

Framework for Interstate and Intrastate Movement Decisions During a Foot and Mouth Disease Outbreak in the United States

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PREFACE

The Framework for Interstate and Intrastate Movement Decisions During a Foot and Mouth Disease Outbreak in the U.S. (FMD Framework) is the result of a two-year effort to build consensus and develop criteria for making animal movement decisions in the event of a Foot and Mouth Disease outbreak in the United States. The [USDA National Animal Disease Preparedness and Response Program \(NADPRP\)](#) provided funding for the project to Iowa State University's Center for Food Security and Public Health (NADPRP 2021 - **USDA-APHIS-10025-VSSP0000-22-0001**: Support animal movement decisions in a FAD outbreak). The project was endorsed by the National Assembly of State Animal Health Officials.

The project involved multiple discussions with a broad group of stakeholders from across the U.S. to build consensus and develop criteria and documents to support a new approach to interstate and intrastate animal movement decisions during a foot and mouth disease outbreak in the U.S. To accomplish the project objectives, the CFSPH invited representatives from federal, state and tribal organizations, livestock producer organizations and other stakeholders to be part of a working group to review draft documents and provide advice and suggestions to reach a consensus on the concepts presented in the Framework document. As the document and concepts took shape, working group members were invited to share the document widely within their organizations for further input. In June 2023, after several rounds of meetings, comment periods and revisions, a series of three virtual workshops were held to provide a platform for in depth discussions on rapid surveillance of herds, and criteria for designation of states and herds during an outbreak. The Framework document was revised again based on the comments and suggestions received from the workshops.

On August 29-30, 2023, a Tabletop Exercise was held in Manhattan, Kansas to test the concepts developed in the Framework document. Attendees included state and federal regulatory officials, livestock producers, processors, and academia. The Framework document was revised again based on lessons learned from the exercise. The new version was widely distributed with a request for comments and suggestions. Stakeholders were invited to participate in a webinar in December 2023 highlighting the major revisions to the document. The webinar was recorded and made available. The Framework document and associated materials were revised a final time to include comments and suggestions from the previous draft and webinar. A webinar describing the concepts in the Framework has been recorded and can be found at: <https://www.cfsph.iastate.edu/emergency-response/fmd-framework-for-interstate-movement/>

This document represents the efforts of many people, including state and federal officials, livestock producers, veterinarians, packers and other affiliated stakeholders. This document would not be possible without their commitment to this project, as evidenced by reviewing and commenting on multiple drafts, attending webinars and the TTX.

A list of the organizations invited to participate in the working group and the organizations participating in the TTX appears in Appendix G. We would also like to thank other individuals who attended the workshops and webinars and submitted comments. None of the individuals or organizations mentioned above approved the final draft. The contents of this document are the sole responsibility of the authors.

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EXECUTIVE SUMMARY

Purpose

This document provides a framework for discussion between and among Responsible Regulatory Officials (Federal, State, Tribal, territorial) and industry to provide optimal protection from introduction of foot and mouth disease (FMD) virus to a new area during an outbreak while maintaining business continuity for livestock producers and associated industries to the extent possible, and safe and wholesome food to consumers. **While this document focuses on interstate and intrastate movement decisions by State Animal Health Officials, the recommendations may also be useful for movement decisions by producers and packers. Concepts proposed include a Limited Movement Period of 28 days following a 72-hour National Movement Standstill, approaches to reducing risks associated with movements, and the use of State Status to guide movement decisions. The recommendations in this document are guidelines only; Responsible Regulatory Officials will make decisions based on available information and resources at the time of the outbreak.**

Background

- At the beginning of an FMD outbreak in the U.S., the USDA plans to order a 72-hour movement standstill of all susceptible livestock. Livestock already on trucks and in transit will be allowed to proceed to their intended destination (with some exceptions). Animals at meat harvest facilities should be processed on schedule. Animals at auction markets, fairs, exhibitions or other aggregation points will be handled on a case-by-case basis to minimize chances of spreading infection from infected but undetected animals.
- When the first case of FMD is detected in the U.S., it must be assumed that there may also be undetected cases of FMD. The USDA FMD Red Book states that Control Areas will be set up around each infected premises (10 km radius minimum). The Control Areas are needed to monitor and limit the local spread of the FMD virus. However, extensive animal and other movements from premises occur daily that may spread the FMD virus long distances before the premises is known to be infected. Other FMDV-infected premises could potentially be anywhere in the U.S.
- State Animal Health Officials (SAHOs) are responsible for managing the risk of FMD introduction and spread in their state while maintaining animal welfare, food security, and business continuity to the extent possible. This is a difficult balance to achieve.
- The production animal industry is responsible for monitoring their animals for clinical signs of FMD and protecting their animals from infection with FMD virus.
- The FAD PRoP Strategy Document: Classification of Phases and Types of an FMD Outbreak and Response presents guidelines for classifying the type of FMD outbreak on a national scale to facilitate response planning ([Figure 1, page 8](#)).
- It will be very important to try to control the outbreak before it becomes a Type 3 Large Regional outbreak when it may be necessary to allow some FMD-infected herds to recover and to implement vaccination-to-live.

Summary of Major Recommendations to Prevent an FMD Outbreak from Becoming a Type 3 or More Extensive Event

- Areas outside of Control Areas are currently considered Free Areas. This designation indicates that animals are free from regulatory movement restrictions imposed by the Unified Incident Command (UIC). It does not mean that they are free of FMDV. Referring to all areas outside the Control Areas as Free Areas can be confusing. Some producers and others erroneously interpret that designation to mean that the USDA is stating that all premises and animals in the Free Area are free of FMD. In this

document, **all areas of the U.S. outside of the Control Area will be referred to as “Observation Areas” rather than Free Areas. These areas will be monitored for FMD by producers, farm workers, veterinarians, and federal and state inspectors at meat harvest facilities.** State and federal officials will respond to reports of potential FMDV infection and conduct trace-back and trace-forward contacts from infected premises in the Observation Areas.

- **Only essential low-risk movements should be allowed outside of Control Areas for the first 28 days (two maximum FMD incubation periods) after the standstill ends (Figure 3, page 11).** This 28-day Limited Movement Period should apply nationally to all interstate and intrastate movements of susceptible animals. The USDA should consider using the same authority that they used for the National Standstill to extend it to a 28-day limited movement period¹. Producers accepting animals into their herds during this period are taking a chance that they may introduce FMD into their operation. The 72-hour standstill and the 28-day Limited Movement Period provide the best opportunity to find all infected premises, end the FMD outbreak, and return the U.S. to FMD free status. **The Limited Movement Period enables FMD to be detected before large-scale/widespread movements resume.**
- **Movements that are considered essential and low-risk would be allowed during and after the 28-day Limited Movement Period.** The UIC and SAHOs can decide which movements are essential and low-risk during the Limited Movement Period. [Table 1, page 12](#) provides a list of movements that could be considered essential and low-risk, which may be allowed at the end of the 72-hour movement standstill without needing an FMD-related permit from the SAHO. This should help avoid overwhelming the SAHO's ability to issue specific permits and enable some essential low-risk movements to occur quickly at the end of the 72-hour standstill. [Table 2, page 12](#) provides a list of high-risk movements that should be avoided during the Limited Movement Period and perhaps longer depending on the epidemiology of the outbreak. Movements not on either list should only be allowed after review and approval by the shipping and receiving premises and the SAHOs in the shipping and receiving states. See [Appendix A, page 26](#) for a proposed form to request such a movement. Ultimately, it is up to the SAHOs and producers to determine what they consider to be essential movements and low-risk movements.
- State and federal authorities will likely be fully occupied managing the Control Area(s) and investigating epidemiologic links outside the Control Areas. **Reducing the potential for spreading FMDV in the Observation Area is the responsibility of livestock owners with guidance from state and federal authorities and their herd veterinarians. In the first 28 days following the end of the 72-hour standstill, and possibly longer, livestock owners and managers can protect their animals by limiting the movement of animals and associated items to only essential and low-risk movements.** Accepting FMDV-infected but undetected animals into their operation can devastate their herd or flock and damage the economic viability of their operation. **Another means to reduce the risk of moving FMD-infected, but undetected animals in the Observation Area throughout the outbreak is to request that they be FMD-Checked before movement (see Table 4, page 17).**
- The risk of accepting FMD-infected but undetected animals into an operation is borne primarily by the animal owners, the animals on the premises, and the livestock industry. **It is up to the SAHOs and producers to determine what they consider to be essential movements and low-risk movements.**
- [Figure 1, page 8](#) illustrates the potential types of FMD outbreaks based on size during national phase 2 of an FMD outbreak as described in the USDA FMD Red Book. **This Framework proposes a**

¹ “A State may require a movement standstill under its own authority or at the request of USDA, or in some cases, USDA may impose a federal quarantine or other movement control by Federal Order when requested by SAHOs or as directed by the Secretary of Agriculture.” [USDA FMD Red Book](#) (Section 4.10.1 – Page 4-38, Oct 2020).

classification of states according to FMD status during a national phase 2 of an FMD outbreak ([Figure 5, page 20](#)).

- **In Level 1 (Stamping out) or Level 2 (Stamping out with vaccination to kill) FMD-affected states ([Figure 5, page 20](#)) decisions on animal movement should be based on the status of the area (Control Area or Observation Area) rather than the status of the state.** An Observation Area in a Level 1 or Level 2 affected state should not be considered to be at a higher risk for unknown FMD infection than an Observation Area in a state not affected by FMDV ([Figure 4, page 19](#)). However, an entire Level 3 FMD affected State (Vaccinated to Live with No Stamping Out) should be considered a higher risk for FMD-infected but undetected animals than Level 1 or Level 2 affected states.
- **A meat harvest facility in a state with no detections of FMD that receives FMD-positive animals from out of state should not result in the state being designated as an FMD-affected state** (*Note: A meat harvest facility is a facility that is Federally inspected, State inspected, or is Custom Exempt*). A Control Area should be established at the perimeter of the meat harvest facility until the facility undergoes cleaning and disinfection for FMDV. Once cleaning and disinfection are completed and as long as the facility is not in a Control Area established due to infected production premises, the Control Area around the facility could be lifted, and the facility could return to operation. ([Appendix C, page 33](#)). This is consistent with the plans for African Swine Fever (ASF) in the ASF Red Book.

FRAMEWORK FOR INTERSTATE AND INTRASTATE MOVEMENT DECISIONS DURING A FOOT AND MOUTH DISEASE OUTBREAK IN THE UNITED STATES

The Framework is divided into two sections. Section One discusses ways to safely resume animal movements while limiting the likelihood of spreading FMDV after the end of the 72-hour movement standstill. Section Two describes FMD status for states and explains how they could be used to facilitate animal movements and move the nation toward FMD freedom.

SECTION 1: RESUMING ANIMAL MOVEMENTS WHILE LIMITING THE SPREAD OF FMDV

Background Information

Classifying an FMD Outbreak: Phases, Types and Levels

The **FAD PReP Strategy Document: Classification of Phases and Types of an FMD Outbreak and Response** presents guidelines for classifying the type of FMD outbreak on a national scale to facilitate response planning ([Figure 1](#)).

During an FMD outbreak in the U.S., the focus of the response must be finding a balance between the risk of spreading FMD virus (FMDV) and maintaining business continuity and animal welfare. **At the beginning of an FMD outbreak, the highest priority is to take all measures possible to prevent disease spread, to stamp out the disease as rapidly as possible, and to reestablish the United States as an FMD free country.** It is very important to try to control the outbreak before it becomes a Type 3 Large Regional outbreak when it may be necessary to allow some FMDV-infected herds to recover and to implement a vaccination-to-live strategy. If an outbreak in the U.S. becomes a Type 3 outbreak, the return to FMD Free status will be prolonged and require extensive resources. In an extensive outbreak of FMD, the highest priority is to ensure a secure food supply for the nation and the world by facilitating business continuity for food animal producers and all associated industries.

This document proposes a classification of each state by assigning them levels according to their FMD status during Phase 2 of a national FMD outbreak. This will be discussed later in this document ([page 21](#)).

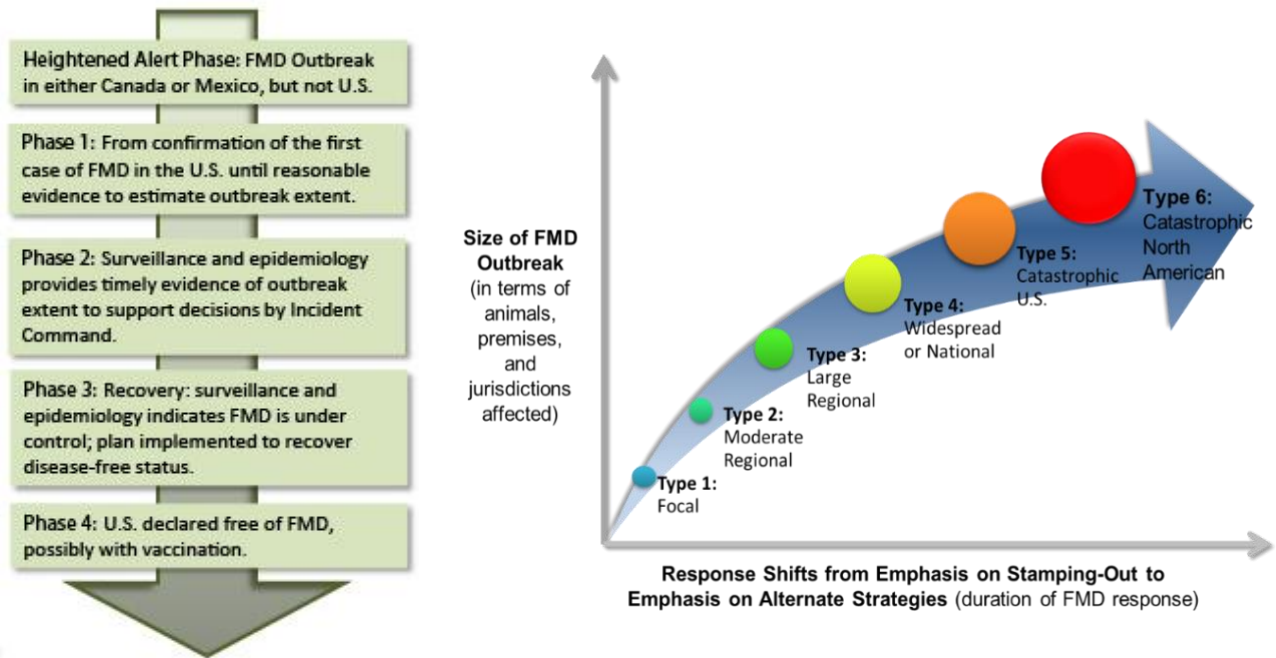


Figure 1: Potential Phases of an FMD Response and Types of an FMD Outbreak During Phase 2 on a National Scale. https://www.aphis.usda.gov/animal_health/emergency_management/downloads/phases-and-types-of-an-fmd-outbreak_2013.pdf (See Pages 9-11)

Control Areas

At the beginning of an FMD outbreak in the U.S., a movement standstill of susceptible species and their germplasm may be implemented nationwide by USDA APHIS or in individual states by state authorities upon the first confirmed case of FMDV infection in the U.S. According to the [USDA FMD Red Book](#) (Section 4.10.1 – Page 4-38, Oct 2020) “Controlled movement orders and 24- to 72-hour standstill notices are likely to be implemented upon detection of FMD in the United States in relevant regions or zones.” “A State may require a movement standstill under its own authority or at the request of USDA, or in some cases, USDA may impose a federal quarantine or other movement control by Federal Order when requested by SAHOs or as directed by the Secretary of Agriculture.”

The USDA FMD Red Book states that Control Areas will be set up around each infected premises (10 km radius minimum) ([Figure 2](#)). The Control Areas are needed to monitor and limit the local spread of the FMD virus. However, extensive animal and other movements from premises occur daily that may spread the FMD virus long distances before the premises is known to be infected. Other FMDV-infected premises could potentially be anywhere in the U.S. The planned 72-hour standstill is an acknowledgment of the possibility that the FMDV may be present on additional undetected premises and is intended to give regulatory authorities and producers time to find any additional infected herds. When the first case of FMD is detected in the U.S., it must be assumed that there may also be undetected cases of FMD.

Approaches to Resuming Movement

Reclassify Free Areas as Observation Areas

Areas outside of Control Areas are currently designated as Free Areas. (Figure 2) This designation indicates that animals are free from regulatory movement restrictions imposed by the Unified Incident Command (UIC). It does not mean they are free of FMDV. At the end of the standstill, there will not have been sufficient time to determine the FMD status of all animals and premises outside the Control Area(s). **Referring to all areas outside the Control Areas as Free Areas can be confusing. Some producers and others erroneously interpret that designation to mean that the USDA is stating that all premises and animals in the Free Area are free of FMD. This document proposes reclassifying the Free Areas as “Observation Areas.”** Animals on premises in the Observation Areas will be monitored for clinical signs of FMD by producers, farm workers, veterinarians, and federal and state inspectors at meat harvest facilities. State and federal officials will respond to reports of potential FMDV infection in the Observation Areas and conduct investigations and trace-back and trace-forward contacts from the infected premises.

Disposition of Animals in Transit at the Beginning of a Standstill

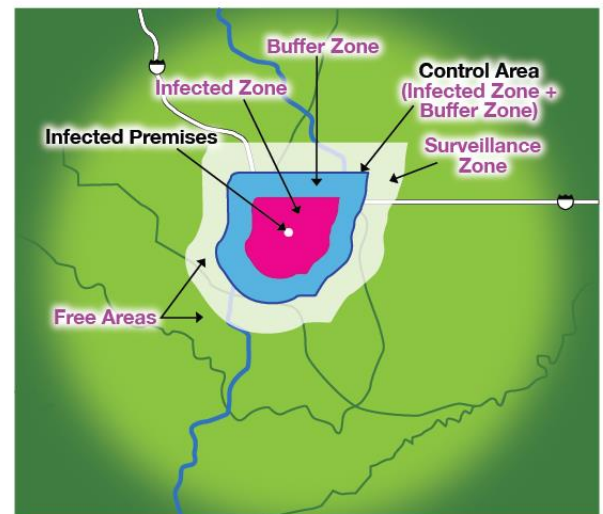
This Framework document proposes that SAHOs agree to standard guidelines for the disposition of animals in transit before an outbreak occurs. This will reduce confusion and facilitate rapid decision making at the beginning of an outbreak.

Refusal to allow animals in transit to cross state lines to either get to their destination or to return to the site of origin will result in many animals being stranded in the state they happen to be in when the standstill is initiated. Unless animals originated from a known infected premises, they should be allowed to continue to their intended destination. An exception is animals intended to arrive at an aggregation site (fairs, exhibitions, auction markets, etc. (See the next section)

The Unified Incident Command (UIC) (federal, state/territorial/tribal officials) will manage regulatory movements of animals and products within FMD Control Areas. The [Secure Food Supply \(SFS\) plans](https://www.cfsph.iastate.edu/pdf-library/FMD-Resources/disease-fmd-sfs-managed-movement-regulatory-officials.pdf) make recommendations regarding managing movement of susceptible livestock species originating from a premises in a Control Area at the beginning of an FMD outbreak: <https://www.cfsph.iastate.edu/pdf-library/FMD-Resources/disease-fmd-sfs-managed-movement-regulatory-officials.pdf>

At the end of the 72-hour standstill, it will be essential to resume some animal movements for animal welfare, food security, and business continuity. A best practice for animals going to another production site would be to quarantine the animals away from other susceptible animals upon arrival at the destination, if possible, for two incubation periods (28 days).

A. Current Zones and Areas



B. Proposed Zones and Areas

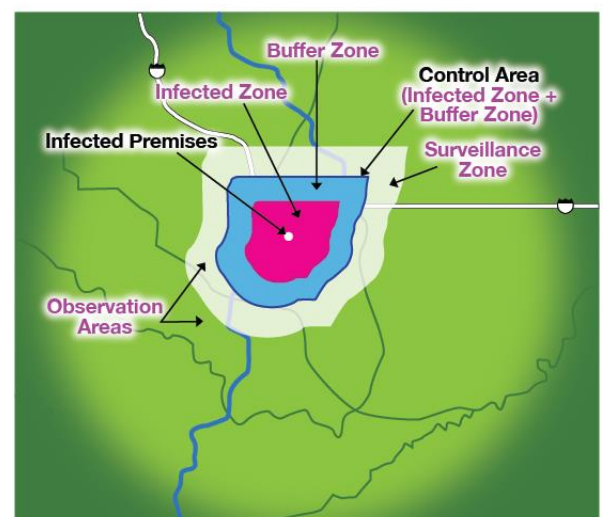


Figure 2: FMD Disease Control Areas and Zones Figure 2A shows current terminology for FMD disease control zones and areas. Figure 2B shows the proposed reclassification of Free Areas to Observation Areas.

Disposition of Animals in Transit to or at Aggregation Sites at the Beginning of an FMD Outbreak

Susceptible animals at aggregation sites (fairs, exhibitions, auction markets, etc.) are a high risk for infectious disease dissemination. They should not be sent forward to production sites or back to where they came from if they may have been exposed. This decision may need to be made by the SAHO in conjunction with the UIC, aggregation site owners, and animal owners on a case-by-case basis.

Some options to consider:

- If animals are on their way to aggregation sites, but have not yet been comingled, they could return to the premises of origin.
- After the standstill is lifted, animals could be sent to slaughter if they are ready.
- Animals could be sent to a production site (or sites) with no other susceptible animals and quarantined for 28 days.
- Animals could be quarantined at the aggregation site for two incubation periods (28 days), then allowed to move depending on clinical signs and testing, if needed. If the aggregation site does not have the capacity or willingness to quarantine for 28 days, animals could be moved to another quarantine site or sites.
- Animals could be depopulated and disposed of (preferably with indemnity).

Movement of Milk

A nationwide movement standstill recommendation will not include stopping movement of milk from premises that are not infected, suspect, or contact premises. The USDA FAD PReP FMD Response Plan: The Red Book (Oct 2020) states: “A national/regional movement standstill notice does not affect the movement of milk. Premises may continue moving milk to processing. All premises moving milk must implement, monitor, and enforce their premises’ biosecurity plans to reduce the risk of FMD introduction. States may choose to implement additional or alternative guidance for premises needing to move milk.”

The Secure Milk Supply Plan, which applies to premises in a Control Area, states:

Dairy premises in any FMD Control Area that are **NOT designated as Infected, Suspect, or Contact Premises** will be informed by Responsible Regulatory Officials that they either:

1. Continue moving milk to processing with or without additional requirements (such as a National Premises Identification Number (PIN), increased premises biosecurity, truck and driver biosecurity, and/or some form of pre-certification by their state) depending on the characteristics of the outbreak.

OR

2. Stop movement of milk, become a Monitored Premises (which requires having a valid PIN, and be inspected to ensure adequate biosecurity and surveillance) and obtain a permit to move milk to processing. In the event a permit is required, guidance is included in the SMS Plan.

The Secure Milk Supply plan discusses the rationale for allowing the continued movement of milk from dairies in control areas under certain circumstances: [http://securemilksupply.org/Assets/Secure-Milk-Supply-Plan for COB.pdf](http://securemilksupply.org/Assets/Secure-Milk-Supply-Plan-for-COB.pdf).

Proposed 28-Day Limited Movement Period

This document recommends allowing only essential low-risk movements for the first 28 days (two maximum FMD incubation periods) after the 72-hour standstill ends (Figure 3). **Just as the 72-hour standstill applies to all interstate and intrastate movements of susceptible animals, the proposed 28-day Limited Movement Period should also apply nationally to all interstate and intrastate movements of susceptible animals.** This will likely require the USDA to use the same authority used to issue the 72-hour movement standstill for the 28-day Limited Movement Period. Producers accepting animals into their herds during this 28-day period are taking a risk that they may introduce FMD into their operation. The 72-hour standstill followed by the 28-day Limited Movement Period provides the best opportunity to find all infected premises, end the FMD outbreak, and return the U.S. to FMD free status. The Limited Movement Period also allows time for the National Veterinary Stockpile to acquire and distribute FMD vaccine.

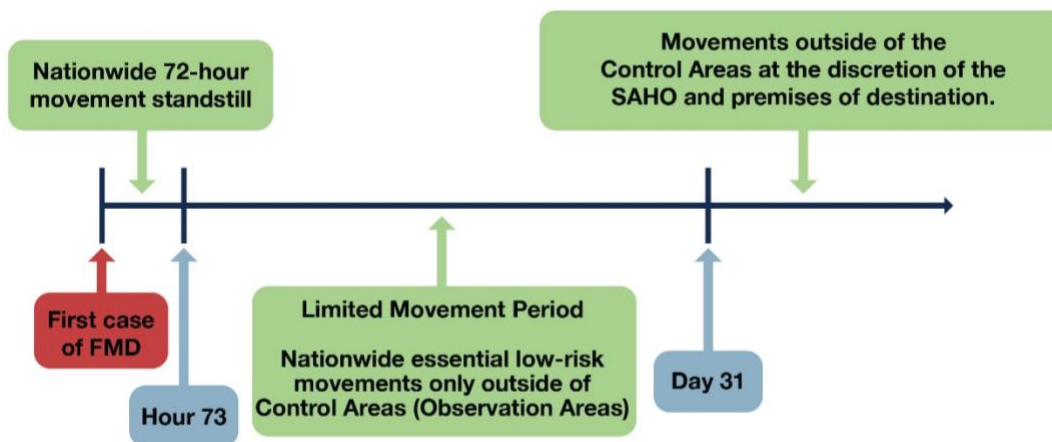


Figure 3. Timeline of a Nationwide 72-hour Movement Standstill of FMD Susceptible Animals Followed by a Nationwide 28-day Limited Movement Period of only Essential Low-Risk Movements outside of the Control Areas. If infected premises are still being detected after the Limited Movement Period ends, Federal or State officials may decide to extend the Limited Movement Period.

Allow Only Essential Low-Risk Movements During the Limited Movement Period

The Limited Movement Period provides time to detect additional FMD cases before animal movements resume on a larger scale. This document proposes only allowing movements that can be considered essential and low-risk and suggests steps that can be taken to reduce the risk of moving FMD-infected but undetected animals during and after the 28-day Limited Movement Period. The UIC and SAHOs should decide which movements are essential and low-risk during the Limited Movement Period. The destination premises also need to carefully evaluate the risk of accepting animals onto their premises during this period.

[Table 1](#) lists movements which could be considered as low-risk and could be allowed without further review by regulatory officials at the end of the 72-hour standstill. **This framework proposes that the USDA issue a recommendation that the low-risk movements listed in [Table 1](#) be allowed beginning at hour 73 (or the end of the movement standstill) just as they were before the outbreak except with an emphasis on truck and driver biosecurity.** SAHOs should determine which essential low-risk movements they would allow based on their state's situation and communicate this information to producers and other stakeholders. Allowing certain low-risk essential movements to resume in the Observation Areas after the end of the standstill provides an orderly pathway to resuming animal movements while reducing risk and minimizing demands on SAHOs to review movement requests and issue permits. Proposed movements not on the list of approved essential low-risk movements will require review and approval by the SAHOs in the sending and receiving states (if interstate movement is involved) and the receiving premises. The sending premises must explain why the movement

should be considered essential and low-risk. See [Appendix A](#) for a proposed form that can be used by a producer to request permission for an essential low-risk movement not included in [Table 1](#).

Table 1: Essential Low-Risk Movements

The following movements (either intrastate or interstate) could be considered essential low-risk movements at the end of the 72-hour standstill and should be allowed without the need for an FMD-related permit:

- Movement of animals outside of a Control Area to a meat harvest facility
- Movement of animals in a biosecure building to another biosecure building (according to the Secure Food Supply plans) if it is essential to move the animals for welfare purposes.
- Movement of animals from an isolated location (e.g., pasture, lot, or building) to another location without exposure to new animals if it is essential for welfare purposes.

Permission for other intrastate or interstate movements during the Limited Movement Period should be requested from the SAHO by providing documentation that the movement is essential and is low-risk (See [Appendix A](#)).

[Table 2](#) provides a list of high-risk movements that should be avoided during the Limited Movement Period and perhaps longer depending on the epidemiology of the outbreak. It is in the best interest of producers to avoid high-risk movements to protect their animals. An additional factor limiting movements at the beginning of an FMD outbreak is that animal and product prices are expected to decrease and fluctuate. It may be difficult to establish a fair price until the outbreak stabilizes.

Table 2: High-Risk Movements that Should Not Occur Until the Extent of the FMD Outbreak is Known

The following movements should be considered high-risk movements and should be avoided during the Limited Movement Period, and perhaps longer depending on the epidemiology of the outbreak:

- Any movements of animals to animal aggregation sites such as markets, fairs, exhibitions, shows, etc.
- Any movements of animals that are not immune due to vaccination, or in a biosecure environment to premises where they will be exposed to other FMD-susceptible animals (e.g., Feedlot, backgrounder, dairy, breeding operation, etc.).

At the end of the 28-day Limited Movement Period, any state that still has no detections of FMD may be considered an [FMD Monitored State](#) (No detections of FMD for 28 days). It will be up to the SAHOs and the premises receiving animals to decide if they want to continue to allow only essential low-risk movements of animals after the initial 28 days. This may depend on the epidemiology of the outbreak at this point in time.

Movement of Animals to Meat Harvest Facilities

Restarting the movement of animals to meat harvest facilities after the 72-hour standstill is essential for animal welfare, food security, business continuity, and removing animals from potential exposure to infection. Animals that are ready should be sent to a meat harvest facility as soon as possible. These should be considered essential low-risk movements as long as no live animals leave the harvest facility and transport vehicles are cleaned and disinfected, or a staged loadout procedure is followed to ensure that any viral contamination on the truck returning to a premises is not tracked into the animal holding areas. A staged loadout procedure may be essential in freezing or other inclement weather when adequate truck wash

facilities are not available (https://www.securebeef.org/Assets/SBS_Info-Manual-for-Enhanced-Biosecurity-FMD-Feedlots.pdf).

Harvest facilities and SAHOs in states with harvest facilities are encouraged to accept apparently healthy animals (with implemented truck and driver biosecurity) from Observation Areas after the 72-hour standstill without further FMD-related documentation. This will facilitate business continuity, food security, and animal welfare. Trucks hauling animals from premises in the Observation Area should not pass through a Control Area on their way to a meat harvest facility. USDA Food Safety Inspection Service (FSIS) or state inspection will ensure that processed animals are healthy, and the products are safe and wholesome for consumption. The procedures required if a harvest facility is found to have received animals infected with FMDV need to be defined (See [Appendix C](#)). The meat harvest facility is likely to be required to finish processing all healthy animals, then clean and disinfect all areas that may have been contaminated. The risk and benefit of keeping meat harvest facilities operating should be considered based on the conditions at the time. See [Appendix C](#) for a discussion of State designation when FMD is detected in a meat harvest facility.

FMDV infected and FMD vaccinated animals are not public health or food safety concerns. Processors should avoid stating they do not process animals that may be infected with FMDV. This would imply to the public that FSIS-inspected products from healthy animals that may be pre-clinically infected with FMDV are not safe and wholesome for consumption. As an FMD outbreak progresses, processors may find they have unknowingly processed animals that were pre-clinically infected with FMDV or may need to process vaccinated or recovered animals that are not proven to be FMDV-free to meet the demand for products and would then need to change their messaging. This may be alarming to the public.

Responsibility of Livestock Owners for Managing FMD

Livestock owners and managers are responsible for protecting their animals from diseases. They work daily to protect their animals' welfare and prevent economic losses. **In the first 28 days following the end of the 72-hour standstill, and possibly longer, livestock owners and managers can protect their animals by limiting the movement of animals and associated items to only essential and low-risk movements. Accepting FMDV-infected but undetected animals into their operation can devastate their herd or flock and reduce the economic viability of their operation.**

Steps that livestock owners and managers can take during an outbreak to reduce the potential for FMDV spread, to protect their animals, and to protect U.S. animal agriculture:

- Producers should plan to raise animals on site until they are ready for harvest, if possible. Producers who normally buy animals for further production or breeding purposes may be hesitant to buy them because of concern about introducing FMDV into their herds and because of uncertainty around the fair market value early in an FMD outbreak.
- Large livestock production operations and perhaps others may need to move animals to other production sites for welfare purposes. A method to provide some assurance that the animals are free of FMD is to implement the relevant [Secure Food Supply \(SFS\) plan](#) to facilitate the movements of animals and other materials if their uninfected premises is included in a Control Area. This includes having a Premises Identification Number (PIN), being ready to fill out epidemiology questionnaires, and implementing the recommended biosecurity and surveillance. **This will facilitate business continuity but will not mean a return to business as usual.** The SFS plans were developed to enable livestock producers in a Control Area to demonstrate to the UIC and SAHOs that the animals are likely to be negative for FMDV so they can receive a permit to move out of the Control Area. The SFS plans could be equally effective in demonstrating that animals in the Observation Area will likely be free of FMDV. Producers may want to implement the relevant SFS plan proactively to be prepared to provide evidence of FMDV freedom and enhance the likelihood that they will be able to move animals. Using

the SFS plans to provide evidence of FMDV freedom in both the Control Areas and the Observation Area provides an extra incentive for producers to implement the SFS plans.

- Premises of destination should avoid receiving new animals until the animals to be received have been “**FMD-Checked**” (see [Table 4](#)) or their animals have been vaccinated and the animals to be received are vaccinated. If possible, newly arrived animals should be quarantined for two incubation periods (28 days) before being adding to a herd or flock.
- In many cases, commercial swine operations must move feeder pigs to operations capable of securely housing and feeding them until they are ready for harvest. This often involves movement to a new state where feeding operations and harvest facilities are located. Commercial swine operations with Secure Pork Supply (SPS) plans in place, including biosecurity, should be able to safely move swine between premises using truck and driver biosecurity practices.

Responsibility of State Animal Health Officials and the Unified Incident Command for Managing FMD

Over the past few years, foot and mouth disease exercises (USDA Agriculture Response Management and Resources [ARMAR], Foreign Animal Disease Southern Agriculture Functional Exercise [FAD SAFE], Framework for Interstate Movement Tabletop Exercise) have made it apparent that individual states will respond differently to an FMD outbreak. Livestock and processing industries vary widely between states, and each state has different resources, statutes, and regulations that impact how the SAHO will respond to the outbreak and implement movement controls.

State Animal Health Officials (SAHOs) are responsible for managing the risk of FMD introduction and spread in their state while maintaining animal welfare, food security, and business continuity to the extent possible. This is a difficult balance to achieve. Movement of animals during an FMD outbreak must be weighed against the risk of moving FMD-positive but undetected animals. Restarting animal movement after the 72-hour standstill to premises for further production should be done cautiously and only when necessary for animal welfare until the extent of the outbreak is more fully understood. After the 72-hour standstill, only essential low-risk animal and associated movements ([Table 1](#)) should occur for at least the next 28 days (two incubation periods) to provide more time for officials and producers to discover any additional infected premises. To be effective, this should apply to both intrastate and interstate movements nationwide. In addition, high-risk movements ([Table 2](#)) should not occur until there is evidence that the outbreak is contained, or the animals are immune due to vaccination.

The UIC will impose movement controls on animals within a Control Area and on contact premises. The UIC is not expected to impose regulatory movement restrictions on animals in the Observation Area after the expiration of the mandatory standstill. However, SAHOs of receiving states and/or the premises of destination may want some assurance that animals from the Observation Area are not likely to have an undetected FMDV infection, especially at the beginning of an outbreak or if the outbreak is spreading. One potential approach to increasing confidence that animals originating from the Observation Area are not likely to be infected with FMDV is to request that they be “**FMD-Checked.**” A request that animals be FMD-Checked could be initiated in writing by the destination premises (further production or processing) or the SAHO of the receiving state as part of the interstate movement requirements. Statements that animals are FMD-Checked should also be in writing and signed by either the herd owner/manager, or an accredited veterinarian. Documentation (electronic or hard copy) should be retained by both the sending and receiving premises and available in the event of a traceback or trace forward. If clinical signs indicate testing is needed, samples would be collected, and laboratory testing would be performed. As part of the FMD-Checked designation, test results would be included with the documentation. The FMD-Checked designation should increase confidence (but not guarantee) that the herd is negative.

It is up to the SAHOs and producers to determine what they consider to be essential movements and low-risk movements. The risk of accepting FMD-infected but undetected animals into their operation is borne primarily by the animal owners, the animals on the premises, and the livestock industry.

Reducing Risk of Movement

Rapid surveillance to find infected herds and re-establish safe movement of animals

The first case of FMD in the U.S. may only be the first case discovered, not the actual first case in the U.S. FMDV may have spread from the initial infected premises to other premises before it was detected. It is essential to conduct rapid surveillance, traceback, and trace forward to find any other cases. The UIC will assign Control Areas and Surveillance Zones around each infected premises and will manage surveillance and movement in those areas and zones. They will also manage surveillance and movement on known contact or suspect premises. **The use of Control Areas during an FMD outbreak was established more than 100 years ago to control local movement of virus. Today, long distance movements of animals, feed, other inputs, products, vehicles, and people are very common and may move FMD virus over long distances quickly. Premises outside of the Control Area will be considered to be in the “Observation Area” for this document instead of “Free Area”.**

Re-establishing movement of animals after the mandatory standstill presents risks of unknowingly moving the FMD virus. There will not be enough federal and state resources or foreign animal disease diagnosticians (FADDs) to conduct surveillance of the livestock production premises in the Control Area, Surveillance Zone, and known contact premises, as well as premises in the Observation Area that need to move animals. Livestock owners in the Observation Area should conduct active observational surveillance (AOS) (as described in the USDA FMD Red Book and the SFS plans) of their animals. If they observe **an unusual incidence of clinical signs consistent with FMDV infection (Table 3) or any incidence of vesicles or erosions, they must contact their herd veterinarian and/or their SAHO.** Accredited veterinarians, who have completed specific training (in development and outlined in [Appendix B](#)) may be allowed to conduct clinical evaluation and, with permission of the SAHO, collect (or direct the collection of) and submit samples from herds which meet criteria for FMDV testing to a NAHLN laboratory (see below). A state will not be designated as FMD affected until the USDA APHIS Foreign Animal Disease Diagnostic Laboratory (FADDL) confirms a positive diagnosis. Rapid and extensive clinical observation, and when warranted, testing for FMDV will provide a clearer picture of FMDV infection in the U.S. to guide decision making to control the outbreak.

Table 3: Clinical Signs Compatible with FMD (see training materials for further information)

- Abortion and/or sudden death in neonates
- Anorexia
- Depression
- Fever
- Lameness and lesions in interdigital space
- Reduced milk production
- Increased salivation and mouth lesions
- Vesicles and lesions on the teats

FMD-Checked Status

Plans for creating an FMD-Checked designation for herds or flocks in the Observation Area need to be feasible for the premises to implement and document and for state officials and premises of destination to monitor to preserve business continuity, animal welfare, and food security during all phases and types of FMD outbreaks.

Testing recommendations must be feasible for NAHLN laboratories to conduct while still performing other testing required for the response. **Each SAHO can decide which FMD-checked statements they are willing to accept for interstate or intrastate movements. Receiving premises can also determine which statements they will accept.**

State officials and the UIC will be busy with disease control and eradication and permitted animal movements within Control Areas and may have neither the time nor the resources to administer FMD-Checked plans outside of Control Areas. This Framework document does not envision that the UIC/SAHO will maintain or audit records on FMD-checked; however, SAHOs can decide if they want to collect records related to these movements. At a minimum, however, premises employing FMD-Checked should maintain records to document the basis for designating animals as FMD-checked, including the results of any FMD laboratory testing. Recipients of FMD-checked animals should retain records as well. This is to facilitate tracing by the UIC in the event an FMD case is thought to arise from an animal movement.

A livestock herd in the Observation Area can be designated as “FMD-Checked” by any of the methods summarized in [Table 4](#).

Recommendations for FMDV PCR Testing of Livestock in an Observation Area Before Movement

FMDV PCR testing of livestock without clinical signs suggestive of FMD is not recommended. Risk-based sampling and PCR testing of animals with clinical signs compatible with FMD increases the likelihood of detection of infection and reduces the number of samples needed compared to random sampling of livestock without clinical signs (see USDA FMD RED BOOK Appendix F).

- If an unusual incidence of any of the clinical signs suggestive of FMD, with no other known cause is observed (see [Table 3](#)), animals from the herd must not be moved. The owner/manager of the herd must notify the herd’s accredited veterinarian, the SAHO or AVIC. If the accredited veterinarian observes an unusual incidence of clinical signs suggestive of FMD, they must contact the SAHO, explain the situation, and recommend that the clinically affected animals in the herd be sampled and tested for FMDV infection. The SAHO may request that an FADD or the accredited veterinarian (or someone trained by the accredited veterinarian) collect and submit samples from clinically affected animals to a NAHLN laboratory for FMDV PCR testing. If samples are submitted for FMDV PCR testing, the premises must be quarantined by the SAHO until negative results are obtained. Documentation stating that animals from the herd were tested with negative results should accompany the shipment of animals.

Active Observational Surveillance (AOS) for Livestock (see the relevant SFS plan)

- Cattle and swine herds typically show obvious clinical signs due to FMDV infection after the incubation period. All cattle and swine herds will likely have a low-level incidence of many of the clinical signs in [Table 3](#) due to causes other than FMDV. It is only when an unusually high incidence of clinical signs associated with FMDV infection with no known cause occurs that a cattle or swine herd in the Observation Areas should be tested for the presence of FMDV.
 - An exception is that any time an animal has vesicles or erosions, they must be tested for FMDV. Animals with clinical signs should have vesicular tissue or oral or lesion swabs tested by PCR for FMDV with negative results before movement. Documentation to this effect should accompany the shipment of animals.
- Sheep and goats infected with FMDV may only have mild or no clinical signs. They require careful examination to detect vesicles, erosions or other clinical signs associated with FMD. A sheep flock or goat herd may have been infected for a prolonged time without detection. Due to this, movement of infected but undetected sheep or goats presents a major risk of moving the virus during an FMD outbreak (See: [Factors to Consider Regarding Surveillance, Biosecurity, and Movement Permitting of Sheep in an FMD Outbreak](#)). **If possible, sheep and goats should only be moved as a group without exposing other susceptible livestock or moved directly to harvest. If they must be moved to another**

premises with susceptible livestock, the best practice would be to quarantine the animals at the new location for 2 incubation periods (28 days) to observe for clinical signs before mingling with other livestock.

- An exception to mild clinical signs induced by FMDV in sheep and goats is that pregnant animals may have a high incidence of abortion and there may be a high incidence of sudden death in neonates. If a sheep flock or goat herd has pregnant animals and/or neonates and the incidence of abortions and sudden death in neonates is not unusually high, it is unlikely to be infected with FMDV. Extra care must be taken to avoid exposing pregnant sheep or goats or young animals to FMDV infected but undetected animals.

Table 4: Livestock may be designated as “FMD-Checked” by one of the following methods:

Methods for designating Livestock as “FMD-Checked.”	
(All statements documenting FMD-Checked status must be in writing and signed)	
Herd owner/manager signed statement	Category 2 accredited veterinarian signed statement
<ul style="list-style-type: none"> • The premises has met the requirements of the relevant secure food supply plan for at least two incubation periods (28 days) before animals are moved to another production site. <p>OR</p> <ul style="list-style-type: none"> • Active observational surveillance has been conducted daily for at least two incubation periods (28 days) before movement with no unusual incidence of clinical signs consistent with FMDV infection. <p>OR</p> <ul style="list-style-type: none"> • The animals have been housed in a biosecure environment or in an isolated location away from other livestock for at least two incubation periods (28 days) and do not have an unusual incidence of clinical signs associated with FMD. 	<ul style="list-style-type: none"> • Livestock have been observed by an accredited veterinarian within two days of movement and have not been observed to have an unusual incidence of clinical signs consistent with FMDV infection. <p>AND</p> <ul style="list-style-type: none"> • Active observational surveillance has been conducted daily since the accredited veterinarian observed the animals.
<ul style="list-style-type: none"> • Animals exhibiting clinical signs compatible with FMD must be reported to the SAHO. The SAHO may order sampling and testing at a NAHLN laboratory for FMDV by PCR. Sampling may be conducted under the authority of a trained, accredited veterinarian, with the SAHO’s permission. The Animals are quarantined until a negative result is returned. Documentation of any testing and receipt of negative results must accompany any statements documenting an FMD-checked designation. 	

Notes:

- A request for FMD-Checked status by the SAHO of the state of destination for movements of animals in the Observation Area may only be recommended during an FMD outbreak in the U.S. when there is limited confidence of the extent of the outbreak. As the FMD response progresses, and there is increased confidence that the disease is contained, movement decisions may be based on State FMD status (see below) and vaccination status rather than herd FMD-Checked status.

- The only sample types approved (as of January 2024) for FMDV PCR testing (of cattle, sheep, goats, pigs, camelids, cervids (including cloven-hoofed zoo animals and wildlife)) by NAHLN Labs are vesicular tissue or oral or lesion swabs in tris-buffered tryptose broth (TBTB). Testing for FMDV antibodies by NAHLN labs is not currently approved. For up-to-date information on approved sample types, see: https://www.aphis.usda.gov/animal_health/nahln/downloads/nahln-sample-chart-regulatory-submitters.pdf (December 8, 2023).
Interstate movements, regardless of whether a Control Area is involved, must meet all the regular requirements for movements between states, in addition to any requirements specific to FMD during an outbreak.

SECTION 2: PROPOSED STATE STATUSES DURING FMD NATIONAL PHASES

Using Proposed State FMD Status Designations for Movement Decisions

The rationale for the designation of state FMD status proposed in this document is based on a SAHO's jurisdiction over their state. Each SAHO will be responsible for working toward FMD freedom for their state. This document proposes possible designations for the FMD status of individual states in [Figure 5](#). Applying the state status designations proposed in this framework document could lead to agreement on 1) movements between states based on each state's status, 2) assignment of priorities for allocation of vaccine and other resources, and 3) a process for moving toward FMD free status for the nation.

The approach to managing risk is likely to change as the outbreak progresses through Phase 1 (the beginning of an FMD outbreak), Phase 2 (as the outbreak is spreading), and Phase 3 (as the outbreak is being brought under control). In considering their own state's approach, SAHOs need to consider recommendations made by Federal Animal Health Officials regarding animal movement, their state's need to protect its livestock industries from infection, business continuity needs of the industry, and the public's need for a safe and wholesome food supply. In some cases, USDA may impose a federal quarantine or other movement controls by Federal Register Order (under the Animal Health Protection Act and Code of Federal Regulations) when requested by SAHOs or as directed by the Secretary of Agriculture. **This framework of potential state responses, including rapid surveillance approaches and movement authorizations based on the situation in each state, will help reduce uncertainty and encourage uniformity and cooperation.** For example, states could decide to join with other states in a region and form a bloc of states with common plans and agreements to allow animal movement between states within the region. This could be advantageous if neighboring states share the same status in an outbreak and animals must cross state lines for harvest or further production. For example: a group of FMD Monitored states (No FMD detection for 28 days) or FMD Vaccinated States could form a bloc. **For the U.S. to be declared FMD free with or without vaccination, all 50 states will need to achieve that designation.**

The proposed state designations of state FMD status are based on the assumption that Control Areas would be placed around infected premises throughout the duration of the outbreak and response when appropriate. The establishment of Control Areas around each infected premises ensures that all areas outside of a Control Area are at least 10 km from a known infected premises. This is assumed to be far enough away to control local spread of the virus. Long-distance spread of FMD could occur anywhere in the U.S. Infectious agents do not respect state boundaries, but a SAHO's jurisdiction is based on state boundaries. A control area near the border of an FMD free state will mean that parts of a state with no detections of FMD are closer to a Control Area than parts of the Affected state (See Figure 4).

In the case of states designated either Level 1 (stamping out) or Level 2 (stamping out with vaccination to kill) it is not logical to assume that the entire FMD-affected state is a higher-risk for animal movement than the neighboring states. **For Level 1 and Level 2 States (Figure 5), decisions on animal movement should be based on the status of the area where the premises is located (Control Area or Observation Area with no detections of FMD) rather than the status of the state.** An Observation Area in a Level 1 or Level 2 affected state after the 28-day Essential Low-Risk Movement period should not be considered to be a higher risk for unknown FMD infection than an Observation Area in a state that is not affected with FMD. However, an entire Level 3 State (Vaccinated to Live with No Stamping Out) should be considered to be a risk for FMD-infected but undetected animals. Vaccinated herds (three weeks after vaccination) should be considered immune and not shedding virus.



Figure 4: Hypothetical case where Missouri has a Control Area and is designated a Level 1 FMD Affected State (Stamping Out without Vaccination). All areas outside of the Control Area in Missouri are FMD Observation Areas. Kansas, Nebraska, and Iowa are States with No Detections of FMD. All areas in those states are also FMD Observation Areas. After 28 days with no case of FMD those three states could be designated as an FMD Monitored State (No Detections of FMD for 28 days).

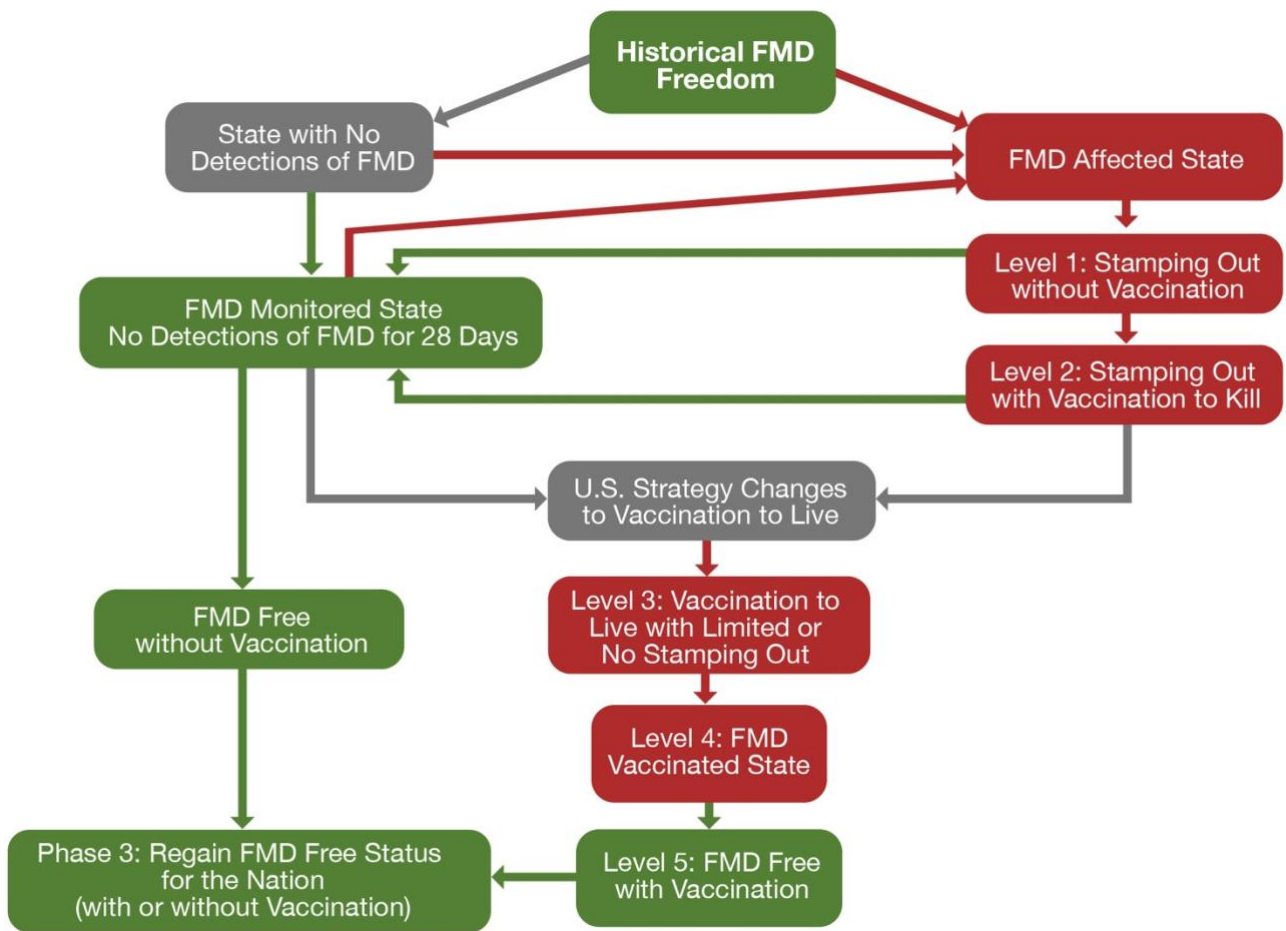


Figure 5: Proposed FMD Status of States During Phase 2 of an FMD Outbreak

Proposed State Statuses During an FMD Outbreak

National Phase 1 – The period of time from the confirmation of the first FMD case in the United States until there is reasonable evidence to estimate the extent of the outbreak. The transition to Phase 2 should be accomplished as soon as possible, with a goal of less than 4 days (U.S. Nationwide 72-hour Standstill of Susceptible Animals).

Proposed State Status in National Phase 1 (See Phases and Types of FMD Outbreak document: <http://www.cfsph.iastate.edu/pdf/phases-and-types-of-an-fmd-outbreak/>):

All states are FMD Free States before the first case of FMD in the U.S. After the first case in the U.S., during Phase 1, every state will receive one of these designations:

State with No Detections of FMD:

FMD is confirmed in the U.S., but not in this state. It must be assumed that the first case of FMD discovered in the U.S. may not be the actual first case. Adequate surveillance, epidemiologic investigation, and movement controls are **not yet in place** to give confidence of absence of FMDV infection in the state. (See [Appendix C](#) for a discussion of State designation when FMD is detected in a meat harvest facility).

FMD Affected State:

FMDV infection in the state confirmed by FADDL.

National Phase 2 – Surveillance and epidemiology provide timely evidence of the extent of the outbreak to support planning and decision making by Incident/Area Command.

Proposed State Status in National Phase 2 (See Phases and Types of FMD Outbreak document:

<http://www.cfsph.iastate.edu/pdf/phases-and-types-of-an-fmd-outbreak>):

During National Phase 2, SAHOs will determine if they will allow susceptible animals from other states to enter their state for harvest or further production. Factors that may be considered include:

- The FMD status of other states
- Whether the animals come from within or outside of a Control Area
- The epidemiology of the outbreak: Are additional infected premises in the U.S. found frequently, or is it rare for additional infected premises to be discovered?
- Surveillance and biosecurity
- Compliance with SFS Plans
- FMD-Checked status of a herd
- Animal welfare concerns
- The vaccination and/or recovery status of the animals
- The urgency of the animal movement

State with No Detections of FMD:

FMD has been confirmed in the U.S. It must be assumed that the first case of FMD discovered in the U.S. may not be the actual first case. The state has alerted veterinarians, and producers of FMD susceptible livestock in the state to be aware of the clinical signs associated with FMD and to contact the SAHO if an unusual incidence of clinical signs are observed. In addition, the state is participating in trace back and trace forward of animals from all known infected herds in other states. The state is limiting animal movement to essential low-risk movements only. If no FMDV infected animals have been found for at least 28 days after the end of the movement standstill, then the state can be designated an FMD Monitored State (No Detections of FMD for 28 Days). (See [Appendix C](#) regarding FMD found at a meat harvest facility.)

FMD Monitored State (No Detections of FMD for 28 Days):

A State with no detections of FMDV for 28 days (two incubation periods) after the end of the 72-hour movement standstill may be designated as an FMD Monitored State. The state may have detected FMDV and eliminated it through stamping out, perhaps with the assistance of vaccination to kill or slaughter. No FMD vaccinated or recovered animals remain in herds within the state. Animals originating from an FMD Monitored State (No Detections of FMD for 28 Days) may be allowed to move between states and between production sites with a high degree of confidence that they will not be moving FMDV. (See [Appendix C](#) regarding FMD found at a meat harvest facility).

FMD Free State without Vaccination:

The state has conducted surveillance and has movement controls in place suitable to convince regulatory officials and trading partners that there are no FMDV-infected animals in the state. This will be expensive and labor intensive and perhaps should not be attempted until the U.S. is in Phase 3 of the outbreak and most states are FMD Monitored States (No Detections of FMD for 28 days).

FMD Affected State: FMDV Infection Anywhere in the State Confirmed by FADDL:

Rapid Surveillance Sampling ([Appendix B](#)) can allow accredited veterinarians with proper training to collect, or direct collection of, samples from any herds outside of a Control Area that meet criteria for suspicion of FMDV

infection (with permission of the SAHO) as described above and submit to an approved NAHLN Lab. A positive test result is followed by trace back and trace forward investigations from the infected premises for movements occurring during the previous 28 days. This will enable State Officials to quickly gather epidemiologic evidence of the extent of the outbreak in their state and to gather evidence that would facilitate control and/or elimination of FMDV-infected herds, allocation of vaccine, and to establish FMD-Checked status for premises outside of the Control Area.

Level 1, FMD Affected State – Stamping out:

Focal area of infection limited to one herd or a small number of herds with low to moderate livestock numbers. Epidemiologic investigation and surveillance indicate that FMDV has not spread beyond the initial few premises. The infected premises have not had extensive animal movements and are not too large to depopulate quickly. Rapid stamping-out is feasible.

- Rapid stamping out of infected premises without vaccination.
- Continue strict quarantines/movement controls for animals, vehicles, etc. within the Control Area(s) (movement by permit consistent with specific SFS business continuity plans).
- Continue stamping-out with rapid depopulation, disposal, and virus elimination on infected premises.
- Design and implement surveillance to obtain data to establish that the state, and Control Areas within the state, are free of FMDV infection without vaccination.
- The state may be designated as an FMD Monitored State after 28 days have passed with no detections of FMD.

Level 2, FMD Affected State – Stamping Out with Vaccination to Kill:

A few focal areas of infection are limited to an area with low to moderate livestock numbers on small to medium size premises. Epidemiologic investigation and surveillance indicate FMDV has not spread beyond the Control Area(s) within the state. The infected premises have not had extensive animal movement out of the Control Area and are not too large to depopulate and dispose of animals.

- Continue strict quarantines/movement controls for animals, vehicles, etc. within the Control Area and stamping out of all infected premises. Allow permitted movement of animals with no evidence of infection out of the Control Areas according to the SFS Plans.
- Consider establishing a Suppressive² Vaccination Zone and/or Protective³ Vaccination Zone. This would be a vaccinate-to-kill plan with eventual depopulation and disposal, or harvest, of vaccinated animals (unless the epidemiologic situation changes). Vaccinated animals will need to be identified/tagged so they can be tracked and removed.
- The state may be designated an FMD Monitored State after 28 days have passed with no detections of FMD and 28 days after all vaccinated animals have been killed or slaughtered.

² Suppressive Vaccination

Suppressive (or ‘damping down’) emergency vaccination is conducted in the immediate infected area where the virus is already circulating. It is intended to reduce virus transmission, aid control efforts and prevent FMD from spreading beyond the Control Area. For example, the Netherlands used suppressive vaccination to prevent FMDV from spreading when suspect farms could not be culled rapidly. Suppressive vaccination is likely to face a more severe virus challenge than protective vaccination: Infected animals may already be present on a farm in areas where this form of vaccination is used. In contrast, animals in uninfected areas (protective vaccination) are likely to be exposed to smaller amounts of virus in aerosols and on fomites.

³ Protective Vaccination

Protective emergency vaccination, which is conducted among animals in uninfected areas, creates a zone of animals with reduced susceptibility around the infected area.

NOTE on Proceeding to Affected State Levels 3 and 4:

Levels 3 and 4 in this Framework involve vaccinating susceptible animals to live to prevent infection, allowing some infected animals to recover, and vaccination of infected and recovered animals. The decision to progress to a vaccinate-to-live policy will be made at the Federal level because it may affect the approach used in the entire U.S. to restore FMD free status. **Proposed criteria for determining whether such animals can be considered immune or of low-risk for spreading FMD are presented in Appendix D for consideration and discussion.**

Level 3, FMD Affected State – Vaccination to Live with Limited or No Stamping Out:

Multiple areas of infection are detected in the state, or the type, number and/or size of infected and contact herds are too great to depopulate quickly enough to suppress disease spread. Stamping-out of some or all infected premises may need to be discontinued. Some herds may be allowed to recover. Large quantities of vaccine will be ordered but may be slow to be delivered.

- A vaccinate-to-live policy may be considered to reduce the shedding and spread of the virus.
- Allow some FMDV-infected herds that are too large to depopulate to recover with strict biocontainment. Implement suppressive and protective vaccination as vaccine becomes available. Vaccinate known infected herds that are allowed to recover to induce more uniform immunity. Resume intrastate and interstate movement of animals according to SFS Plans.
- Infected premises that are not depopulated may need to demonstrate there is no evidence of FMDV transmission after the herd has recovered (see 2023 OIE Terrestrial Animal Health Code Chapter 8.8). https://www.woah.org/fileadmin/Home/eng/Health_standards/tahc/current/chapitre_fmd.pdf. Some herds or severely affected individual animals on infected premises may be euthanized based on epidemiologic or humane considerations. Some recovered herds may be depopulated through controlled marketing.
- Continue strict quarantines/movement controls for live animals and vehicles, etc. within the Control Area(s). Consider allowing movement of animals with no evidence of infection (including vaccinates) according to the SFS Plans.
- Begin vaccinating as soon as vaccine becomes available, with a goal of vaccinating all designated susceptible animals (see [Appendix E](#)) in the state. Allow all animals that can pass FSIS inspection (including vaccinates and recovered animals) to move to harvest.
- Before the U.S. can be designated as FMD free with vaccination, all vaccinated animals will need to be officially accounted for according to a nationally standardized schema for surveillance and monitoring purposes (See [Appendix F](#)).
- After widespread vaccination of all designated susceptible animals (including infected and recovered herds), animals with no evidence of infection, vaccinated animals and recovered animals can be moved to slaughter in state or to other states as appropriate (may depend on the FMD status of other states). Vaccinated and recovered animals can be moved to other vaccinated or recovered production sites within the state or to other states in Level 3 or 4 status, as needed (with permission of the SAHO).

Level 4, FMD Vaccinated State – Any State That Has Achieved a Protective Level of Vaccination for All Designated Herds in the State:

A state, regardless of its FMD infection status that has achieved a protective level of vaccination for all designated herds in the state may be designated by Federal Officials as a Level 4 FMD Vaccinated State. It is not feasible to achieve a 100% vaccination rate of all designated animals in a state because newborn animals are continually being added to some herds and because booster vaccinations will be needed on a recommended schedule. It should be feasible to eventually vaccinate enough designated animals and herds in a state to achieve protective herd immunity (See [Appendix D](#)).

Responsible Regulatory Officials will decide which species are eligible for vaccination, the phases of production on which to focus vaccination, the frequency of vaccination and the appropriate age of vaccination (See [Appendix E](#)). The following species will be considered: Bovine (beef and/or dairy), porcine, ovine, caprine, and zoo and exotic species. When sufficient vaccine is not available for all designated susceptible animals, the SAHO for each state will decide the priority for allocation of vaccine available to that state. The justification for the prioritization will be provided to USDA with the request for vaccine. All designated animals will be vaccinated in a state, region, or the entire nation when sufficient vaccine becomes available unless the owners petition to be exempted from having certain animals vaccinated. Animals that are not vaccinated will need to be maintained in a biosecure environment, be monitored for FMD, and may only move with a permit.

An **FMD vaccinated herd** should have sufficient herd immunity to prevent FMDV spread within the herd. An **FMD vaccinated state** should have a very low level, or no, FMDV circulation within the vaccinated herds in the state. Herds and flocks that have recovered from FMDV infection should be vaccinated to ensure the herd has uniform herd immunity to suppress FMDV spread.

- Multiple states in Level 4 status may agree to form a Level 4 Region with common plans for allowing vaccinated animals to cross state borders.
- FMD susceptible animals that are not designated to be vaccinated by the Federal or State authorities may still need to be FMD-Checked before movement (as described above).

Level 5, FMD Vaccinated State – FMD Free with Vaccination:

After a state is declared to be an FMD vaccinated state (Level 4), extensive serologic and virus testing is likely to be required to demonstrate that the state is free with vaccination. This testing will be labor intensive and expensive. It may be best to not initiate testing to demonstrate that the state is FMD free with vaccination until most states are designated as FMD Vaccinated States.

Serologic and virus testing to demonstrate that an FMD Vaccinated State is FMD free with vaccination:

- FMD vaccinated herds will need to be tested for detection of infection in vaccinated animals (DIVA) by testing the herd for antibodies to FMDV non-structural proteins (assuming that the vaccines used are DIVA compatible). DIVA testing for FMD infection in vaccinated animals is only validated for use in herds of cattle.
- If animals that were allowed to recover from FMD are still present in the state, DIVA testing using serology cannot be used on those herds. It will be necessary to demonstrate that FMDV is not still circulating in the recovered herd. It may be best to wait until all FMD-recovered animals are depopulated or harvested before pursuing FMD freedom with vaccination status for the state.
- FMD susceptible livestock that are not designated to be vaccinated by USDA will need to follow the relevant SFS plan or be FMD-Checked to demonstrate that they are not likely to be infected with FMDV. At this stage of FMD eradication, serologic testing for antibodies to FMDV structural or non-structural proteins may be the most efficient method to demonstrate FMD freedom in a herd that is not vaccinated.

Note: An FMD Monitored State (No Detections of FMD for 28 Days) may be required to become a Level 5, FMD Free with Vaccination State if the USDA decides that the entire country needs to be FMD vaccinated to facilitate interstate movements and to seek national FMD Free with Vaccination status.

National Phase 3 – FMD affected states have an acceptable plan for control and elimination of FMDV infection, and a surveillance and testing plan.

Proposed Transition to National Phase 3, the Recovery Phase: Surveillance and epidemiologic evidence indicates that the outbreak is coming under control and a plan is implemented to regain FMD free status for the nation (possibly with vaccination) (<http://www.cfsph.iastate.edu/pdf/phases-and-types-of-an-fmd-outbreak>):

For the U.S. to enter Phase 3, it is likely each FMD affected state will need to have a plan for control and elimination of FMDV infection. This must be accompanied by a surveillance plan to include testing capable of detecting infection in vaccinated herds (DIVA serologic testing) and detection of FMD virus circulation in recovered herds (if applicable). The recovery phase for FMD free status will likely be state-by-state initially. Individual states are designated to be in the Recovery Phase after they file a plan acceptable to the USDA to recover FMD free status, perhaps with vaccination. The recovery plan will depend on the Type or Level of outbreak on a national, regional, or state scale. The options available to the states may be determined by federal officials based on the characteristics of the national outbreak and the status of the outbreak in that state. For example, if the U.S. progresses to a type 4 or 5 outbreak, all states may be required to vaccinate all designated susceptible animals (This is likely to be vaccination of all cattle when sufficient vaccine becomes available) to suppress virus circulation in the U.S. to a very low level before entering the recovery phase. An extensive surveillance program could then be implemented to demonstrate that the FMD virus is not circulating within the state, including in wildlife. Livestock production systems with acceptable biosecurity may be allowed to request an exemption from the requirement to vaccinate. They will need to continue extensive surveillance to demonstrate a lack of evidence of infection.

APPENDIX A: Request for Approval of an Essential Low-Risk Interstate or Intrastate Movement During the 28 Day Limited Movement Period in an FMD Outbreak – Proposed Form

Note: The document below is a proposed version of a form that may be used by producers to request a movement of animals not otherwise designated as an essential low-risk movement by presenting information demonstrating the low-risk and essential nature of the movement to the SAHO.

This form is a draft meant to provide guidance to SAHOs addressing questions about essential low-risk animal movements and protecting animal health, animal welfare and food security during an FMD outbreak. State officials are encouraged to modify the form as needed.

Introduction

Moving animals from one premises to another during an FMD Outbreak involves the risk of transporting animals with undetected FMD infections. During the 28-day Limited Movement Period it is recommended that only essential low-risk movements of animals occur to prevent the further spread of FMD and to protect producers from introducing FMDV onto their premises.

State Animal Health Agencies may adopt a list of essential low-risk movements similar to Table 1 below. The animal health regulatory agencies in both the sending and receiving states must consider the proposed movement to be essential and low-risk to proceed with an interstate movement. In addition to any FMD-specific requirements, parties involved in sending and receiving animals are required to comply with all applicable state and federal statutes and regulations for the interstate shipment of animals.

Table 1: Essential Low-Risk Movements

The following movements (either intrastate or interstate) could be considered essential low-risk movements at the end of the 72-hour standstill and should be allowed without the need for an FMD-related permit:

- Movement of animals outside of a Control Area to a meat harvest facility
- Movement of animals in a biosecure building to another biosecure building (according to the Secure Food Supply plans) if it is essential to move the animals for welfare purposes.
- Movement of animals from an isolated location (e.g., pasture, lot, or building) to another location without exposure to new animals if it is essential for welfare purposes.

Permission for other intrastate or interstate movements during the Limited Movement Period should be requested from the SAHO by providing documentation that the movement is essential and is low-risk.

State Animal Health Agencies may have adopted a list of animal movements considered to be high-risk and not allowed during the 28-day Limited Movement Period or until the extent of the FMD outbreak is known. Table 2 lists movements that may not be allowed during the 28-day Limited Movement Period.

Table 2: High-Risk Movements Should Not Occur Until the Extent of the FMD Outbreak is Known

The following movements should be considered high-risk movements and should be avoided during the Limited Movement Period, and perhaps longer depending on the epidemiology of the outbreak:

- Any movements of animals to animal aggregation sites such as markets, fairs, exhibitions, shows, etc.
- Any movements of animals (that are not immune due to vaccination, or in a biosecure environment) to premises where they will be exposed to other FMD-susceptible animals (e.g., Feedlot, backgrounder, dairy, breeding operation, etc.).

HOW TO USE THIS FORM

When directed by the State Animal Health Official, this form must be used to request an essential intrastate or interstate low-risk movement (not listed in Table1) of susceptible animals or materials from a premises in the Observation Area to another premises in the Observation Area during the Limited Movement Period of an FMD response. Contact your State Animal Health Official for additional information.

SENDING/ORIGIN PREMISES

Provide contact information, including phone and email, for the party responsible for the animal movement.

- **Explain why this movement is essential:** Use this text box to explain why this movement is essential and should be approved at this time. Describe how continuity of business, animal health or animal welfare would be adversely affected if the movement was not allowed.
- **Explain why this movement should be considered low-risk:** Use the text box to describe why this movement should be considered low-risk for transmission of FMDV. Include any specific measures taken to reduce the risk of spread of FMD by this movement.
- **If required, complete and attach the epidemiology questionnaire provided with this form. Requests will not be reviewed without this information.**

DESTINATION/RECEIVING PREMISES

- Provide contact information, including phone and email, for the party responsible for accepting the shipment of animals.
- **Description of Receiving Premises:** Use this text box to describe the operation receiving the animals -type of premises, number of animals, and species. Include information about any biosecurity measures taken to reduce risk of disease exposure from planned animal movement.

SENDING PREMISES

NAME OF OWNER OR RESPONSIBLE PARTY:	
TYPE OF MOVEMENT: INTERSTATE <input type="checkbox"/> INTRASTATE <input type="checkbox"/>	
PROPOSED MOVEMENT DATE:	PIN:
ADDRESS:	
CITY AND STATE:	ZIP CODE:
COUNTY:	PHONE:
EMAIL:	
IS THE SENDING PREMISES CURRENTLY PARTICIPATING IN THE SFS PLAN?	<input type="checkbox"/> YES <input type="checkbox"/> NO
SPECIES, NUMBER, AND TYPE OF ANIMALS:	
DESCRIBE WHY THIS MOVEMENT IS ESSENTIAL:	
WHY SHOULD THIS MOVEMENT BE CONSIDERED LOW-RISK?	

DESTINATION PREMISES

NAME OF OWNER OR RESPONSIBLE PARTY:	
ADDRESS:	
CITY AND STATE:	ZIP CODE:
COUNTY:	PHONE:
EMAIL:	PIN:
IS THE DESTINATION PREMISES CURRENTLY PARTICIPATING IN THE SFS PLAN?	<input type="checkbox"/> YES <input type="checkbox"/> NO
DESCRIPTION OF DESTINATION PREMISES	
NAME OF TRANSPORT COMPANY:	
CONTACT NAME:	

ADDRESS:		
EMAIL:	PHONE:	
ARE TRANSPORT VEHICLES ADHERING TO SFS BIOSECURITY REQUIREMENTS?	<input type="checkbox"/> YES	<input type="checkbox"/> NO

SIGNATURES

Signatures of the owners of the sending premises and receiving premises indicate that these individuals have reviewed the information provided in this request and found it to be correct to the best of their knowledge.

Owner/Manager	Sending Premises Date
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Owner/Manager	Receiving Premises Date
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Signatures of the Animal Health Officials or their designees on this document indicate that they have reviewed the information provided in this document and have determined the animal movement proposed in this document is an essential low-risk movement of FMD susceptible animals.

State Animal Health Official or Designee	Sending State Date
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State Animal Health Official or designee	Receiving State (if applicable) Date
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APPENDIX B:

Sample Collection and Submission for FMDV Testing by Accredited Veterinarians or their Designees

It is likely that the first confirmed case of FMD in the U.S. is just the first case discovered and that the FMDV has spread from the initial infected premises to other premises before it was detected. It will be essential to conduct rapid surveillance, perform trace backs and trace forwards to identify other infected premises.

Depending on the extent of the outbreak, FADDs and other state and federal resources may be overwhelmed investigating reports of suspected FMD and conducting trace backs, trace forwards and surveillance of premises in Control Areas and Surveillance Zones with little excess capacity.

Premises located outside of Control Areas are designated by the FMD Red Book as being in the Free Area. This does not mean the premises are free of FMDV, only that these premises are free from any regulatory movement controls imposed by the UIC as a result of the outbreak. For the purposes of this document, the Free Area is referred to as the "Observation Area." Once the movement standstill is lifted, premises outside of the Control Areas may move animals. This Framework recommends that only essential low-risk movements occur for at least the first 28 days after the end of the movement standstill. Producers and processors accepting animals from outside of the Control Areas, especially right after movements resume, may want some assurance that animals they are receiving are unlikely to be infected. FADDs, state and federal regulatory officials and responders will be busy conducting trace backs and trace forwards, investigating potential FMD outbreaks and conducting surveillance in Control Areas and Surveillance Zones and may not have the resources to address the concerns of other producers and processors outside of the Control Areas.

Using Accredited Veterinarians for Rapid Surveillance Sampling

To alleviate the shortage of qualified personnel, the rapid surveillance sampling plan allows category 2 accredited veterinarians (or their designees) with appropriate training to collect and submit samples to NAHLN labs for FMDV testing under the direction of the SAHO or UIC.

The SAHO, working with the UIC, would determine whether to authorize the use of accredited veterinarians or their designees in the state. Accredited veterinarians (and their designees) provide the UIC with additional personnel with the background and training to collect diagnostic samples for FMDV testing.

During the initial stages of the response, using accredited veterinarians to assist with rapid surveillance sampling can help the UIC and SAHOs more quickly understand the extent of the FMDV infection in the U.S. and help guide decision making. Later in the response as animal movements resume, rapid surveillance sampling may be used to address concerns among other stakeholders, for example:

- Herd veterinarian notices signs consistent with FMD in a herd.
- Owners and managers of livestock premises may be concerned that their animals have symptoms consistent with FMD and may contact their herd veterinarian to examine the animals.
- The decision to use accredited veterinarians and their designees for FMD sample collection and submission is at the discretion of the SAHO and UIC. In deciding whether to use accredited veterinarians as part of the rapid surveillance sampling program, the UIC and SAHO must consider:
 - Whether state veterinary practice act has limitations on the ability of veterinarians to designate individuals to collect and submit samples on their behalf.
 - Need for approval by USDA APHIS VS for the submission of FMD samples collected by individuals working under the authority of a category 2 accredited veterinarian.
 - That the sample submissions by accredited veterinarians will not interfere with other FMD testing priorities and that NAHLN labs have adequate capacity to process increased numbers of samples.

- That there is a process to ensure that information about premises where accredited veterinarians collect samples for FMD testing are logged in EMRS or other systems and the UIC and the SAHO are kept informed of the sample collections, test results, and follow-up investigations on these premises.

Rapid Surveillance Sampling Procedure

Rapid surveillance testing, when authorized by the SAHO or UIC, is appropriate in situations where an accredited veterinarian or herd owner/manager determines animals are exhibiting clinical signs of FMDV ([Table 3](#)) which are out of the ordinary for the particular group of animals. Many of the signs of FMD are similar to other diseases, so producers and veterinarians need to know what is normal for that group of animals and be suspicious of anything outside of normal. **Vesicles and erosions must always be reported and investigated.**

Herd managers/owners should be encouraged to conduct active observational surveillance when there is a high risk that FMD may be in the U.S. Active observational surveillance training materials can be found on the Secure Food Supply websites for the relevant production animals: <https://www.cfsph.iastate.edu/secure-food-supply/>. The information is found under the Training Materials tab, then Disease Monitoring: Observe.

Upon observing signs consistent with FMD, the herd veterinarian or herd owner/manager contacts the SAHO. The premises must be quarantined until test results are received. Based on the information reported, the SAHO and UIC would determine whether to dispatch an FADD or to request that the accredited veterinarian collect samples and submit them to an approved NAHLN laboratory for testing. The accredited veterinarian could work with the producer to collect documentation regarding recent animal movements and contacts.

Non-negative results from a NAHLN lab would require confirmation from FADDL if this is the first case of FMD in the state. After the detection of the first FMD case in the state, a positive result from the NAHLN lab is actionable, but the UIC or SAHO may request that an FADD conduct an FADI and that FADDL confirm the positive result. If the results are negative, the quarantine is lifted. Negative test results would accompany any documentation submitted as part of the FMD-Checked designation if the animals are moved.

Participation by Accredited Veterinarians in the FMD-Checked Designation

Accredited veterinarians can assist their clients and other producers using the FMD-Checked designation to provide extra assurances that animals shipped from a premises are unlikely to be infected with FMDV. The FMD-Checked designation could be used in the following situations;

- Production premises planning to receive animals from premises outside of the Control Area may want assurances that the animals are not likely to be infected with FMDV.
- SAHOs for states that will receive animals from outside of the Control Area may want assurances that the animals are not likely to be infected with FMDV before issuing interstate movement permits allowing these animals into their state.
- Transporters for animals from premises outside of the Control Area may want assurances that the animals are not likely to be infected with FMDV and that the destination premises has agreed to accept the animals before agreeing to haul them

To designate livestock as FMD-Checked an accredited veterinarian may submit signed documentation stating that:

- Livestock have been observed by an accredited veterinarian within two days of movement and have not been observed to have an unusual incidence of clinical signs consistent with FMDV infection. In addition to the accredited veterinarian's statement, the animals have been observed daily using Active Observational Surveillance following the Accredited Veterinarian visit until they are shipped.

Training

Once it is determined that Rapid Surveillance Testing or FMD-Checked will be used in the response, training could be offered as on-line, on-demand, just-in-time modules for accredited veterinarians. The training will introduce accredited veterinarians to rapid surveillance testing and the FMD-Checked designation and their roles in the programs. It will:

- Explain the importance of rapid surveillance to the initial response to an FMD outbreak.
- Describe when rapid surveillance sampling by accredited veterinarians or their designees may be requested and how requests will be coordinated.
- Describe how the FMD-Checked designation can aid in providing assurances that animals scheduled to move are not likely to be infected.
- Explain the role of accredited veterinarians in the FMD-Checked designation.

The CFSPH has prepared a draft of the training for accredited veterinarians in PowerPoint. This presentation can be modified to fit SAHO or USDA requirements and then converted to an on-line, on-demand training. Contact authors for more information.

Species-specific technical training on the collection of samples will need to be developed (it is not part of this project). This training will cover sample types approved for FMD PCR testing by NAHLN labs and will be designed for accredited veterinarians to use with sample collectors under their supervision. Techniques for animal restraint and sample collection, completion of appropriate forms, packing and shipping requirements will be covered in detail. This training will be similar to the Certified Swine Sample Collector training offered through the Secure Pork Supply Plan.

Note: As of January 2024, the only sample types approved for FMDV PCR testing (of cattle, sheep, goats, pigs, camelids, cervids (including cloven-hoofed zoo animals and wildlife)) by NAHLN labs are vesicular tissue or oral or lesion swabs in tris-buffered tryptose broth (TBTB). Testing for FMDV antibodies by NAHLN labs is not currently approved. For up-to-date information on approved sample types see:

https://www.aphis.usda.gov/animal_health/nahln/downloads/nahln-sample-chart-regulatory-submitters.pdf

APPENDIX C:

Designation of State Status if FMD is Detected in an Animal at a Meat Harvest Facility

This FMD Framework document suggests that FMD detection in a meat harvest facility should be handled similarly to ASF detection in a meat harvest facility as described in the USDA APHIS ASF Response Plan. That is, if the meat harvest facility is outside of a Control Area, the Control Area will be the perimeter of the meat harvest facility. Further, if the facility is in a state with no detections of FMD, an FMD Monitored State (No Detections of FMD for 28 Days), or an FMD Free state, the presence of FMDV in a meat harvest facility due to an animal received from another state, should not cause the status of the state with the meat harvest facility to change status to FMD Affected. This consideration is needed for business continuity to encourage SAHOs in states with no detections of FMD to allow the meat harvest facility to accept apparently healthy animals from other states.

The USDA APHIS ASF Response Plan: Infected/Positive Meat Harvest Facility (May 15, 2023) contains extensive information related to euthanasia/depopulation, disposal, and decontamination procedures for meat harvest facilities that receive swine that are presumptive or confirmed positive for ASF https://www.aphis.usda.gov/animal_health/downloads/animal_diseases/swine/asf-mhf-infected-premises-plan.pdf. Page 10 of this document addresses “Ensuring the Meat Harvest Facility is Decontaminated and Reopening”. Sections 3. a. and 3. b. address Control Area Release:

3. Control Area Release

- a. If the meat harvest facility is the only Infected Premises within a 5 km area, or not within another Control Area, then the Control Area will be the perimeter of the meat harvest facility and the Control Area will be released after completion of virus elimination and sanitation of the facility. Once the Control Area is released, the meat harvest facility’s premises status will change from Infected Premises to a Free Premises and the quarantine will be lifted.*
- b. If the meat harvest facility is in a Control Area with other Infected Premises, then the Control Area Release will be based on requirements for all Infected Premises. For infected swine production sites, the minimum time a Control Area is released is two incubation periods (30 days) after disposal and virus elimination requirements are completed on the last Infected Premises. ...*

APPENDIX D:

PROPOSED CRITERIA FOR VACCINATED AND/OR RECOVERED ANIMALS TO BE CONSIDERED IMMUNE AND SAFE TO MOVE WITHOUT SPREADING INFECTION

Proposed criteria for vaccinated animals (herds) to be considered immune and safe to move without spreading infection

Information on vaccine induced immunity to FMD can be found in “NAHEMS Guidelines:

Vaccination for Contagious Diseases: Appendix A: Foot-And-Mouth Disease

(<https://www.cfsph.iastate.edu/pdf/fad-prep-nahems-appendix-a-vaccination-for-foot-and-mouth-disease>).

The onset of protective immunity after vaccination with commercially available inactivated FMD vaccines depends on:

- The potency of the vaccine and the adjuvant
- The antigenic relatedness of the vaccine virus strain and field virus strain
- The exposure route and virus dose
- The species of animal

Onset of immunity may begin with partial protection from clinical signs by 5 to 10 days¹⁻⁶. More complete protection may require 3 weeks in cattle^{7,8} or 3 to 4 weeks in swine¹. A booster dose may be required 2 to 4 weeks after the first dose for optimal immunity if the vaccine is low potency or not closely matched to the outbreak strain⁹⁻¹¹. The onset of protective immunity for the specific outbreak strain and the specific vaccine used may not be known at the beginning of an outbreak. The Unified Incident Command will make recommendations for the vaccination schedule depending on what is known about the vaccine and the outbreak strain. A reasonable assumption for the onset of protective immunity after vaccination would be 3 weeks after vaccination for a one-dose vaccine or 2 weeks after the second dose for a 2-dose vaccine. These time periods may be adjusted as more information about the onset of protective immunity after vaccination during the outbreak becomes available. For a herd to be considered immune, all of the designated animals in the herd should be vaccinated, including booster vaccination as recommended.

In sheep, some vaccines may decrease the shedding and transmission of FMDV as soon as 3-7 days after immunization.^{12,13} Challenge studies conducted 2 or 3 weeks after vaccination also reported decreased virus shedding and transmission.¹⁴⁻¹⁶ Protection from illness is more difficult to assess in sheep and goats than cattle or pigs, as even nonvaccinated animals may have few or no clinical signs.

Proposed criteria for recovered animals (herds) to be allowed to move to slaughter or to another FMD immune production setting with low-risk of spreading FMDV infection

FMD viremia after infection usually lasts 2-3 days and ends when circulating antibodies appear¹⁷⁻¹⁹. Viruses in the blood become undetectable as soon as 3-5 days after the first signs of illness¹⁷. The time required for an infected herd to become immune and stop shedding virus will depend on the transmission rate within the herd. FMD usually has a high transmission rate in cattle and swine. At least four weeks after the last clinical signs of FMD in a cattle or swine herd have subsided should be sufficient to ensure that the herd is not susceptible to virus transmission. Virus transmission within sheep flocks and goat herds may be slower and it is difficult to determine when the last clinical signs have occurred. It will be more difficult to determine when virus shedding may have ended in sheep flocks and goat herds. Vaccinating recovered animals can provide assurance that the animals are not shedding virus.

The recovered animals could be sent to harvest facilities, with permission of the SAHO of the sending and receiving states and the harvest facility, when they are ready for harvest and can pass FSIS inspection.

Precautions will need to be taken so that the animals and transport vehicles do not serve as fomites for virus transmission.

Animals that have recovered from FMD should not be sent to another production site unless all of the animals on that site are vaccinated and any recovered animals are also vaccinated to ensure uniform immunity.

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APPENDIX E:

Priority for FMD Vaccine Use

An estimated 23 different vaccine strains are needed to provide immunity to the various FMDV strains found in the world. Some strains are much more common than others. The U.S. has access to vaccine banks with multiple strains stored as vaccine antigen concentrate (VAC). FMD vaccine will not be available until several days after the FMD virus strain infecting animals in the U.S. is identified. The vaccine will be produced from VAC (if available) by the manufacturer, then shipped to the U.S. and distributed to states. Only a few million doses may be available for use in the U.S. during the first weeks of an outbreak. For a large outbreak, it may take a year or more to obtain enough vaccine to vaccinate all of the animals designated to be vaccinated.

As an FMD outbreak unfolds, the priority for vaccine use will change. At the beginning of an FMD outbreak, the USDA will allocate available vaccine to states based on their requests and the national and local priorities for vaccine use. SAHOs will decide the priority for vaccine use within their states. Having a common understanding of priorities for vaccine use may help to facilitate decisions on allocating vaccine between and within states. However, special circumstances are likely to arise resulting in individual decisions on vaccine use that differ from the generally agreed upon priorities.

During a Type 1 national outbreak, no vaccine will be used because the focus will be on rapid stamping out.

During a Type 2 national outbreak and a Level 2 outbreak in an affected state the highest priority for vaccine use should be to help control the outbreak. Vaccine may be used in any susceptible species that the UIC or SAHO determines should be vaccinated to prevent or suppress virus spread.

During a Type 3 or greater national outbreak and a Level 3 or greater outbreak in a state FMD virus has spread widely, some infected animals are allowed to recover, and a vaccination to live policy is implemented. The priority for use of limited vaccine should gradually shift from controlling the outbreak to preserving the breeding herds of dairy and beef cattle. The DIVA testing for antibodies to FMDV non-structural proteins necessary to demonstrate that a vaccinated herd does not have circulating virus is only validated for use in cattle. The commercial swine industry has greater potential to control the outbreak through effective biosecurity, and the swine breeding herd can be rebuilt much more quickly than the beef and dairy breeding herds. Sheep and goats often have relatively mild clinical signs and will have a high recovery rate and most should return to production after infection without vaccination.

If the U.S. progresses to a prolonged outbreak with a goal of becoming FMD free with vaccination, the decision may be to follow a successful model used in South America which is to vaccinate all cattle (and buffalo). Cattle under 2 years of age (starting at 3 months of age) receive a dose of vaccine every 6 months until 2 years of age. Cattle older than 2 years of age receive a booster dose annually. The vaccination schedule needs to be coordinated at the state and federal level. Before the outbreak is under control, it may be necessary to also vaccinate swine, sheep, and goats in some circumstances to safely move them to other production settings. After the outbreak is under control, the countries in South America have found that they only need to vaccinate cattle and buffalos because FMD virus infection is not sustained in other livestock or in wildlife. This has allowed some countries and zones in South America to be declared FMD free with vaccination.

APPENDIX F:

Approach to Nationally Standardized Identification of Livestock that Are Vaccinated for and/or Recovered from Foot and Mouth Disease

The WOAHA Terrestrial Animal Health Code (2023) and the USDA FMD Red Book (2020) outline some of the basic requirements for animal identification systems.

WOAHA Terrestrial Animal Health Code (2023)

Chapter 1.11 of the WOAHA Terrestrial Animal Health Code sets out requirements for countries wishing to obtain recognition as FMD Free with or without vaccination (Articles 1.11.1, 1.11.2). Countries seeking a return to **FMD Free status without vaccination** need to provide the following information:

- Description of animal identification measures, including identifying vaccinated animals
- Description of vaccination programs, including records of animals receiving vaccines
- Statement as to whether vaccination was used during FMD eradication and how vaccinated animals were identified and the fate of vaccinated animals
- If vaccination was applied within the last 24 months, a description and justification of the vaccination strategy and programme, including:
 - Identification of vaccinated animals
 - The way in which the vaccination of animals was certified or reported and the records maintained

Applications from countries seeking **FMD Free with vaccination** status must include the items listed above and:

- A statement that vaccination is carried out for the purposes of the prevention of FMD;
- Evidence of vaccination coverage and population immunity -
 - Provide detailed evidence of vaccination coverage and population immunity as follows:
 - Describe how the number of animals intended for vaccination and the number of vaccinated animals are estimated
 - For serological surveys to estimate population immunity, provide detailed information on the sampling frame (target population, age, species and vaccination status) and survey design (expected prevalence, acceptable error, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How long after vaccination are samples collected? Describe how the threshold for protective immunity has been established. Provide the results of the vaccination coverage and population immunity by year, serotype, species, as relevant. Provide details of any additional methods applied for monitoring the performance of vaccination. 1.11.2.3(d)

USDA FMD Red Book (2020)

The USDA FMD Red Book describes various situations where FMD vaccination may be used as part of the disease control process.

Sections 3.3.2 – Stamping out Modified with Emergency Vaccination to-kill or to-Slaughter, 3.3.3 – Stamping-Out Modified with Emergency Vaccination to-Live, and 3.3.4—Emergency Vaccination to-Live without Stamping-Out outline the different strategies that may be employed.

Each of these strategies mention:

- vaccinated animal identification, movement controls, traceability, and an effective, scalable permitting system
- the possibility that DIVA testing may be necessary for movements between zones, interstate commerce, and international trade and
- the establishment of vaccination zones

Identification of FMD vaccinated and/or recovered animals in the U.S

A foot and mouth disease (FMD) outbreak in the U.S. may range from a small focal outbreak to a widespread national outbreak. The response may involve a vaccinate to kill or a vaccinate to live policy. In a large outbreak, the response may also involve allowing infected animals to recover (Vaccination to live without stamping out)¹. Recovered animals may also be vaccinated as part of the response. For the U.S. to manage the FMD outbreak and to regain FMD free status (with or without vaccination), it will be essential to correctly identify all animals that are vaccinated, recovered, and both recovered and vaccinated and track them until the end of their lives. Methods used to demonstrate that the FMD virus is not circulating in a herd differ between unvaccinated, vaccinated, and recovered animals. Identification of vaccinated and recovered animals should be nationally standardized so that an animal's vaccination and/or recovered status will be apparent no matter where they are in the U.S. The disposition of vaccinated and recovered animals also must be documented.

During the course of the FMD outbreak an animal's FMD status may change and the identification needs to reflect the current status:

- Not infected with FMD virus and not vaccinated for FMD
- Infected with FMD virus
- Recovered from FMD
- Vaccinated for FMDV, including receiving booster doses
- Recovered from FMD and vaccinated.

This list describes characteristics of an optimal identification method for FMD vaccinated and recovered animals:

- Identification system and records will satisfy trading partners and comply with WOA requirements for regaining FMD Free Status (with or without vaccination)
- Identification can be easily applied and recorded to minimize delays in vaccinating animals
- The identification can be easily, rapidly, and accurately detected and recorded
- Permanent visual markers (e.g. metal ear tags of different colors) will easily identify and differentiate between FMD vaccinated animals and/or FMD recovered animals
- The status of the animal can easily be changed if its FMD status changes
- The vaccination status can be updated when the animal receives a booster vaccine
- Ear tags have unique numbers, are tamper-resistant and have a high retention rate for the life of the animal
- A sufficient quantity of the identification method is available to identify all vaccinated and recovered animals
- The identification method is nationally standardized
- The identification method would stay with the animal from the time it is first identified until the end of its life

It is likely to be impossible to meet all of these optimal characteristics. An additional complication is the current national shortage of ear tags, including radio frequency identification (RFID) tags². The National Veterinary Stockpile has a limited number of pink metal ear tags for use in cattle and swine (and corresponding

applicators) to identify FMD vaccinated animals. In order to know that the animal has received the recommended booster doses of vaccine, it would be necessary to read and record the metal tag number each time the animal receives a booster dose and to report that information to the SAHO who would enter it into USDA APHIS Emergency Management Response System (EMRS). There are apparently not enough pink metal FMD ear tags in stock to identify all cattle and swine that may be vaccinated. An alternative option for identification of vaccinated animals could be ear tattoos or freeze branding. However, those methods do not identify the individual animal and don't allow for identifying administration of booster doses.

One solution might be using a different colored metal ear tag to identify animals that have recovered from FMD infection. Animals that have been vaccinated after recovering from FMD infection would have metal tags of both colors and both numbers would be entered into the EMRS record for the animal.

Identification as a group: If vaccinated animals and/or recovered animals can move as a group (e.g., groups of ruminants on pasture or in a feedlot, swine in a production system), then the group will be tracked as a lot/group of cattle, swine, sheep, etc. without the need for individual animal identification. This would require fewer ear tags than doses of vaccine. As time and availability of resources allow, and if a vaccinated and/or recovered group has not been harvested or euthanized, the individual animals will need to receive an official tag and their information recorded before they can leave the group. If animals are identified as a group, information on the group must be recorded and entered into EMRS (number, species, breed, age, gender, ear tag numbers, any other identifying features, location, owner, accredited veterinarian responsible for vaccination, date of vaccination).

A state emergency FMD vaccination plan needs to include a plan for identification of FMD vaccinated animals based on currently available resources. Possible approaches to identifying FMD vaccinated animals:

- If the animals will be moved as a group, the group will be tracked as a lot/group without the need for individual animal identification.
- If animals in a group may move individually, or as a sub-group, each vaccinee will need to be tagged/identified individually. Possible options are:
 - Animals that already have an RFID tag will have their tag number recorded as having been vaccinated. If sufficient tags are available, they will also receive a pink metal FMD vaccinated tag and the number recorded
 - Animals without an RFID tag will receive an official RFID tag (if sufficient tags are available) and the tag number will be recorded as having been vaccinated. If sufficient tags are available, they will also receive a pink metal FMD vaccinated ear tag and the number recorded
 - Animals without RFID tags, and for which RFID tags are not available, will receive a pink metal FMD vaccinated tag
 - If sufficient RFID tags and pink metal FMD vaccinated tags are not available, then vaccinated animals should be identified with ear tags that have unique numbers, are tamper-resistant and have a high retention rate in the animal.

If an FMD outbreak in the U.S. spreads widely and rapidly, it may become a Type 3, 4, 5, or 6 outbreak. That will likely involve multiple herds of animals that become infected and are allowed to recover. All of those animals will need to be identified, tracked, and shown to not have FMDV circulating before the U.S. can regain FMD freedom. In addition, all vaccinated animals will need to be identified, tracked, and shown not to have circulating virus. If the ability to identify vaccinated animals is insufficient, as described above, regulatory officials will need to decide if it is important to rapidly vaccinate herds to stop disease spread even if they cannot be adequately identified. In a large FMD outbreak, the sampling and testing of vaccinated and recovered animals that will be required will be labor intensive and expensive. It would likely be best to wait until it appears that the outbreak is under control before initiating a sampling and testing program to demonstrate that the U.S. is FMD free with or without vaccination. This will likely require many years, during which time all recovered animals could be removed by controlled marketing and the FMD vaccination program can be standardized, including an official animal identification program.

APPENDIX G: ORGANIZATIONS INVITED TO PARTICIPATE IN THE WORKING GROUP, TABLETOP EXERCISE AND REVIEW AND CONTRIBUTE TO THE PROJECT

Organizations invited to participate in the working group

American Association of Bovine Practitioners
American Association of Small Ruminant Practitioners
American Association of Swine Veterinarians
American Goat Federation
American Sheep Industry Association
Livestock Marketing Association
National Association of State Animal Health Officials
National Cattlemen's Beef Association
National Pork Board
National Tribal Emergency Management Council
North American Deer Farmers Association
North American Elk Breeders Association
North American Meat Institute
USDA APHIS CEAH
USDA APHIS FADDL
USDA APHIS NAHLN
USDA APHIS VS Commodity Staff
USDA APHIS VS EMRS
USDA APHIS VS NPIC

Organizations that participated in the August 29-30 Tabletop Exercise

American Association of Bovine Practitioners
American Association of Small Ruminant Practitioners
American Association of Swine Veterinarians
American Goat Federation
American Sheep Industry Association
Cargill - North American Meat Institute
Clemson LPH (South Carolina State Veterinarian's Office)
Colorado Department of Agriculture

Illinois Department of Agriculture
Indiana State Board of Animal Health
Kansas Dept. of Agriculture, Division of Animal Health
Kansas State University
Livestock Marketing Association
Michigan Department of Agriculture and Rural Development
Missouri Department of Agriculture
National Beef - North American Meat Institute
National Cattlemen's Beef Association
Nebraska Department of Agriculture
Oregon Department of Agriculture
Preventalytics
U.S. CattleTrace
USDA APHIS, Center for Epidemiology and Animal Health
USDA APHIS - NAFMDVB/NAVVCB
USDA APHIS Veterinary Services
USDA APHIS VS D&B FADDL
USDA APHIS VS Swine Team
Utah Department of Agriculture and Food
Virginia Department of Agriculture and Consumer Services
Wisconsin Department of Agriculture, Trade and Consumer Protection
Washington State Department of Agriculture, Animal Services
Wyoming Livestock Board

TERMS/DEFINITIONS

As used in this document

Accredited veterinarian refers to a category 2 accredited veterinarian.

Foot and Mouth Disease (FMD) is defined as an infection with FMD virus.

FMD Positive refers to the status of an animal.

FMD Infected refers to the status of a premises.

FMD Affected refers to the status of a state or region.

FMD Eradication refers to the status of the U.S.

FMD Elimination refers to the status of a premises, region, or state.

Meat Harvest Facility refers to any meat harvest facility that is Federally Inspected, State Inspected, or is Custom Exempt

ABBREVIATIONS AND ACRONYMS

As used in this document

AOS = Active observational surveillance

APHIS = USDA Animal and Plant Health Inspection Service

AVIC = USDA APHIS Area Veterinarian in Charge

CA = Control area

DIVA = Detection of infection in vaccinated animals

FA = Free area

FAD = Foreign animal disease

FADD = Foreign animal disease diagnostician

FADDL = USDA APHIS Foreign Animal Disease Diagnostic Laboratory

FADI = Foreign animal disease investigation

FAD PReP = FAD Preparedness and Response Plan

FMD = Foot and mouth disease

FMDV = Foot and mouth disease virus

FSIS = USDA Food Safety Inspection Service

NADPRP = National Animal Disease Preparedness and Response Program

NAHLN = National Animal Health Laboratory Network

PCR = Polymerase chain reaction

PIN = Premises identification number

SAHO = State Animal Health Official

SFS = Secure food supply

SMS = Secure milk supply

SZ = Surveillance zone

TAHC = WOAHP Terrestrial Animal Health Code

UIC = Unified Incident Command

U.S. = United States

USDA = United States Department of Agriculture

WOAH = World Organization for Animal Health