in a particular environment. Known as the reservoir, this can include humans, animals, and the physical environment. The reservoir is often, but not always, the source of infection.

A multitude of transmission modes exist. An understanding of the modes of pathogen transmission is required during an epidemiological investigation. Generally, transmission may be direct or indirect.

- **Direct transmission** – when an infected animal is in direct contact with a susceptible animal. The pathogen is transmitted via mucous membranes, open wounds, blood transfer, saliva, or oronasal contact. Short-range droplet spread (several feet) is also considered direct transmission.
- **Indirect transmission** – when an intermediate vehicle transmits the pathogen between infected and susceptible animals. More specifically, this may include contact with fomites (inanimate objects) such as tools, boots, or vehicles and/or vectors (living carriers of disease) such as insects. Aerosol transmission occurs when infectious agents are carried by dust or suspended in air; it is considered an indirect form of disease transmission.

Diseases transmissible between animals and humans are known as zoonotic diseases, or zoonoses. They may be transmitted directly or indirectly. For additional information on transmission routes, see Appendix D.

Finally, a susceptible host is required for disease transmission to occur. A number of factors affect susceptibility; they include (but are not limited to) genetic factors, immune status, prior exposure to the pathogen, and general health/body condition.

6.3 Disease Occurrence

Another important task of epidemiologists is to describe disease occurrence. This includes the level (or amount) of disease occurring in an area and the factors that work together to cause disease. Again, in the event of a novel FAD outbreak, limited information may be available to epidemiologists.

6.3.1 Levels of Disease

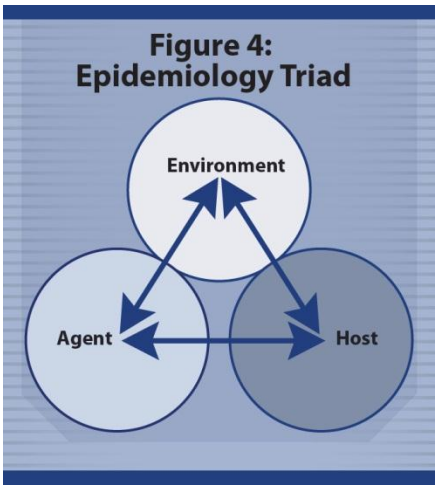
Epidemiologists must understand the amount of disease that occurs before, and during, an FAD event. The following terms are used to describe amounts of disease in a population or area:

- **Endemic** – present in a population or geographical area at all times
- **Outbreak** – the occurrence of more cases of disease than expected in a given area, or among a specific group, over a particular time period; many epidemiologists use the terms outbreak and epidemic interchangeably
- **Pandemic** – an outbreak/epidemic that has spread over several countries or continents

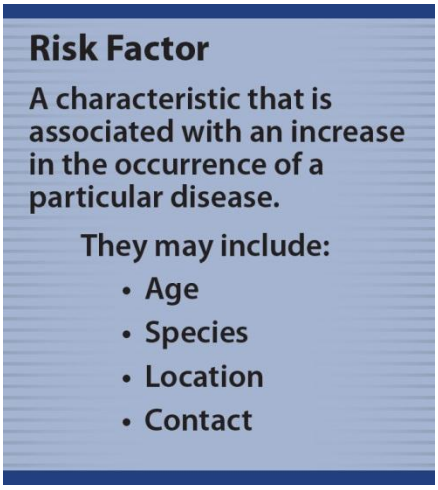
6.3.2 Causation

Agent, host, and environmental factors interrelate in a variety of complex ways to produce disease (shown in Figure 4). This interaction explains why some animals are more susceptible to disease than others. These factors may include:

- **Agent factors** – host range, environmental resistance, tissue affinity, dose, mode of transmission
- **Host factors** – species, breed, age, nutritional status, immune status
- **Environment factors** – husbandry, housing, climate/season, presence of vectors



A critical concept in epidemiology is that disease does not occur randomly in a population. It is more likely to occur in some members of the population than others because of risk factors that may not be distributed randomly in the population. Risk factors may be related to the agent, host, or environment; they can include age, species, geographic location, and contact with other animals or fomites. Epidemiologists will study the presence/absence of risk factors in diseased and non-diseased animals in order to better understand an FAD agent.



6.4 Understanding Data

Data are essentially facts (i.e., observations, clinical signs, and laboratory test results) that are collected for the purpose of gaining information. Groups of collected data are known as data sets. Data may be qualitative or quantitative in nature; qualitative data are non-measurable and include characteristics such as breed or sex. Quantitative data are numeric and describe amounts such as temperature or weight.

Quantitative data are often summarized using descriptive statistics. Measures of central tendency (mean, median, and mode) can be used to describe the central value of a data set. The spread, or width, of a data set can also be measured. The range describes the difference between the largest and smallest value in a data set. The standard deviation describes the amount of spread around the mean value in the data set.

For many statistical measures, epidemiologists calculate a corresponding confidence interval. This interval represents the range within which the value lies. Confidence intervals are calculated based on a percentage; 95 percent is commonly used. A 95 percent confidence interval means that the true value falls within the given range 95 percent of the time. For example, in a dairy, if the average daily milk production per cow is 50 pounds, the calculated confidence interval could be 40 to 60 pounds per day (50 pounds +/- 10 pounds). In this example, 95 percent of the time the true mean will fall between 40 to 60 pounds, and 5 percent of the time the mean will be outside this range.

6.4.1 Measures of Disease in a Population

In addition to measures of central tendency and spread, epidemiologists use more complex statistics to describe disease in a population. Among these, incidence, prevalence, mortality rate, and case-fatality rate are frequently used; they are defined as follows.

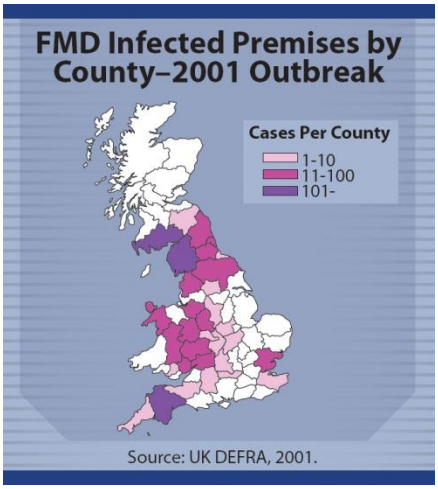
- **Prevalence** – the total number of cases of a disease in a given population at a specific time (i.e., a "snapshot" in time). There is no distinction between old and new cases, so prevalence reflects only the presence of disease. For example, a prevalence of 25 percent means that 25 out of 100 animals are infected with an FAD agent.
- **Incidence** – the number of new cases of disease in a defined population over a specific time period. For example, an incidence of 20 percent (during a two-week period) means that 20 out of 100 animals became infected with an FAD agent during that time. Additional animals may have been infected prior to that time or may become infected afterward.
- **Mortality rate** – the number of deaths in a defined population during a specific time period. Many variations can be calculated (e.g., crude death rate, cause-specific death rate, etc.)
- **Case-fatality rate** – the tendency of a specific disease to cause death among animals affected by the disease (the proportion of infected animals that die of the disease). For example, if 100 animals are infected with FMD and 20 die from the disease, the case fatality rate is 20/100 or 20%.

6.4.2 Measures of Association

Epidemiologists measures disease in subsets of the population and compare the differences in disease occurrence to factors that may influence the occurrence in two subpopulations. This allows them to quantify the relationship between exposure and disease among the two subpopulations (or groups). "Exposure" can mean exposure to other animals, food products, vectors (insects, etc.), or fomites (clothing, vehicles, etc.). Exposure can also include a biological characteristics (e.g., immune status), living condition, or environment (e.g., barn, pasture, fence contact).

Two common measures of association are the risk ratio and the odds ratio. Both compare the likelihood of disease among one group with the likelihood among another group. In an FAD outbreak, animal groups usually differ by exposure to a suspected risk factor. For example, swine that ate garbage may be compared to swine that did not eat garbage in an African swine fever outbreak. For more information on data analysis and statistical techniques, refer to *Veterinary Epidemiology, 3rd ed*., 2007, by M. Thrusfield.

6.4.3 Displaying Data



Data are often displayed in tables, graphs, and charts. Tables present data arranged in rows and columns. They can demonstrate patterns, differences, and other relationships. Graphs display numeric data in a visual form. They can demonstrate trends, similarities, and differences in data that may not be evident from tables. Charts can exhibit various forms (e.g., bar chart, pie chart). They provide a visual means for comparing data. Maps and geographic information systems (GIS) can also provide a visual representation of data. In an FAD response, epidemiologists will work with the GIS Cell to develop maps showing the geographic distribution of disease. Maps may pinpoint the location of disease cases/events. They may also use shading or coloring to show different levels of disease numbers or rates in different areas. This example shows the number of cases (infected premises) by county in the 2001 UK outbreak of FMD.

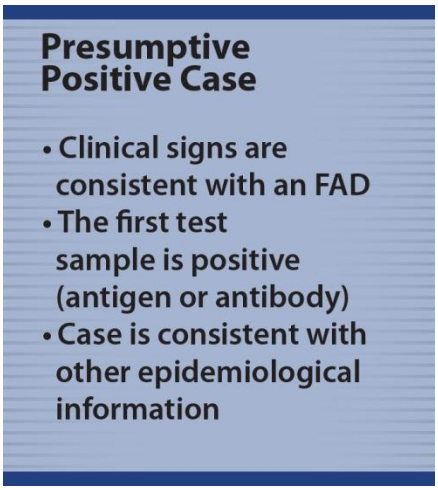
7. EPIDEMIOLOGY IN AN FAD OUTBREAK

7.1 Role of Epidemiologists

Data collected by surveillance efforts is utilized by epidemiologists in an FAD outbreak. Three basic epidemiological principles form the foundation for the response strategies to contain, control, and/or eradicate a contagious FAD:

- Prevent contact between the FAD agent and susceptible animals. This is accomplished through quarantine of infected animals and movement controls in infected areas, as well as biosecurity procedures to protect non-infected animals.
- Stop the production of the FAD agent by infected or exposed animals. This is accomplished by slaughter or mass depopulation (and disposal) of infected and potentially infected animals.
- Increase the disease resistance of susceptible animals to the FAD agent. This is accomplished by strategic emergency vaccination.

7.2 Epidemiology Response



Generally, disease outbreaks are investigated in three phases: the descriptive phase, the analytic phase, and the intervention phase. These phases are presented sequentially in this manual; however, they may occur simultaneously in an FAD response.

7.2.1 Descriptive Phase

In the descriptive phase, information on case chronology, geography, and demography is collected. The case definition is then developed. Epidemiologists also consider the herd and environmental history during this phase. In an FAD response, epidemiologists (in conjunction with State animal health officials, Foreign Animal Disease Diagnosticians, the National Center for Animal Health Emergency Management, and Veterinary Services) establish case definitions within 24 hours of the first presumptive or confirmed positive case (index case). The case definition is modified over time based on additional information or changing needs of the emergency response effort.

Diagnostic testing also occurs in the descriptive phase. Testing is performed on a census or statistical sample of animals/premises. Testing cannot ensure 100 percent freedom from infection; however, it helps epidemiologists locate new cases. All premises that undergo diagnostic testing will be quarantined if diagnosed as infected. Premises with negative test results in the CA will be retested until the quarantine is removed. Testing on Free Premises (in the Free Area) will be used to demonstrate that the Free Area is free of disease. Diagnostic samples will be collected and delivered to designated laboratories for testing in this phase. See the *FAD PReP/NAHEMS Guidelines: Quarantine and Movement Control (2011)* for more information.

7.2.2 Analytic Phase

In the analytic phase, descriptive data and corresponding laboratory results are used to determine disease risk factors. Associations between suspected risk factors and disease status are examined, and the FAD agent and source are determined (if possible). The nature of the outbreak will be characterized, risk factors will be identified, and mitigation strategies will be developed within 96 hours of identifying the index case. Premises classification and a priority of investigation will be assigned within 6 hours of identifying a potential IP or CP through tracing activities. A daily epidemiological investigation report will be generated and include information related to the origin of the outbreak, the total number of positive animals/premises, the total number of states with confirmed positive animals, and tracing information.

7.2.3 Intervention Phase

In the intervention phase, disease control measures are addressed. Preventive options are considered, and economic benefits and consequences of control measures are assessed. Disease control measures in an FAD response may include quarantine and movement control and enhanced biosecurity practices. These measures are discussed further in section 10. In addition, vaccination may be employed to stop the production of the FAD agent by infected or exposed animals and to increase the disease resistance of susceptible animals. Mass euthanasia and disposal may be required to control the spread of disease. For some FAD responses, knowledge of specific risk factors for disease exposure/transmission (gained through epidemiologic analysis) may be used to determine additional control measures that could be implemented.

8. TRACING

Tracing is the ability to ascertain the movements of an animal (or group of animals) during a specific time frame. Tracing will aid in the control of the spread of an FAD agent or a hazard, and limit the impact of the outbreak by detecting potentially infected premises or animals. In the event of an FAD outbreak, all movements both to and from the affected premises should be assessed.

- Trace-back is identifying the origin of all animals, animal products, fomites, people, vehicles, equipment, and possible vectors that have been moved onto an infected premises to establish the original source of the agent/hazard.

- Trace-forward is the tracing of all animals, animal products, fomites, people, vehicles, equipment, and possible vectors that have left the infected premises and could have possibly carried the agent to other animals. Animals located on exposed premises should be investigated and kept under surveillance and/or quarantine until additional data suggest they have remained unaffected.

8.1 Tracing Considerations

8.1.1 Tracing Period

The tracing period will vary according to the FAD agent. Trace-back and trace-forward information will usually be collected for a minimum of two maximum incubation periods before the appearance of clinical signs in an animal infected with a highly-contagious FAD. Additional trace-forward information will be collected for movements that occurred up to the time that the quarantine is imposed. It is highly likely that the first animal and premises identified with disease (the index case/premises) will not be the first animal/premises that had infection or disease.

8.1.2 Tracing Information Sources

Tracing information will be obtained from many sources. Epidemiologists and animal health officials are encouraged to use all available resources to successfully complete FAD traces in the time frames needed for effective and efficient control of a contagious FAD. The following sources of information are available for FAD traces and investigations.

- Owners/livestock producers
- Generic database
- Animal disease traceability information system
- Auction/market records
- Test charts (brucellosis, etc.)
- Accredited veterinarians and health certificates
- Import permit systems
- Livestock transporters' manifests and owner/shipper statements
- Brand inspection records
- Official identification devices

8.1.2.1 Owners/Livestock Producers

In an FAD outbreak, it may be necessary to contact animal owners to obtain information on animal movements. However, the type, format, and quality of farm records may be highly variable. The amount of information on animal movements is also likely to vary, but owners/producers are an important potential source of information. In previous outbreaks, such as FMD in the UK (2001), owners/producers were a critical resource for animal tracing. Owners or livestock producers may also report suspect cases of disease in an FAD outbreak.

8.1.2.2 Generic Database

The USDA's Generic Database houses information that may be useful for tracing purposes; it is accessible by Federal and State personnel. The Generic Database maintains premises records for livestock, market, and slaughter facilities. They include the premises' name, the premises' address, livestock species present on the premises, information about identification devices used on the premises (i.e., eartags, etc.), event reasons (such as shipment of livestock) and event dates. The database also includes test and inspection histories, as well as the premises' disease status for various domestic disease control programs (e.g., tuberculosis [TB]). Information on market test charts (see below) can be entered into this database system as well. Database information may be accessible during an FAD outbreak; however, not all states use the Generic Database and available information may vary greatly by state. The Generic Database will be replaced by a commercial software product in the near future. Trace First Limited's CoreOne software will be housed in a USDA data center and will be available for State animal health officials to use as well as Federal personnel.

8.1.2.3 Animal Disease Traceability Information System

The Animal Disease Traceability Information Systems (ADTIS) are in place to support the animal disease traceability framework. These systems are provided to States and Tribes as an optional method for administering traceability activities. Information on farm locations and contact information is collected at the discretion of States and Tribes. The premises system is capable of determining and recording the geolocation of each premises for future mapping purposes. Other systems within the ADTIS contain official identification and distribution records and other animal events. For more information on the USDA Animal Disease Traceability database, see http://www.aphis.usda.gov/traceability/.

8.1.2.4 Auction/Market Records

Commission firms, dealers, inspectors, and veterinarians may have auction/market test charts and/or records that contain information on animal movements (buyers, sellers, etc.). However, the accessibility and quality of the data varies widely. In addition to animal movements, personnel employed by the market facility may provide information on their movements since the time of exposure to infection and contact with other animals.

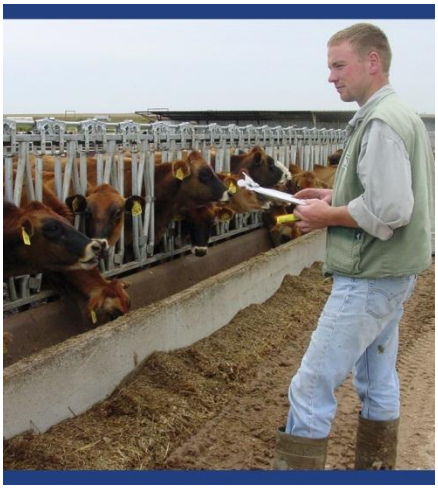
8.1.2.5 Test Charts (Brucellosis, TB, etc.)

Information is collected on animals that undergo testing for USDA program diseases such as brucellosis and TB. For example, bison and cattle 18 months of age and older are blood-tested for brucellosis at harvest facilities, and milk from dairy herds is tested for evidence of brucellosis. If an infected herd is located, the infection is contained by quarantining all infected and exposed animals and limiting their movement control until the disease can be eliminated. Test charts/records verify an animal's location at a specific point in time and may contain information relevant to animal movements.

8.1.2.6 Accredited Veterinarians and Health Certificates

8.1.2.6.1 Accredited Veterinarians

Accredited veterinarians routinely write certificates of veterinary inspection that are required for animal movements across state lines and within states or to exhibitions. Inspection and certification activities by accredited veterinarians are instrumental in disease surveillance, tracing, and monitoring, and also ensure that animals moved are less likely to introduce disease at their next destination. Health certificate information is readily available from the state of entry or destination (see below). In addition to information that may be gleaned from health certificates, accredited veterinarians may also report suspect cases of disease in an FAD outbreak.



8.1.2.6.2 Health Certificates

Specific requirements for animal health certificates are determined by the state of destination. Properly completed health certificates are necessary for adequate health certification when inspecting, testing, and certifying animals for the purpose of controlling animal diseases and facilitating trade and travel.

There are two general types of health certificates for movement:

- Federal health certificates are issued for international movement and referred to as International Health Certificates (IHC). For more information on export regulations, contact the National Center for Import and Export (http://www.aphis.usda.gov/regulations/vs/iregs/animals/) or contact the VS Area Office for your state (http://www.aphis.usda.gov/animal_health/area_offices/).
- State health certificates are issued for interstate and intrastate movement and referred to as Certificates of Veterinary Inspection (CVI). Individual State CVIs are available from the office of the State animal health official. Health certificates and other VS forms related to animal movement are available in the National Veterinary Accreditation Program Reference Guide (2011), Appendix D, at: http://www.aphis.usda.gov/animal_health/vet_accreditation/downloads/nvap_ref_guide.pdf.

Increasingly, electronic CVIs (eCVIs) are being used in the U.S. The eCVI allows accredited veterinarians to access State regulations, request permits for entry, send electronic certificates of veterinary inspection directly to State officials, and attach test charts and vaccination records. There are several potential benefits to the use of eCVI: they may be uploaded to the system quickly, they are possibly searchable, they are easy to organize, they permit the state of destination to be alerted to animal movements prior to the animals' entry into the state of destination, and they maintain a file copy long term compared to paper certificates. The information contained in CVIs is critical for documenting the location of animals at the time of inspection. The usefulness of this information depends on how readily the information can be found. Some states are more automated than others.

To utilize eCVI, accredited veterinarians may subscribe to a commercial web-based platform that provides electronic records (such as GlobalVetLink). USDA-APHIS has also developed the Veterinary Services Process Streamlining (VSPS) website, designed to offer a single point of access to electronic forms, applications and certification processes required for interstate and international movement of animals and animal products. The site is available at http://vsps.aphis.usda.gov/vsps/public/Login.do.

8.1.2.7 Import Permit Systems

Live animals imported into the U.S. must have a valid permit; the Application for Import or In Transit Permit (VS Form 17-129) must be completed. Alternatively, APHIS' ePermits system may be utilized. Permits include the country from which the animal is to be shipped; the animal description (number, breed, species, sex, age, identification, etc.); the planned route of travel; planned shipping and arrival dates; and port of entry. Individual states also have animal import systems. In addition, the Animal Import Module (found on the VSPS website) collects information at the time of import (i.e., information about the animal(s) actually imported), which may or may not be the same as the information collected on the import permit. Using this system, Port Veterinarians can also process release or refusal papers issued at the ports.

8.1.2.8 Livestock Transporters' Manifests and Owner/Shipper Statements

Manifests or Bills of Lading are documents that livestock transporters carry; they are required to accompany livestock shipments. They usually include information about the number and type of livestock onboard, and the origin and destination of the movement. Transportation firms may maintain records of these documents. Transportation enforcement officers may stop transport vehicles to verify compliance and can request to see this documentation in the event of an FAD outbreak.

Owners who transport their animals themselves to livestock markets or harvest facilities are often able to provide their own documentation of the animals involved on the owner/shipper statement. Documentation will be maintained at the market or harvest facility.

8.1.2.9 Brand Inspection Records

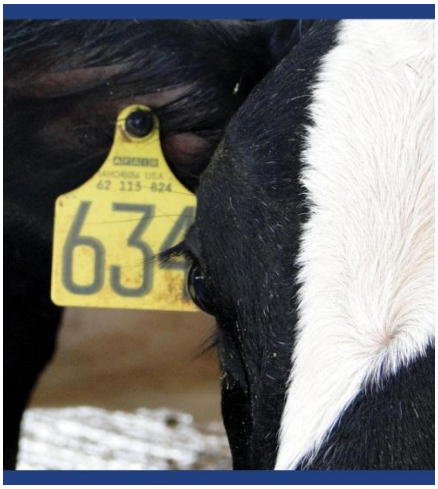
Some (especially those located in the Western U.S.) but not all states require cattle moving from one location to another to have a visual brand inspection. Ownership and transfer of ownership must also be documented. Documents generated from this inspection are generally maintained by the brand inspection authority of each state. These documents, coupled with the laws that facilitate registering of specific brands, can be used to trace groups of cattle moving from one location to another. However, a brand is not an individual form of animal information.

8.1.2.10 Official Identification Devices

8.1.2.10.1 Backtags

Animals that move through a livestock dealer or auction market are currently identified by backtags. Backtags are a temporary form of animal identification (applied with glue). Records kept by the livestock dealer or auction market may provide information on the animal's consignor and buyer. Again, the type, format, and quality of dealer/market records may be highly variable.

8.1.2.10.2 Eartags



Animals that move through a livestock dealer, auction market, or are sold private treaty may be identified by official eartags. For example, breeding age cattle are generally identified with eartags; however, feeder cattle may not be required to be identified by individual eartags. Records kept by the livestock dealer or auction market, or information recorded on Certificates of Veterinary inspection, may provide information on the animal's movements before and after the sales transaction. The type, format, and quality of dealer/market or veterinary records may be highly variable.

A variety of eartag types are manufactured. The simplest forms are for visual inspection only (e.g., panel type eartag; see photo). Electronic eartags are also available. Read by portable, hand-held, or stationary radio-frequency readers, information from these eartags may be collected as part of an animal disease traceability information system.

8.1.2.10.3 State-Issued Identification Devices

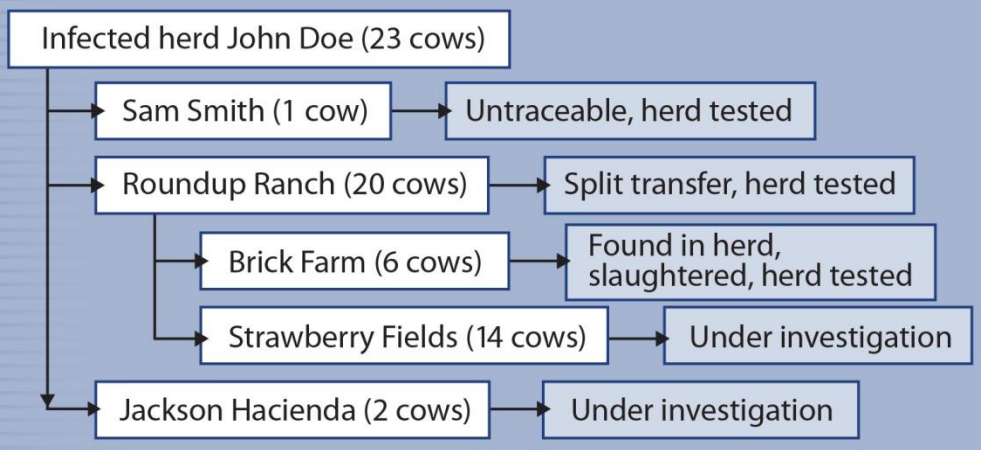
The regulatory authority in each state issues identification devices (i.e., eartags). The range of numbers and characters comprising the identification is recorded. Regulatory authorities may assist with tracing activities when diseased animals with identifiers are sighted. The first entity that received the identification device (e.g., veterinarian or market) can be identified from records. This provides a location from which a trace can be initiated to follow the movements of the tagged animal. The time required to search for a specific eartag number will depend on how the records are maintained. Not all states have electronically searchable eartag distribution databases.

8.2 Reporting Trace Information

The EMRS, or a similar future system, will be used to collect and report epidemiological data, including movement and tracing information, locally and nationally. The tracing section of EMRS allows for tracing animals and/or items.

Animal movements may be complicated and involve multiple points of sale or transfer. Tracing databases, such as EMRS, have the capability to schematically represent trace results. Figure 5 shows a schematic representing multiple traces. In some cases, animals may be untraceable. In addition, if animals are moved multiple times, the trace is "split" and all subsequent movements must also be traced.

Figure 5: Schematic of Traces



Source: USDA APHIS. Trace Concepts and EMRS. PowerPoint Presentation, 2010.

9. ELECTRONIC DATA MANAGEMENT

The EMRS is a computer-based system designed to automate and manage data related to all aspects of an animal disease outbreak or animal-associated disaster. It serves as a repository for disease surveillance and epidemiological data. EMRS, or a future system with similar capabilities, is essential for routine reporting of FAD investigations, surveillance and control programs, state-specific disease outbreaks, and national animal health emergency responses. The current system was first deployed in 2001 but is expected to undergo changes or be replaced in coming years.

Regardless of the specific data management program, users will likely need to register and be granted access based on their employer and position. Currently, authorized users may enter data directly into the EMRS. Personnel in area offices also transfer information collected by field staff into the EMRS. In the event of an FAD outbreak, several groups and/or cells within the ICS will utilize the EMRS for different purposes. They include:

- Diagnosis and Inspection Group – enters case information into the EMRS
- Vaccination Group – records inventory of vaccine and vaccinated animals in the EMRS
- Tactical Epidemiology Group – inputs field data and case information into the EMRS; extracts data as necessary
- Animal Movement and Permits Group – executes movement control and permitting actions and inputs data into the EMRS
- Disease Reporting Cell – retrieves routine and specialized reports from the EMRS; validates all reports of animal disease investigations and results of laboratory tests, to assure the completeness and accuracy of data entry into the EMRS

10. ADDITIONAL OPERATIONAL PROCEDURES

In order to contain, control, and/or eradicate an FAD a variety of strategies will be required. The following operational procedures are related to surveillance and epidemiology/tracing activities and will be implemented in an FAD response: biosecurity, health and safety, personal protective equipment, cleaning and disinfection, and quarantine and movement control. For more information on operational procedures, see the corresponding FAD PReP/NAHEMS Guidelines.

10.1 Biosecurity

Biosecurity is a series of management practices designed to prevent the introduction and spread of disease agents on an animal production facility. Implementing biosecurity measures as standard practice helps ensure that all those working with farm animals or coming into contact with them do not spread disease when they enter or leave a premises. Some personnel involved in surveillance, epidemiology, and tracing activities will be required to work with farm animals and travel from premises to premises; biosecurity protocols must be followed at all times whether or not any disease outbreaks have been reported on each premises. Biosecurity procedures are described in the *FAD PReP/NAHEMS Guidelines: Biosecurity (2011).*

10.2 Health and Safety

In addition to preserving animal health, the occupational health of responders must be considered. Surveillance, epidemiology, and tracing are necessary activities, but the health and safety of personnel that perform these duties must be assured. Responders may encounter hazards that are physical, environmental, and/or psychological in nature. They must also be prepared for emergencies such as fire/explosion, hazardous materials release, and severe weather. Health and safety procedures are described in the *FAD PReP/NAHEMS Guidelines: Health and Safety (2011).*

10.3 Personal Protective Equipment

Responders must take appropriate precautions to protect themselves from exposure to harmful agents, and they must ensure that they do not spread an agent to other people or animals. The phrase personal protective equipment (PPE) refers to special clothing and equipment that places a barrier between an individual and a hazard. PPE serves two purposes in an animal health emergency: (1) protection of the responder against potentially harmful hazards (e.g., HPAI) and (2) with appropriate use and decontamination/disposal, the prevention of the spread of hazards (e.g., FMD) between animals or locations. Personal protective equipment is described in the *FAD PReP/NAHEMS Guidelines: Personal Protective Equipment (2011).*

10.4 Cleaning and Disinfection

Cleaning involves the removal of organic material (e.g., manure, bedding), and washing involves the removal of materials (e.g., oils, grease) that can inhibit the action of disinfectants. Disinfection is a process that destroys most pathogenic and non-pathogenic microorganisms (but not all microbial forms such as bacterial spores) to an acceptable level. Cleaning and disinfection procedures are used to remove, inactivate, reduce, or destroy contagious agents from contaminated premises and fomites; this prevents the spread of pathogens.

When surveillance and/or epidemiology/tracing personnel enter a premises to conduct FAD response activities, they must follow all cleaning and disinfection procedures. Cleaning and disinfection procedures may vary according to the FAD agent. Cleaning and disinfection (C&D) procedures for vehicles, equipment, clothing, and personnel are described in the *FAD PReP/NAHEMS Guidelines: Cleaning and Disinfection (2011).*

10.5 Quarantine and Movement Control

Upon detection of an FAD in livestock, quarantine and control areas will be established by State or Federal animal health officials. This will involve a defined geographic area surrounding an Infected Premises. Quarantines stop movement of infected animals, infected animal products, and fomites originating from Infected, Contact, and Suspect Premises. Quarantines also help to establish movement control zones. Any surveillance and/or epidemiology/tracing activities conducted in these areas will be subject to the established quarantine and movement control procedures. Quarantine and movement control procedures are described in the *FAD PReP/NAHEMS Guidelines: Quarantine and Movement Control (2011).*

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12. FOR MORE INFORMATION

U.S. Department of Agriculture, Animal and Plant Health Inspection Service

Animal Health: Area Offices
http://www.aphis.usda.gov/animal_health/area_offices/

Animal Health: Packaging and Labeling Submissions
http://www.aphis.usda.gov/animal_health/lab_info_services/packaging_labeling.shtml

Animal Health Monitoring and Surveillance: National Animal Health Surveillance System
http://www.aphis.usda.gov/vs/nahss/

Memo 580.4: Procedures for the Investigation of Potential Foreign Animal Disease/Emerging Disease Incidents
http://www.aphis.usda.gov/animal_health/lab_info_services/downloads/VS_Memo580_4.pdf

National Animal Health Surveillance System: Animal Health and Productivity Surveillance Inventory
http://nsu.aphis.usda.gov/inventory/index.faces

Regulations and Assessments: International Animal Export Regulations
http://www.aphis.usda.gov/regulations/vs/iregs/animals/

Veterinary Services Process Streamlining
https://vsps.aphis.usda.gov/vsps/public/Login.do

U.S. Department of Agriculture, Food Safety and Inspection Service

Regulations and Policies: Regulations, Directives, and Notices. Available at:
http://www.fsis.usda.gov/regulations_&_policies/regulations_directives_&_notices/index.asp

World Organization for Animal Health (OIE)

Terrestrial Animal Health Code, Chapter 1.4
http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.1.4.htm

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Glossary

Accredited Veterinarian
A veterinarian approved by USDA APHIS to perform the duties listed in 9 CFR 160-162.

Animal and Plant Health Inspection Service
Agency within USDA responsible for protecting livestock and plant health.

Animal Product
Blood or any of its components, bones, bristles, feathers, flesh, offal, skins, and any by product containing any of those components that originated from an animal or bird.

At-Risk Premises
Premises with susceptible animals, but none have clinical signs compatible with the FAD. Premises objectively demonstrates that it is not an Infected Premises, Contact Premises, or Suspect Premises. At-Risk premises seek to move susceptible animals or products within the Control Area by permit. Only At-Risk premises are eligible to become Monitored Premises.

Biosecurity
A series of management practices designed to prevent the introduction or spread of disease agents in an animal production facility.

Buffer Zone
Zone that immediately surrounds an Infected Zone or a Contact Premises.

Case Definition
A combination of clinical signs and/or laboratory tests required to categorize a case as suspect, presumptive positive, or confirmed positive.

Confidence Interval
Represents the range within which a value lies. Confidence intervals are calculated based on a percentage; 95 percent is commonly used.

Contact Premises
Premises with susceptible animals that may have been exposed to the Foreign Animal Disease (FAD) agent, either directly or indirectly, including but not limited to exposure to animals, animal products, fomites, or people from an Infected Premises.

Containment Vaccination Zone
Emergency Vaccination Zone typically inside the Control Area. This may be a secondary zone designation.

Control Area
An Infected Zone and Buffer Zone. Has individual premises quarantine for Infected Premises, Suspect Premises, and Contact Premises and movement restrictions for At-Risk Premises and Monitored Premises.

Endemic
Present in a population or geographical area at all times.

Epidemiology
The study of disease in populations and of factors that determine its occurrence.

Etiology
The causes or origin of disease, or the factors that produce or predispose toward a certain disease or disorder.

Fomite
An inanimate object or material on which disease-producing agents may be conveyed (e.g. feces, bedding, harness, clothes).

Foreign Animal Disease
A terrestrial animal disease or pest, or an aquatic animal disease or pest, not known to exist in the United States or its territories.

Free Area
Includes a Surveillance Zone, but extends beyond the Surveillance Zone.

Free Premises
Premises outside of the Control Area and not a Contact or Suspect Premises.

Incidence
The number of new cases of disease in a defined population over a specific time period.

Incident Command System
A standardized, on-scene, all-hazards incident management approach that allows for the integration of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure; enables a coordinated response among various jurisdictions and functional agencies, both public and private; and establishes common processes for planning and managing resources.

Incubation Period
The period of time between infection and the development of clinical signs.

Infected Premises
Premises where presumptive positive case or confirmed positive case exists based on laboratory results, compatible clinical signs, case definition, and international standards.

Infected Zone
Zone immediately surrounding the Infected Premises.

Infectious Period
Period of time that an infected animal can transmit the pathogen to another susceptible animal.

Latent Period
The period of time between host infection and the ability to infect others.

Maximum Incubation Period
The longest period that elapses between the introduction of the FAD agent into a susceptible animal and the occurrence of the first clinical signs compatible with the FAD agent.

Monitored Premises
Premises that objectively demonstrate that they are not Infected Premises, Contact Premises, Suspect Premises, or At-Risk Premises.

Mortality Rate
The number of deaths in a defined population during a specific time period.

Outbreak
The occurrence of more cases of disease than expected in a given area, or among a specific group, over a particular time period; many epidemiologists use the terms outbreak and epidemic interchangeably

Pandemic
An outbreak/epidemic that has spread over several countries or continents.

Premises
Includes a tract of land, and all of its buildings, as well as a separate farm or facility that is maintained by a single set of services and personnel.

Prevalence
The total number of cases of a disease in a given population at a specific time.

Protection Vaccination Zone
Emergency Vaccination Zone typically outside the Control Area. This may be a secondary zone designation.

Quarantine
To place animals in strict isolation to prevent the spread of disease.

Reservoir
The environment in which a pathogen lives, grows, and multiplies. Can include humans, animals, and the physical environment. The reservoir is often, but not always, the source of infection.

Risk Factor
An aspect of behavior, an environmental exposure, or a hereditary characteristic that is associated with an increase in the occurrence of a particular disease.

Sensitivity
The proportion of true positives that are detected by a diagnostic test.

Sentinel
A susceptible population, farm, or animal that is repeatedly sampled in order to assess health status over time; the 'sentinel' must be representative of the at-risk populations, farms, or animals.

Specificity
The proportion of true negatives that are detected by a diagnostic test.

Stamping-Out
The killing of the animals which are affected and those suspected of being affected in the herd and, where appropriate, those in other herds which have been exposed to infection by direct animal to animal contact, or by indirect contact of a kind likely to cause the transmission of the causal pathogen.

Suppressive Vaccination
Emergency vaccination conducted both within and around infected zones. Suppressive vaccination can take place throughout a country or compartment; however, this strategy may require large quantities of vaccine and sufficient human resources.

Surveillance
An intensive form of data recording that encompasses gathering, documenting, and analyzing data. Information is then disseminated so that action can be taken to evaluate disease status and eradicate or control a disease.

Surveillance System
A comprehensive and coordinated system that will collect, collate, and analyze animal health data and promptly disseminate animal health information.

Surveillance Zone
Zone outside and along the border of a Control Area.

Susceptible Animal
Any animal that can be infected with and replicate the disease pathogen of concern.

Suspect Premises
Premises with susceptible animals under investigation for a report of compatible clinical signs for the FAD agent.

Targeted Vaccination
Vaccination of selected animals or populations (e.g., uninfected animals of high value including livestock with valuable or unusual genetic backgrounds, long-lived production animals, zoo animals, or endangered species). Can also be directed at uninfected areas where there is a high density of susceptible animals.

Trace-Back
Identification of the origin and movements of all animals, animal products, possible fomites, people, possible vectors, and so on that have entered onto an infected premises.

Trace-Forward
Tracing of all animals, people, fomites, and so on that have left an infected premises. The premises that received the animals or goods should be investigated and kept under surveillance or quarantine.

Tracing
Information gathering on recent movements (during a defined time period) of animals, personnel, vehicles, and fomites (both to and from affected farms) to identify potential spread of disease to other livestock premises and to detect a putative source of infection for the affected farm.

Vaccinated Premises
Premises where emergency vaccination has been performed; this may be a secondary premises designation.

Vector
An insect or any living carrier that transports an infectious agent from an infected individual to a susceptible individual or its food or immediate surroundings.

World Organization for Animal Health (OIE)
The intergovernmental organization created by the International Agreement of 25 January 1924, signed by 28 countries. In April 2011, the OIE totaled 178 Member Countries. OIE standards are recognized by the World Trade Organization as reference international sanitary rules. The purpose of the OIE is to guarantee the transparency of animal disease status world-wide.

Zoonotic Diseases/Zoonoses
Diseases that are transmissible between animals to humans under natural conditions.

Acronyms

ADTIS
Animal Disease Traceability Information System

APHIS
Animal Plant Health Inspection Service

ARP
At-Risk Premises

BZ
Buffer Zone

CA
Control Area

CP
Contact Premises

CVI
Certificate of Veterinary Inspection

CVZ
Containment Vaccination Zone

DRO
Disease Reporting Officer

eCVI
Electronic Certificate of Veterinary Inspection

EMRS
Emergency Management Response System

FA
Free Area

FAD
Foreign Animal Disease

FADDL
Foreign Animal Disease Diagnostic Laboratory

FMD
Foot-and-Mouth Disease

FP
Free Premises

FSIS
Food Safety Inspection Service

GIS
Geographic Information Systems

GPS
Global Positioning System

HPAI
High Pathogenicity Avian Influenza

ICS
Incident Command System

IHC
International Health Certificate

IP
Infected Premises

IZ
Infected Zone

MP
Monitored Premises

NAHLN
National Animal Health Laboratory Network

NSU
National Surveillance Unit

NVSL
National Veterinary Services Laboratories

OIE
Office International des Epizooties' (World Organization for Animal Health)

PPE
Personal Protective Equipment

PVZ
Protection Vaccination Zone

SP
Suspect Premises

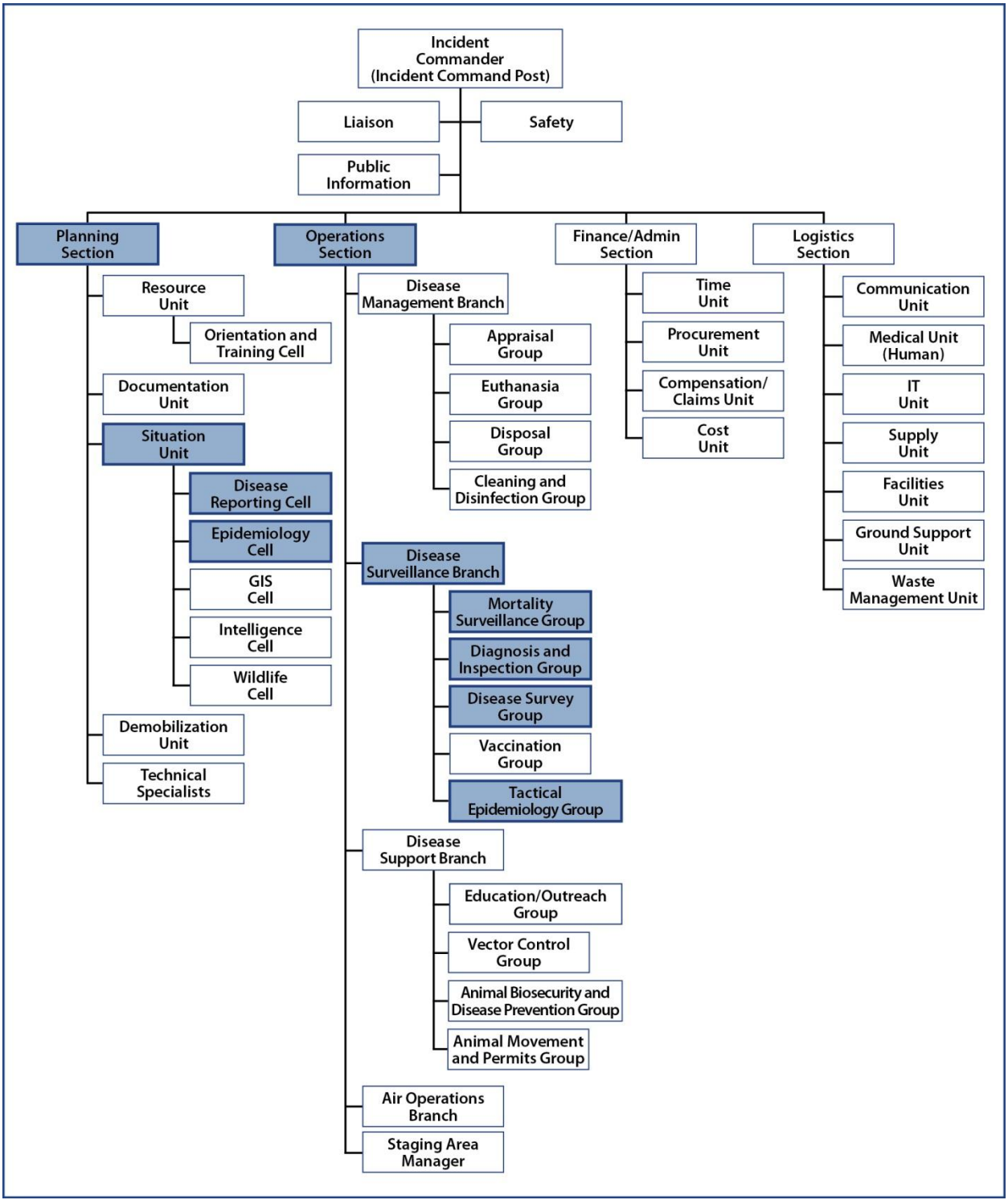
SZ
Surveillance Zone

USDA
United States Department of Agriculture

VP
Vaccinated Premises

VS
Veterinary Services; a division of APHIS

APPENDIX A: SAMPLE ICS STRUCTURE



APPENDIX B: OUTBREAK SURVEILLANCE TOOLBOX

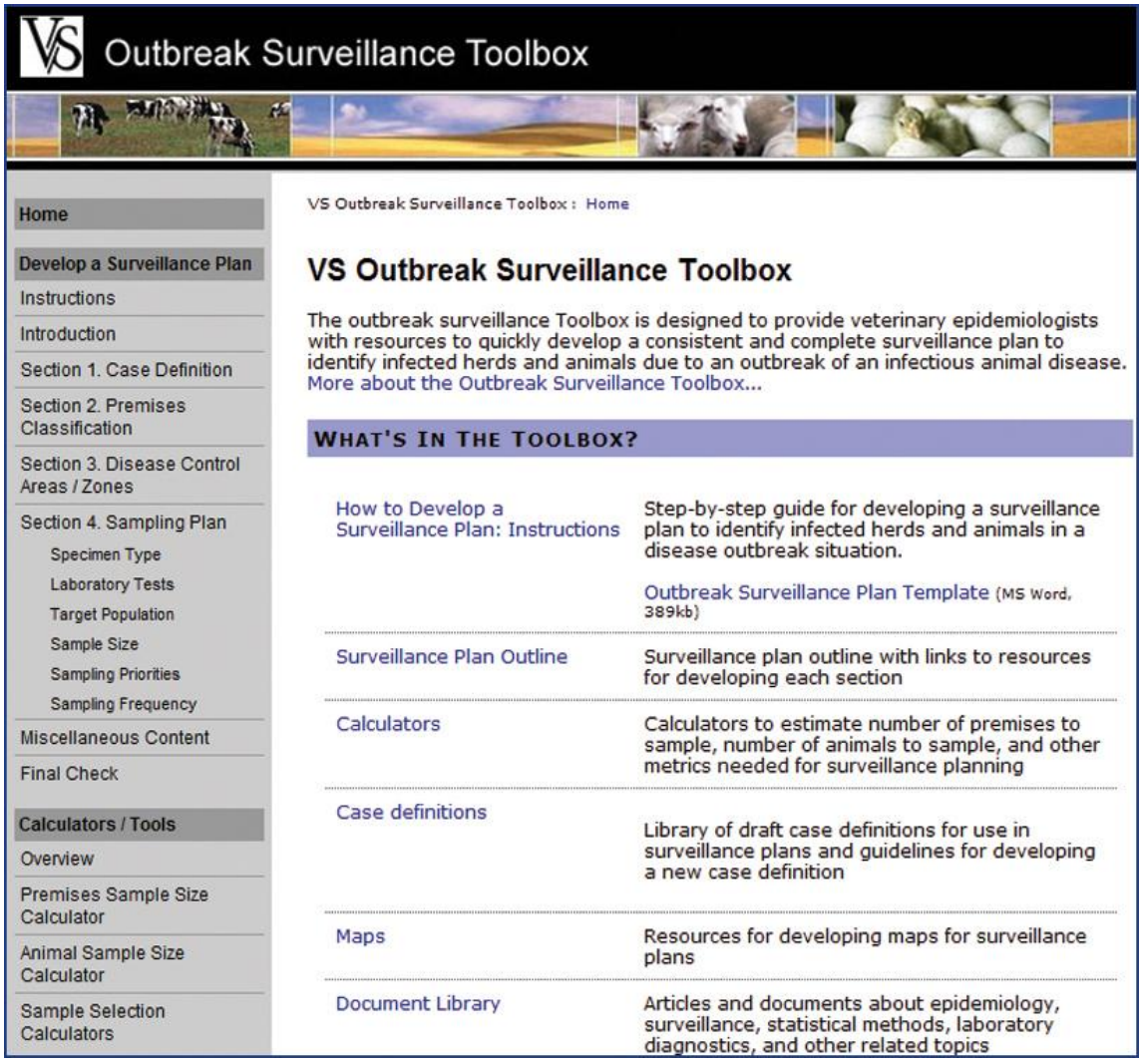
The VS Outbreak Surveillance Toolbox includes four sections that cover:

- Case definitions
- Premises classification
- Disease control areas/zones
- Sampling plan (including specimen type, laboratory tests, target population, sample size, sampling priorities, and sampling frequency)

The following calculators are also included:

- Premises sample size calculator
- Animal sample size calculator
- Sample size calculators (including random and interval sampling)
- Probability of failure to detect diseased animals.

In addition, the toolbox provides resources for developing maps for surveillance plans, and a document library that provides information on surveillance, statistical methods, laboratory diagnostics, and related topics.



For individuals who have access to the APHIS intranet, the Toolbox is available on the internal APHIS FAD PReP website: http://inside.aphis.usda.gov/vs/em/fadprep.shtml. Other individuals who wish to view the VS Outbreak Surveillance Toolbox site should send a request e-mail to national.surveillance.unit@aphis.usda.gov with the following information: name, organization/employer name, and "request access to the VS Outbreak Surveillance Toolbox" included in the email body or subject line.

APPENDIX C: SURVEILLANCE PARAMETERS TO CONSIDER IN AN FAD OUTBREAK

A surveillance plan indicates the frequency, number, and distribution of animals and premises to be sampled. Surveillance plans are developed by selecting combinations and levels of the six tools listed below. Developing a FAD surveillance plan requires tradeoffs to be made between these six surveillance parameters, employing initial information collected, ongoing evaluation of outbreak conditions, and best estimates to the many questions listed below. The six surveillance parameters are:

1) ***Design (threshold) prevalence***: The goal is to determine the lowest feasible prevalence that can be used to detect infected animals on premises. In other words, the chosen proportion of animal or premises infected that if exceeded will indicate the disease has been detected for a given confidence level and population size (1 percent vs. 5 percent vs. 15 percent). Factors that influence the design prevalence choice are:
   a) Available tests (such as visual inspection and laboratory)
      i) The test sensitivity and specificity, and
      ii) The turn-around time for the test results.
   b) If visual inspection is the selected detection method, at what herd prevalence can the clinical sigs be observed?
   c) How severe are the clinical signs?
   d) What is the prevalence of detectable infected animals on the premises given the test selection?
   e) How quickly will there be enough detectably infected animals (such as those with clinical signs) so that the chosen test can detect the infected animals?
      i) Has the disease spread throughout the premises?
      ii) How many animals are detectably ill?
      iii) How long has the disease been on the premises?

2) ***Confidence level***: The selected level (90 percent confident vs. 95 percent confident) that the disease can be detected for the chosen design prevalence, given the population size. Questions to consider are:
   a) At a chosen confidence level, how many samples are required to be taken, given the number of animals or premises?
   b) Does sampling more premises less intensively supply more usable outbreak information than a higher confidence level sampling, where more herds are sampled on fewer premises?
   c) Can the same level of overall sampling confidence be achieved by more frequent sampling using a sampling scheme with lower confidence level? For example, does sampling every third day with an 85 percent confident sampling scheme equal sampling once a week with a 95 percent confident sampling scheme?
   d) If an infected animal is easily detected early, will a sampling scheme with a lower confidence level achieve acceptable detection results?

3) ***Types of tests***: Test choices—visual inspection, polymerase chain reaction testing, serology testing, etc.—and the test cutoff values can influence the design prevalence choice. Each test has a sensitivity and specificity that varies with the cutoff values. Following are questions to consider when selecting tests:
   a) What tests are available?
   b) What are the test sensitivities (assume that this is a screening test)?
   c) Can the test detect infection early in the disease process?
   d) Is the test reliable and test results repeatable?
   e) Is the test rapid and easy to administer?

f) How much labor is required to take samples of the herds or premises?
g) How many trained personnel are available to administer the test or sample the herds?
h) Is the disease easily transmitted by the sample taker?
i) What is the optimum frequency interval at which the test can be applied?
j) Does the sampling/testing activity seriously disrupt the normal premises work flow?
k) What is the cost of the tests?

4) ***Sampling frequency***: Previous negative test results can augment information gained from negative test results if the time period between sampling is short—ideally daily, but definitely less than the incubation period. The value of the previous negative test results decreases as the interval between sampling increases (daily vs. every other day). The following are questions to consider when determining the frequency of sampling:
   a) How frequently should the premises in each zone (IZ, BZ, SZ and Free Area [FA]) area be inspected?
   b) How long is the disease incubation period?
   c) How long is the latent period?
   d) How long is the infectious period?
   e) How rapidly is the disease spreading through the premises?
   f) How likely is the disease to spread to other premises?

5) ***Risk-based sampling***: Selecting populations with a higher proportion of infected animals (1 percent vs. 10 percent) reduces the number of samples needed for a given confidence and population size. The following are several questions to consider:
   a) How many animals are on the farm?
   b) Is there a high risk population (assumed higher prevalence rate) that can be sampled to reduce the sample numbers required or is a census or random sample of the premises entire population required?

6) ***Sampling scheme***: Within the selected population (risk-based or total population), a random, convenience, or other scheme may be used, and the choice will influence the number of animals/premises sampled. Questions to consider when developing a sampling scheme include:
   a) Is it possible to target a high-risk population that should have a higher FAD prevalence rate, for example, sick or dead animals?
   b) Will convenience sampling supply the same confidence level as random sampling?
   c) Is random sampling possible?

The surveillance plan, created based on the six criteria above, will change as new information becomes available by adjusting the combination of these six surveillance tools. It is expected that the surveillance plan will continue to evolve as new information is incorporated by IC personnel.

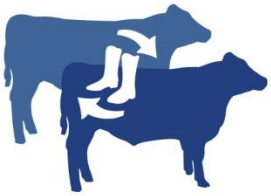
APPENDIX D: TRANSMISSION ROUTES

Disease causing agents can be spread from animal-to-animal or animal-to-human and vice versa, through a variety of transmission routes.

Aerosol: Droplets are passed through the air from one animal to another. Examples include foot-and-mouth disease (FMD), Nipah, and rinderpest.

Direct Contact: A susceptible animal becomes exposed when the disease agent directly touches open wounds, mucous membranes, or the skin through blood, saliva, nose to nose contact, rubbing, or biting. Examples include FMD, rinderpest, and peste des petits ruminants virus.

Reproductive: A subtype of direct contact that includes diseases spread through mating or to the fetus during pregnancy. An example would be bluetongue virus.

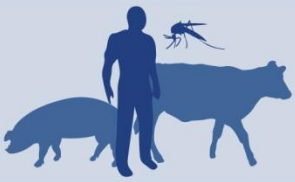


Fomite: An inanimate object carrying a disease agent from one susceptible animal to another. Examples include FMD, rinderpest, and vesicular stomatitis.

Traffic: A subtype of fomite transmission in which a vehicle, trailer, or human spreads organic material to another location.

Oral: Consuming disease causing agents in contaminated feed, water, or licking/chewing on contaminated environmental objects. Examples include Hendra and Nipah.

Vector-borne: An insect acquires a disease agent from one animal and transmits it to another. Examples include Japanese encephalitis, equine encephalitis, and vesicular stomatitis.



Zoonotic: Diseases transmitted from animals to humans. Examples include Nipah, Japanese encephalitis, and vesicular stomatitis (rarely).

Environmental Contamination: must always be taken into consideration.

This information was developed by staff veterinarians at the CFSPH and approved by APHIS for use as training materials for the USDA APHIS National Animal Health Emergency Management System.

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