

Operation Guidance Manual for Harvest Facilities during FAD/EDI Investigations

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Background

Purpose

This document provides guidance for livestock harvesting facilities operating during a foreign animal disease (FAD) or an emerging disease incident (EDI) investigation. The document informs facility management of expectations during the process of an FAD/EDI investigation. While this manual is based on USDA APHIS Veterinary Services (VS) policy and procedures in VS Memorandum 12001, and other relevant USDA documents, investigations will involve State and federal regulators. This manual seeks to clarify the FAD/EDI investigation process, helping to minimize unintended consequences. These guidelines will also increase the level of preparedness within a harvest facility to increase support and expedite investigations. Furthermore, the document will guide harvesting facilities in developing management plans to mitigate the negative impacts of a potential FAD/EDI investigation and help maintain business continuity while minimizing the possibilities of spreading the foreign animal disease.

Scope

This document focuses on the investigation process, from the point of identification of an FAD/EDI suspect animal in the receiving or animal holding areas at a livestock harvest facility under USDA FSIS jurisdiction, through to the reporting and confirmation of diagnostic results and conclusion of the investigation. This manual does not address guidance for the operation of a plant following the definitive diagnosis of an FAD/EDI in the facility or among suppliers to the plant.

Structure of Document

The document has three major sections.

1. FAD/EDI investigation process. This will provide guidance to facility management about what to expect during this process
2. Issues for Consideration / General Recommendations for Facilities. This outlines actions that a facility can take to better prepare for a potential FAD/EDI investigation and support the actual investigation process, while considering individual facility needs and continuity of business concerns, as well as concerns about potential disease spread.
3. Resources that will provide the information required to update existing protocols or develop new ones after review.

Using this Document

This document will guide facility managers in developing or revising their establishments' FAD/EDI management plans in the interval from when an FAD/EDI suspect animal is identified until a diagnosis is confirmed or negated. It focuses on issues to be considered in managing operations, facilities and communications, while mitigating potential negative consequences of an investigation. It is not a list of instructions, but provides a guideline to help establishments assess their level of preparedness and to develop an FAD/EDI response plan that will facilitate an efficient investigation process.

1. Investigation of FAD/EDI Suspect Livestock at a USDA Inspected Harvest Facility

Identification and Reporting

Harvest facilities receive livestock from many sources, often across large geographic areas. Due to this concentration and inspection of animals, harvest facilities are likely locations for detection of animals with signs that are “suspect” of FAD/EDIs. Consequently, facility personnel/employees will be key in early recognition of suspect animals after arrival to a facility and should be familiar with signs of FAD/EDI.

- A plant employee should notify the Food Safety and Inspection Service (FSIS) Public Health Veterinarian (PHV) immediately of suspicious FAD/EDI, if the plant employee recognizes clinical symptoms. The PHV may also recognize suspicious clinical symptoms before or during routine ante mortem inspection (ante or post mortem). If PHVs observe animals exhibiting the signs described below, the animals are considered “U.S. Suspects” under 9 CFR 309.2. PHVs will notify the FSIS District Office (DO) as soon as possible when they suspect that any undiagnosed or unusual disease condition is reportable, foreign, or both.
- The DO will notify the APHIS Assistant Director (AD), the State Animal Health Official (SAHO) or both, and provide the information gathered by the PHV.
- The SAHO or AD will determine how the case is to be handled and give the DO specific instructions at that time. If the AD determines that an investigation is warranted, a Foreign Animal Disease Diagnostician (FADD) from APHIS or the State will be assigned to investigate.
 - The PHV will work with plant personnel to segregate the suspect animal and its lot (if part of a lot).

It is important to note that while the PHV is a USDA FSIS representative they do not have the jurisdiction to complete an FAD/EDI investigation. The PHV will be a resource for the FADD regarding normal plant operations and should work cooperatively with the FADD on the investigation process. *VS Guidance Document 11201.1* also provides further information on blood and tissue collection at slaughter establishments that receive interstate shipments of livestock or poultry.

FAD Investigation by FADD

The FADD is the main contact person for the harvest facility during the investigation period. FADDs have specialized training in FAD/EDI investigation and serve as the onsite incident command leader during the investigation phase. It is critical that a thorough FAD/EDI investigation is done to accurately determine the risk of an FAD/EDI infection.

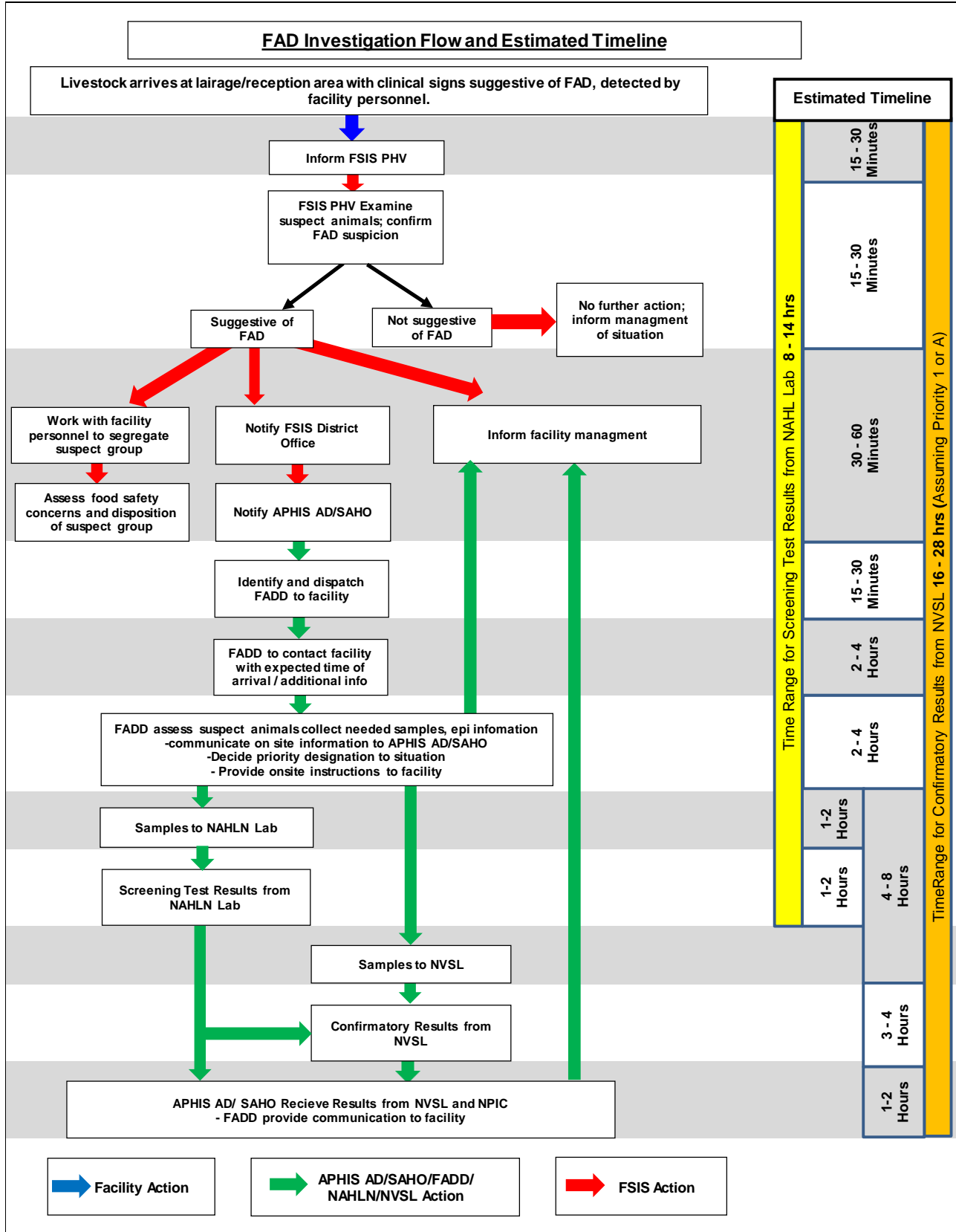
The FADD will follow all procedures and policy as explained in *VS Guidance Document 12001.2* (available [here](#)), as well as in the *FAD Investigation Manual* (available [here](#)). This includes procedures for communication (including with the National Preparedness and Incident Coordination Center [NPIC]), assigning a sample priority, and diagnostic sampling reporting. These two documents provide detailed information on the initiation and completion of FAD

investigations. The ready reference guide, a short 2-page document that explains these activities, is also available [here](#).

FADD Investigation Timeline

FAD/EDI investigation timelines will include: time to travel to premise, time to gather information, time to collect appropriate samples, shipment of samples to laboratories, and testing time requirements. All efforts will be made to ensure these steps are done most efficiently, with more expedited timelines for higher likelihood classifications. See Figure 1 for time range estimates; please note that the timeline illustrated in Figure 1 is a realistic timeline when things go as planned, but only applies in the event of a Priority 1 or Priority A designation from the FADD (per *VS Guidance Document 12001.2*).

Figure 1. Diagram of Investigation Process and Likely Timeline



Movement Restrictions

The SAHO, AD, and other appropriate officials will consult and determine recommendations to the proper authorities on the need for establishment of intrastate quarantine or hold orders (authority of the SAHO) and potential interstate movement restrictions (authority of the Secretary of Agriculture) during the investigation period.

2. Issues for Consideration/General Recommendations for Facilities

It is important to note that the final decision concerning the response during the FAD/EDI investigation period lies in the hands of AD and SAHO. The following recommendations are, therefore, presented in a non-prescriptive manner that allows a plant to be adequately prepared, given its unique characteristics and structure.

Investigation Process Protocol Development

Previous discussions with stakeholders have revealed that, despite the protocol articulated in *VS Guidance Document 12001.2*, there may be areas requiring further explanation for FAD/EDI investigations to occur at a pork harvest facility. In addition, due to the size and scale of large harvest facilities, more clarity in the investigation process would increase the efficiency and accuracy of FAD/EDI investigations.

As a primary concern for harvest facilities is maintaining continuity of business during an FAD/EDI investigation, it is important to be cognizant of the objectives of the Foreign Animal Disease Diagnostician (FADD) as outlined in *VS Guidance Document 12001.2*. Recognizing that one of the most important objectives is collecting samples appropriate for an accurate diagnosis, it will be important to explore opportunities to expedite this goal. In addition, the importance of minimizing disease spread must be recognized; preventive measures should be dictated by disease likelihood classifications.

The scope of these preparedness efforts are focused on activities/decisions that are triggered at a harvest facility when an animal(s) with suspicious lesions or clinical signs is identified at the receiving area or in the lairage. Plant personnel, in tandem with FSIS employees, have the greatest understanding of the day-to-day slaughtering process. Utilizing existing knowledge and procedures by plant and FSIS personnel will enable the FADD to collect samples and associated information efficiently, while causing the least disruption to plant operations.

To this end, it is proposed that a round table discussion with key stakeholders involved in an FAD/EDI investigation be held. Major consideration for this process shall be:

- Identification of Stakeholders
- Communications
- Logistics
- Information needed by FADD.

Although the emphasis is on what the plant and FSIS could do to aid the FADD during an FAD/EDI investigation, proposed protocols should also identify preparatory actions a plant can undertake prior to an FADD arriving at the facility.

Identification of Stakeholders

At a minimum, stakeholders will include:

- Facility Management
 - Procurement
 - Quality Control
 - Communications
- Federal Regulators
 - USDA FSIS
 - FSIS in-plant PHV
 - FSIS District Office Representative
 - USDA APHIS
 - AD in State or region of facility location (or representative of)
- State Regulators
 - SAHO (State Veterinarian or representative of)
 - Department of Agriculture (if separate from SAHO's Office)
 - FADD (may be State or federal or both)

Communications

One responsibility of the FADD is to serve as the main point of contact for communications with the management of the facility or premises that is undergoing an FAD/EDI investigation. It is desirable that the FADD has established a working relationship with the plant and has had prior contact with plant management. It is also desirable that plant management have a prior understanding of the FADD role in disease control. Creating opportunities to have dialogue with FADDs in the area prior to a suspect investigation is recommended, particularly when there has been turnover in these positions.

Facilities should identify one person in charge of communications for the facility during an FAD/EDI investigation. This person should be the key point of contact between the FADD and the facility during the investigation process.

It is recommended that facilities develop a plan for continued communication and review of plans with key stakeholders. This will facilitate keeping plans up-to-date and provide continuity as people and processes change.

Beyond defining the key communication contact, there should be broader considerations of communications by facility management, both for internal and external communications.

Internal Communications

Communication processes within the plant during the investigation process are designed to keep information flowing across functional units in the establishment. These are essential to ensure plant operations during the investigation.

External communications

External communications will involve communications with all audiences outside of the harvest facility's employees, including federal officials, professional associations/networks and the

public. External communications to the public and media should be coordinated with State and federal officials, to determine if communications with these audiences is necessary during the investigation, and to assure consistent and accurate information is delivered when appropriate.

Two broad areas need to be considered:

- Development of communication channels with stakeholders
 - Proactive development of channels during the planning process
 - Develop the communication channel for the FADD to the facility
 - Maintaining communication channels during an FAD/EDI event
- Message development
 - Proactive development of key messages with stakeholders during the planning process (Industry, USDA, FSIS, SAHO, etc.)

Logistics

Logistic considerations for the sampling plan are key to making an investigation of a suspect animal work smoothly and efficiently. We suggest that the FAD/EDI investigative protocol be tailored to the existing processing procedures of a harvest facility. Furthermore, information should be conveyed to the plant and FSIS personnel in a matter that matches the current inspection language.

Logistic details should specify:

- Training of plant employees on recognition of clinical signs consistent with an FAD/EDI, as well as communication channels to appropriate officials (FSIS PHV and plant management).
- A plan to separate suspect livestock that includes identification of individuals, group cohorts, and potential contact groups.
- Isolation capabilities within the facility (consider both live animals and carcasses).
- Entry point for FADD to facility.
- Information exchange point with FADD.
- A plan for supporting sample collection by the FADD.
- Point in the process (location) of sample collection.
- Tools/equipment/resources needed.
- Euthanasia options that comply with FSIS humane standards.
- Disposition of animals and carcasses (ownership, compensation, disposal if condemned, needed segregation if suspect).
- Catalog of resources, skills, and technical capacity of those trained in management of FAD/EDI scenarios within the establishment.

Information Needed by FADD

In order for the FADD to complete the investigation in the most timely, accurate and efficient manner, it will be valuable to have relevant information collected and available for the FADD by

the time of arrival to the facility. The needed information may be different depending on facility and should be developed for each facility.

Information should include at a minimum:

- Detailed information on the suspect animal/animals
 - Source details (PIN, system, owner, trucker)
 - Arrival time
 - History (previous shipments from same source premises)
 - Facility details at the time of arrival (extreme heat, environmental exposures, etc.).
- Normal animal flow of animals through the plant from arrival to slaughter (map of facility and animal movement patterns).
- Traffic log of vehicles carrying livestock entering and leaving the plant; details of origin and destination.
- Record of live animal movements off of premises.

Other considerations

While the investigation process calls for the potential movement restrictions, these will likely depend on the classification that is reached during the investigation process. Guidelines for these recommendations may not be clear, and harvest facilities are high traffic areas for livestock, people, and finished animal products, at a high speed of commerce. Therefore, the facilities need to proactively assess measures that they can institute to address the potential for disease spread during the investigation period. This will allow facilities to identify existing and potential resources needed in the event of a suspect investigation to address potential disease spread, while considering continuity of business.

Likely areas to consider are:

- High Risk Movements
 - Livestock
 - People
 - Vehicles.
- Normal Operations Procedures.

High Risk Movements

Livestock

Livestock movement at harvest facilities is commonly ongoing 24 hours a day. While incoming animals are not likely a risk, facilities may want to restrict the number of animals onsite when an uncertain disease situation is under investigation. The movement of live animals from the site is a potentially high risk activity that should be stopped immediately. We recommend that facilities consider the following:

- Maintain contact information for livestock transport vehicle drivers.
- Maintain contact information for sources of livestock shipments (owner info, PIN, etc.).
- Develop a strategy to quickly limit and/or postpone incoming shipments of livestock not already in transit.

- Postpone the movement of any livestock off site at the time of suspect identification.

People

The movement of people at a harvest facility is complex and varies from potential high risk (animal and animal product contact) to low risk (office workers). We recommend that facilities consider the following:

- ✓ Maintain a list of employee/staff involvement with animals outside the establishment.
- ✓ Convenience or obligation for employees with animal and animal product contact to remove work clothing and shoes prior to leaving the facilities to go home.
- ✓ Ability to set up or use hand washing and footbath stations at exit points of the facility.
- ✓ Segregation of nonessential staff or visitors from animal and animal product areas.

Vehicles

Vehicles have the potential to serve as vectors for disease spread. Vehicle traffic can be broken down into vehicles that are involved with livestock shipments, non-livestock shipments, and employee/personal vehicle traffic. We recommend that facilities consider the following:

- ✓ Separate parking and entrances for livestock, non-livestock, and personal vehicle traffic.
- ✓ Segregated traffic flows for vehicles entering the livestock areas from non-livestock areas when leaving facility.
- ✓ Contingency plan to set up truck washing/cleaning and disinfecting (C&D) for vehicles entering the livestock areas when leaving the facility.
- ✓ Ability to contact drivers and owners of previous livestock shipments.

Normal Operations Procedures

While suspect animals will be separated and held awaiting the official investigation, there is also the potential for the normal slaughter/processing to be interrupted during an investigation period. Any stoppage of normal harvest/processing at a large scale facility has great potential to negatively impact business continuity. APHIS ADs and SAHOs will provide guidance to managers of slaughter/processing plants on the response activities, timelines, and necessary restrictions, depending on the level of FAD/EDI suspicion. We recommend that facilities consider the following to facilitate continued normal operations while reducing potential for disease spread.

- ✓ Ability to identify and segregate suspect animals and any potential contact animals.
 - Contact animals may be all animals in lairage at time of entrance of suspects.
- ✓ Ability to segregate/hold carcasses from animals deemed potential contacts from the start of the investigation period through conclusion.
 - Quantify based on inventory capacity and timelines.
- ✓ Ability to trace any shipments off site.
- ✓ Develop ability and procedures to complete C&D procedures in the animal handling and processing areas that meet USDA guidelines for FAD/EDI.

In summary, we suggest that the plant should continue to process incoming animals that meet FSIS ante mortem inspection criteria, and segregate carcasses and products produced from potential contact animals throughout the investigation and until conclusion of the investigation.

3. Resources

USDA APHIS VS has an extensive library of FAD preparedness and response documents, known as the FAD Preparedness and Response Plan (FAD PReP). FAD PReP materials, including disease response plans, concept of operations documents, general guidelines on veterinary activities, standard operating procedures, and ready reference guides, are all available at www.aphis.usda.gov/fadprep. The purpose is to provide a single source for critical FAD planning, response, and analytical documents.

The beef, pork, dairy and sheep industries have collaborated to develop the “Cross-Species Communications Team” in order to increase industry preparedness and messaging in the event of an FMD outbreak. This group can serve as a huge asset in message development and has many developed and agreed upon messages developed from the perspective of the industry as well as regulatory officials such as USDA, APHIS. They can be contacted through the website they maintain at <http://www.fmdinfo.org>.

Glossary

For the purposes of this document the following definitions apply.

- *APHIS* – Animal and Plant Health Inspection Service; The Animal and Plant Health Inspection Service is a multi-faceted agency with a broad mission that includes protecting and promoting U.S. agricultural health under the Animal Health Protection Act, regulating genetically engineered organisms, administering the Animal Welfare Act, and carrying out wildlife damage management activities.
- *AD* – Assistant Director (under APHIS VS); ADs are Federal officials responsible for animal disease surveillance, supplies for disease eradication programs, veterinary accreditation, animal health monitoring, and endorsement of health certificates in a specific geographical area. In the event of an outbreak, the responsible AD in the VS District will work with the State Veterinarian and APHIS to quarantine infected animals, euthanize animals if necessary, dispose of carcasses, disinfect premises, and collect epidemiological information.
- *C&D* – Cleaning and Disinfecting; Cleaning is the physical removal of visible organic material or soil from objects, environmental surfaces and skin. Disinfection is the use of physical or chemical methods that eliminates all pathogenic microorganisms, except bacterial spores, from inanimate objects. The C&D appendix provides details on FAD PReP guidelines for C&D.
- *CFIA* – Canadian Food Inspection Agency; The CFIA is dedicated to safeguarding food, animals and plants, which enhances the health and well-being of Canada’s people, environment and economy.
- *CFR* – Code of Federal Regulations; the complete Code of Federal Regulations contains the regulations of all the various Federal agencies.

- *DO* – District Office of the FSIS, where the PHV reports a suspected FAD/EDI event. There are ten (10) DOs nationwide, and they serve as a centralized office within a jurisdiction that manages the inspection services for their respective establishments.
- *Emerging Animal Disease* – is defined as any terrestrial animal, aquatic animal, or zoonotic disease not yet known or characterized or any known or characterized terrestrial animal or aquatic animal disease in the United States or its territories that changes or mutates in pathogenicity, communicability, or zoonotic capacity.
- *EDI* – Emerging Disease Incident; any terrestrial animal, aquatic animal, or zoonotic disease not yet known or characterized, or any known or characterized terrestrial animal or aquatic animal disease in the United States or its territories that changes or mutates in pathogenicity, communicability, or zoonotic potential to become a threat to terrestrial animals, aquatic animals, or humans (*VS Guidance Document 12001.2*).
- *EMRS* – Emergency Management Response System; a computer based system designed to automate and manage data related to all aspects of an animal disease outbreak or animal-associated disaster. It is the system of record for all FAD incidents and other animal health events management by APHIS VS.
- *FAD* – Foreign Animal Disease; an FAD is a terrestrial animal disease or pest, or an aquatic animal disease or pest, not known to exist in the United States or its territories.
- *FAD/EDI* – Foreign Animal Disease / Emerging Disease Incident.
- *FAD/EDI investigation period* – the time from when the investigation is initiated until the time an FAD/EDI is ruled out or confirmed by an FADD field investigation, official NVSL laboratory diagnostic testing or study results, or by official VS case definitions.
- *FAD PReP* – Foreign Animal Disease Preparedness and Response Plan; FAD PReP identifies the veterinary functions and countermeasures necessary to contain and control an FAD/EDI, resources can be found at www.aphis.usda.gov/fadprep.
- *FADD* – Foreign Animal Disease Diagnostician; an FADD is a federal or State employed veterinarian who has successfully completed specialized FADD training at the NVSL, Foreign Animal Disease Diagnostic Laboratory (FADDL) facility at Plum Island; as well as any other specialized training and continuing education as required and administered by VS.
- *FADDL* – Foreign Animal Disease Diagnostic Laboratory; FADDL is where APHIS studies certain infectious foreign animal disease agents, develops critical vaccines and validates technologies to be used at other laboratories across the country; it is located at Plum Island, New York (NVSL-FADDL).
- *FMD* – Foot-and-mouth disease; FMD is an extremely contagious viral disease primarily of cloven-hoofed animals that is characterized by fever, vesicular lesions and subsequent erosions of the epithelium of the mouth, tongue, nares, muzzle, feet or teats.
- *FSIS* – Food Safety and Inspection Service; the Food Safety and Inspection Service is the public health agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged.
- *NAHLN* – National Animal Health Laboratory Network; the NAHLN, created in 2002, is a comprehensive, coordinated, and modernized network of federal and State animal

health laboratories and public agricultural institutions that address emergency biological and chemical threats to animal agriculture and the security of the food supply. Personnel in NAHLN laboratories are trained, proficiency tested, and approved to test for multiple FADs of high consequence. With the approval of the SAHO and AD, two sets of FAD samples can be collected, with one sent to the local NAHLN laboratory and the other to NVSL.

- *NPIC* – National Preparedness and Incident Coordination Center; NPIC develops strategies and policies for effective incident management and helps coordinate incident responses.
- *NVSL* – National Veterinary Service Laboratories; The USDA APHIS NVSL safeguards United States animal health and contributes to public health by ensuring that timely and accurate laboratory support is provided by their nationwide animal-health diagnostic system. NVSL is the official reference laboratory for FAD/EDI diagnostic testing and study in the United States. NVSL must perform or officially confirm the results of all diagnostic testing and studies related to FAD/EDI investigations in the United States unless otherwise specified by the APHIS Administrator, or as delegated to the VS Deputy Administrator.
- *NAHEMS* – National Animal Health Emergency Management System; NAHEMS Guidelines (part of FAD PReP) provide general veterinary guidance for dealing with animal health incidents in the United States, such as the incursion of a foreign animal disease or a natural disaster.
- *OIE* – World Organization for Animal Health, (Formerly Office Internationale des Epizooties); OIE is the intergovernmental organization responsible for improving animal health worldwide.
- *PIN* – Premises Identification Number, also known as a PremID
- *PHV* – Public Health Veterinarian; PHVs are FSIS employees and supervise other public health professionals to ensure establishments under FSIS jurisdiction comply with sanitation standards and properly implement systems that control hazards from entering the food supply.
- *PPE* – Personal Protective Equipment
- *SAHO* – State Animal Health Official; The State Animal Health Official who is responsible for the livestock and poultry disease control and eradication programs of a State.
- *SOP* – Standard Operating Procedure; Established procedures to be followed in carrying out a given operation or in a given situation.
- *USDA* – United States Department of Agriculture; the overall mission of USDA is to protect and promote food, agriculture, natural resources and related issues.
- *VS* – Veterinary Services; APHIS VS protects and improves the health, quality, and marketability of our nation's animals, animal products and veterinary biologics by preventing, controlling and/or eliminating animal diseases, and monitoring and promoting animal health and productivity.

- *VS Guidance Document 12001* – This document provides VS policy for the investigation and communication of an FAD/EDI. It also details the classification of investigations, designation of diagnostic sample priority and reporting of laboratory results.

Appendix 1: Operations Manual Checklist for Investigation Process Development

- ✓ Identification of key stakeholders to participate in protocol development.
- ✓ Establishment of a roundtable discussion with stakeholders.
- ✓ Develop plans for key communications.
 - Identify facility contact for communications during an FAD/EDI investigation.
 - Establish working relationship with FADD and communication channel with facility contact.
 - Plan for communications with stakeholders.
 - Identification and development of key messages.
- ✓ Develop a process to collect and make available needed information.
- ✓ Develop logistical details.
 - Training of plant employees on recognition of clinical signs consistent with an FAD/EDI, as well as communication channels to appropriate officials (PHV and plant management).
 - A plan to separate suspect livestock that includes identification of individuals, group cohorts, and potential contact groups.
 - Isolation capabilities within the facility (live animal and carcass).
 - Entry point for FADD to facility during an FAD/EDI investigation.
 - Information exchange point with FADD.
 - A plan for supporting sample collection by the FADD (see appendix for example sampling plan).
 - Point in the process (location) of sample collection (see appendix for example sampling plan).
 - Tools/equipment/resources needed (see appendix for example sampling plan).
 - Euthanasia options that comply with FSIS humane standards.
 - Disposition of animals and carcasses (ownership, compensation, disposal if condemned, needed segregation if suspect).
 - Catalog of resources, skills and technical capacity of those trained in management of FAD/EDI scenarios within the establishment.

Appendix 2: Additional Considerations Checklist for Continuity of Business

Recommended facilities consider identifying their capacity to do or develop protocols/processes to be able to enact the following. These actions may be implemented at various levels during an outbreak investigation depending on the likelihood classification by a facility to limit the potential spread of a disease.

Information

- ✓ Maintain contact information for livestock transport vehicle drivers.
- ✓ Maintain contact information for sources of livestock shipments (owner info, PIN, etc.).
- ✓ Maintain a list of employee/staff involvement with animals outside the establishment.

Operations

- ✓ Develop a process to quickly limit and/or postpone incoming shipments of livestock not already in transit.
- ✓ Develop a process to postpone the movement of any livestock off site at the time of suspect identification.
- ✓ Develop ability to segregate/hold carcasses from animals deemed potential contacts from the start of the investigation period through conclusion.
- ✓ Quantify based on inventory capacity and timelines.
- ✓ Process to trace any shipments off site.
- ✓ Process for employees with animal and animal product contact to remove work clothing prior to leaving the facilities.
- ✓ Ability to set up or use hand washing and footbath stations at exit points of the facility.
- ✓ Segregation of nonessential staff or visitors from animal and animal product areas.
- ✓ Separate parking and entrances for livestock, non-livestock, and personal vehicle traffic.
- ✓ Segregated traffic flows for vehicles entering the livestock areas from non-livestock areas when leaving facility.
- ✓ Develop ability and procedures to set up truck washing / C&D for vehicles entering the livestock areas when leaving the facility.
- ✓ Develop ability and procedures to complete C&D procedures in the animal handling and processing areas that meet USDA guidelines for FAD/EDI.

Appendix 3: Example Sampling Strategy

Through a series of meetings and discussions with a major harvest facility and key stakeholders as outlined in the *Operation Guidance Manual for Harvest Facilities during FAD/EDI Investigations*, a sampling strategy for that facility was developed. This strategy is presented as an example for the purpose of this document. All names and affiliations have been removed. Figure 2 illustrates the example provided here.

“Suspect” animal reporting will follow standard channels for a harvest facility, whether detected by the FSIS PHV or by plant employees. In either case, the reporting chain will go through the PHV and the FSIS District Office (DO). Following notification by the DO, the AD /SAHO will follow standard procedures to assign and dispatch an FADD to the facility.

- Following the initial reporting and confirmation of FAD/EDI suspicion, the PHV will notify the plant management (preferably concurrent with DO notification) and will serve as the initial USDA contact until the FADD arrives on site. In addition, the PHV will work with plant personnel to:
 - Clearly identify suspect individuals, lot cohorts, and potential contact lots.
 - When possible, segregate the suspect group to prevent contamination of other lots and areas (maintain in current location if this does not interfere with animal flow, move to separate area if it does).
 - Segregation areas should be well lit and allow for animal inspection.
- Following notification and dispatch, the FADD will contact the facility via pre-established DO contact and/or through the FSIS PHV to indicate estimated time of arrival.
- In anticipation of the FADD arrival facility management will perform the following:
 - Collect all available information about suspect group(s) of animals and potential contact groups, etc.
 - Work with PHV to identify individuals, group cohorts, and potential contact groups.
 - Segregate suspect groups.
 - Assemble predetermined equipment needed for animal sampling. This may include:
 - Table, lights, hot water source, restraint equipment, euthanasia equipment, and supplies for C&D following sampling.
 - Make arrangements to suspend the shipment of any live animals off the premises
- FADD will enter facility through Gate XXX (predetermined) and park near the predetermined door (preferably near the animal holding area on a hard surface that allows PPE procedures).
- Immediately on arrival of the FADD, there will be an entrance meeting convened. This will allow for information exchange and updates on situation, confirmation of predetermined communication channels and chain of command, and develop a clear synchronized plan. The meeting will involve at minimum:
 - Plant FSIS PHV – Officially hand over the investigation to the USDA APHIS/State investigation team. Provide guidance on acceptable practices in the harvest facility, including animal welfare.
 - FADD (State and/or APHIS) – Lead the investigation at the plant and be the main communication contact between the plant and APHIS AD/SAHO.

- State Emergency Planning Coordinator/Director (on phone) – Advise on the scalability of response and be prepared to engage the State emergency response apparatus into action if warranted by the scope of disease spread.
 - FSIS DO Representative (on phone) – Support the FSIS PHV and be the main communication link between FSIS team and APHIS/State authorities.
 - APHIS AD/SAHO/NPIC Director/Other APHIS (on phone) – Advise the FADD and response team on the investigation process and sampling procedures including selection samples to collect and mode of transportation.
 - Harvest Facility Head of Procurement – Help with tracebacks and proper identification of suspect pigs. Proper holding and separation of suspects. Understand rendering capacity to deal with condemned pigs.
 - Harvest Facility Head of Quality Assurance and Food Safety – Advise on sample collection options on kill floor and past kill floor.
 - Harvest Facility Representative from the Legal and Communications Department (optional) – communicate plant perspectives and messages or information to be relayed to the public.
 - Harvest Facility Designated Plant Spokesperson for the Event (optional) – important to know who from the plant will be communicating with the investigation team.
 - Security and Traffic Control Representative – Control of human and vehicle movement in, out, and within plant premises.
- FADD will assess / examine suspect animals and in combination with situation information and consultation with the APHIS AD/SAHO decide on samples needed, likelihood classification and priority designation.
 - FADD will collect needed samples through predetermined plan. Two options developed in this case.

Batch Approach

For invasive sampling that would result in animals being considered condemned, animals that meet the condemned criteria already (high fever, etc.) or for facilities not able or willing to let them enter the processing chain, approach is as follows:

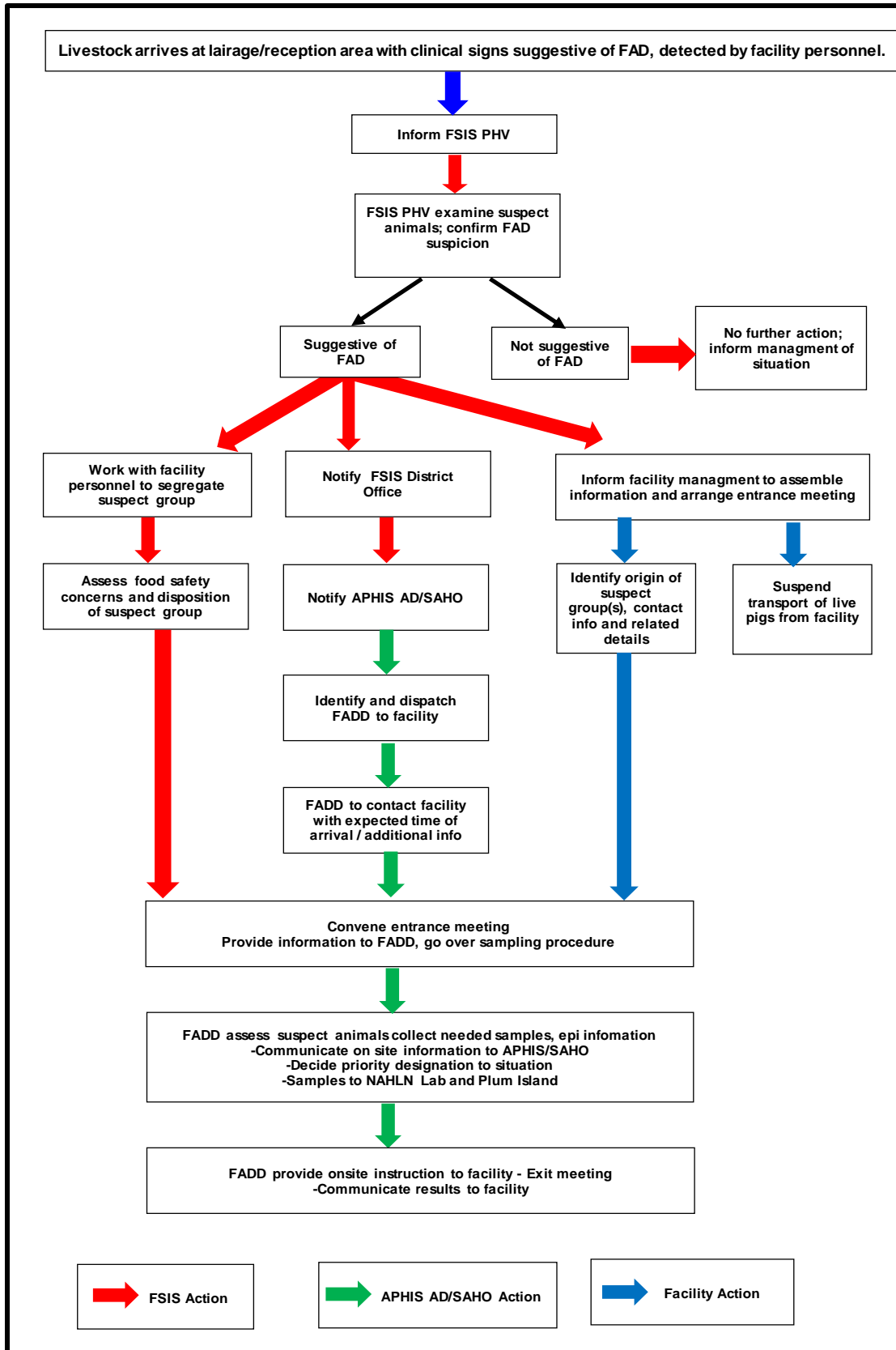
- All suspect animals to be sampled moved to a segregated area in the suspect pen area within the harvest facility. (Suspect pen area will likely have available resources such as ability to stun or euthanize, chain hoists, hot water, good lighting, etc.).
- Animals will be euthanized following FSIS rules and guidelines and appropriate samples will be taken.
- Suspects that are sampled prior to the harvest process become FSIS Condemned (not eligible for food), and thus must be sent to rendering after sampling.

In line – Targeted Systematic Approach

For sampling situations that require less invasive samples that would not result in animals being condemned, large number of animals to be sampled, and facilities that have adequate/suitable facilities to allow for in line sampling that does not disrupt the process significantly.

- Suspect animals will have suitable FSIS-approved identification applied prior to entering the processing line.
 - Suspect tags and/or slap tattoos.
- Suspect animals shall be sampled in line at the bleeding pit area on the slow belt.
- If internal samples are necessary, the identified suspect may be railed off (FSIS rail out), samples taken, and then returned to the line.
 - Any samples taken by FADD beyond the blood pit will require use of company knives and hooks or tools used by FSIS.
 - Samples collected on the kill floor must be taken under direct supervision of FSIS personnel to ensure food safety is not compromised.
- Suspect animals and cohort group carcasses will be segregated and held separately in cooler.
- Timing of sampling would be ideally at end of shift to accommodate any needed C&D or unforeseen delays.
- To expedite turnaround time of preliminary results, duplicate samples should be collected if permitted by the AD/SAHO (one to NAHLN laboratory and another concurrently to NVSL).
- FADD to arrange for sample delivery.
- Exit meeting including same people as entrance meeting to wrap up and provide updated guidance and information.
- FADD to continue to serve as primary contact for facility until conclusion of investigation.

Figure 2. Example Sampling Strategy



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