FOOT-AND-MOUTH DISEASE RESPONSE PLAN
THE RED BOOK

FAD PReP
Foreign Animal Disease Preparedness & Response Plan

National Center for Animal Health Emergency Management

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

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USDA APHIS, Veterinary Services
National Center for Animal Health Emergency Management
Preparedness and Incident Coordination Staff

This version of the *USDA APHIS FMD Response Plan: The Red Book (June 2012)* has been updated according to comments received and revisions to current Foreign Animal Disease Preparedness and Response Plan (FAD PReP) materials that are referenced here. The following list summarizes the important changes that were made in 2012.

- Revision of Chapter 3, Appendix A, and Appendix B to reflect changes in the APHIS Foreign Animal Disease Framework documents.
- New maps illustrating the various strategies for an FMD response effort.
- Corrections and clarifications made in response to comments throughout the plan.

The previously revised version of the *FMD Response Plan (2011)* was updated to reflect the comments made on the November 2010 version of the plan. While much of the document remained the same, there were important changes both in substance and organization. The bulleted list below summarizes the key changes that were made in 2011.

- Revision of the chapter on the goals and strategy for an FMD response, including the addition of revised illustrations demonstrating these different strategies.
- Clarification of the intent and purpose of this document.
- Development of new movement control tables.
- Revised incident command organizational charts and figures.
- Corrections and clarifications made in response to comments throughout the plan.

This plan will continue to be reviewed as needed. We realize that preparing for and responding to an FMD outbreak will be a complex effort, requiring collaboration for multiple stakeholders. As such, we will continue to accept comments on the *FMD Response Plan* for incorporation into future versions.

The Foreign Animal Disease Preparedness and Response Plan (FAD PReP) mission is to raise awareness, define expectations, and improve capabilities for FAD preparedness and response.

For more information, please go to:

https://fadprep.lmi.org (Request access)

http://inside.aphis.usda.gov/vs/em/fadprep.shtml (APHIS employees)

or e-mail FAD.PReP.Comments@aphis.usda.gov

Executive Summary

This *Foot-and-Mouth Disease (FMD) Response Plan: The Red Book (2012)* incorporates comments received on the *FMD Response Plan: The Red Book (2010)* and *FMD Response Plan: The Red Book (2011)* and updates to current Foreign Animal Disease Preparedness and Response (FAD PReP) materials. The objectives of this plan are to identify (1) the capabilities needed to respond to an FMD outbreak and (2) the critical activities that will be involved in responding to that outbreak, and time-frames for these activities. These critical activities are the responsibility of Incident Command in an outbreak situation.

This plan promotes agricultural security, secures the food supply, guards animal health, and protects public health by providing strategic guidance on responding to an FMD outbreak. Developed by the National Center for Animal Health Emergency Management of the Animal and Plant Health Inspection Service (APHIS), the plan gives direction to emergency responders at the local, State, Tribal, and Federal levels to facilitate FMD control and eradication efforts in domestic livestock in the United States. This plan complements, not replaces, existing regional, State, Tribal, local, and industry plans.

The FMD virus is considered the most highly contagious disease agent of livestock. Currently, the United States is free from the FMD virus. However, FMD is present throughout approximately two-thirds of the world and endemic in parts of Africa, Asia, Eastern Europe, the Middle East, and South America. FMD is easily spread through direct contact between susceptible and infected livestock, or through fomites, such as footwear, clothing, and equipment. Aerosol transmission is also possible in environmentally favorable conditions. An FMD outbreak in the United States would have a major economic impact and lasting trade repercussions; the social and psychological impact of mass depopulation of livestock may also be significant. FMD, however, is not a threat to public health.

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

Achieving these three goals will allow individual livestock facilities, States, Tribes, regions, and industries to resume normal production as quickly as possible. They will also allow the United States to regain FMD-free status without the response effort causing more disruption and damage than the disease outbreak itself.

Four key outbreak response strategies, which are not mutually exclusive, are detailed in this plan. These strategies are: stamping-out; stamping-out modified

with emergency vaccination to slaughter; stamping-out modified with emergency vaccination to live; and emergency vaccination to live without stamping-out.

During an FMD outbreak response effort, many activities—such as epidemiology, surveillance, biosecurity, quarantine and movement control, and depopulation—must occur in a deliberate, coordinated fashion. In addition to providing strategic direction on these various activities, this plan explains the underlying Incident Command System structure, applying National Response Framework (NRF) and National Incident Management System (NIMS) principles and systems to control and eradicate an outbreak of FMD in domestic livestock.

Incorporating current scientific knowledge and policy guidance on FMD, this plan does the following:

- Identifies the audience for and purpose of the document.
- Provides technical information on FMD and the impact an FMD outbreak could have in the United States.
- Explains the integration of the NRF, NIMS, and other Foreign Animal Disease Preparedness and Response Plan (FAD PReP) documents.
- Describes U.S. Department of Agriculture preparedness and response activities, both domestic and international, including the APHIS Incident Management Structure.
- Presents 23 critical activities and tools, such as case definitions, surveillance, cleaning and disinfection, health and safety and personal protective equipment, and depopulation.
- Details the World Organization for Animal Health standards for FMD surveillance, virus inactivation, and disease freedom.
- Supplies information on proof-of-freedom procedures and restocking after an FMD outbreak.

This response plan is carefully integrated with other FAD PReP documents, including the FMD Standard Operating Procedures, and National Animal Health Emergency Management System Guidelines. Together, these documents provide a comprehensive preparedness and response framework for an FMD outbreak.

Please visit the FAD PReP collaboration website, which promotes preparedness relationships and advances response capabilities: https://fadprep.lmi.org.

This plan is a dynamic document that will be updated and revised on the basis of future knowledge and stakeholder input. Your comments and recommendations on this document are invited. Please send them to the following e-mail address: FAD.PReP.Comments@aphis.usda.gov.

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Preface

The Foreign Animal Disease Preparedness and Response Plan (FAD PReP)—*Foot-and-Mouth Disease (FMD) Response Plan: The Red Book* provides strategic guidance for responding to an animal health emergency caused by FMD in the United States. This *FMD Response Plan (June 2012)* updates the *FMD Response Plan (2011)* and replaces previous FMD summary response plans. Information in this plan may require further discussion and development with stakeholders.

This *FMD Response Plan* is under ongoing review. This document was last updated in **June 2012.** Please send questions or comments to:

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Chapter 1
Introduction and FMD Information

1.1 Introduction to Response Plan

This *Foot-and-Mouth Disease (FMD) Response Plan: The Red Book (June 2012)* incorporates comments received on the *FMD Response Plan: The Red Book (2011)* and *FMD Response Plan: The Red Book (2010)* and updates to current Foreign Animal Disease Preparedness and Response Plan (FAD PReP) materials. The objectives of this plan are to identify the (1) capabilities needed to respond to an FMD outbreak and (2) critical activities that will be involved in responding to that outbreak, and time-frames for these activities. These critical activities are the responsibility of Incident Command (IC) in an outbreak situation.

To achieve these objectives, this plan provides current information on FMD and its relevance to the United States, and presents the organizational strategy for an effective FMD response. In addition, it offers guidance on four key, but not mutually exclusive, outbreak response strategies. This plan also contains updated guidance on 23 critical response activities and tools, such as disposal, appraisal and compensation, and quarantine and movement control. As indicated by links throughout the document, this plan is integrated and coordinated with other new and forthcoming Foreign Animal Disease Preparedness and Response Plan (FAD PReP) documents such as FMD standard operating procedures (SOPs), National Animal Health Emergency Management System (NAHEMS) Guidelines, and existing Animal and Plant Health Inspection Service (APHIS) memoranda. (Appendix A provides a list of documents related to FMD outbreak response and an overview of FAD PReP).

This plan does not replace existing regional, State, Tribal, local, or industry preparedness and response plans relating to FMD. Regional, State, Tribal, local, and industry plans should be aimed at more specific issues in FMD response. In particular, States should develop response plans focused on the specific characteristics of the State and its livestock industry.

FMD is a highly contagious viral disease that may affect domestic cloven-hoofed animals (cattle, swine, sheep, and goats) and many wild animals (deer, bison, pronghorn antelope, and feral swine). The disease is characterized by fever, vesicular (blister-like) lesions, and subsequent erosions (ulcers) of the surfaces of the mouth, tongue, nostrils, muzzle, feet, and teats. FMD is not typically considered a public health risk. It is considered the most contagious disease of livestock, and is a high priority concern for the U.S. Department of Agriculture (USDA) APHIS.

The United States has been FMD-free since 1929. However, the disease is still found in about two-thirds of the world. There are many susceptible animals in the United States, including approximately 94.5 million cattle, 67 million swine, and 8.5 million sheep and goats. Although FMD does not typically kill adult livestock, it does have very detrimental effects on productivity (meat and milk). In addition, high mortality rates may occur in young animals.

An outbreak of FMD in the United States would have a significant economic impact, considering the loss of international trade as well as costs directly associated with depopulation, disposal, and disinfection. There would also be costs related to lost production.

1.2 Purpose of Document

This plan provides strategic guidance for USDA APHIS and responders at all levels in the event of an FMD outbreak in domestic livestock. It provides current policy information and a framework for the control and eradication of FMD, should an outbreak occur in the United States.

1.3 Audience

This document is intended for animal health emergency responders at all levels of government, as well as industry partners. It provides strategic guidance and offers additional resources for tactical information for responders and other individuals who will act during an FMD outbreak in domestic livestock.

1.4 FMD Information

These sections provide an overview of FMD and cover the following subjects:

- Etiology
- History and global distribution
- Impact of an FMD outbreak
- Ecology
- Diagnosis
- Immunity.

Further information on FMD can be found in the FMD Overview of Etiology and Ecology SOP. Chapter 5 of this plan includes the current case and laboratory definitions for FMD.

1.4.1 Etiology

1.4.1.1 OVERVIEW

The FMD virus (FMDV) is an Aphthovirus in the family Picornaviridae. FMDV is the etiologic agent of an acute systemic vesicular disease affecting cloven-hoofed animals worldwide. There are seven immunologically distinct FMDV types: A, O, C, South African Territories types SAT-1, SAT-2, SAT-3, and Asia 1. More than 65 strains of FMDV have been recognized. There is a substantial amount of genetic variability in FMD viruses, and new strains occasionally develop spontaneously. There is no cross protection between serotypes, and protection between strains varies depending on their antigenic similarity. FMD is also known as fiebre aftosa, fievre aphteuse, and maul-und-klauenseuche.

1.4.1.2 WORLD ORGANIZATION FOR ANIMAL HEALTH (OIE) DEFINITION OF FMDV INFECTION

The OIE *Terrestrial Animal Health Code (2011)* "defines the occurrence of FMDV infection" as:

1. FMDV has been isolated and identified as such from an animal or a product derived from that animal; or
2. viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of FMDV has been identified in samples from one or more animals, whether showing clinical signs consistent with FMD or not, or epidemiologically linked to a confirmed or suspected outbreak of FMD, or giving cause for suspicion of previous association or contact with FMDV; or
3. antibodies to structural or nonstructural proteins of FMDV that are not a consequence of vaccination, have been identified in one or more animals showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected outbreak of FMD, or giving cause for suspicion of previous association or contact with FMDV.

1.4.2 History and Global Distribution

FMD is present in approximately two-thirds of the world and endemic in parts of Africa, Asia, Eastern Europe, the Middle East, and South America. North America (the United States, Canada, and Mexico) and Central America are free of FMD, as is Western Europe, Australia, and New Zealand. FMD is still a significant threat to agriculture. For example, in 2010 – 2011, FMD outbreaks have occurred in countries including Japan, China, Kazakhstan, Botswana, Bulgaria, Nigeria, Zimbabwe, South Africa, South Korea, Namibia, and North Korea. Many of these outbreaks occurred outside endemic infection zones.

The United States has not experienced an FMD outbreak since 1929, Canada since 1952, and Mexico since 1954.

1.4.2.1 Prevalence of Serotypes

The seven FMDV serotypes demonstrate some regionalism; the O serotype is most common, followed by Asia 1. All serotypes produce disease that is clinically indistinguishable but immunologically distinct. There is no cross protection between serotypes. Figure 1-1 maps the distribution of serotypes worldwide, as typically found.

Figure 1-1. Distribution of FMD Serotypes Worldwide

1.4.2.2 Threat of FMD in the United States

Although the United States has been FMD-free (without vaccination) since 1929, international travel and trade pose a substantial risk that it could enter the country. The disease is a critical threat to the United States because of the millions of susceptible cloven-hoofed livestock and wild animals, such as feral swine. FMD can be transmitted over long distances by animal products, fomites, people, and other mechanical vectors; the virus is also considered a potential agent for agricultural terrorism.

1.4.3 International Trade

Currently, the United States does not import livestock from countries that are not considered FMD-free. USDA maintains a list of countries and regions considered FMD-free: http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_fmd.shtml.

In addition, the United States takes additional precautions for FMD-free countries that employ import standards less restrictive than those of the United States and countries sharing a border with countries or regions not free of FMD.

Certain meat products can be exported from countries that are not recognized as free of FMD, provided that specific conditions are met and documented. For example, Uruguay is not considered by the United States to be FMD-free, but is permitted to export fresh beef under specific conditions. Additional information on the products eligible for importation into the United States from other countries is provided here: http://www.fsis.usda.gov/Regulations_&_Policies/index_of_certified_countries/index.asp.

1.4.4 Impact of an FMD Outbreak

1.4.4.1 Economic

The 2001 FMD outbreak in the United Kingdom cost an estimated $13 billion and reduced the British gross domestic product by 0.2 percent. A U.S. outbreak contained in California would likely cost between $6 and $14 billion. In particular, the value of lost exports would be a substantial detriment to the economy. In addition to these indirect costs, an FMD response effort would involve direct costs for depopulation, indemnity payments, animal disposal, disinfection, and movement control measures. Additional indirect costs would be incurred by consumers and related sectors of the economy, such as feed producers and suppliers. Any FMD outbreak in the United States would likely have a sizeable and lingering economic impact.

1.4.4.2 Public Health Implications

FMD is *not* considered a public health threat. FMDV infections in humans are very rare: about 40 cases have been diagnosed since 1921. These cases are typically characterized by vesicular lesions and influenza-like symptoms. The disease in humans is generally mild, short-lived, and self-limiting.[1] FMD differs from hand, foot, and mouth disease of humans. FMD can survive in the human respiratory tract for 24 hours, allowing people with very close contact with infected animals to potentially serve as a source of virus exposure for susceptible animals.

An FMD outbreak *may* have public health implications from the mental health effects resulting from the mass depopulation and disposal of animals on personnel

[1] A. R. Spickler, J. A. Roth, J. Galyon, and J. Lofstedt, eds., *Emerging and Exotic Diseases of Livestock,* 4th Ed (Ames, IA: Iowa State University, College of Veterinary Medicine, 2010); UK Department for Environment, Food, and Rural Affairs (DEFRA), *Summary Profile for Foot and Mouth Disease*. Available from http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/vetsurveillance/profiles/documents/sp-fmd.pdf (June 13, 2012).

and individuals associated with the response effort. These effects on mental health may include post-traumatic stress disorder and depression. Support should be made available to those involved, particularly to responders and owners of affected livestock.

1.4.5 Ecology

FMD affects cloven-hoofed animals. Susceptible species include the following:

- Cattle
- Pigs
- Sheep
- Goats
- Deer
- Elk
- Bison.

The disease is generally most severe in cattle and pigs. New World camels in the family Camelidae (alpacas, llamas, guanacos, and vicuñas) have low susceptibility to FMDV but can develop clinical illness. Old World camels (dromedaries, Bactrian camels) are more susceptible. While rare, FMD has been documented in several other species including elephants and hedgehogs.

1.4.5.1 CARRIERS

There is no known natural reservoir of FMD—instead, there is a "carrier state." FMDV carriers are defined as "recovered or vaccinated and exposed animals in which FMDV persists in the oropharynx for more than 28 days."[2] Carriers of FMD can include cattle, sheep, goats, and African buffalo, though sheep and goats seem to become carriers less often and for shorter periods than cattle. Most cattle carry the virus for 6 months or less. Persistent infections have also been reported for a limited period in some experimentally infected wildlife, including white-tailed deer, kudu, and fallow deer. However, how an animal develops the carrier state and the role of FMD carriers in the infection of susceptible cattle are not well understood.[3] Animals can become carriers regardless of whether they had clinical signs of the virus.

[2] Fernández, P.J. and White, William R. (2010). *Atlas of Transboundary Animal Diseases.* OIE.

[3] For more information on carrier animals, see Tenzin, A. Dekker, H. Vernooij, A. Bouma, and A. Stegeman, "Rate of Foot-and-Mouth Disease Virus Transmission by Carriers Quantified from Experimental Data." *Risk Analysis,* 28(2), 2008, pp. 303–309.

1.4.5.2 Introduction and Transmission of FMD

FMDV is thought to be introduced through infected animals, contaminated fomites, and possibly carrier animals, though evidence conflicts on the conditions in which specific species of carrier animals can transmit FMDV to naïve animals. Wildlife does not appear to be a common means of introduction of FMD into domestic animals. Historically, meat products have been an important mode of introduction.

FMDV is highly contagious and there are multiple modes of transmission. Direct contact between infected and susceptible live animals is the most common mode of transmission, particularly when animals are in proximity. FMDV can be found in all secretions and excretions from acutely infected animals, including expired air, saliva, nasal secretions, milk, urine, feces, and semen. Animals can shed FMDV for up to 4 days prior to the onset of clinical signs. Fomites contaminated with secretions and excretions from infected animals also commonly serve as transmission pathways.

FMDV can also spread via aerosol transmission under favorable environmental conditions. Pigs, particularly, excrete large amounts of virus through their respiratory tract, which can lead to infectious aerosols that can be inhaled by other animals (typically cattle) in proximity. FMDV has also been known to spread through windborne transmission, where the virus infects naïve animals located some miles from known infected animals without any history of contact. The distance of windborne transmission over land surfaces depends on the atmospheric conditions and the amount of virus emitted into the air by the infected animals. Sources suggest FMDV may spread to distances of approximately 60 kilometers over land in favorable conditions and potentially even greater distances over water. The conditions for long distance spread are likely to be highly specific, including high relative humidity, steady wind, minimal convection currents, and lack of topographical obstructions. These conditions tend to be met more often over water than over land.

1.4.5.3 Persistence in Environment and Animal Products

FMD viruses are susceptible to both acid and alkaline pH, and are quickly inactivated by pH < 6.0 and pH > 9.0.[4] FMDV is preserved by refrigeration and freezing, but progressively inactivated by temperatures above 50ºC. FMDV can survive in frozen bone marrow or lymph nodes for long periods. Higher relative humidity increases the survival time of airborne FMDV. FMDV is resistant to many disinfectants such as hypochlorite and phenol, particularly when organic matter is present.

Meat must be subjected to heat treatment at 70ºC for 30 minutes to ensure FMDV deactivation. Typical industrial processes for salami inactivate FMDV. FMDV

[4] OIE, *Foot-and Mouth Disease*, Technical Disease Card, 2009, http://www.oie.int.

can persist in dairy products, and typical pasteurization may not inactivate the virus. For milk or cream for human consumption, the OIE suggests three procedures for inactivation of FMDV: (1) a sterilization process applying a minimum temperature of 132ºC for at least 1 second, (2) if the milk has a pH less than 7.0, a sterilization process applying a minimum temperature of 72ºC for at least 15 seconds, or (3) if the milk has a pH of 7.0 or over, applying the process in (2) twice.[5]

FMDV can also persist in wool, hair, and other products for substantial periods. Please refer to the FMD Overview of the Etiology and Ecology of SOP, as well as the OIE *Terrestrial Animal Health Code (2011)* for further information (https://fadprep.lmi.org and http://www.oie.int).

1.4.6 Diagnosis

Producers as well as veterinarians should be familiar with signs of vesicular disease, as they may be the initial detectors of an FMD outbreak. The incubation period is typically 2–14 days, depending on the dose of the virus and the route of infection. The OIE *Terrestrial Animal Health Code (2011)* defines the incubation period as 14 days. The incubation period varies between species.

1.4.6.1 Clinical Signs

Animals affected with FMD show a variety of clinical signs; FMD is typically recognized by vesicular symptoms. Clinical signs are usually more prominent in cattle and pigs than in sheep and goats, and are indistinguishable from other vesicular diseases.

1.4.6.1.1 Cattle

Common signs in cattle include the following:

- Pyrexia (fever), anorexia, shivering, reduction in milk production for 2–3 days, followed by
  - smacking of the lips, grinding of the teeth, and drooling,
  - excess nasal mucous secretions,
  - lameness, stamping, or kicking caused by vesicles on buccal and nasal mucous membranes or between the claws and coronary band,
  - ruptured vesicles, and
  - vesicles on mammary gland

[5] OIE, Article 8.5.38 "Procedures for the inactivation of the FMD virus in milk and cream for human consumption," *Terrestrial Animal Health Code*, 2011, http://www.oie.int.

- Vesicles on the tongue
- Abortion
- Sudden death in young animals.

The infection usually resolves in 8–15 days unless there is a serious secondary bacterial infection.

1.4.6.1.2 Pigs

Typical signs of FMD in pigs include the following:

- Pyrexia (fever) and blanching of the coronary bands, followed by
  - severe foot lesions,
  - severe lameness,
  - reluctance to move,
  - no drooling, and
  - lesions on snout, muzzle, gums, and interdigital spaces
- High mortality in piglets
- Possible abortion.

1.4.6.1.3 Sheep and Goats

Clinical signs of FMD in sheep and goats are typically less pronounced and frequent than in pigs and cattle and may go unrecognized:

- Possible mild lameness where there are small vesicles or erosions on coronary band
- Death of young animals
- Lesions in dental pad of sheep
- Agalactia in milking animals
- Possible abortion.

1.4.6.2 GROSS PATHOLOGICAL LESIONS

Lesions typically include vesicles or blisters on the tongue, dental pad, gums, cheek, hard and soft palate, lips, nostrils, muzzle, coronary bands, teats, udder,

snout of pigs, corium of dewclaws, and interdigital spaces. Post-mortem lesions can be on rumen pillars, as well as in the myocardium. Necrosis may also occur.

Lesions will vary among cattle, swine, and sheep. For extensive pictures demonstrating the aging of FMD lesions, see http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/fmd/documents/ageing-lesions.pdf.

1.4.6.3 Differential Diagnoses

Vesicular stomatitis, swine vesicular disease, and vesicular exanthema of swine are all clinically indistinguishable from FMD. FMD also has common features with bovine viral diarrhea, mucosal disease, infectious bovine rhinotracheitis, and bluetongue.

1.4.7 Immunity

1.4.7.1 Natural Infection

Infection with FMDV causes animals to develop a humoral antibody that is transient and also specific for the subtype of the infecting FMDV. Approximately 7 to 14 days post-infection, protective antibodies are developed against FMDV structural proteins. Evidence has not suggested any maternal antibodies are produced.

1.4.7.2 Vaccination

Vaccination of cattle against FMDV has been practiced with relatively positive immunity results. Vaccine has not only prevented clinical disease, but helps control FMDV transmission in an outbreak. Vaccination campaigns are more likely to succeed if the interval between vaccination and exposure is sufficient to ensure animals develop adequate immunity to FMDV. However, certain limitations of vaccination, in terms of immunity, should be acknowledged.

- Vaccines provide only serotype-specific protection. Vaccination against one serotype may fail to protect fully or at all against other strains within the serotype. This protection depends on
  - the similarity between the field strain and the vaccine, and
  - the potency of the vaccine (more potent vaccines are likely to be protective against even less well-matched strains).
- Onset of immunity is not immediate. Inactivated FMD vaccines may decrease viral shedding and clinical signs in cattle and sheep in challenge studies as early as 4 days after vaccination with protection improving for the next 2–3 weeks.

  - Swine appear to be more difficult to protect shortly after challenge; limited studies have reported some protection as soon as 3–4 days after vaccination. However, with more severe challenges, pigs may not be completely protected against disease until 21–28 days after vaccination.[6]

- No currently available vaccine provides "sterilizing immunity" which will prevent subsequent infection.

- It is possible that individual vaccinated cattle infected with FMDV could still become asymptomatic virus carriers.[7,8]

Differentiating field infected animals from vaccinated animals, known as a "DIVA" strategy, may be critical to emergency vaccination in an FMD outbreak. DIVA diagnostic techniques typically use tests for antibodies against viral non-structural proteins (NSPs) to differentiate animals that are infected with FMDV in the field (natural infection) from those that have been vaccinated with an FMD vaccine. This diagnostic DIVA capability may be important for an effective vaccination campaign, business continuity processes, and FMDV surveillance.

Emergency vaccination and DIVA are further discussed later in this document, in the FMD Vaccination SOP, and in the NAHEMS Guidelines: Vaccination, with the Appendix A: Foot-and-Mouth Disease. Both the SOP and the NAHEMS Guidelines are available at https://fadprep.lmi.org.

[6] National Veterinary Stockpile (NVS). 2007. *National Veterinary Stockpile Countermeasures Working Group Report: Foot-and-Mouth Disease.*

[7] National Veterinary Stockpile (NVS). 2007. *National Veterinary Stockpile Countermeasures Working Group Report: Foot-and-Mouth Disease.*

[8] For more information on vaccination and carrier animals, see D. Schley, D.J. Paton, S.J. Cox, S. Parida, and S. Gubbins, 2009, "The effect of vaccination on undetected persistence of foot-and-mouth disease virus in cattle herds and sheep flocks." *Epidemiol. Infect.,* 137, 1494–1504.

Chapter 2
Framework for FMD Preparedness and Response

2.1 National Response Framework, National Incident Management System, and National Animal Health Emergency Management System Integration

Successful emergency preparedness for and response to FMD requires integration between the National Response Framework (NRF), National Incident Management System (NIMS), and NAHEMS. This FMD-specific plan fits into this hierarchy to provide more detailed information and specific direction on response requirements in the event of an FMD outbreak in the United States.

2.1.1 National Response Framework

The NRF is a guide to how the Nation conducts all-hazards response. It describes specific authorities and establishes a comprehensive approach for responding to domestic incidents that range from serious but purely local events to large-scale terrorist attacks or catastrophic natural disasters. It builds on NIMS, which provides a consistent template for managing incidents. The NRF is available from http://www.fema.gov/emergency/nrf/.

2.1.2 National Incident Management System

NIMS, a companion document to the NRF, provides a systematic, nationwide, proactive approach guiding departments and agencies at all levels of government, the private sector, and non-governmental organizations. Its goal is to help these organizations work seamlessly to prepare for, prevent, respond to, recover from, and mitigate the effects of incidents, regardless of cause, size, location, or complexity, to reduce the loss of life, liberty, property, and harm to the environment. NIMS provides a core set of concepts, principles, procedures, organizational processes, terminology, and standard requirements. NIMS information is available at http://www.fema.gov/emergency/nims/.

NIMS consists of five key components:

1. A set of preparedness concepts and principles for all hazards;

2. Essential principles for a common operating picture and interoperability of communications and information management;

3. Standardized resource management procedures that enable coordination among different jurisdictions or organizations;

4. Scalability, for use in all incidents (ranging from day to day to large scale); and

5. A dynamic system that promotes ongoing management and maintenance.

2.1.3 National Animal Health Emergency Management System

APHIS and its stakeholders established NAHEMS to provide a functional framework for responding to foreign animal disease (FAD) emergencies through NAHEMS Guidelines, disease response plans (such as this FMD-specific plan), SOPs, and other associated documents. The purpose of the NAHEMS Guidelines is to ensure a successful response commensurate with the severity of the outbreak. Federal, State, and local agencies; Tribal nations; and other groups involved in animal health emergency management activities should integrate the information provided in NAHEMS Guidelines into their preparedness plans.

NAHEMS Guidelines (and other FAD PReP documents) offer

- competent veterinary guidance on cleaning and disinfection, disposal, mass depopulation, and other activities;
- information on disease control and eradication strategies and principles;
- guidance on health, safety, and personal protective equipment (PPE) issues;
- biosecurity information and site-specific management strategies; and
- training and educational resources.

In particular, NAHEMS Guidelines provide a foundation for coordinated national, regional, State, Tribal, and local activities in an emergency situation. These guidelines serve as a practical guide and complement non-Federal preparedness activities.

These NAHEMS documents can be found at the FAD PReP website (https://fadprep.lmi.org) or at http://inside.aphis.usda.gov/vs/em/fadprep.shtml for APHIS employees.

2.1.4 Coordination and Collaboration

This *FMD Response Plan* is coordinated with the other FAD PReP documents, which follow NRF and NIMS. This document provides strategic guidance for responding to an FMD outbreak. Other FAD PReP documents provide information on general veterinary activities and include industry or facility manuals for industry stakeholders as well as SOPs for planners and responders. Together, these documents provide strategic and tactical details for Federal, State, Tribal, and local officials that are useful for FMD preparedness and response.

Building on existing planning and response relationships, raising awareness on critical issues, and collaborating to address significant problems are key goals of FAD PReP efforts. Exercises and real events can improve FMD preparedness and response planning and collaboration.

2.2 Federal Roles, Responsibilities, and Planning Assumptions

2.2.1 Overview

Understanding the roles and responsibilities of Federal departments or agencies involved in responding to a domestic incident of an FAD promotes an effective, coordinated emergency response. The subsection that follows describes the roles, responsibilities, and authority of USDA in an FMD response. The functions described are consistent with the roles and responsibilities outlined in the NRF.

Federal response to the detection of an FAD such as FMD is based on the response structure of NIMS as outlined in the NRF. The NRF defines Federal departmental responsibilities for sector-specific responses. During the course of an FMD outbreak response, the USDA may request Federal-to-Federal support (FFS) from other Federal departments and agencies. FFS refers to the circumstance in which a Federal department or agency requests Federal resource support under the NRF that is not addressed by the Stafford Act or another mechanism.

2.2.2 USDA Roles and Responsibilities Overview

As the primary Federal agency for incident management during an FAD event of livestock, like an FMD outbreak, USDA coordinates incident management teams, manages incident response, manages public messages, and takes measures to control and eradicate FMD. Measures used to control and eradicate FMD include quarantine and movement control, epidemiologic investigation, appraisal and compensation, depopulation (euthanasia) of affected livestock, carcass disposal, cleaning and disinfection, active surveillance for additional cases, diagnostics, and, potentially, emergency vaccination.

The USDA (not including the additional ESFs of the U.S. Forest Service, which is a part of USDA) performs the coordination role in Emergency Support Function (ESF) #11—Agriculture and Natural Resources—under the NRF. It also plays supporting roles in the following ESFs:

- ESF #3—Public Works and Engineering
- ESF #5—Emergency Management
- ESF #6—Mass Care, Emergency Assistance, Housing, and Human Services
- ESF #7—Logistics Management and Resource Support
- ESF #8—Public Health and Medical Services
- ESF #10—Oil and Hazardous Materials Response
- ESF #12—Energy
- ESF #14—Long-Term Community Recovery (primary agency role)
- ESF #15—External Affairs.

During the course of an FMD outbreak response, USDA may request support as necessary from other Federal agencies. If the President declares an emergency or major disaster, or if the Secretary of Agriculture requests the Department of Homeland Security (DHS) lead coordination, the Secretary of Homeland Security and DHS assume the lead for coordinating Federal resources. USDA maintains the lead of overall incident management.

For more information on the roles of other Federal agencies, such as the Departments of Health and Human Services (HHS) and the Interior (DOI), in the event of an FMD outbreak, see the *APHIS Foreign Animal Disease Framework: Roles and Coordination* (FAD PReP Manual 1-0) and *APHIS Foreign Animal Disease Framework: Response Strategies* (FAD PReP Manual 2-0). (Appendix B of this plan contains an organizational chart showing the coordination between DHS/Federal Emergency Management Agency and USDA in the event of a major FMD outbreak.)

2.3 AUTHORITY

The Animal Health Protection Act (AHPA), 7 *U.S. Code* 8301 et seq., authorizes the Secretary of Agriculture to restrict the importation, entry, or further movement in the United States or order the destruction or removal of animals and related conveyances and facilities to prevent the introduction or dissemination of livestock pests or diseases. It authorizes related activities with respect to

exportation, interstate movement, cooperative agreements, enforcement and penalties, seizure, quarantine, and disease and pest eradication. The act also authorizes the Secretary to establish a veterinary accreditation program and enter into reimbursable fee agreements for pre-clearance abroad of animals or articles for movement into the United States.

Section 421 of the Homeland Security Act, 6 *U.S. Code* 231 transfers to the Secretary of Homeland Security certain agricultural import and entry inspection functions under the AHPA, including the authority to enforce the prohibitions or restrictions imposed by USDA.

The Secretary of Agriculture has the authority to cooperate with other Federal agencies, States, or political subdivisions of States, national or local governments of foreign governments, domestic or international organizations or associations, Tribal nations, and other persons to prevent, detect, control, or eradicate FMD. If measures taken by a State or Indian Tribe to control or eradicate a pest or disease of livestock are inadequate, the AHPA authorizes the Secretary, after notice to and review and consultation with certain State or Tribal officials, to declare that an extraordinary emergency exists because of the presence in the United States of a pest or disease of livestock that threatens the livestock of the United States (7 *U.S. Code* 8306).

For further information on USDA APHIS authorities, see the *APHIS Foreign Animal Disease Framework*: *Roles and Coordination* (FAD PReP Manual 1-0) at https://fadprep.lmi.org.

Chapter 3
USDA FMD Preparedness and Response

3.1 USDA

USDA APHIS is the Federal agency with primary responsibility and authority for animal disease control and will interface with Federal, State, Tribal, and local partners in FMD eradication and control efforts. If the President declares an emergency or major disaster, or if the Secretary of Agriculture requests that DHS lead coordination, the Secretary of Homeland Security and DHS leads the coordination of FFS and Federal resources for the incident while USDA maintains the lead of overall incident management.

USDA is the primary Federal liaison to the U.S. animal industry. In addition, it operates the National Veterinary Services Laboratories (NVSL), including the Foreign Animal Disease Diagnostic Laboratory (FADDL), which is an OIE reference laboratory for identifying and confirming FMD.

The following subsections detail USDA activities to prepare for an FMD outbreak.

3.1.1 Preparedness Exercises

Preparedness and response exercises help ensure our Nation is able to respond quickly and effectively to an FMD outbreak. They are an ideal, no-fault learning environment to discuss, practice, and implement plans, procedures, and processes in advance of an actual event. APHIS exercises are conducted in accordance with Homeland Security Exercise and Evaluation Program guidance.

Multiple preparedness exercises have been conducted to simulate an FMD outbreak and response effort in the United States. These exercises allow responders to discuss and practice activities relating to this highly contagious animal disease, such as movement control, and to consider the social and economic implications of an FMD outbreak. They help prepare the United States and responders for the difficult decisions that will be made regarding animal depopulation and business continuity.

The NVS has also conducted multiple exercises to assess and test its ability to deliver supplies (including vaccine) and services and State and Tribal ability to receive and stage these items in the event of an FMD outbreak. These exercises have incorporated multiple States, various State agencies, as well as industry and academia to simulate a response effort.

Multi-state exercises have enhanced coordination and collaboration between States and between States and the Federal government. Valuable logistics lessons have been learned and important recommendations have resulted from the evaluation of these exercises.

3.1.2 Domestic Activities

USDA has a variety of ongoing preparedness and response activities with respect to FMD. Domestically, the USDA prevents the introduction of FMD into the country and also performs FAD investigations as needed for suspected cases or reported vesicular conditions. The following list details a selection of USDA activities:

- *Smuggling Interdiction and Trade Compliance (SITC)*. SITC conducts risk management and anti-smuggling activities to prevent unlawful entry and distribution of prohibited agricultural commodities. It looks at domestic markets likely to have illegal imported animal products to establish baseline estimates on how much product is bypassing ports of entry.

- *National Center for Import and Export (NCIE)*. NCIE facilitates international trade, monitoring the health of animals presented at the border as well as regulating the import and export of animals and animal products. All cattle must go through a 60-day quarantine before export to the United States. In addition, all cattle (except those from Canada and Mexico) must be quarantined for 30 days at a USDA Animal Import Center. Cattle from countries affected with FMD are not permitted to be imported into the United States.

- *Vesicular disease surveillance*. USDA rapidly responds to reported or suspected cases of vesicular conditions in the United States with FAD investigations. These investigations are intended to rapidly detect and diagnose any vesicular disease in the United States. APHIS is planning for additional, collaborative surveillance for vesicular diseases.

- *Other preparedness and disease models*. USDA uses various models to develop computer-generated scenarios for FMD. This allows it to evaluate the potential consequences of FMD in the United States, as well as the countermeasures, materials, and supplies needed for control and eradication.

- *Emergency veterinary assistance*. USDA will work to assist States in training and maintaining State incident management teams and veterinary reserve corps, such as the National Animal Health Emergency Response Corps, (NAHERC) (Subsection 3.5). State groups will serve as early response teams for an FMD event and can educate groups on the signs, symptoms, and reporting procedures.

3.1.3 International Activities

USDA also conducts international activities in support of FMD eradication and to bolster preparedness planning and response capabilities. The following list details a selection of USDA activities:

- *Hemispheric collaboration*. APHIS works with South American countries in support of FMD eradication and coordinates planning with international organizations, reducing duplication of effort and increasing sociopolitical support for FMD eradication. APHIS offers support for vesicular disease outbreaks and provides resources for diagnostic testing. USDA has contributed significant funds to eradication in South America. In addition, USDA supports programs to maintain a buffer zone between North and Central America, which are FMD-free, and South America, which is not.

- *International coordination*. USDA APHIS collaborates with interagency and international partners to mitigate animal health threats outside the United States through the sharing of information and development of infrastructure.

- *Global Foot-and-Mouth Disease Research Alliance (GFRA)*. USDA's Agricultural Research Service also participates in GFRA, a worldwide association of animal research organizations involved in combating FMD. This global alliance creates collaborative partners and results in sharing of progressive FMD control and eradication measures.

- *Emergency veterinary assistance*. USDA has also sent veterinarians to assist in FMD response efforts at the request of foreign governments. In providing this assistance, USDA not only gains a bank of valuable expertise in FMD response and control efforts, but also helps to ensure the rapid eradication of FMD.

3.1.4 International Trade

USDA, in collaboration with the Department of State and the United States Trade Representative, will promptly address foreign governments that impose unjustifiable U.S. livestock and livestock product trade restrictions because of an FMD outbreak.

USDA overseas embassy offices also have guidance on how to rapidly report trade disruptions to Washington, DC, headquarters and how to help foreign officials respond to such events. Multiple USDA agencies, led by the Foreign Agricultural Service, will coordinate a response to any such trade disruption and communicate with industry in the United States. USDA would also quickly fulfill any official requests for additional scientific information, including case surveillance, movement control measures, and laboratory diagnostics.

These efforts focus on cases where bans are inconsistent with OIE standards. OIE member countries, like the United States, are to "immediately" notify the OIE of any confirmed FMDV infection, as defined in the OIE *Terrestrial Animal Health Code*. International standards for FMD *do* allow countries to impose bans on imports from FMD-infected countries and zones.

Countries recognized as FMD-free by the United States are listed here: http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_fmd.shtml.

3.1.5 Compartmentalization

Another tool that may mitigate the economic consequences of a disease outbreak is compartmentalization. Compartmentalization defines subpopulations of distinct health status by management and husbandry practices, as related to biosecurity. Compartmentalization is best implemented, as suggested by the OIE in the *Terrestrial Animal Health Code (2011)*, by trading partners through the establishment of parameters and agreement on necessary measures *before a disease outbreak*.

Implementation of compartmentalization will rely on producers, industry, and State and Federal animal health authorities. The importing country must be satisfied that its animal health status is appropriately protected by the biosecurity measures undertaken by the exporting country.

Because of the nature of FMDV, compartmentalization may be difficult to achieve. In addition, animals in compartments cannot be vaccinated for FMD. Currently, no FMD compartmentalization plans have been internationally accepted or implemented.

Chapters 4.3 and 4.4 of the OIE *Terrestrial Animal Health Code (2011)* explain the concept and the application of compartmentalization. More information on compartmentalization can be found in the NAHEMS Guidelines: Regionalization for International Trade for a U.S. FAD Response.

3.2 USDA Organizational Strategy

In the event of an FMD outbreak, effective and efficient management of the situation and clear communication pathways will be critical. A synchronized management and organizational structure will help to support the control and eradication actions. Accordingly, APHIS has adopted NIMS and Incident Command System (ICS) organizational structures to manage the response to an FMD outbreak. The ICS is designed to enable efficient and effective domestic incident management by integrating facilities, equipment, personnel, procedures, and communications operating within a common organizational structure. The next section discusses the APHIS incident management organizational structure.

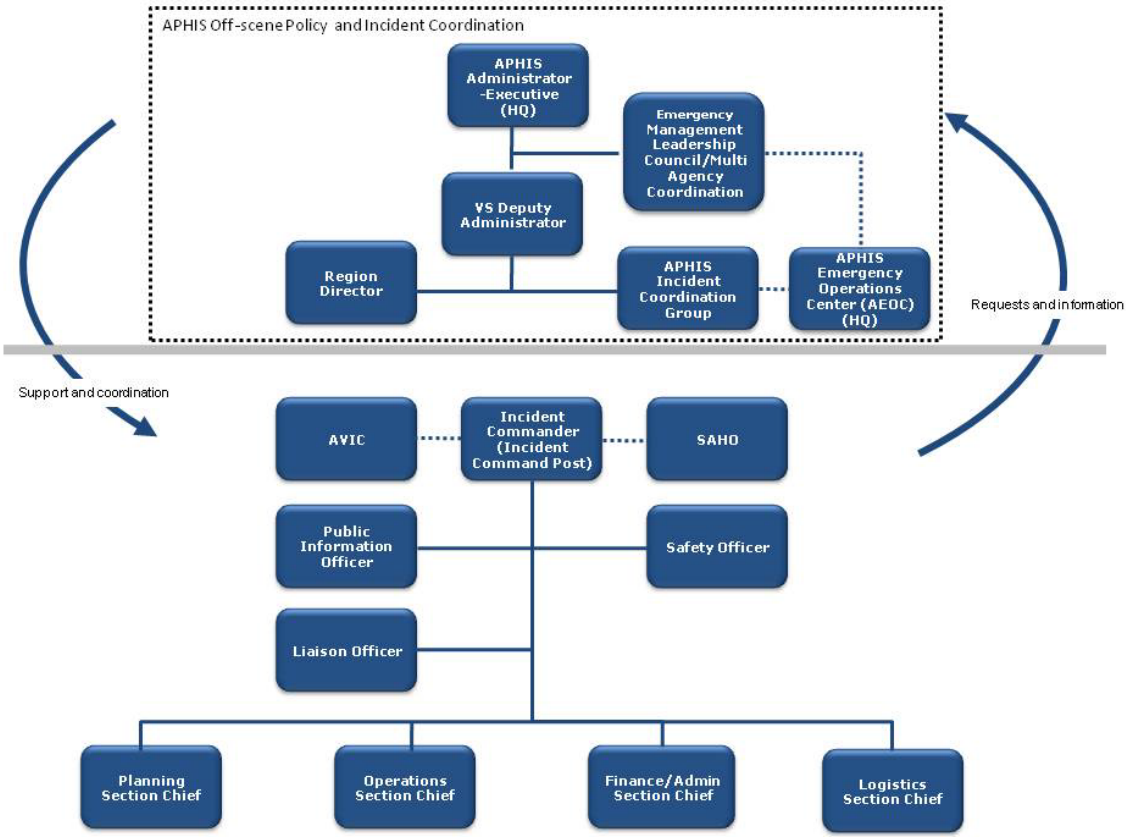
3.3 APHIS INCIDENT MANAGEMENT STRUCTURE

The APHIS Administrator is the Federal executive responsible for implementing APHIS policy during an FMD outbreak. The APHIS Administrator will delegate much of the actual multiagency coordination (MAC) functions to the Veterinary Services (VS) Deputy Administrator, who is the Chief Veterinary Officer (CVO) of the United States, and the APHIS Emergency Management Leadership Council (EMLC).

The VS Deputy Administrator and EMLC will establish an APHIS Incident Coordination Group (ICG) to oversee the staff functions associated with the incident at the APHIS headquarters level. The APHIS ICG will work closely with the personnel in charge of establishing operations for the incident response at the Area Command (AC) or Incident Command Post (ICP) in the field and coordinate with the APHIS Multiagency Coordination (MAC) Group.

Figure 3-1 displays the APHIS FAD incident management organizational structure, starting with the APHIS Administrator.

Figure 3-1. APHIS Multiagency Coordination Structures and APHIS Emergency Operations Center: Relationship to Incident Management Team (Assuming a Single Incident)



Note: AVIC = Area Veterinarian in Charge; SAHO = State Animal Health Official.

The following subsections describe the MAC Group and APHIS ICG, as well as the APHIS organization for single and multiple events. (Appendix B contains further information and organizational diagrams describing APHIS's Incident Management Structure.) Also, see the *APHIS Foreign Animal Disease Framework: Roles and Coordination* (FAD PReP Manual 1-0) and *NCAHEM Incident Coordination Group Plan*.

3.3.1 Multiagency Coordination Group

The APHIS *Emergency Mobilization Guide* defines coordination for FMD responses at the APHIS level. In the event of an FMD outbreak, the EMLC typically serves as the APHIS MAC Group, unless the members decide to transfer responsibility for a specific incident (please see Appendix B for a list of EMLC members). The APHIS MAC Group structure is adaptable and easily expands and contracts to provide flexibility. The MAC Group—formed if the FMD response needs more support—establishes supportive relationships among the agencies preparing for and responding to an FMD outbreak.

The APHIS MAC Group offers guidance on the most efficient way to allocate resources during an FMD outbreak. General functions of the group include

- incident prioritization,
- resource allocation and acquisition, and
- identification and resolution of issues common to all parties.

If additional support is needed, particularly in the event there are significant threats or consequences to public health and welfare, the natural environment, or the economy, the USDA may also stand up other MAC Groups, which may be composed of representatives from other programs and agencies.

3.3.2 APHIS Incident Coordination Group

The APHIS ICG is responsible for acquiring resources, formulating policy options, and assisting in implementing response and recovery strategies for an FMD outbreak. For additional information, see the *NCAHEM Incident Coordination Group Plan.* APHIS ICG responsibilities in an FMD outbreak include

- providing guidance to ensure responder and public health and safety,
- supporting ICP(s) and AC(s),
- assisting in coordinating resources and integrating response organizations into the ICS, and

- providing information to the Joint Information Center (JIC) for use in media and stakeholder briefings.

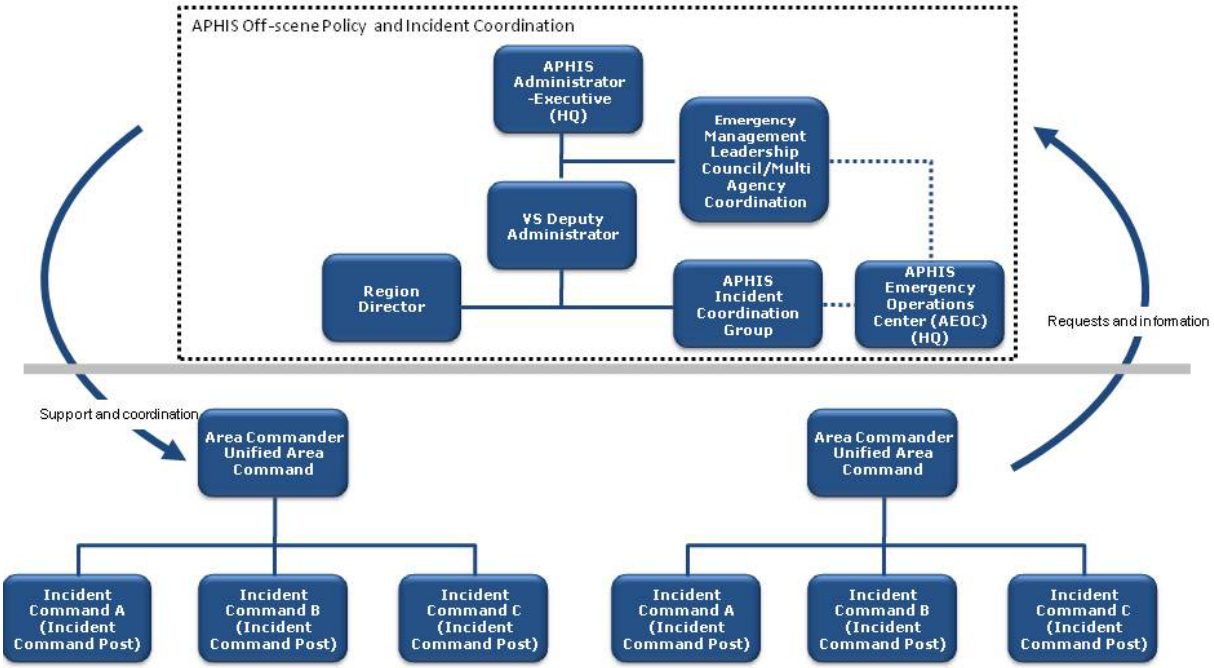
3.3.3 Organization for a Single Incident

In the event of a single FMD incident, the SAHO, or designee, and AVIC, or designee, will initially serve as the Co-Incident Commanders for the unified IC. The AVIC and SAHO may be relieved by a VS Incident Management Team if there is a delegation of authority.

3.3.4 Organization for Multiple Incidents

When more than one FMD incident happens simultaneously, more than one ICP may be established. An AC may also be established. The VS Region Director will establish a Unified Area Command, and the Area Commander will be responsible for managing the multiple incidents. The AVIC and SAHO for each incident (or the Incident Management Team) will report to the AC. Figure 3-2 shows the organization for multiple incidents.

Figure 3-2. APHIS Multiagency Coordination Structures and APHIS Emergency Operations Center: Relationship to Multiple Incident Management Team Structures (Assuming Multiple Incidents and Unified Area Command)



If the emergency response becomes too complex for a single APHIS MAC Group to handle efficiently—for example, a large multistate FMD incident with numerous response activities—cooperation with other agencies or committees will be implemented. As stated previously, this is referred to as multiagency

coordination. Other MAC Groups would likely be stood up. These groups, comprised of representatives from across USDA sub-agencies or other government agencies, would make decisions regarding the prioritizing of incidents and the sharing and use of critical resources. However, these groups are not part of the on-scene IC.

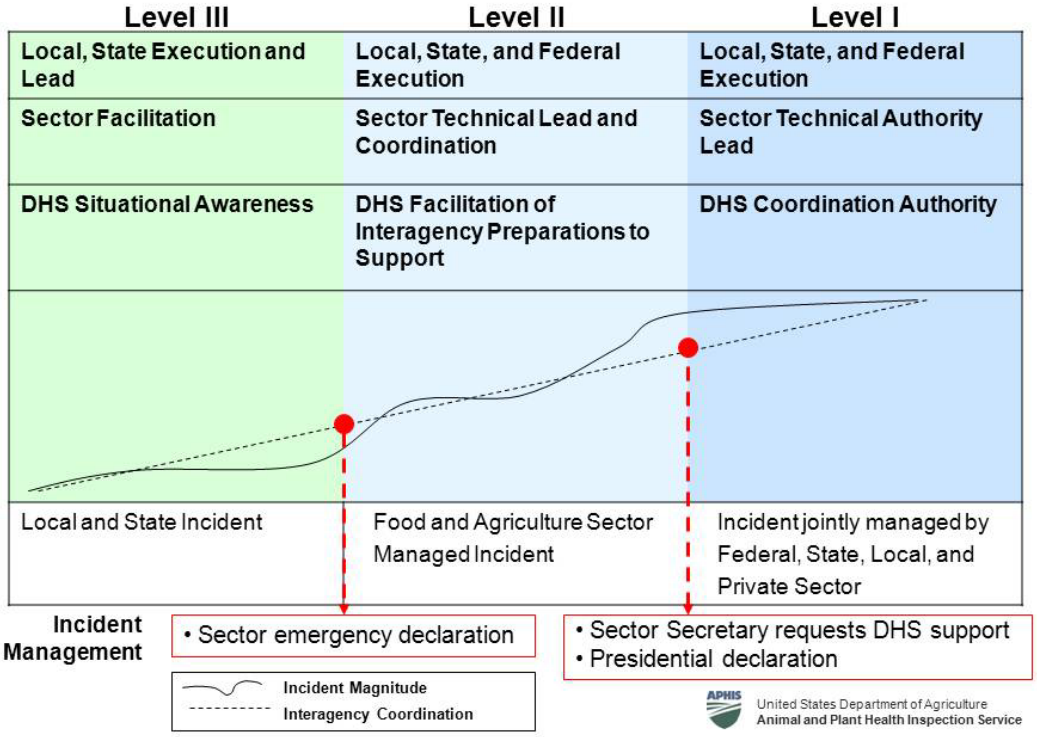
3.3.5 Guidance on Incident Management and Organizational Strategy

See Appendix B for further information on incident management and organizational structure.

3.4 APHIS INCIDENT MANAGEMENT LEVELS

APHIS uses a three-level system of emergency response types. The levels range from Level III, which has the lowest significance, to Level I, which is an event of national significance. The levels are used both within APHIS and externally to communicate the resource requirements for an event or incident. Figure 3-3 illustrates these three incident management levels. In Figure 3-3, sector refers to the agriculture sector and USDA. Additional information can be found in the *APHIS Emergency Mobilization Guide* and in the *APHIS Foreign Animal Disease Framework: Roles and Coordination* (FAD PReP Manual 1-0).

Figure 3-3. Incident Management Levels



These levels are as follows:

- *Level III*. A response to an event or incident, the scope or severity of which the lead program unit is evaluating or that requires a limited response. In either case, enough resources (Federal, State, or local personnel) are available in the area or State to staff the evaluation or initial response effort. An equine piroplasmosis outbreak would be a Level III incident.

- *Level II*. A response to an event or incident that requires resources beyond an area or State's resource capacity but which is within the lead program unit's ability to provide resources to support the response. Requests for additional resources outside the lead program unit are not necessary for a Level II response. However, volunteers will be considered for assignment from outside the unit if they wish to be considered for the assignment, have supervisory approval, and are qualified for the position requested. Typically, a highly pathogenic avian influenza outbreak in domestic poultry would be a Level II event.

- *Level I*. A response that requires resources or expertise beyond the lead program unit's capacity to respond. In many cases, these emergencies will be of national significance. If the lead program unit lacks qualified resources to meet the response needs, it will make a request through the EMLC to the APHIS Administrator to declare a total mobilization. If qualified volunteers are insufficient, direct assignments will be made. A multistate FMD outbreak would be a Level I event.

3.5 National Animal Health Emergency Response Corps (NAHERC)

In addition to the activities just discussed, NAHERC assists and augments Federal and State response to domestic and international animal disease outbreaks, threats, or natural disasters. NAHERC is composed of veterinarians and veterinary technicians who volunteer to become temporary Federal employees in the event of a national animal health emergency. For further information on NAHERC and NAHERC deployment, see the NAHEMS Guidelines: NAHERC Deployment Guide.

3.6 Diagnostic Resources and Laboratory Support

USDA also has critical diagnostic resources and laboratory support that will be leveraged in an FMD outbreak.

3.6.1 National Veterinary Services Laboratories

The NVSL is the official reference laboratory for FAD diagnostic testing and study in the United States. The NVSL performs animal disease testing in support of USDA-APHIS programs designed to protect the health of the Nation's livestock. The NVSL provides *all* confirmatory testing for FMD on all specimens found presumptively positive at a National Animal Health Laboratory Network (NAHLN) laboratory or other USDA-approved laboratory. The NVSL has two locations for FAD diagnostic testing: Ames, IA (NVSL-Ames), and FADDL at Plum Island, NY (NVSL-FADDL).

NVSL-FADDL is where FMD viruses would be isolated and the serotype and strain would be identified to determine the vaccine to stock or use for the outbreak. FADDL also assists in testing currently available vaccines.

3.6.2 National Animal Health Laboratory Network

As of the date of publication, the NAHLN consists of more than 60 laboratories and coordinates the veterinary diagnostic laboratory capacity of State animal health laboratories and their extensive infrastructure, including facilities, equipment, and professional expertise. Of these laboratories, over 40—including NVSL-Ames and NVSL-FADDL—are currently approved to conduct FMD testing diagnostics (Appendix C).

The NAHLN provides a means for early detection of FMD, rapid response through surge capacity to test outbreak samples, and recovery by the capability to test large numbers of samples to show freedom from FMD. The confirmation of an FMD outbreak will be made at NVSL-FADDL. After positive confirmation of FMD, subsequent samples from premises inside the established Control Area (CA) may be sent to laboratories that are part of NAHLN. Please see Subsection 5.4 for more information.

3.6.3 Center for Veterinary Biologics

APHIS's Center for Veterinary Biologics is responsible for licensing new products, including new diagnostic test kits and vaccines for FMD. This work—centered on enforcement of the Virus Serum Toxin Act—ensures that pure, safe, potent, and effective veterinary biologics are available for the diagnosis, prevention, and treatment of animal diseases.

Chapter 4
FMD Outbreak Response Goals and Strategy

This chapter covers a wide range of information about how USDA APHIS, States, Tribal Nations, localities, and stakeholders would respond to an FMD outbreak in the United States. In particular, this chapter

- identifies USDA APHIS goals for responding to an FMD outbreak;
- identifies tools and critical activities required to achieve the response goals;
- discusses the epidemiological principles for any FMD response strategy;
- defines and describes the four key response strategies;
- reviews factors that may influence the response strategies;
- identifies types of FMD outbreaks and phases of FMD response;
- illustrates the implementation of response strategies in an FMD outbreak in the United States; and
- reviews the international standards from the OIE for FMD-free status.

The information contained in this chapter is also summarized in the *Foot-and-Mouth Disease (FMD) Response: Ready Reference Guide—Understanding Response Strategies.*

4.1 Response Goals

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

Achieving these three goals will allow individual livestock facilities, States, Tribes, regions, and industries to resume normal production as quickly as possible. They will also allow the United States to regain FMD-free status without the response effort causing more disruption and damage than the disease outbreak itself.

4.2 PRINCIPLES AND CRITICAL ACTIVITIES OF AN FMD RESPONSE

4.2.1 Critical Activities

In order to achieve the goals of an FMD response, critical activities and tools must be implemented to execute the response strategy. Box 4-1 lists these critical activities and tools. A science- and risk-based approach that protects public and animal health and stabilizes animal agriculture, the food supply, and the economy will be employed at all times. Please see Chapter 5 for more information on these critical activities and tools, (i.e., movement control, disposal, and epidemiological investigation and tracing).

Box 4-1. Critical Activities and Tools for an FMD Response

Critical Activities and Tools for Containment, Control, and Eradication

- Public awareness campaign
- Swift imposition of effective quarantine and movement controls
- Rapid diagnosis and reporting
- Epidemiological investigation and tracing
- Increased surveillance
- Continuity of business measures for non-infected premises and non-contaminated animal products
- Biosecurity measures
- Cleaning and disinfection measures
- Effective and appropriate disposal procedures
- Mass depopulation and euthanasia (as response strategy indicates)
- Emergency vaccination (as response strategy indicates)

4.2.2 Epidemiological Principles

Three basic epidemiological principles form the foundation of any response strategy to contain, control, and eradicate FMD in the U.S. domestic livestock population:

1. *Prevent contact between FMDV and susceptible animals*.

    a. This is accomplished through quarantine of infected animals, movement controls in the Infected Zone(s) and Buffer Zone(s) (CAs), and biosecurity procedures to protect non-infected animals.

    b. Certain circumstances may warrant accelerating the depopulation of animals at risk for exposure to FMD to decrease the population density of susceptible animals.

c. There is a serious but lesser transmission risk posed by other people, material, conveyances, and animals that may have been in contact with FMD and serve as mechanical vectors. Contact with susceptible animals should be prevented and transmission risk mitigated through biosecurity and cleaning and disinfection measures.

2. *Stop the production of FMDV in infected or exposed animals*. This is accomplished by slaughter or mass depopulation (and disposal) of infected and potentially infected animals.

3. *Increase the disease resistance of susceptible animals to FMDV or reduce the shedding of FMDV in infected or exposed animals*. This can be accomplished by emergency vaccination if a suitable vaccine is available and can be administered in a timely manner.

4.2.3 Coordinated Public Awareness Campaign

One of the most important critical activities is a public awareness campaign. Box 4-2 details the importance of a coordinated public awareness campaign in an effective response strategy.

Box 4-2. Coordinated Public Awareness Campaign

Coordinated Public Awareness Campaign

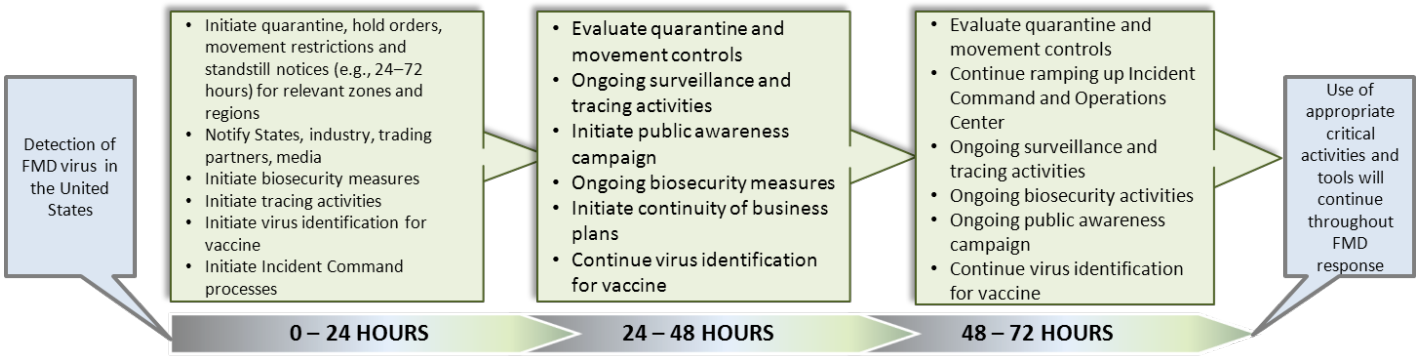
Regardless of the response strategy or strategies selected, a public awareness campaign must be effectively coordinated. This will support the response strategy by

- engaging and leveraging Federal, State, Tribal, local, and stakeholder relationships to provide unified public messages for local, national, and international audiences;
- addressing the issues and concerns relating to food safety, public health, and animal welfare;
- addressing issues and concerns related to interstate commerce, continuity of business, and international trade; and
- widely disseminating key communication messages to consumers and producers.

4.2.4 Timeline in any FMD Response for the First 72 Hours

In the first 72 hours after the detection of FMD in the United States, specific actions will occur, regardless of outbreak characteristics. These critical tasks are fundamental to the rapid control and containment of FMD. Figure 4-1 highlights these tasks.

Figure 4-1. Critical Activities in the First 72 Hours of a U.S. FMD Outbreak



4.3 Response Strategies for Control and Eradication of FMD in Domestic Livestock

There are four generally accepted strategies for the control and eradication of FMD in domestic livestock following an outbreak.

- Stamping-out
- Stamping-out modified with emergency vaccination to slaughter
- Stamping-out modified with emergency vaccination to live
- Emergency vaccination to live without stamping-out.

This section defines and describes each of these strategies in turn. Depending upon the circumstances and scale of the outbreak, a combination of one or more of these strategies can be applied. As mentioned, a coordinated public awareness campaign will support any response strategy or strategies. Analogous strategies are recognized in the OIE *Terrestrial Animal Health Code (2011),* Article 8.5.47.

4.3.1 Stamping-Out

4.3.1.1 Defining Stamping-Out as a Response Strategy

Box 4-3 defines stamping-out.

Box 4-3. Stamping-Out

Stamping-Out

Depopulation of clinically affected and in-contact susceptible animals.

4.3.1.2 DESCRIBING STAMPING-OUT AS A RESPONSE STRATEGY

Stamping-out has been a common approach in past FMD outbreaks in countries that were previously FMD-free. This strategy is most appropriate if the outbreak is contained to a jurisdictional area or a region in which FMD can be readily contained and further dissemination of the virus is unlikely. Stamping-out is currently defined in the OIE *Terrestrial Animal Health Code (2011)*, as

> carrying out under the authority of the Veterinary Authority, on confirmation of a disease, the killing of the animals which are affected and those suspected of being affected in the herd and, where appropriate, those in other herds which have been exposed to infection by direct animal to animal contact, or by indirect contact of a kind likely to cause the transmission of the causal pathogen. All susceptible animals, vaccinated or unvaccinated, on an infected premises should be killed and their carcasses destroyed by burning or burial, or by any other method which will eliminate the spread of infection through the carcasses or products of the animals killed.
>
> This policy should be accompanied by the cleansing and disinfection procedures defined in the Terrestrial Code.
>
> The term modified stamping-out policy should be used in communications to the OIE whenever the above animal health measures are not implemented in full and details of the modifications should be given.

Box 4-4 lists the critical elements of stamping-out. The OIE recognizes that if outbreaks cannot be confined to a Containment Zone (equivalent to a CA), response strategies other than just stamping-out may be necessary.

Box 4-4. Critical Elements of Stamping-Out

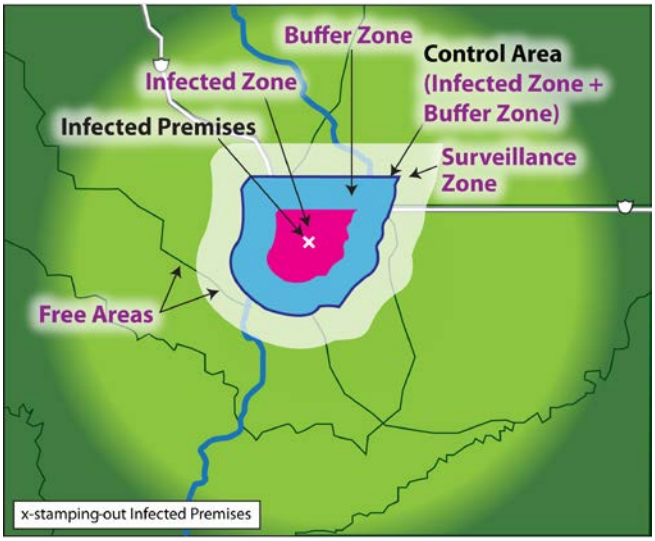
Stamping-Out: Critical Elements

- Within 24 hours, or as soon as possible, after classification of premises as Infected Premises (IP), the infected and susceptible livestock will be euthanized or depopulated. In many cases, susceptible livestock on Contact Premises (CP) may also be depopulated as soon as possible.
- Where resources are limited, premises will be prioritized so that those with the highest potential for active FMD spread are "stamped-out" first.
- Based on an epidemiological assessment, animals with clinical signs may be prioritized for depopulation to reduce virus excretion.
- Public concerns about stamping-out will require a well-planned and proactive public relations and liaison campaign. Stakeholders, the public, and the international community must be involved.
- Care should be taken to consider mental health implications for owners and responders in the event a stamping-out strategy is implemented.

4.3.1.3 Zones and Areas in Relation to Stamping-Out

Figure 4-2 shows an example of a stamping-out response strategy, where IP are depopulated. See Subsection 5.5 in Chapter 5 for more information on zones, areas, and premises for FMD outbreak response.

Figure 4-2. Example of Zones and Areas in Relation to Stamping-Out (Infected Premises would be Depopulated)



Note: Figure is not to scale.

4.3.2 Stamping-Out Modified with Emergency Vaccination to Slaughter

4.3.2.1 Defining Stamping-Out Modified with Emergency Vaccination to Slaughter as a Response Strategy

Box 4-5 defines stamping-out modified with emergency vaccination to slaughter.

Box 4-5. Stamping-Out Modified with Emergency Vaccination to Slaughter

Stamping-Out Modified with Emergency Vaccination to Slaughter

Depopulation of clinically affected and in-contact susceptible animals and vaccination of at-risk animals, with subsequent slaughter of vaccinated animals. Stamping-out modified with emergency vaccination to slaughter can be as follows.

a. Delayed depopulation and disposal of vaccinated animals.
b. Slaughter of vaccinated animals, if animals are eligible for slaughter under USDA Food Safety and Inspection Service (FSIS) authority and rules and/or State and Tribal authority and rules.

4.3.2.2 Describing Stamping-Out Modified with Emergency Vaccination to Slaughter as a Response Strategy

This strategy involves the depopulation of clinically affected and in-contact susceptible animals and vaccination of at-risk animals, *with* subsequent slaughter of vaccinated animals. Stamping-out modified with emergency vaccination to slaughter can be (a) delayed depopulation and disposal of vaccinated animals, or (b) slaughter of vaccinated animals, if animals are eligible for slaughter under USDA FSIS authority and rules and/or State and Tribal authority and rules. This strategy involves the following:

- A suppressive emergency vaccination strategy.
- The goal is to suppress virus replication in high-risk susceptible animals by using emergency vaccination and then slaughtering vaccinates at a later date as determined by IC and the VS Deputy Administrator (U.S. CVO).
- The targeted vaccination of high-risk susceptible animals in an IZ, CA, or Vaccination Zone (VZ). Ring or regional vaccination around an IP or IZ is a frequently cited example for this strategy.

- DIVA testing may be necessary for movement between zones, interstate commerce, and international trade.[1]
- Vaccinated animal identification, movement controls, traceability, and an effective, scalable permitting system may be necessary.

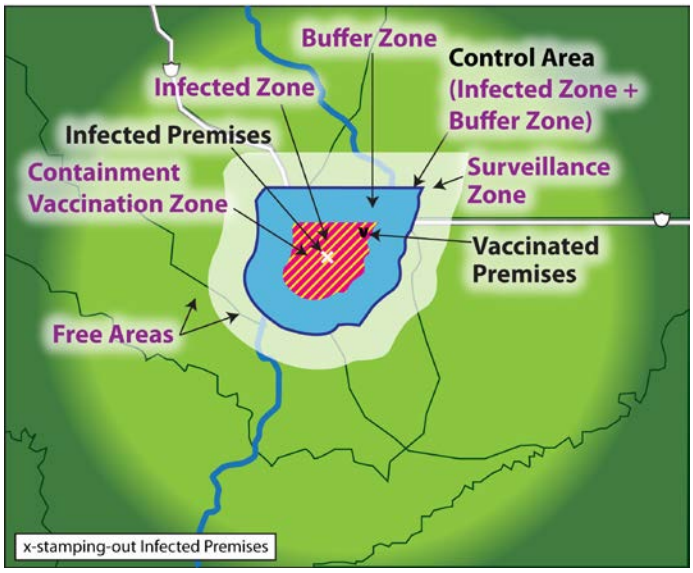
4.3.2.3 Zones and Areas in Relation to Stamping-Out Modified with Emergency Vaccination to Slaughter

Figure 4-3 shows four examples of how a stamping-out modified with emergency vaccination to slaughter response strategy might be implemented. Animals on IP would be depopulated, while other animals in a Containment Vaccination Zone (CVZ) may be vaccinated. Stamping-out modified with emergency vaccination to slaughter can be (1) delayed depopulation and disposal of vaccinated animals, or (2) slaughter of vaccinated animals, if animals are eligible for slaughter under USDA FSIS authority and rules and/or State and Tribal authority and rules.

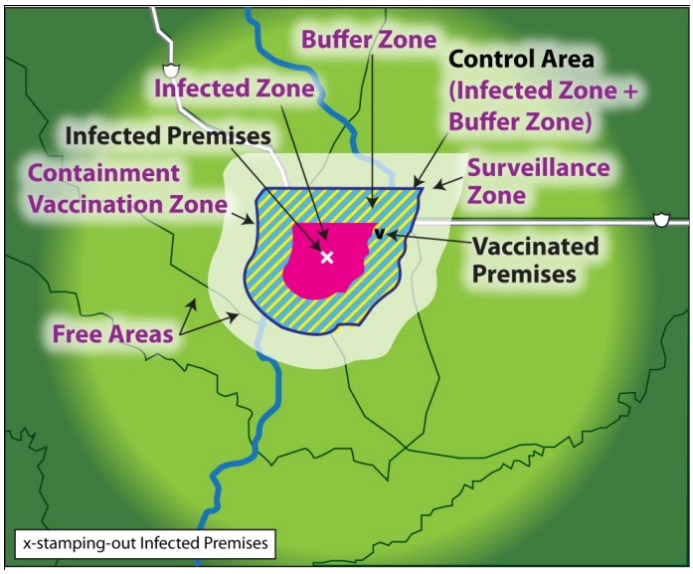
[1] See Chapters 1, 5, and Appendix E for more on vaccination and DIVA.

Figure 4-3. Examples of Zones and Areas in Relation to Stamping-Out Modified with Emergency Vaccination to Slaughter (Infected Premises would be Depopulated)

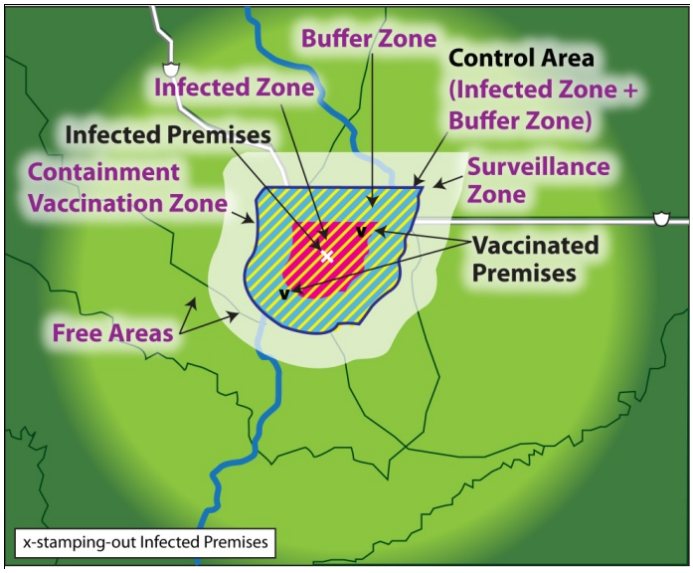
Emergency Vaccination in Infected Zone



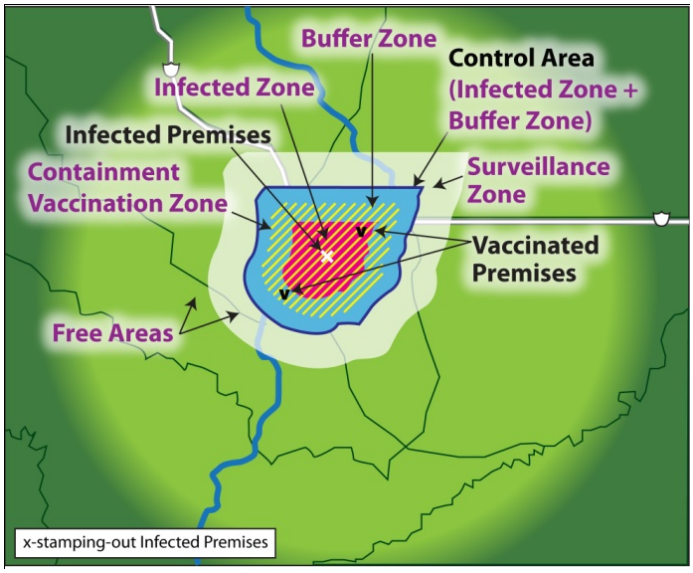
Emergency Vaccination in Buffer Zone



Emergency Vaccination in Control Area



Emergency Vaccination in Infected Zone and Partial Buffer Zone



Note: Figures are not to scale.

4.3.3 Stamping-Out Modified with Emergency Vaccination to Live

4.3.3.1 Defining Stamping-Out Modified with Emergency Vaccination to Live as a Response Strategy

Box 4-6 defines stamping-out modified with emergency vaccination to live.

Box 4-6. Stamping-Out Modified with Emergency Vaccination to Live

Stamping-Out Modified with Emergency Vaccination to Live

Depopulation of clinically affected and in-contact susceptible animals and vaccination of at-risk animals, without subsequent slaughter of vaccinated animals. Stamping-out modified with emergency vaccination to live can be

a. vaccinated animals intended for slaughter can go to slaughter, if animals are eligible for slaughter under USDA FSIS authority and rules and/or State and Tribal authority and rules; or
b. vaccinated animals intended for breeding, milking, or other purposes can live out their useful lives.

4.3.3.2 Describing Stamping-Out Modified with Emergency Vaccination to Live as a Response Strategy

This strategy involves the depopulation of clinically affected and in-contact susceptible animals and vaccination of at-risk animals, *without* subsequent slaughter of vaccinated animals because of their vaccination status. Stamping-out modified with emergency vaccination to live can be (1) vaccinated animals intended for slaughter can go to slaughter, if animals are eligible for slaughter under USDA FSIS authority and rules and/or State and Tribal authority and rules, or (2) vaccinated animals intended for breeding, milking, or other purposes can live out their useful lives. This strategy involves the following:

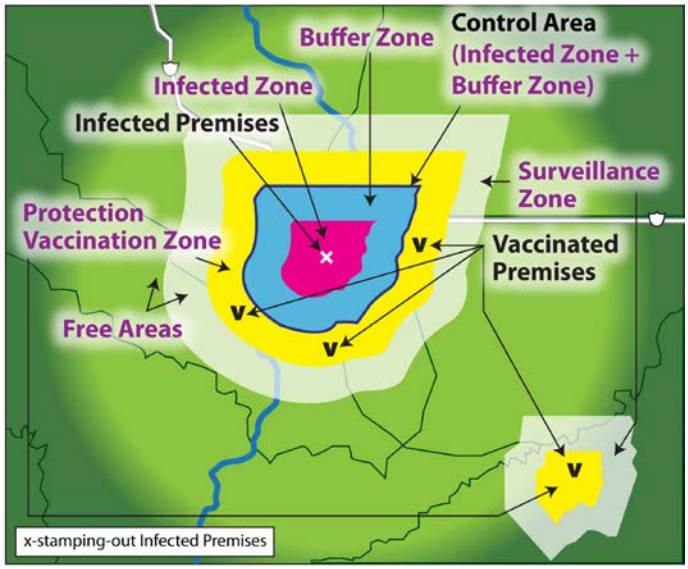
- A protective emergency vaccination strategy.
- The goal is to protect susceptible animals from infection using emergency vaccination with the deliberate intent to maintain vaccinates for the duration of their usefulness.
- The targeted vaccination of non-infected animals. This may include valuable genetic stock, long-lived production animals, or areas with a high-density population of susceptible animals at high risk of becoming infected.

- Requires the establishment of one or more VZs free of FMD, the establishment of one or more CAs for infected animals, and movement controls to keep infected animals out of VZs free of FMD.
- DIVA testing may be necessary for movement between zones, interstate commerce, and international trade.[2]
- Vaccinated animal identification, movement controls, traceability, and an effective, scalable permitting system may be necessary.

4.3.3.3 Zones and Areas in Relation to Stamping-Out Modified with Emergency Vaccination to Live

Figure 4-4 shows how a stamping-out modified with emergency vaccination to live response strategy might be implemented. Animals on IP would be depopulated, while other animals in a Protection Vaccination Zone (PVZ) would be vaccinated. Any animals vaccinated would not be subsequently slaughtered on the basis of vaccination status.

Figure 4-4. Examples of Zones and Areas in Relation to Stamping-Out Modified with Emergency Vaccination to Live (Infected Premises would be Depopulated)



Note: Figure is not to scale.

[2] See Chapters 1, 5, and Appendix E for more on vaccination and DIVA.

4.3.4 Emergency Vaccination to Live without Stamping-Out

4.3.4.1 Defining Emergency Vaccination to Live without Stamping-Out as a Response Strategy

Box 4-7 defines emergency vaccination to live without stamping-out.

Box 4-7. Emergency Vaccination to Live without Stamping-Out

Emergency Vaccination to Live without Stamping-Out

Vaccination used without depopulation of infected animals or subsequent slaughter of vaccinated animals. This can be described as emergency vaccination to live without stamping-out.

4.3.4.2 Describing Emergency Vaccination to Live without Stamping-Out as a Response Strategy

This strategy involves targeted emergency vaccination of susceptible animals, with the intention of not slaughtering these animals at a later date because of their vaccination status. This strategy is reserved for an FMD outbreak in which FMD is widely disseminated across the United States, affecting many animal industries, where resources are not available for stamping-out, and a policy decision has been made not to stamp-out. Although this strategy is highly unlikely to be employed initially in an FMD outbreak response, it is possible that given the course of an outbreak that the decision might be made to switch to this strategy if the disease becomes widespread.

This strategy involves the following:

- A protective emergency vaccination strategy.
- The goal is to protect susceptible animals from infection with emergency vaccination, with the intention of not slaughtering vaccinates at a later date because of vaccination status.
- Requires the establishment of one or more VZs free of FMD, the establishment of one or more CAs for infected animals, and movement controls to keep infected animals out of VZs free of FMD.
- DIVA testing may be necessary for movement between zones, interstate commerce, and international trade.[3]

[3] See Chapters 1, 5, and Appendix E for more on vaccination and DIVA.

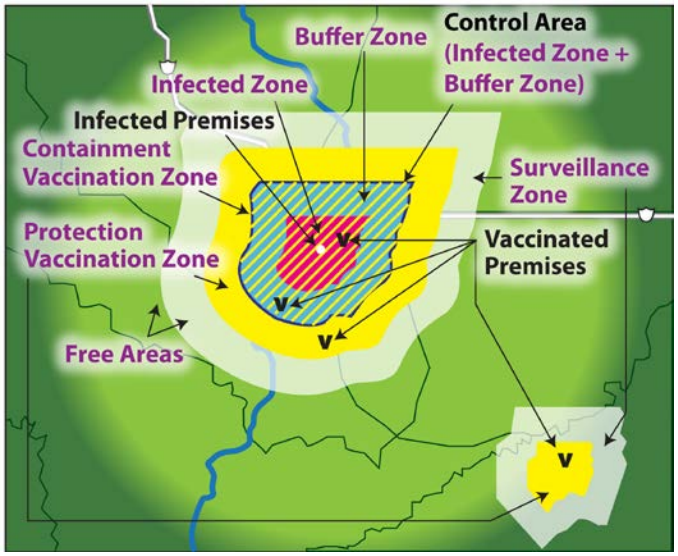
- Vaccinated animal identification, movement controls, traceability, and an effective, scalable permitting system may be necessary.

4.3.4.3 Zones and Areas in Relation to Emergency Vaccination to Live without Stamping-Out

Figure 4-5 provides examples of emergency vaccination to live without stamping-out. There would be no stamping-out under this response, only emergency vaccination to live. This strategy would not be employed unless FMD is widely disseminated across the United States, resources are not available for stamping-out, and a policy decision has been made to not stamp-out. While it is highly unlikely that this would be the initial strategy employed in an FMD outbreak response, it is possible that given the course of an outbreak that the decision might be made to switch to this strategy if disease becomes widespread.

Figure 4-5. Examples of Zones and Areas in Relation to Emergency Vaccination to Live without Stamping-Out

Containment Vaccination Zone and Protection Vaccination Zone



Note: Figure is not to scale. Yellow signifies a Vaccination Zone. Containment Vaccination Zones are typically inside a Control Area; Protection Vaccination Zones are typically outside a Control Area. Protection Vaccination Zones are intended to be zone(s) without infected animals.

4.3.5 Note on Emergency Vaccination Strategies

At this time, any FMD response strategy in the United States that employs emergency vaccination will involve the North American Foot-and-Mouth Disease Vaccine Bank (NAFMDVB). The SAHO or Tribal official and the APHIS VS Deputy Administrator (the U.S. CVO) must agree on the decision to vaccinate before activating the NAFMDVB. FMD vaccine use in Mexico, Canada, and the United States follows the guidance of the NAFMDVB, which is jointly

administered by the CVOs of Mexico, Canada, and the United States. Chapter 5 of this *FMD Response Plan* discusses the NAFMDVB and its role in any vaccination strategy, and provides key sections of the NAFMDVB Guidelines (2007).

4.3.6 Summary of FMD Vaccination

Box 4-8. FMD Response and Vaccination Strategies

FMD Response and Vaccination Strategies

The use of emergency vaccination strategies may be considered in an FMD outbreak. An emergency vaccination strategy can help to achieve the goals of an FMD response effort, and is founded upon the three epidemiological principles of response. In order to be effective, vaccines used in emergency vaccination must be matched to a specific serotype, and ideally matched with the field strain causing the outbreak. There are many challenges to using emergency vaccination in an FMD response, but also many benefits. An FMD response may use one strategy or a variety of strategies in order to detect, control, contain, and ultimately eradicate FMD in domestic animals. The use of emergency vaccination will be determined by the Unified Command IC, the SAHOs, and the VS Deputy Administrator (U.S. CVO).

4.3.7 Authorization for Response and Associated Activities

When the criteria for a presumptive FMD case have been met (see Chapter 5 for case definitions), the APHIS Administrator or VS Deputy Administrator (U.S. CVO) can authorize APHIS personnel—in conjunction with State, Tribal, and IC personnel—to initiate activities such as the depopulation and cleaning and disinfection of the index case and the epidemiological investigations of CP.

When FMD is detected, SAHOs and Tribal officials issue a quarantine or hold order for the IP. A Federal quarantine may be issued when requested by SAHOs or as directed by the Secretary of Agriculture. The Incident Commander works with the Operations Section and Situation Unit in the Planning Section to determine zone, area, and premises designations during an FMD outbreak.

4.3.8 Management of Incident

The outbreak response effort should be implemented through a Unified Command (ICS) with an appropriate span of control and delegation of authority. Responses will be as local as possible. Good communication within the chain of command is imperative.

An Incident Commander should be identified and an ICP established. In-State resources (whether State, Federal, Tribal, or privately owned) should be used to

manage a local response. Out-of-State resources may be used to support the State impacted by the outbreak.

Incident management will include quarantine and movement control, tracing, and activation of response plans to communicate these actions to all stakeholders, the public, and the international community. Cooperative Federal, State, Tribal, local, and industry response measures will be carried out with extreme urgency using the broadest geographic scope possible. (Appendix B contains organizational charts and further information on organizational structure in an incident.)

4.4 Factors Influencing the Selection of Response Strategy or Strategies

The previous sections have identified and described the response strategies. However, choosing one strategy, multiple strategies, or modifying strategies as an outbreak unfolds is an important, but very complex decision process. Depending upon the circumstances and scale of the outbreak, a combination of one or more of the response strategies can be applied.

If it becomes apparent at any point in the response that stamping-out will not achieve control, containment, and ultimately eradication of FMD, alternative strategies will immediately be considered. Currently, it is not possible to delineate *a priori* the specific factors that might signal the need to modify the response to an FMD outbreak.

This section identifies the wide range of factors which may impact the choice of response strategy in an FMD outbreak.

4.4.1 General Factors that Influence the Response Strategy

The scope of regulatory intervention and the selection of a response strategy or strategies in an FMD outbreak depend on the following:

- *Consequences of the outbreak.* The consequences of the FMD outbreak, and the impact of the response, in terms of disruptions to interstate commerce and international trade, national security, food security, animal health, the environment, the economy, and regulatory issues.
- *Acceptance*. Acceptance of response policy (social and political) by different communities, from local to international.
- *Scale of the outbreak.* The number of animals infected, species infected, number of premises affected, and susceptible animal population density for infected areas or areas at high-risk of becoming infected with FMDV.

- *Rate of outbreak spread.* The rate of spread of infection in terms of number of premises, types of premises, number of animals, types of animals; rate at which each IP leads to infection of one or more additional IP.

- *Veterinary countermeasures available.* The availability and efficacy of veterinary countermeasures such as FMD vaccines.

- *Resources available to implement response strategies.* The capabilities and resources available to eradicate FMD in domestic animals and to control and eradicate FMD in potential wildlife reservoirs.

4.4.2 Determining an Appropriate FMD Response Strategy

Table 4-1 highlights key factors to be considered when determining whether a particular response strategy would be appropriate and advantageous for responding to an FMD outbreak. This table simply lists important factors that will be considered in determining the initial response strategy or modifying this strategy. No single factor listed below will *independently* dictate a response strategy, or a decision of whether to employ an emergency vaccination strategy.

Table 4-1. Factors Influencing a Response Strategy or Strategies for U.S. FMD Outbreak

Factor or criterion supporting the response strategy…	Strategy			
	Stamping-out	Stamping-out modified with emergency vaccination to slaughter	Stamping-out modified with emergency vaccination to live	Emergency vaccination to live without stamping-out
Suitable vaccine for FMD outbreak strain	Not available/ feasible	Available	Available	Available
Resources for stamping-out (such as disposal)	Adequate	Adequate	Limited	Limited
Resources for vaccination (such as diagnostic testing, tracing efforts, and permitting activities)	Limited	Adequate	Adequate	Adequate
Population density of susceptible animals at high risk of becoming infected	Low	High	High	High
Population density of virus amplifying animals	Low	Moderate	High	High
Movement of infected animals, products, or fomites out of Control Area	No evidence of extensive movement	Evidence of extensive movement	Evidence of extensive movement	Evidence of extensive movement
Origin of outbreak	Known	Unknown	Unknown	Unknown
Location of initial outbreak	Isolated premises	Livestock producing area	Livestock producing area	Livestock producing area
Spread of outbreak	Slow	Rapid	Rapid	Rapid

Table 4-1. Factors Influencing a Response Strategy or Strategies for U.S. FMD Outbreak

Factor or criterion supporting the response strategy…	Strategy			
	Stamping-out	Stamping-out modified with emergency vaccination to slaughter	Stamping-out modified with emergency vaccination to live	Emergency vaccination to live without stamping-out
Distribution of outbreak	Limited or restricted	Widespread	Widespread	Widespread
Risk of infection in valuable, rare, endangered, or high-value genetic livestock	High	High	Moderate	Low
Likelihood that FMD could become prevalent in feral swine, deer, or other wildlife	High	High	Moderate	Low
Public acceptance of stamping-out strategy	Neutral reaction or weak opposition	Weak opposition	Strong opposition	Strong opposition
Surveillance, diagnostic, and laboratory resources for serosurveillance after vaccination	Limited	Limited	Available	Available
Domestic stakeholders' acceptance of regionalization with vaccination to live or vaccination to slaughter	No	Yes	Yes	Yes
Third-country acceptance of regionalization with vaccination to slaughter	N/A	Accepted	N/A	N/A
Third-country acceptance of regionalization with vaccination to live	N/A	Not Accepted	Accepted	Accepted
Assessments and economic analysis of competing control strategies (particularly for producers)	It is likely that a control strategy without stamping-out will lead to significantly higher economic losses, or longer duration of the outbreak	It is likely that a control strategy without stamping-out modified with emergency vaccination to slaughter will lead to significantly higher economic losses or longer duration of the outbreak	It is likely that a control strategy without stamping-out modified with emergency vaccination to live will lead to significantly higher economic losses or longer duration of the outbreak	It is likely that a control strategy without emergency vaccination to live will lead to significantly higher economic losses or longer duration of the outbreak

4.4.3 Desired FMD-Status Post-Outbreak

To select an appropriate response strategy, the U.S. preferred FMD-status post-outbreak and the desired timeline to achieve that status must be considered. The

OIE recognizes FMD-free status with and without vaccination in both countries and zones.[4] (Subsection 4.6 details the OIE requirements for FMD-free status for a country or zone.)

4.4.3.1 FMD-FREE DESIGNATIONS

- *FMD-free country where vaccination is not practiced*
  - The OIE recognizes 65 countries (as of June 2012) as having this OIE status.
  - The United States does not recognize all of these countries as FMD-free for import purposes.[5]
  - This is the most desired outcome after an FMD outbreak, particularly when the country has previously been classified as having this status.
  - Stamping-out is the most efficient strategy for achieving this status though vaccination to slaughter and vaccination to live strategies could achieve this status over a longer period.
- *FMD-free country where vaccination is practiced*
  - The OIE recognizes one country (as of June 2012) as having this status.
  - The United States does not recognize this country as FMD-free, but it is permitted to export fresh beef to the United States.[6]
  - Vaccination to slaughter and vaccination to live strategies could be used to achieve this status over time.
  - This status could be achieved in the interim before an FMD-free country where vaccination is *not* practiced is achieved.
- *FMD-free zone where vaccination is not practiced*
  - The OIE recognizes ten member countries with zones (as of June 2012) having this status.

[4] OIE, "List of Foot and Mouth Disease Free Members," 2011. http://www.oie.int/en/animal-health-in-the-world/official-disease-status/fmd/list-of-fmd-free-members/.

[5] APHIS, USDA, Foot-and-Mouth and Rinderpest: Countries/Regions Free of Foot-and-Mouth Disease (FMD) and Rinderpest, 2012, http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_fmd.shtml.

[6] Under specific conditions. See APHIS, USDA, Foot-and-Mouth and Rinderpest: Countries/Regions Free of Foot-and-Mouth Disease (FMD) and Rinderpest, 2012, http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_fmd.shtml.

- The United States recognizes two of these zones as FMD-free for import purposes.[7]
- This is a possible outcome if FMD-free country status is not obtainable.
- This status could be achieved in the interim before an FMD-free country status where vaccination is *not* practiced is achieved.
- Stamping-out, vaccination to slaughter, or vaccination to live strategies could all be used to achieve this status over time.

◆ *FMD-free zone where vaccination is practiced*

- The OIE recognizes four member countries with zones (as of June 2012) having this status.
- On the basis of risk assessments, the United States does not recognize any FMD-free zones where vaccination is practiced for import purposes.[8]
- Vaccination to slaughter and vaccination to live strategies could be used to achieve this status over time.
- This status could be achieved in the interim before an FMD-free country where vaccination is *not* practiced is achieved.

◆ *Countries not recognized as FMD-free*

- The remaining OIE member countries, those not recognized as FMD-free, are generally considered to be FMD-infected countries.
- A country will not be recognized as FMD-free until the requirements are met for one of the FMD-free classifications, per OIE standards, as described in Subsection 4.6.

4.4.3.2 OIE Minimum Time to FMD-Free Designations

If the United States is recovering its free status after an outbreak, the following minimum time requirements apply in coordination with surveillance efforts and other documentation. Subsection 4.6 lists complete requirements from the OIE

[7] APHIS, USDA, Foot-and-Mouth and Rinderpest: Countries/Regions Free of Foot-and-Mouth Disease (FMD) and Rinderpest, 2012, http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_fmd.shtml.

[8] APHIS, USDA, Foot-and-Mouth and Rinderpest: Countries/Regions Free of Foot-and-Mouth Disease (FMD) and Rinderpest, 2012, http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_fmd.shtml.

Terrestrial Animal Health Code (2011) Article 8.5.9. These time requirements apply to both free countries and free zones where vaccination is not practiced:

- Three months, if a stamping-out policy is employed, after the last case
- Three months, if a stamping-out policy modified with emergency vaccination to slaughter is employed, after the slaughter of all vaccinated animals
- Six months, if a stamping-out policy modified with emergency vaccination to live is employed, after the last case or last vaccination.

Again, these time requirements are in coordination with appropriate serological surveillance to ensure the absence of FMDV infection in the remaining population. These time requirements are minimum OIE standards. Regardless of OIE recommendations, it is quite possible that international trade will not resume for many months after an FMD outbreak given particular circumstances of the outbreak.

4.4.4 North American FMD Vaccine Bank Guidelines and FMD Vaccine Decision Tree

In addition to the factors listed previously, the NAFMDVB Guidelines (2007) will be considered in the decision to adopt an emergency vaccination strategy. This section highlights this guidance.

Any emergency vaccination strategy employed in the United States, using vaccine from the NAFMDVB, will follow the NAFMDVB Guidelines (2007). (Chapter 5 has more information on vaccination, and Appendix D has further information on the NAFMDVB decision tree.)

4.4.4.1 North American FMD Vaccine Bank Emergency Vaccination Policy

The NAFMDVB Guidelines provide the following policy for emergency vaccination (Chapter 4 of the Guidelines):

1. Mexico, Canada, and the United States shall ensure that the use of FMD vaccines is prohibited in their countries except as provided in this Program.
    a. Member countries shall ensure that the production, manipulation, storage, supply, distribution and marketing of FMD vaccines are authorized by competent authority and under official control in accordance with their country's legislation.

b. Member countries shall ensure that the use of vaccines against foot-and-mouth disease in laboratory investigations is authorized by competent authority and carried out under appropriate biosecurity conditions.

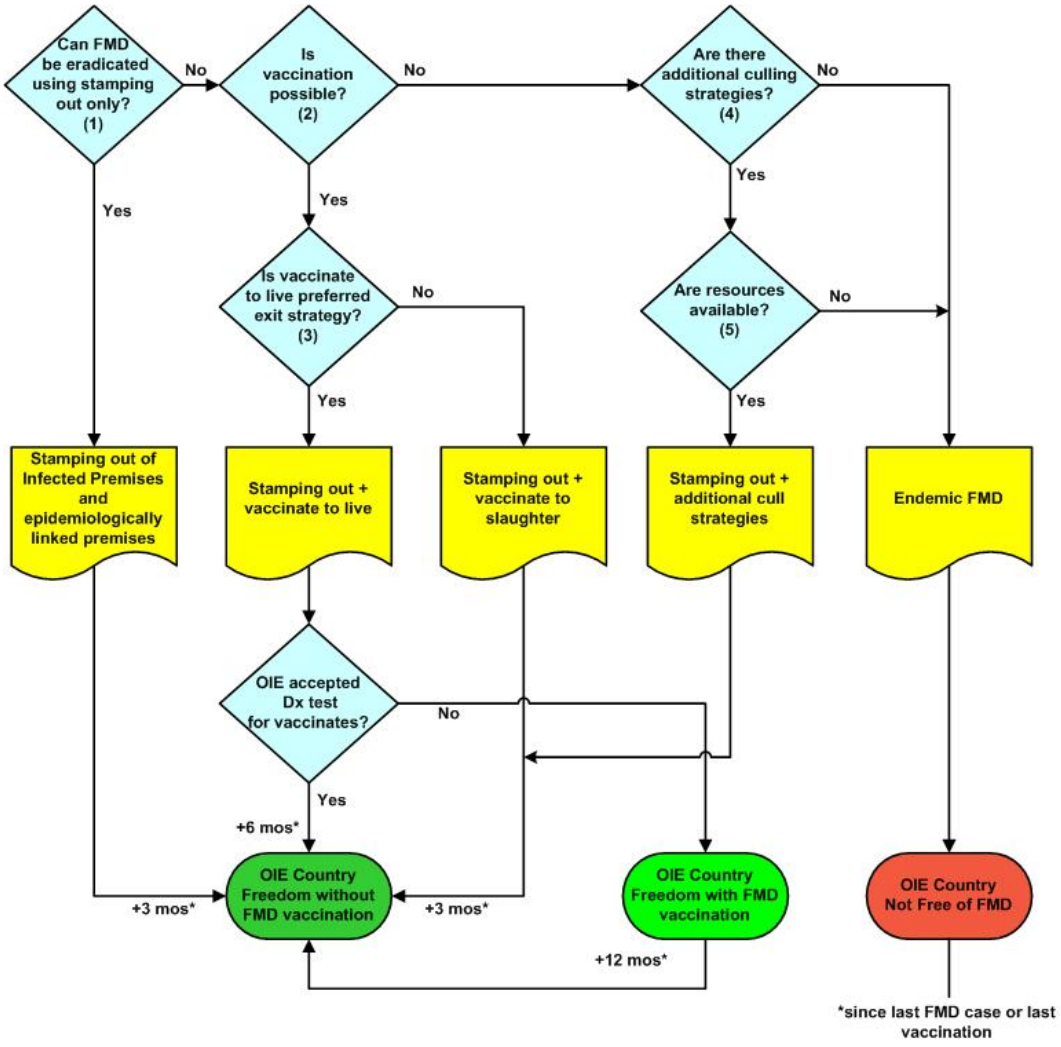
2. Notwithstanding the above, it may be decided to use targeted emergency vaccination in specific geographic areas with particular animal husbandry and management characteristics when FMD has been confirmed and threatens to become extensive.
3. Each member country will establish an expert group to evaluate the epidemiological and clinical situation in the event of an outbreak of FMD to determine the:
   a. Origin of the infection;
   b. Estimated date of introduction of the FMD virus;
   c. Possible spread of the disease.
4. The expert group will weigh the factors as described in the North American Decision Tree for FMD Vaccine Use (Appendix 3, p.46) to recommend emergency vaccination to the Chief Veterinary Officer (CVO).
5. In the event that emergency FMD vaccination is considered necessary, affected stakeholders, such as federal, state or provincial and local governments shall be consulted.
6. The CVO(s) of the infected country(ies) will make a recommendation for decision to the Minister or Secretary of Agriculture.
7. The decision to activate the NAFMDVB shall be taken according to the Chapter on Activation, Chapter 17.

The complete Guidelines are available at https://fadprep.lmi.org and to APHIS employees at http://inside.aphis.usda.gov/vs/em/fadprep.shtml.

4.4.4.2 DECISION TREE

Figure 4-6 shows the NAFMDVB decision tree. Each of the decision boxes in this tree is supported by a decision matrix that weighs factors that will impact the decision node. Appendix D of this *FMD Response Plan* contains Appendix 3 of the NAFMDVB Guidelines, which details the criteria upon which this tree is based. This information should be reviewed in coordination with Figure 4-6. (Chapter 5 and Appendix E contain additional scientific information on vaccination.)

Figure 4-6. North American Guidelines for FMD Vaccine Use



4.5 Implementing A Response Strategy or Strategies in the Event of an FMD Outbreak in the United States

In order to achieve the goals of an FMD response—to (1) detect, control, and contain FMD in animals as quickly as possible; (2) eradicate FMD using strategies that seek to stabilize animal agriculture, the food supply, the economy, and protect public health; and (3) provide science- and risk-based approaches and systems to facilitate continuity of business for non-infected animals and non-contaminated animal products—one or more response strategies may need to be employed at any time during the outbreak. The strategies employed may vary by region, species, or other defining characteristic. In each case, the decision and application of a specific response strategy or strategies will be based on weighing many criteria, such as those discussed in Subsection 4.4. Any response strategy or

strategies with emergency vaccination need to be approved by the U.S. CVO prior to implementation, with agreement from the SAHO and the Unified Command Incident Commander.

In the event of FMD detection, USDA and the affected States and Tribal nations will work together in a Unified Command, per NIMS, to detect, control, and contain FMD as expeditiously as possible. Detection of FMD in the United States will result in emergency intervention by State, Tribal, and Federal authorities. Any response strategy or strategies with emergency vaccination need to be approved by the U.S. CVO prior to implementation.

4.5.1 Phases and Types of FMD Outbreaks

An FMD outbreak in the United States will be a complex event. Having pre-defined phases and potential types of an FMD outbreak may be useful to facilitate the development of adaptable emergency response plans and processes. This information is intended to be guidance, acknowledging that any FMD outbreak will be unique and responders will need to tailor the response accordingly. The phase and the type of the FMD outbreak will change over the course of the outbreak. Box 4-9 defines phase and type.[9]

Box 4-9. Phases and Types of FMD Outbreaks—Definitions

Phases and Types of FMD Outbreaks

Phase: A temporal stage in FMD outbreak response.

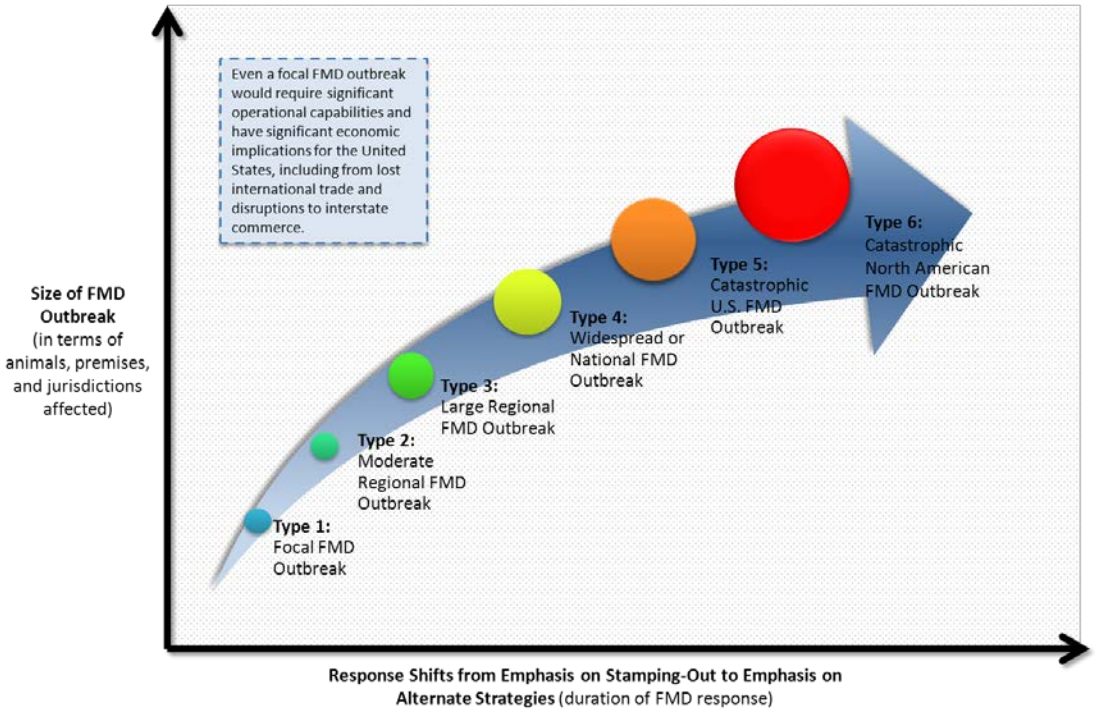
Type: A categorical measure of magnitude of an FMD outbreak.

4.5.1.1 Six Types of FMD Outbreaks

Figure 4-7 illustrates the six types of an FMD outbreak. It is important to understand the magnitude of the FMD outbreak to better assess the operational capabilities required and understand the economic consequences. Even a focal FMD outbreak would require significant operational capabilities and have significant economic implications for the United States, including from lost international trade and disruptions to interstate commerce.

[9] This is one approach to describing a response to an FMD outbreak in the United States. Roth, J. 2011. "Guidelines for Classification of Phases and Types of FMD Outbreak and Response."

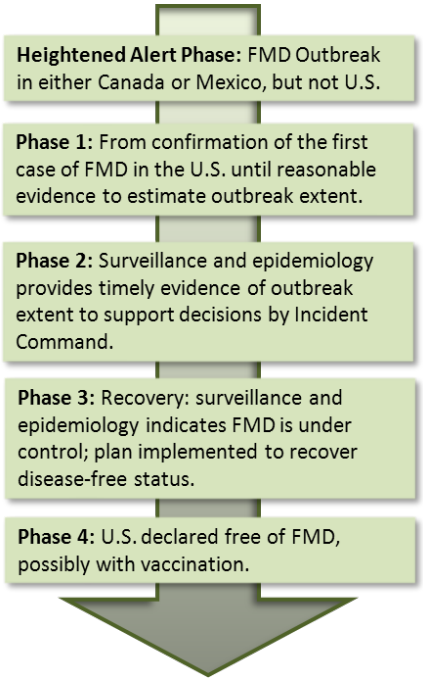
Figure 4-7. Six Types of FMD Outbreaks



4.5.1.2 PHASES OF FMD RESPONSE

Figure 4-8 illustrates the phases of FMD response.

Figure 4-8. Phases of FMD Response



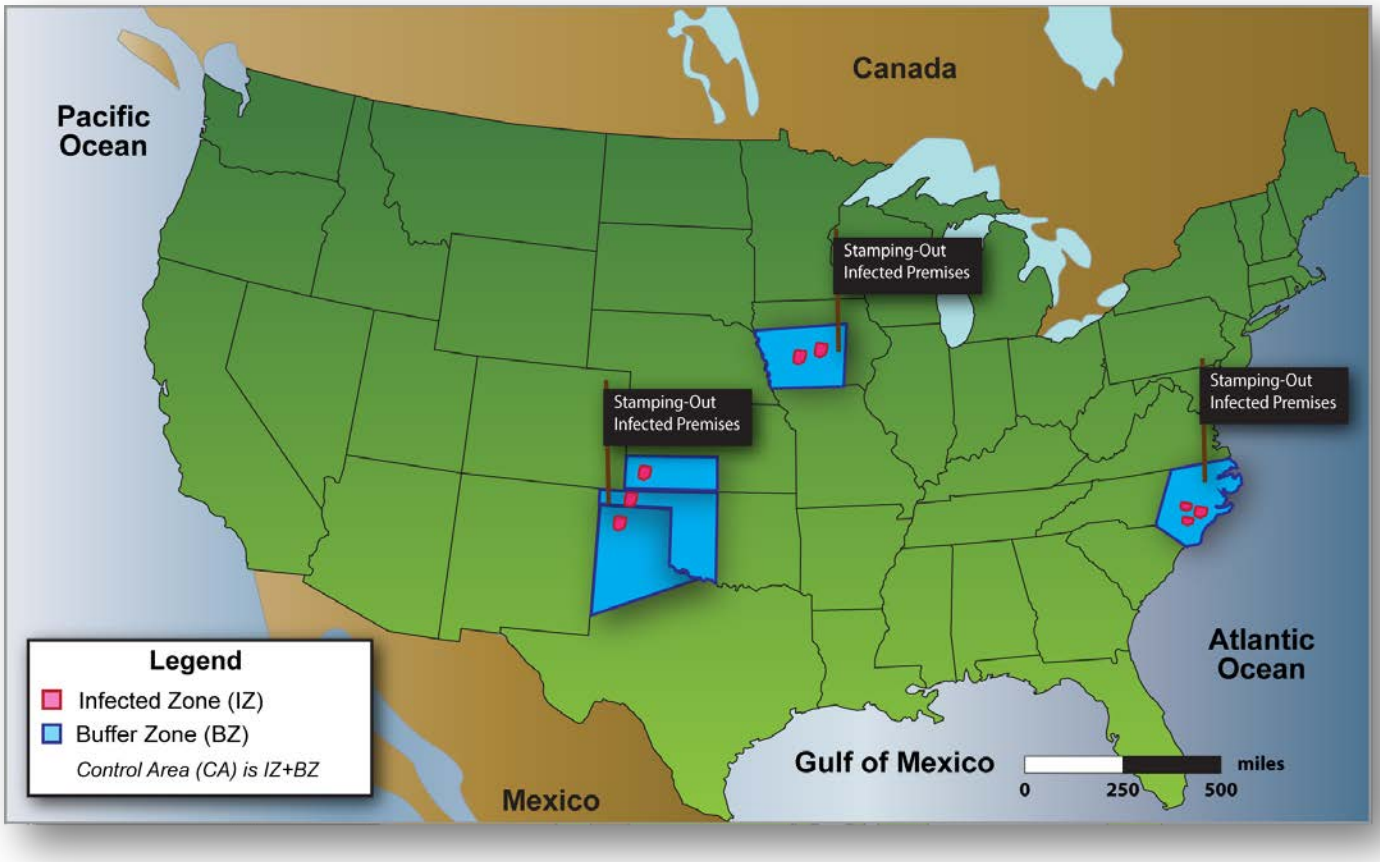
4.5.2 Examples of Strategies for an FMD Response, including Emergency Vaccination

4.5.2.1 Stamping-Out

Figure 4-9 illustrates a stamping-out strategy for controlling, containing, and eradicating FMD in the United States. This map is not prescriptive—it is only an illustration. In this example, the IP would be stamped-out, and there would be no emergency vaccination strategies employed.

Figure 4-9. Example of Stamping-Out

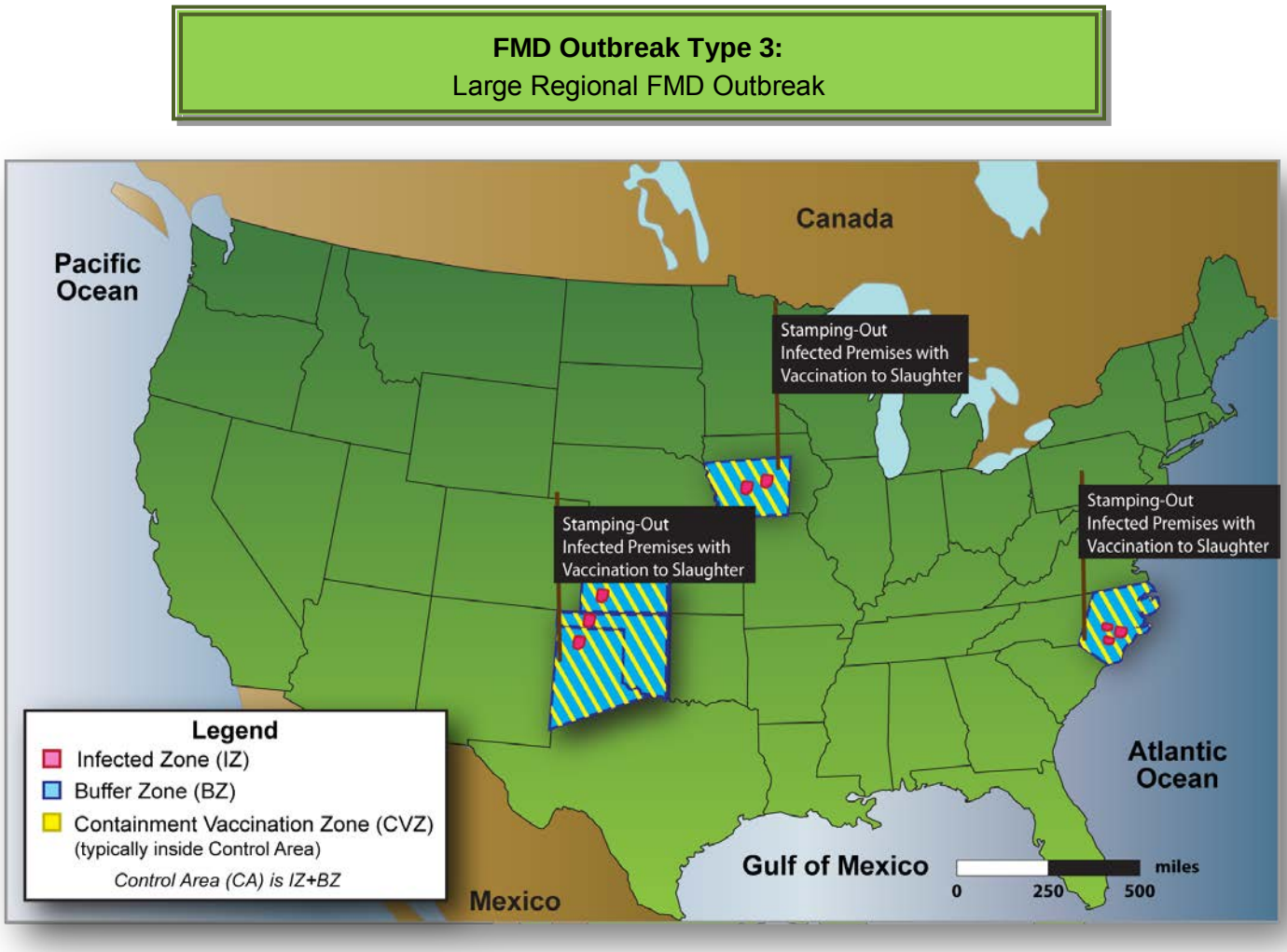
FMD Outbreak Type 3:
Large Regional FMD Outbreak



4.5.2.2 EXAMPLE OF STAMPING-OUT MODIFIED WITH EMERGENCY VACCINATION TO SLAUGHTER

Figure 4-10 illustrates a stamping-out strategy modified with vaccination to slaughter, for controlling, containing, and eradicating FMD in the United States. This map is not prescriptive—it is only an illustration. In this example, the IP would be stamped-out, and there would be emergency vaccination to slaughter within the CAs in CVZs.

Figure 4-10. Example of Stamping-Out Modified with Emergency Vaccination to Slaughter

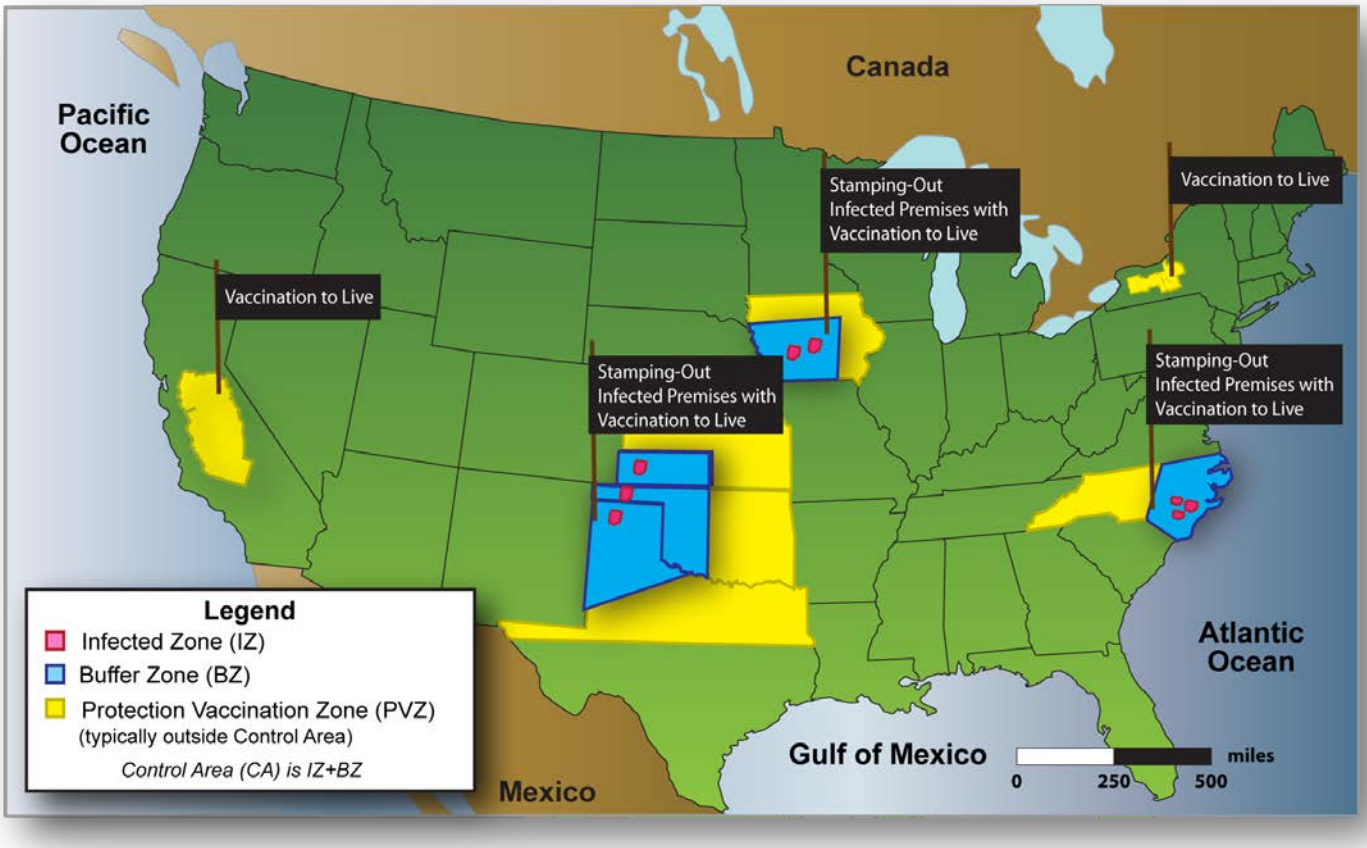


4.5.2.3 Example of Stamping-Out Modified with Emergency Vaccination to Live

Figure 4-11 illustrates a stamping-out strategy modified with emergency vaccination to live for controlling, containing, and eradicating FMD. This map is not prescriptive—it is only an illustration. In this example, the IP would be stamped-out, and there would be emergency vaccination to live outside of the CAs in PVZs.

Figure 4-11. Example of Stamping-Out Modified with Emergency Vaccination to Live

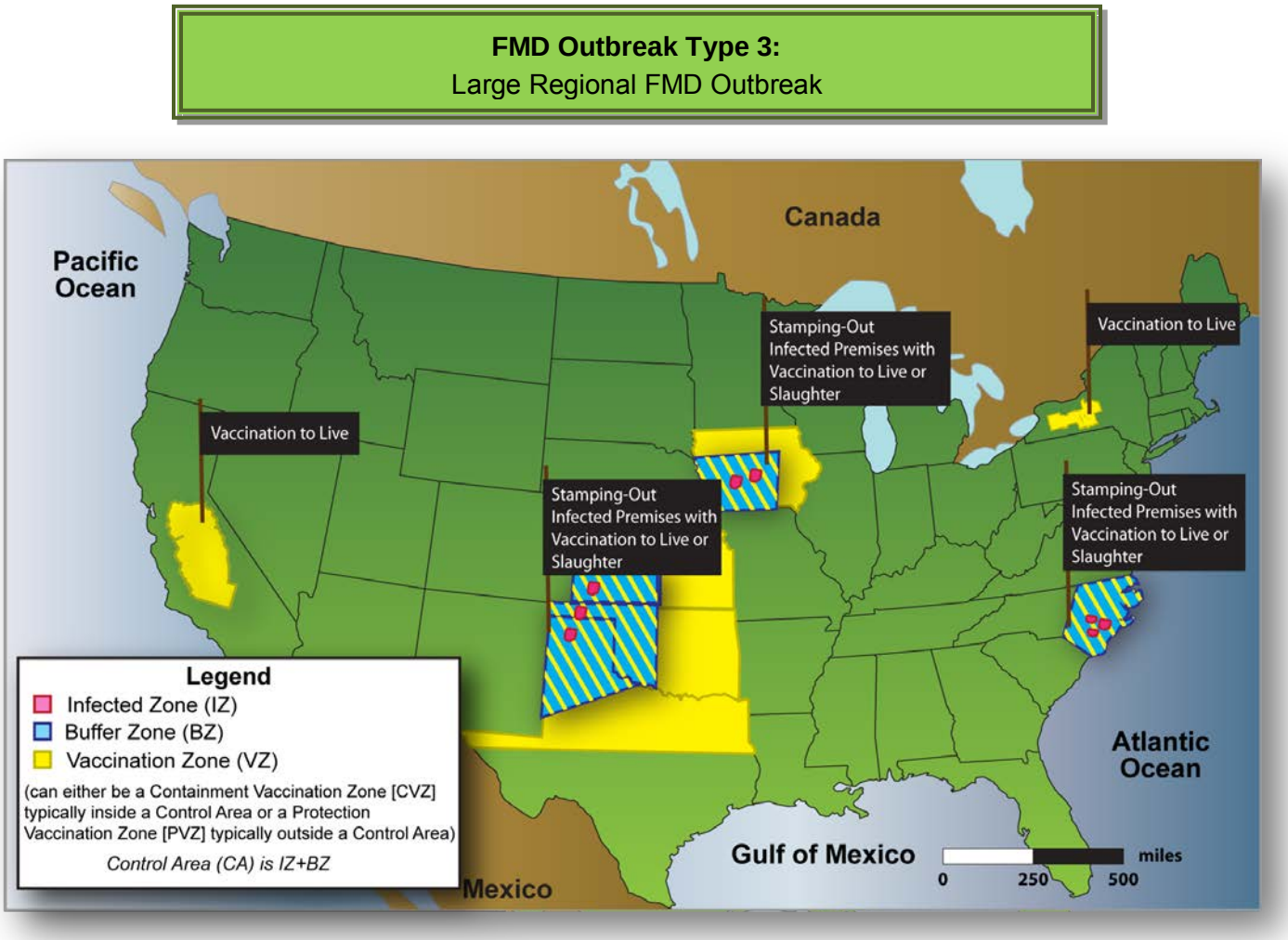
FMD Outbreak Type 3:
Large Regional FMD Outbreak



4.5.2.4 Example of Stamping-Out Modified with Emergency Vaccination to Slaughter and Emergency Vaccination to Live

Figure 4-12 illustrates a stamping-out strategy, modified with emergency vaccination to slaughter and vaccination to live. This map is not prescriptive—it is only an illustration demonstrating the possibility of employing multiple vaccination strategies during an outbreak. In this example, the IP would be stamped-out, and there would be emergency vaccination both inside (in CVZs) and outside (in PVZs) the CAs. Emergency vaccinated animals may be destined for slaughter or to live out their intended useful lives.

Figure 4-12. Example of Stamping-Out Modified with Emergency Vaccination to Slaughter and Emergency Vaccination to Live

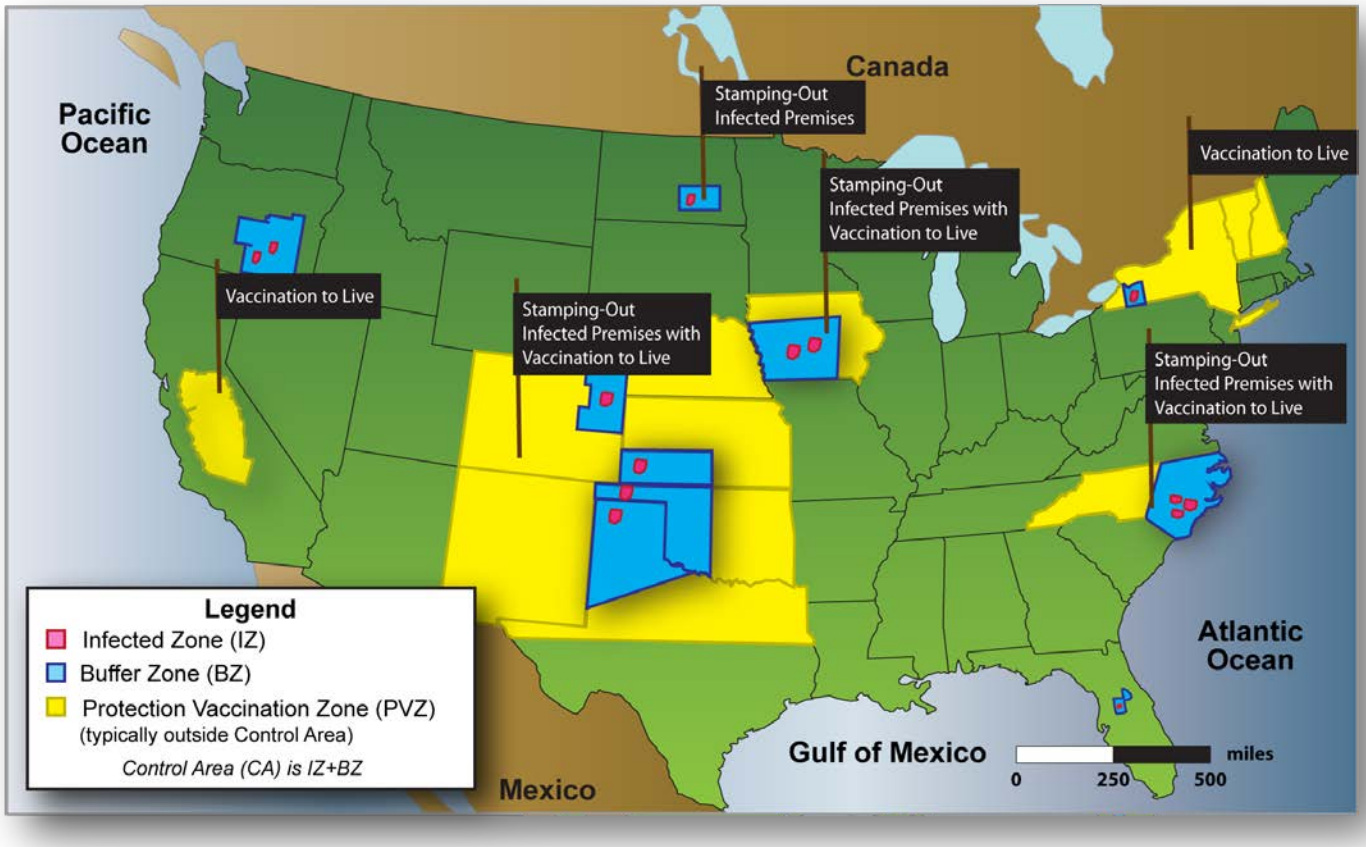


4.5.2.5 Example of Stamping-Out Modified with Emergency Vaccination to Live (Regional)

Figure 4-13 illustrates a stamping-out strategy, modified with emergency vaccination to live. This map is not prescriptive—it is only an illustration demonstrating the possibility of employing emergency vaccination to live in regions in the United States. In this example, the IP would be stamped-out, and there would be emergency vaccination outside (PVZs) the CAs. Emergency vaccinated animals would live out their useful lives.

Figure 4-13. Example of Stamping-Out Modified with Emergency Vaccination to Live (Regional)

FMD Outbreak Type 4:
Widespread or National FMD Outbreak

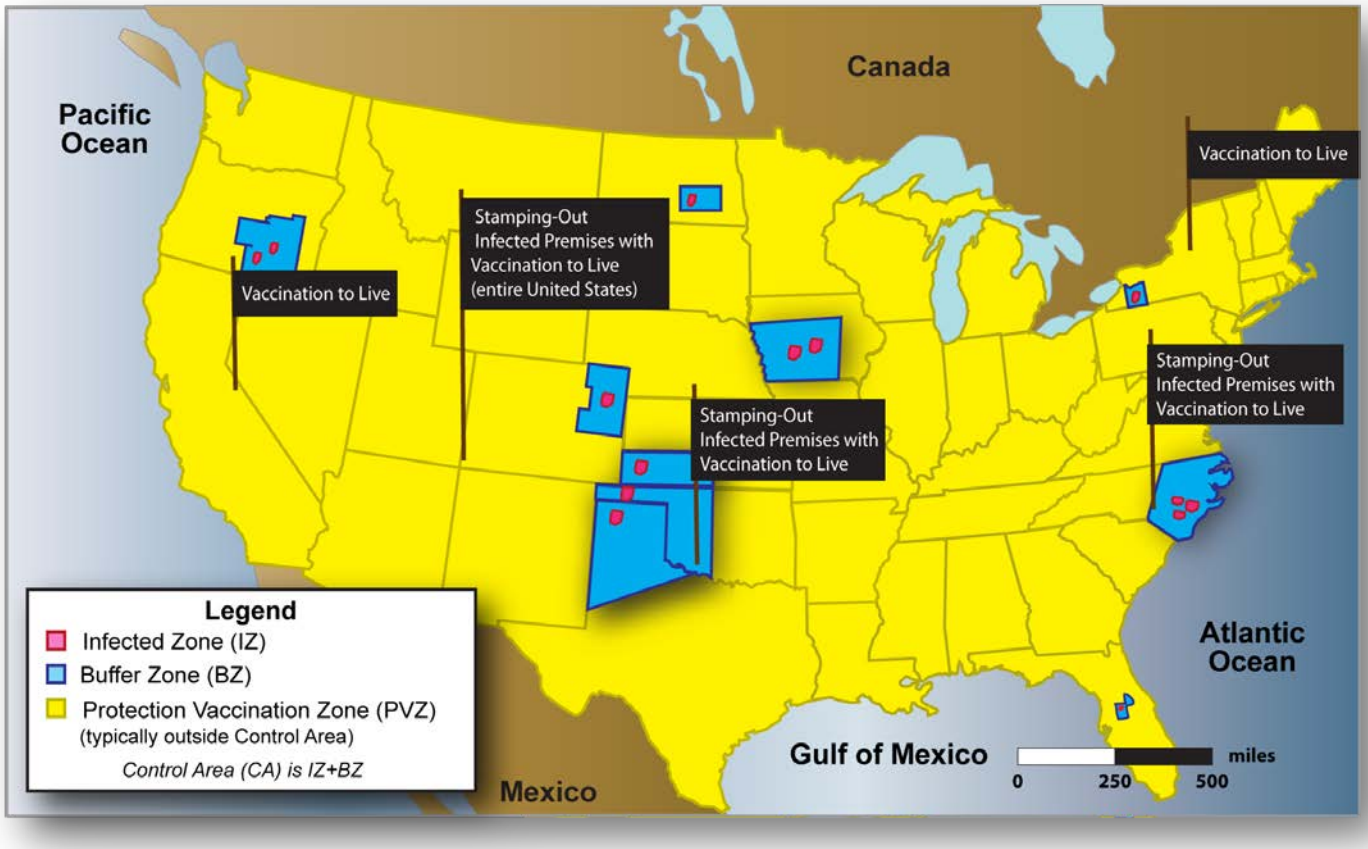


4.5.2.6 EXAMPLE OF STAMPING-OUT MODIFIED WITH EMERGENCY VACCINATION TO LIVE (LARGE-SCALE)

Figure 4-14 illustrates a stamping-out strategy modified with emergency vaccination to live. This map is not prescriptive—it is only an illustration demonstrating the possibility of employing emergency vaccination to live across the entire United States. In this example, IP would be stamped-out, and there would be emergency vaccination outside (PVZs) the CAs. Emergency vaccinated animals would live out their intended useful lives.

Figure 4-14. Example of Stamping-Out Modified with Emergency Vaccination to Live (Large Scale)

FMD Outbreak Type 4:
Widespread or National FMD Outbreak

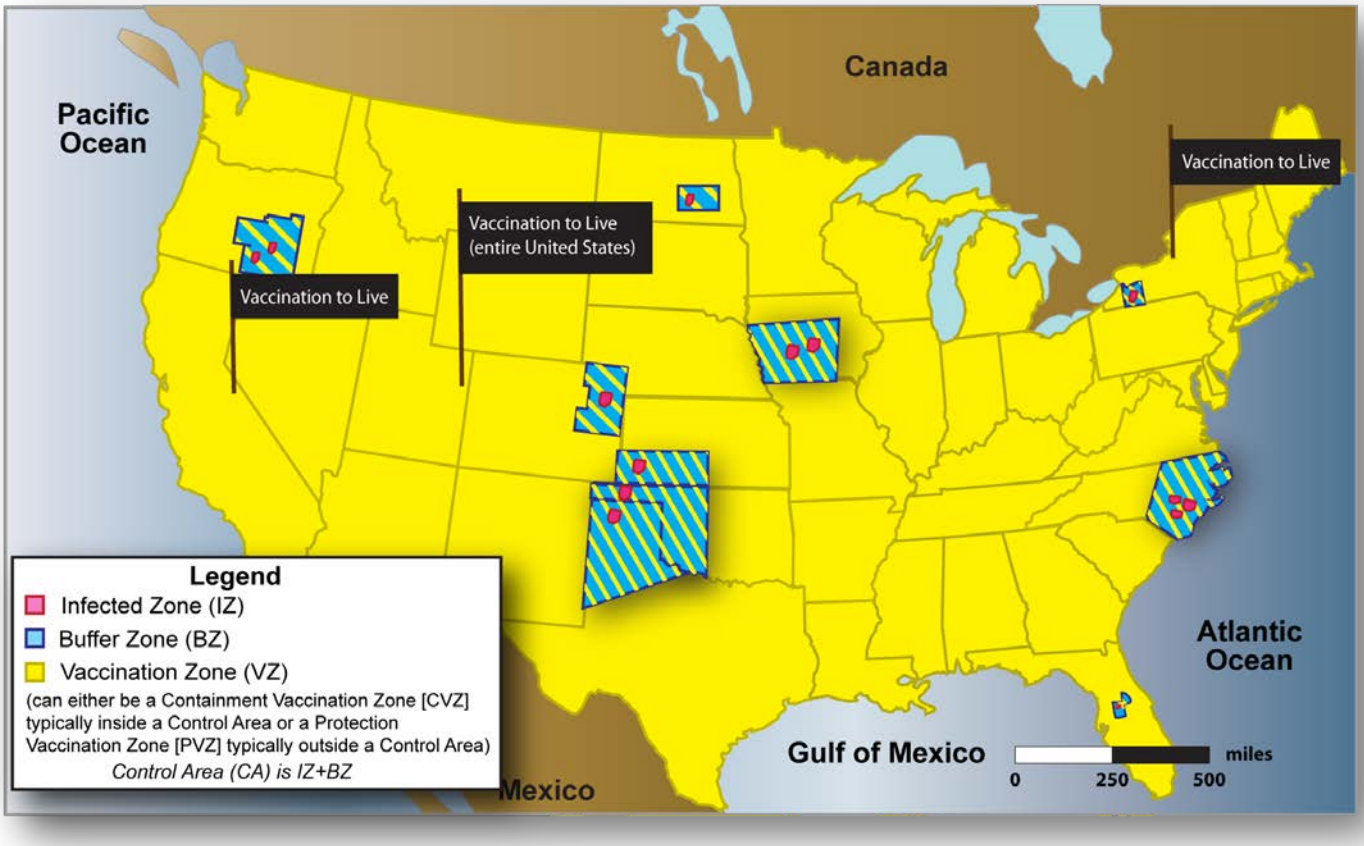


4.5.2.7 EXAMPLE OF EMERGENCY VACCINATION TO LIVE (NO STAMPING-OUT)

Figure 4-15 illustrates an emergency vaccination to live strategy, where there is not stamping-out on the IP. In this example, emergency vaccination to live will be employed both inside (in CVZs) and outside (in PVZs) the CAs. Emergency vaccinated animals would live out their useful lives for their intended purposes.

Figure 4-15. Example of Emergency Vaccination to Live (No Stamping-Out)

FMD Outbreak Type 4:
Widespread or National FMD Outbreak



4.6 INTERNATIONAL STANDARDS FOR FMD

This section describes the OIE standards for FMD-free status.

4.6.1 Recognition of Disease-Free Status

In May 1994, the World Assembly of Delegates of the OIE requested the Foot-and-Mouth Disease and Other Epizootics Commission (now called the Scientific

Commission for Animal Diseases) to develop a procedure for the OIE to officially recognize the FMD-free status of members. In 1998, the official agreement between the World Trade Organization and the OIE further confirmed the OIE's mandate to recognize disease-free areas (Agreement on the Application of Sanitary and Phytosanitary Measures) for trade purposes.

Any member that wishes to be included in the list of disease-free countries or to change its status (for example, to move from the list of countries or zones free where vaccination is practiced to the list of countries or zones where vaccination is not practiced) sends a request to the OIE Director General, accompanied by specific documentation and FMD-relevant questionnaires. The Director General then submits the request to the Scientific Commission for evaluation.

4.6.2 Criteria Needed for FMD-Free Status

The OIE has six official country recognitions for FMD: (1) FMD-free country where vaccination is not practiced; (2) FMD-free country where vaccination is practiced; (3) FMD-free zone where vaccination is not practiced; (4) FMD-free zone where vaccination is practiced (in an FMD-free country where vaccination is not practiced or in a country of which parts are infected); (5) FMD-free compartment; and (6) FMD-infected country or zone. (The OIE *Terrestrial Animal Health Code (2011)* Articles 8.5.2 to 8.5.7 list the criteria for these recognitions.)

4.6.2.1 Recovery of Free Status

There are separate requirements for the recovery of free status in previously FMD-free countries. These requirements are listed in the OIE *Terrestrial Animal Health Code (2011)* Article 8.5.9.

1. When an FMD outbreak or FMDV infection occurs in an FMD free country or zone where vaccination is not practiced, one of the following waiting periods is required to regain the status of FMD free country or zone where vaccination is not practiced:
    a. three months after the last case where a stamping-out policy and serological surveillance are applied in accordance with Articles 8.5.42 to 8.5.49; or
    b. three months after the slaughter of all vaccinated animals where a stamping-out policy, emergency vaccination and serological surveillance are applied in accordance with Articles 8.5.42 to 8.5.47 and Article 8.5.49; or
    c. six months after the last case or the last vaccination (according to the event that occurs the latest), where a stamping-out policy, emergency vaccination not followed by slaughtering of all vaccinated animals, and serological surveillance are applied in accordance with Articles 8.5.42 to 8.5.47 and Article 8.5.49, provided that a serological survey based on the detection of

antibodies to nonstructural proteins of FMDV demonstrates the absence of infection in the remaining vaccinated population.

Where a stamping-out policy is not practiced, the above waiting periods do not apply, and Article 8.5.2 or 8.5.4 applies.

2. When an FMD outbreak or FMDV infection occurs in an FMD free country or zone where vaccination is practiced, one of the following waiting periods is required to regain the status of FMD free country or zone where vaccination is practiced:

   a. 6 months after the last case where a stamping-out policy, emergency vaccination and serological surveillance in accordance with Articles 8.5.42 to 8.5.47 and Article 8.5.49 are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation; or

   b. 18 months after the last case where a stamping-out policy is not applied, but emergency vaccination and serological surveillance in accordance with Articles 8.5.42 to 8.5.47 and Article 8.5.49 are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation.

3. When an FMD outbreak or FMDV infection occurs in an FMD free compartment, Article 8.5.6 applies.

4.6.2.2 FMD-Free Country where Vaccination Is Not Practiced

Susceptible animals in the FMD free country where vaccination is not practiced should be protected from neighboring infected countries by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a protection zone.

To qualify for inclusion in the existing list of FMD free countries where vaccination is not practiced, a Member should:

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that:
   a. there has been no outbreak of FMD during the past 12 months;
   b. no evidence of FMDV infection has been found during the past 12 months;
   c. no vaccination against FMD has been carried out during the past 12 months;
   d. no vaccinated animal has been introduced since the cessation of vaccination;
3. supply documented evidence that:

a. surveillance for both FMD and FMDV infection in accordance with Articles 8.5.42 and 8.5.47 and Article 8.5.49 is in operation;

b. regulatory measures for the early detection, prevention, and control of FMD have been implemented;

4. describe in detail the boundaries and measures of a protection zone, if applicable.

The Member will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 2, 3, and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

4.6.2.3 FMD-FREE COUNTRY WHERE VACCINATION IS PRACTICED

Susceptible animals in the FMD-free country where vaccination is practiced should be protected from neighboring infected countries by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a protection zone.

To qualify for inclusion in the list of FMD-free countries where vaccination is practiced, a Member should:

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that:
   a. there has been no outbreak of FMD during the past two years;
   b. no evidence of FMDV circulation has been found for the past 12 months;
3. supply documented evidence that:
   a. surveillance for FMD and FMDV circulation in accordance with Articles 8.5.42 and 8.5.47 and 8.5.49 is in operation;
   b. regulatory measures for the early detection, prevention, and control of FMD have been implemented;
   c. routine vaccination is carried out for the purpose of the prevention of FMD;
   d. the vaccine used complies with the standards described in the Terrestrial Manual;
4. describe in detail the boundaries and measures of a protection zone, if applicable.

The Member will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 2, 3, and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to

points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

If a Member that meets the requirements of an FMD free country where vaccination is practiced wishes to change its status to FMD free country where vaccination is not practiced, the status of this country remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV infection has not occurred during that period.

4.6.2.4 FMD-FREE ZONE WHERE VACCINATION IS NOT PRACTICED

An FMD free zone where vaccination is not practiced can be established in either an FMD free country where vaccination is practiced or in a country of which parts are infected. In defining such zones, the principles of Chapter 4.3 should be followed. Susceptible animals in the FMD free zone should be protected from the rest of the country and from neighboring countries if they are of a different animal health status by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a protection zone.

To qualify for inclusion in the list of FMD free zones where vaccination is not practiced, a Member should:

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that within the proposed FMD free zone:
    a. there has been no outbreak of FMD during the past 12 months;
    b. no evidence of FMDV infection has been found during the past 12 months;
    c. no vaccination against FMD has been carried out during the past 12 months;
    d. no vaccinated animal has been introduced into the zone since the cessation of vaccination, except in accordance with Article 8.5.10;
3. supply documented evidence that:
    a. surveillance for FMD and FMDV infection in accordance with Articles 8.5.42 to 8.5.47 and Article 8.5.49 is in operation;
    b. regulatory measures for the early detection, prevention and control of FMD have been implemented;
4. describe in detail and supply documented evidence that these are properly implemented and supervised:
    a. the boundaries of the proposed FMD free zone;
    b. the boundaries and measures of a protection zone, if applicable;
    c. the system for preventing the entry of the virus (including the control of the movement of susceptible animals) into the

proposed FMDV free zone (in particular if the procedure described in Article 8.5.10 is implemented).

The proposed free zone will be included in the list of FMD-free zones where vaccination is not practiced only after the submitted evidence has been accepted by the OIE.

The information required in points 2, 3, and 4b)-c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

4.6.2.5 FMD-FREE ZONE WHERE VACCINATION IS PRACTICED

An FMD free zone where vaccination is practiced can be established in either an FMD free country where vaccination is not practiced or in a country of which parts are infected. In defining such zones, the principles of Chapter 4.3 should be followed. Susceptible animals in the FMD free zone where vaccination is practiced should be protected from neighboring countries or zones if they are of a lesser animal health status by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a protection zone.

To qualify for inclusion in the list of FMD free zones where vaccination is practiced, a Member should:

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE that within the proposed FMD free zone:
    a. there has been no outbreak of FMD for the past two years;
    b. no evidence of FMDV circulation has been found during the past 12 months;
3. supply documented evidence that:
    a. surveillance for FMD and FMDV infection/circulation in accordance with Articles 8.5.42 to 8.5.47 and Article 8.5.49 is in operation;
    b. regulatory measures for the early detection, prevention and control of FMD have been implemented;
    c. routine vaccination is carried out for the purpose of the prevention of FMD;
    d. the vaccine used complies with the standards described in the Terrestrial Manual.
4. describe in detail and supply documented evidence that these are properly implemented and supervised:
    a. the boundaries of the proposed FMD free zone;
    b. the boundaries and measures of a protection zone, if applicable;

c. the system for preventing the entry of the virus (including the control of the movement of susceptible animals) into the proposed FMD free zone (in particular if the procedure described in Article 8.5.10 is implemented).

The proposed free zone will be included in the list of FMD free zones where vaccination is practiced only after the submitted evidence has been accepted by the OIE. The information required in points 2, 3, and 4b)-c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

If a Member that has a zone which meets the requirements of an FMD free zone where vaccination is practiced wishes to change the status of the zone to FMD free zone where vaccination is not practiced, the status of this zone remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV infection has not occurred in the said zone during that period.

4.6.2.6 FMD-FREE COMPARTMENT

An FMD free compartment can be established in either an FMD free country or zone or in an infected country or zone. In defining such a compartment the principles of Chapters 4.3 and 4.4 should be followed. Susceptible animals in the FMD free compartment should be separated from any other susceptible animals by the application of an effective biosecurity management system.

A Member wishing to establish an FMD free compartment should:

1. have a record of regular and prompt animal disease reporting and if not FMD free, have an official control program and a surveillance system for FMD in place according to Articles 8.5.42 to 8.5.47 and Article 8.5.49 that allows an accurate knowledge of the prevalence of FMD in the country or zone;
2. declare for the FMD free compartment that:
    a. there has been no outbreak of FMD during the past 12 months;
    b. no evidence of FMDV infection has been found during the past 12 months;
    c. vaccination against FMD is prohibited;
    d. no animal vaccinated against FMD within the past 12 months is in the compartment;
    e. animals, semen, and embryos should only enter the compartment in accordance with relevant Articles in this chapter;
    f. documented evidence shows that surveillance in accordance with Articles 8.5.42 to 8.5.47 and Article 8.5.49 is in operation for FMD and FMDV infection;

g. an animal identification and traceability system in accordance with Chapters 4.1 and 4.2 is in place;

3. describe in detail the animal subpopulation in the compartment and the biosecurity plan for FMD and FMDV infection.

The compartment should be approved by the Veterinary Authority. The first approval should only be granted when no outbreak of FMD has occurred within the zone in which the compartment is situated, during the last three months.

4.6.2.6.1 Note on FMD-Free Compartments in the United States

There are no OIE recognized FMD-free compartments in the world. It is unlikely that an FMD compartment would be established in an FMD outbreak in the United States.

4.6.2.7 FMD-INFECTED COUNTRY OR ZONE

For the purposes of this chapter, an FMD infected country is a country that does not fulfill the requirements to qualify as either an FMD free country where vaccination is not practiced or an FMD free country where vaccination is practiced.

For the purposes of this chapter, an FMD infected zone is a zone that does not fulfill the requirements to qualify as either an FMD free zone where vaccination is not practiced or an FMD-free zone where vaccination is practiced.

Chapter 5
Specific FMD Response Critical Activities and Tools

FAD PReP documents identify critical activities and tools to be employed in the event of an FMD outbreak. These critical activities and response tools will assist in controlling, containing, and eradicating FMD while facilitating continuity of business in an outbreak. This chapter describes key parts of these critical activities and tools.

The FAD PReP SOPs and NAHEMS Guidelines referenced in this chapter can be found, for APHIS employees, at http://inside.aphis.usda.gov/vs/em/fadprep.shtml, or, for others, at https://fadprep.lmi.org.

5.1 Etiology and Ecology

Information on the etiology and ecology of FMD promotes a common understanding of the disease agent among responders and other stakeholders (see Chapter 1 for FMD information). The FMD Overview of Etiology and Ecology SOP contains further information.

5.2 Laboratory Definitions and Case Definitions

Laboratory and case definitions provide a common point of reference for all responders. Case definitions and laboratory criteria are developed according to the Case Definition Development Process SOP (see Subsection 5.2.3). These definitions are available here for APHIS employees: http://inside.aphis.usda.gov/vs/ceah/nsu/case_definitions.shtml, and also on the FAD PReP website, https://fadprep.lmi.org.

5.2.1 Laboratory Definitions

The following subsections are the APHIS-VS Centers for Epidemiology and Animal Health (CEAH) National Surveillance Unit (NSU) draft definitions for FMD from February 2011, which are undergoing review. For further information on the diagnostic tests conducted by NVSL-FADDL in the event of an FMD outbreak, please see Subsection 5.4.

5.2.1.1 LABORATORY CRITERIA

1. *Agent identification*: Virus isolation (VI), antigen enzyme-linked immunosorbent assays (ELISAs), and real-time reverse transcriptase polymerase chain reaction (rRT-PCR) assays are used to detect FMDV-infected animals. Samples to collect for testing include vesicular epithelium, vesicular fluid, epithelial tissues, oesophageal-pharyngeal fluid, blood, serum, and oral and nasal swabs.

    a. VI in cell cultures: One of the "gold standard" tests for FMDV detection. VI is highly sensitive and specific when used with antigen ELISAs to confirm the presence of FMDV after cytopathic effect is observed.

    b. Antigen ELISA: The other "gold standard" test for FMDV detection. Detects viral proteins for serotyping (using polyclonal or monoclonal antibodies to FMDV) and is useful for FMD diagnosis in suspect cases. It is also capable of detecting South African Territories (SATs) serotypes.

    c. rRT-PCR: Detects FMDV nucleic acids (RNA). It only takes 2-3 hours to obtain test results. It is used for surveillance and diagnosis, not as a standalone laboratory assay. Most rRT-PCRs detect all known FMDV serotypes, often with equal or greater sensitivity than VI; rRT-PCR does not identify virus serotype or subtype.

    d. Strain characterization by nucleotide sequencing: RT-PCR amplification of the P1 region of FMDV genome or a portion of the P1 region that contains VP1 of the genome, followed by nucleotide sequencing is the preferred method for generating sequence data strain characterization. If necessary, the whole genome of FMDV can be sequenced. Antigen ELISA is used to determine the serotype of the FMD present in the outbreak samples.

2. *Serological tests*: The following serological assays detect FMDV-exposed animals and some help to discriminate vaccinated from infected animals.

    a. Structural protein-based assays: Virus neutralization test (VNT), solid phase competitive ELISA (SPCE), and liquid phase blocking ELISA (LPBE) are OIE-prescribed tests for trade purposes. These are highly sensitive, serotype-specific tests that detect FMDV antibodies. These assays may be utilized for confirmation of infection (previous or on-going) and to monitor immunity following vaccination. Low titer ELISA-positive sera must be confirmed by VNT to exclude false positive results. The VNT confirms the FMDV serotype and a version of this test is used to determine the serotype subtype during vaccine matching.

b. Nonstructural protein (NSP)-based antibody assays: ELISA and enzyme-linked immunoelectrotransfer blot (EITB) assays measure antibodies to NSP (3B, 2C, 3D, and 3ABC). Commercial ELISAs measure antibodies to 3ABC or 3B. The virus infection association antigen, VIAA, is an agarose immunodiffusion (AGID) test that detects antibodies to NSP 3D. These assays are not serotype-specific and they are used as screening tests. The PrioCHECK® FMDV NS (formally Ceditest® FMDV-NS) is an ELISA that detects antibodies to NSP 3ABC of FMDV with specificity greater than 97 percent for vaccinated and non-vaccinated cattle, and greater than 99 percent in non-vaccinated sheep and pigs. The sensitivity of PrioCHECK® is 100 percent in non-vaccinated cattle, but varies greatly in vaccinated cattle, sheep, and pigs depending upon time between infection and testing, clinical signs, and carrier status. PrioCHECK® FMDV NS can discriminate vaccinated from infected animals, and is best used as a herd test rather than an individual animal test.

5.2.2 Case Definitions

The following subsections are the APHIS-VS CEAH NSU draft definitions for FMD from February 2011, which are undergoing review.

5.2.2.1 Suspect Case

An FMD-susceptible animal that has either

- clinical signs consistent with FMD; OR
- inconclusive or positive laboratory test results performed on a sample taken during routine surveillance, with or without presence of clinical criteria.

5.2.2.2 Presumptive Positive Case

A suspect case that has both

- epidemiological information indicative of FMD; AND
- positive laboratory test results (see laboratory criteria above)
  - Identification of antibodies to NSP 3D by AGID or 3ABC by ELISA; or to structural proteins by virus neutralization for serotype identification, OR
  - Identification of FMDV nucleic acid by RT-PCR, OR
  - Identification of FMDV serotype by antigen ELISA.

5.2.2.3 CONFIRMED POSITIVE CASE

An animal from which FMDV has been *isolated* and *identified* at the NVSL-FADDL or other laboratory designated by the Secretary of the USDA.

5.2.2.4 EVOLVING DEFINITIONS

The above presumptive positive and confirmed positive case definitions are for the index case and may change as an outbreak progresses. For example, the positive predictive value of clinical signs will increase if FMD prevalence increases.

5.2.3 Case Definition Development Process

The Case Definition Development Process SOP describes the general process for developing and approving animal disease case definitions for use in animal health surveillance and reporting. Case definitions are developed by NSU, in cooperation with the National Center for Animal Health Emergency Management (NCAHEM). NSU coordinates review with SAHOs, subject matter experts, stakeholders, and VS units. Case definitions are approved by the VS Deputy Administrator (the U.S. CVO) and VS Leadership Team. Case definitions enhance the usefulness of animal disease data by providing uniform criteria for reporting purposes.

In an FMD outbreak, case definitions may be edited within 24 hours of the first presumptive positive or confirmed positive case (index case). The case definition will be reviewed throughout the outbreak and modified on the basis of additional information or the changing needs of the eradication effort.

5.3 SURVEILLANCE

Surveillance is a critical activity during an outbreak of FMD. The following are response goals in an FMD outbreak:

- To implement surveillance plans within 48 hours of the confirmation of an outbreak.
- To implement a surveillance plan that will (1) define the present extent of FMD and (2) detect unknown IP quickly.
- To have the surveillance plan consider the susceptible wildlife population in the area, and to coordinate with APHIS Wildlife Services (WS), the DOI, State wildlife agencies, and State agriculture departments to perform appropriate FMD surveillance in these populations.
- To provide complete surveillance data summaries and analysis at intervals as specified by IC.

- To develop effective surveillance plans that can achieve desired outcomes by leveraging available resources, satisfying jurisdictional requirements, and implementing continuity of business measures.

At the APHIS level, NSU is responsible for surveillance activities. Box 5-1 lists the key objectives of surveillance activities during and immediately after an FMD outbreak.

Box 5-1. Surveillance Objectives in an FMD Outbreak

Surveillance Objectives

- Detect FMD IP during an outbreak.
- Determine the size and extent of an FMD outbreak.
- Supply information to evaluate outbreak control activities.
- Provide information for animal and product movement within the CA.
- Provide information for animal and product movement out of the CA.
- Prove disease freedom (DF) and regain disease-free status after eradication of the outbreak.

5.3.1 Surveillance Planning for FMD Outbreak

5.3.1.1 General Considerations

A surveillance plan will indicate the frequency, number, and distribution of animals and premises to be sampled. This requires tradeoffs be made among six surveillance parameters or tools, listed below. These tradeoffs are made employing initial information collected about the outbreak, and best estimates. During an outbreak, surveillance plans will change as new information becomes available. (Appendix F contains more detailed surveillance information.) The six surveillance parameters are as follows:

1. *Design (threshold) prevalence.* The goal is to determine the lowest feasible prevalence that can be used to detect infected herds on premises. The chosen proportion of animals or premises infected that, if exceeded, will indicate the disease has been detected for a given confidence level and population size (1 percent vs. 5 percent vs. 15 percent).

2. *Confidence level.* The selected level (90 percent confident vs. 95 percent confident) that the disease can be detected for the chosen design threshold, given the population size.

3. *Types of tests.* Test choices—clinical inspection, polymerase chain reaction (PCR) testing, serology testing, etc.—and the test cutoff values can influence the design prevalence choice. Each test has a sensitivity and specificity that varies with the cutoff values.

4. *Sampling frequency.* Previous negative test results can augment information gained from negative test results if the time period between sampling is short—ideally daily, but definitely less than the incubation period. The value of the previous negative test results decreases as the interval between sampling increases (daily vs. every other day).

5. *Risk-based sampling.* Selecting populations with a higher proportion of infected animals (1 percent vs. 10 percent) reduces the number of samples needed for a given confidence level and population size.

6. *Sampling scheme.* Within the selected population (risk-based or total population), a random, convenience, or other scheme may be used, and the choice will influence the number of animals and premises sampled.

5.3.1.2 Surveillance Objectives by Time Period

There are three key segments of surveillance activity in an outbreak. These segments have distinct goals to aid in the control, containment, and eradication of FMD from domestic livestock. For more information on the zone, area, and premises designations referred to in this section, please refer to Subsection 5.5 in this chapter.

1. *The initial 72 hours post FMD outbreak declaration.* The objective is to detect existing infected animals and premises as quickly as possible. During this period, there are three goals of IC.

    a. Create the initial BZ designation and the boundary of the CA.

    b. Create a list of premises with susceptible herds (and species) in the CA.

    c. Determine the boundary of the Surveillance Zone (SZ) and start developing a surveillance plan to be used in the SZ.

2. *The control and eradication period (from initial 72-hour period until last case is detected and eradicated).* Four key objectives need to be accomplished simultaneously in this period.

    a. Detect IP, new and existing, so that control measures can be put in place.

    b. Provide evidence that premises are free of FMD, thereby permitting animal and animal product movements in the CA.

    c. Evaluate the outbreak management control activities.

    d. Provide evidence that the Free Area (FA) is free of disease, thereby enabling unrestricted animal and animal product movement.

3. *Post eradication.* The objective is to prove that the CA and FA are free of disease (using OIE recommendations and requirements on surveillance).

    a. Prove DF on depopulated premises.

    b. Prove DF on At-Risk Premises (ARP) in the CA by random sampling or targeted sampling (choosing populations based on risk) on selected premises and selected herds.

    c. Prove DF in the FA, following OIE guidelines.

5.3.2 Surveillance Sampling

The goal of surveillance sampling is to detect FMD as soon as possible. Currently, there are no validated mass population sampling techniques, such as milk bulk tank sampling, water trough sampling, or saliva sampling from ropes for swine. Without mass population sampling, the only early detection test is by individual sampling using rRT-PCR. It is a priority to get mass population sampling techniques validated, particularly for swine, dairy, and beef, so that additional diagnostics supplement and amplify visual observation and individual animal sampling for early detection.

Given that no validated mass population sampling techniques are available, the following questions provide guidance to develop a surveillance sampling scheme after declaration of an FMD outbreak in a location or area.

1. Are resources limited to intensively survey premises (for example, collect tissue samples from the needed number of animals)?

2. Is it unlikely that the outbreak can be contained locally (such as on a farm or within a small geographic area)?

3. Does evidence suggest that the introduction of virus (for example, start of the outbreak) on the premises or in the zone began at least 7 days ago?

4. Is there evidence that the FMD serotype is highly pathogenic (for example, a high proportion of infected animals will show clinical signs and/or severe clinical signs)?

5. Are there limited movements of animals, vehicles, products, or personnel on and off premises (for example, it is unlikely that virus will be introduced to, or spread from, this premises or zone)?

6. Are sheep present in the zone or on the premises?

7. Are there noncommercial or feral swine in the zone?

8. Are there noncommercial or small premises in the zone?

9. Are there premises with more than one susceptible species?

10. Are there large feedlots or swine operations in the zone?

11. Are dairy cattle, feedlots, or swine operations in the zone managed to present low-risks of exposure (such as biosecurity practices, little opportunity for fomite transmission)?

12. Are there beef cattle (cow-calf or small operations) in the zone?

Figure 5-1 demonstrates how these questions should be used to inform a surveillance sampling scheme.

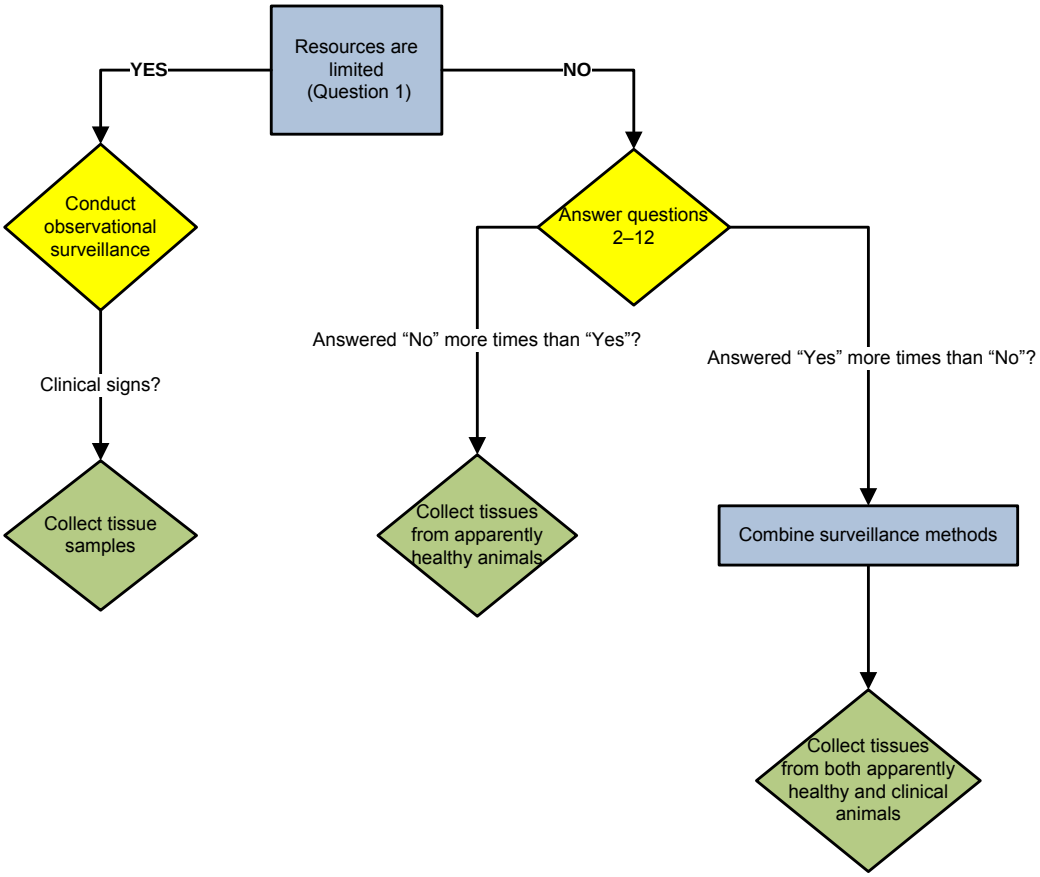
If the answer to Question 1 is "yes," the minimum surveillance to detect FMDV is observational surveillance/routine visual inspection of cattle herds for clinical signs, and targeted tissue sampling of individual animals with clinical signs.

If the answer to Question 1 is "no," and

- there are more "no" than "yes" answers for Questions 2–12, then surveillance may include the collection of tissue samples from herds and animals which appear to be healthy, or

- there are more "yes" than "no" answers for Questions 2–12, then surveillance may include a combination that leads to collection of tissue samples from both animals that appear to be healthy and animals with clinical signs of FMDV.

Figure 5-1. Developing an FMD Outbreak Surveillance Sampling Scheme



It is likely that individual animal sampling may quickly exceed resource capacity, and any surveillance sampling scheme may have to adjust accordingly by switching from individual animal sampling to observation with rRT-PCR confirmation. The plan may require visual inspection on premises least likely to spread the disease and individual animal sampling on premises most likely to transmit FMD.

5.3.2.1 Additional Information

Appendix F of this *FMD Response Plan* contains additional guidance on creating a surveillance scheme based on the sensitivity and specificity of available diagnostics, FMD prevalence in a population, herd size, and other factors for commercial and noncommercial premises. The FMD Surveillance SOP provides additional information on the protocol for a surveillance team responding to FMD IP, the distinction between commercial and noncommercial premises surveillance, equipment checklists, and surveillance for proof of DF.

The Outbreak Surveillance Toolbox, available to people with access to the Inside APHIS webpage (http://inside.aphis.usda.gov/vs/ceah/nsu/toolbox/), or to those outside APHIS by emailing (national.surveillance.unit@aphis.usda.gov), provides additional surveillance resources.

5.4 DIAGNOSTICS

Effective and appropriate sample collection, diagnostic testing, surge capacity, and reporting are critical in an effective FMD response. These activities will require additional resources in the event of an FMD outbreak. In particular, sample collection will require additional personnel. Surge capacity may also be required for diagnostic laboratory testing. Surveillance plan requirements must be fully integrated with current diagnostic sample collection, sample testing, surge capacity, and reporting capabilities.

During a suspected or actual FMD outbreak, the key goals of response are to (1) meet the surge requirements for diagnostic testing at specific intervals, starting at time zero and at 24-hour intervals as the response escalates, and (2) report all diagnostic test results to appropriate personnel and information management systems within 12 of hours of diagnostic test completion.

The FAD PReP Diagnostics SOP offers detailed information on sample collection, diagnostic testing, surge capacity, and reporting. In particular, this SOP provides additional guidance on who is responsible for diagnostic testing, sample collection and processing, and analyzing diagnostic test results. Appendix G, references VS Memo 580.4, which contains more information on submitting diagnostic samples. The procedures outlined in this memo should be followed regarding the submission of diagnostic samples in an FAD investigation. For packaging and labeling submissions, see http://www.aphis.usda.gov/animal_health/lab_info_services/packaging_labeling.shtml.

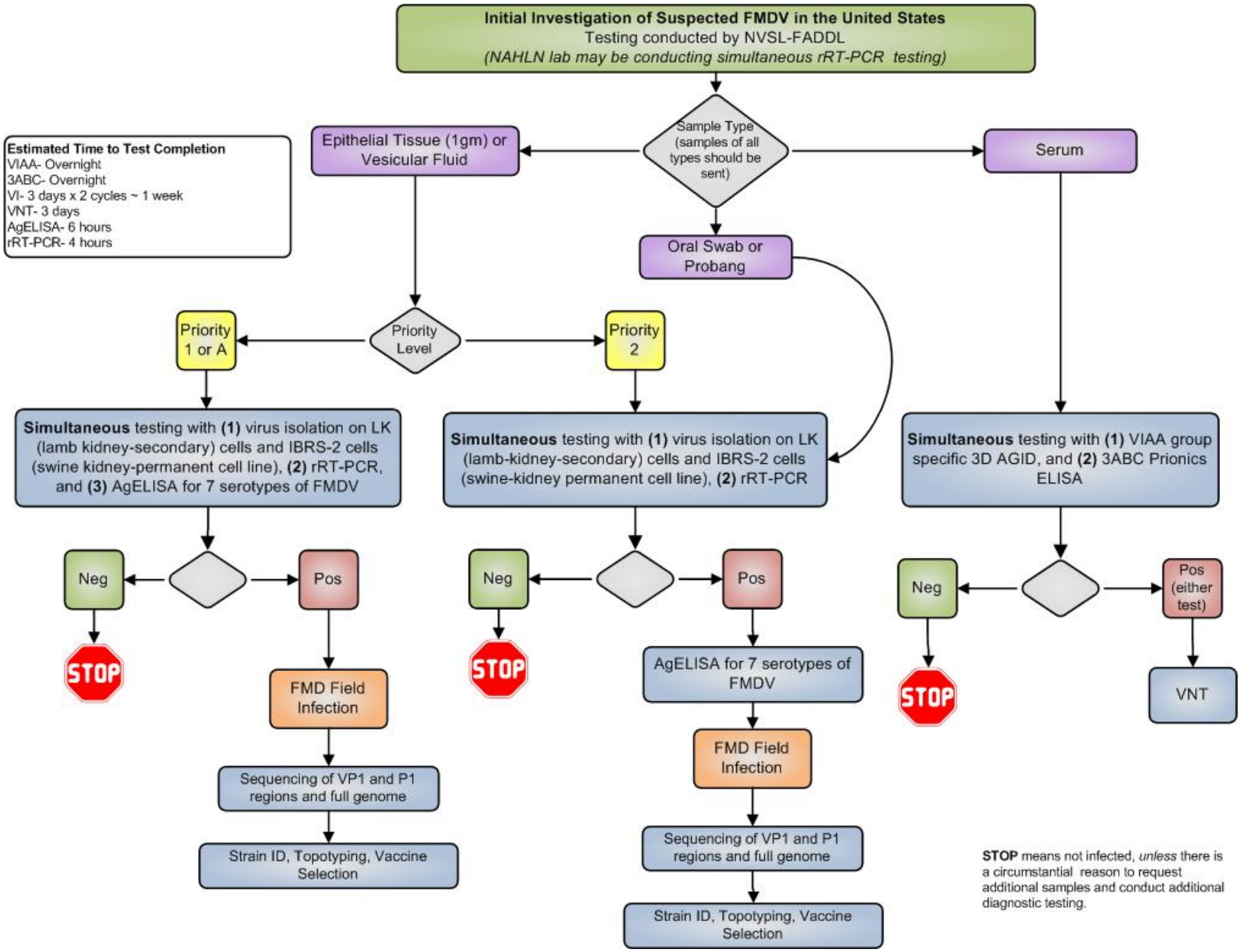
5.4.1 Sample Collection and Diagnostic Testing

Trained personnel and field collection kits are required to effectively collect samples, particularly from large animals. Specific diagnostic tests are used for antigen detection, virus identification, and antibody detection. For antigen detection, rRT-PCRs are used simultaneously with other tests selected on the basis of the type and priority of the sample. Virus isolation is used to confirm a FMD diagnosis, but this can take up to 7 days. The following subsections describe the diagnostic tests performed when FMDV is suspected (Figure 5-2) and when it has been confirmed in the United States (Figure 5-3).

5.4.1.1 DIAGNOSTICS FOR INITIAL FMD INVESTIGATION

Figure 5-2 displays the diagnostics for a suspected case of FMD. In the figure, Priority 1 or A and Priority 2 refer to categorizations explained in VS Memo 580.4. (Appendix G provides the link to this memorandum.) The confirmation of an FMD outbreak will be made by NVSL-FADDL.

Figure 5-2. Diagnostic Flowchart for Initial Investigation of FMD

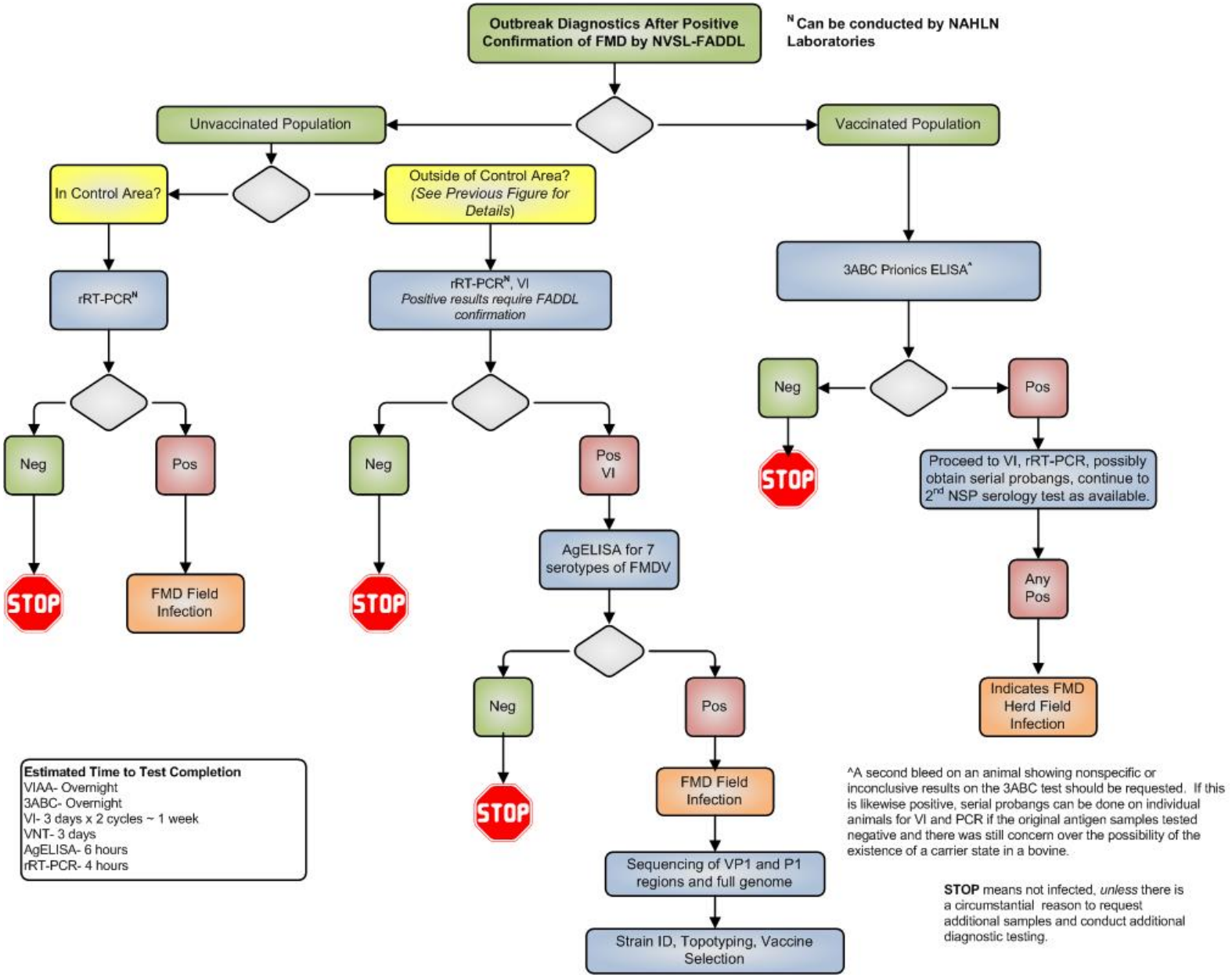


5.4.1.2 DIAGNOSTICS AFTER FMD DETECTION

Confirmation of FMD on any premises not currently in an FMD CA will be done by NVSL-FADDL. After NVSL confirmation of FMD on a premises (index case), subsequent swab samples for rRT-PCR may be sent to USDA-approved laboratories which are part of the NAHLN network. (Appendix C lists NAHLN laboratories approved for FMD testing.) Figure 5-3 illustrates the diagnostic flow after FMD has been detected.

IC will provide specific instructions regarding the direction and collection of samples, which is likely to change as the outbreak evolves. In all cases, (1) NVSL will confirm the index case, (2) presumptive positive samples (on a rRT-PCR) from outside an established CA will be tested and confirmed by NVSL, and (3) NVSL will receive samples routinely from *inside* the CA to monitor for changes in the FMDV.

Figure 5-3. Outbreak Diagnostics after Positive Confirmation of FMD in United States



5.4.2 Surge Capacity

Surge capacity may be needed in an FMD outbreak. Additional resources, such as personnel and materials, will be needed for sample collection. Additional capacity may also be required for laboratory sample testing. Surge capacity can help facilitate a rapid response and continuity of business for non-infected premises. In the event that the state NAHLN laboratory and NVSL-FADDL are overwhelmed by the diagnostic testing requirements, NAHLN labs from across the country will provide surge capacity for diagnostic testing. For more information on surge capacity, please see the NAHLN Activation Guide. Individual laboratories have independent protocols on how to manage personnel if a surge is required. Appendix C contains a list of the NAHLN labs approved to conduct FMD diagnostics.

NAHLN labs currently have the capability to conduct rRT-PCR tests, as shown in Figure 5-3. Ideally, NAHLN labs will also have the capability to conduct 3ABC ELISA tests to detect FMDV in herds. It is a priority to ensure that NAHLN labs have this diagnostic capacity to test samples in the event of an FMD outbreak, particularly for recovering and proving DF.

5.4.3 Reporting

Box 5-2 clarifies reporting and notification of presumptive FMD cases. See APHIS VS Memorandum 580.4 (regarding FAD investigations) for further information on FMD investigation and reporting. This memorandum is available on the FAD PReP website: https://fadprep.lmi.org.

Box 5–2. Reporting and Notification

Reporting and Notification

- Cases of clinical illness that are found to be presumptive positive, based on the current case definition, for FMD at NVSL-FADDL will be reported to the affected States, other States, Tribal Nations, industry, other Federal agencies, trading partners, and the OIE.
- Appropriate Federal-State-Tribal-industry response and containment measures will be initiated during FMD investigations.

5.5 Epidemiological Investigation and Tracing

5.5.1 Summary of Zones, Areas, and Premises Designations

A critical component of an FMD response is the designation of zones, areas, and premises. The Incident Commander will work with the Operations Section and

Situation Unit (in the Planning Section) to (1) determine appropriate zones, areas, and premises designations in the event of a FMD outbreak, and (2) reevaluate these designations as needed throughout the outbreak based on the epidemiological situation (see Appendix B for organizational charts). These zones, areas, and premises designations are used in quarantine and movement control efforts. For details on the zones, areas, and premises, please see the *APHIS Foreign Animal Disease Framework: Response Strategies* (FAD PReP Manual 2-0).

Table 5-1 summarizes the premises designations that would be employed in an FMD outbreak response. Table 5-2 summarizes the zone and area designations that would be used in an FMD outbreak response. Figure 5-4 illustrates these premises, zone, and area designations.

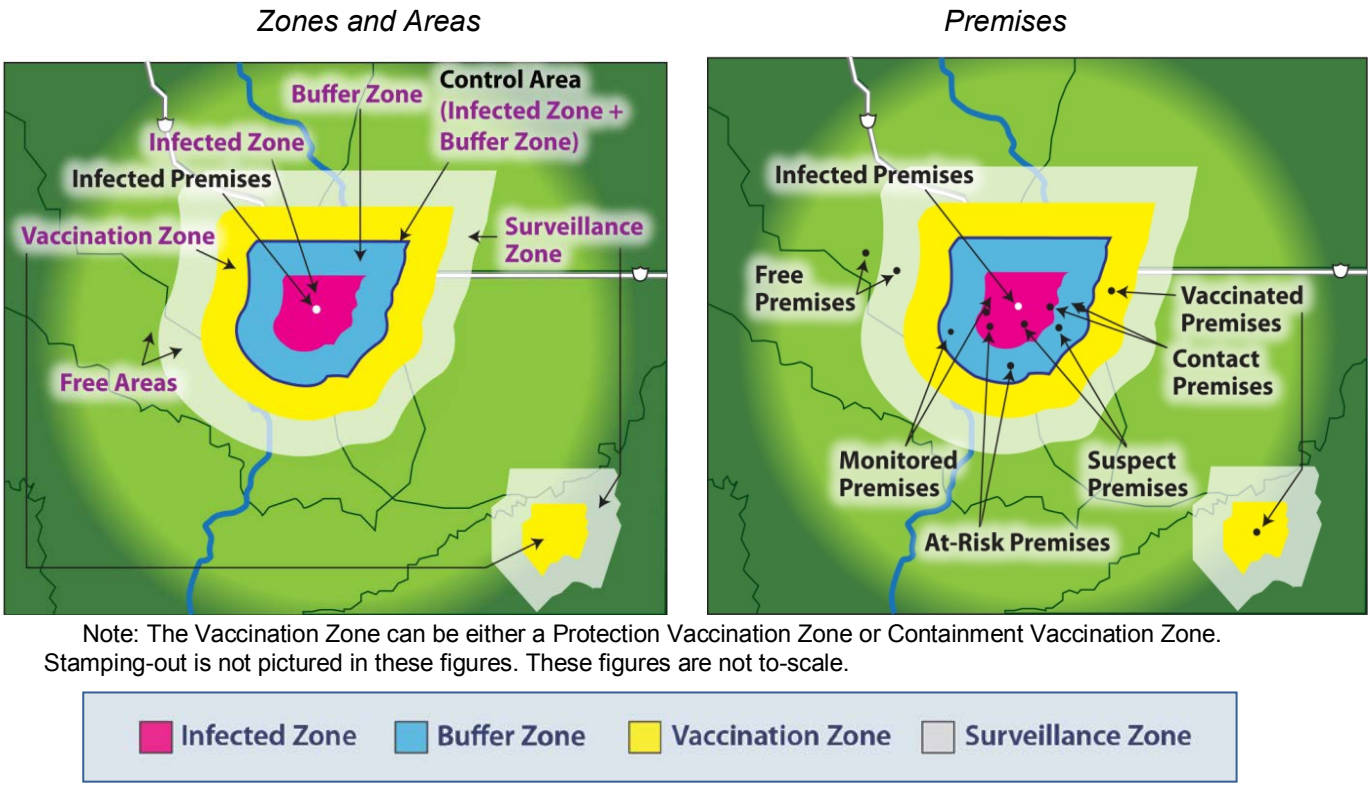
Table 5-1. Summary of Premises

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

Table 5-2. Summary of Zones and Areas

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

Figure 5-4. Example of Zones, Areas, and Premises in FMD Outbreak Response



Note: The Vaccination Zone can be either a Protection Vaccination Zone or Containment Vaccination Zone. Stamping-out is not pictured in these figures. These figures are not to-scale.

5.5.2 Epidemiological Investigation

Epidemiological investigation and movement tracing during an outbreak are critical in controlling and eradicating FMD. In an FMD outbreak, the goals are

- within 96 hours of identifying the index case, characterize the nature of the FMD outbreak, identify the risk factors for transmission, and develop mitigation strategies;
- within 6 hours of identifying potential IP or CP through tracing activities, assign a premises classification and a priority of investigation; and
- within 24 hours of identifying the IP or initial CP, identify all additional CP.

These measures will aid in the control of FMD and lessen the impact of the response effort. Appendix H contains a sample epidemiological questionnaire. Please note that this questionnaire is only an example. In an outbreak, other factors may be considered; the scope of such a questionnaire should be assessed based on the epidemiological situation, and is at the discretion of IC. The FMD Epidemiological Investigation and Tracing SOP as well as the NAHEMS Guidelines: Surveillance, Epidemiology, and Tracing both provide more information.

5.5.3 Tracing

Box 5-3 explains the fundamental importance of movement tracing in an FMD response effort.

Box 5-3. Importance of Movement Tracing in FMD Outbreak

Tracing

One of the single most important and urgent veterinary activities during an FMD outbreak is to rapidly and diligently trace-back and trace-forward movements from an IP. This tracing will aid in the control of the spread of FMDV and limit the impact of the outbreak. Tracing should cover all movements from the premises, including susceptible livestock, non-susceptible species, animal products, vehicles, crops and grains, and people. Tracing will also include consideration of all potential modes of transmission and possible contact with wild-life.

Trace-back and trace-forward information should ideally be collected for at least 28 days before the appearance of clinical signs in animals infected with FMD. Additional tracing information will be collected for movements up to the time quarantine was imposed.

Tracing information will be obtained from many sources (such as reports from field veterinarians, producers, industry, farm service providers, or the public). The Emergency Management Response System (EMRS) will be used to collect and report epidemiological data, including movement tracing information, locally and nationally.

5.5.4 Considerations for Size of Control Area and Minimum Sizes of Other Zones

The perimeter of the CA should be at least 10 km (~6.21 miles) beyond the perimeter of the closest IP. The size of the CA depends on the circumstances of the outbreak, including the IP transmission pathways and estimates of transmission risk, livestock movement patterns and concentrations, distribution of susceptible wildlife in proximity, natural terrain, jurisdictional boundaries, and other factors. The boundaries of the CA can be modified or redefined when tracing and other epidemiological information becomes available.

Table 5-3 provides a description of the minimum sizes of areas and zones. Table 5-4 reviews the factors used to determine the size of the CA.

Table 5-3. Minimum Sizes of Areas and Zones

Zone or Area	Minimum Size and Details
Infected Zone (IZ)	Perimeter should be at least 3 km (~1.86 miles) beyond perimeters of presumptive or confirmed Infected Premises. Will depend on disease agent and epidemiological circumstances. This zone may be redefined as the outbreak continues.
Buffer Zone (BZ)	Perimeter should be at least 7 km (~4.35 miles) beyond the perimeter of the Infected Zone. Width is generally not less than the minimum radius of the associated Infected Zone, but may be much larger. This zone may be redefined as the outbreak continues.
Control Area (CA)	Perimeter should be at least 10 km (~6.21 miles) beyond the perimeter of the closest Infected Premises. Please see Table 5-4 for factors that influence the size of the Control Area. This area may be redefined as the outbreak continues.
Surveillance Zone (SZ)	Width should be at least 10 km (~6.21 miles), but may be much larger.

Table 5-4. Factors to Consider in Determining Control Area Size for FMD

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

5.6 INFORMATION MANAGEMENT

Local, State, Tribal, and Federal information management systems need to be compatible for information and data sharing. In an FMD outbreak, the response goal is to have EMRS information downloads or data entry processes performed in 24-hour or shorter intervals. Field personnel should be provided with access to the mobile technology devices necessary for collecting, monitoring, and sharing information. Rapidly functional, robust, and scalable information technology infrastructure will be needed in an FMD outbreak.

The Overview of Information Management SOP provides information on key selected systems (covered in the SOP in the following order):

- CoreOne (Surveillance Collaboration Services)
- Animal Health and Surveillance Management
- Veterinary Services Process Streamlining
- Animal Disease Traceability Information System
- NAHLN
- EMRS
- National Veterinary Logistics System
- LabWare Laboratory Information Management System
- Licensing, Serial Release, and Testing Information System
- Mobile Information Management.

It also covers the following APHIS information technology systems:

- APHIS Emergency Qualifications System
- Resource Ordering and Status System.

5.7 COMMUNICATION

The FMD Communication SOP provides guidance on communications activities during an FMD outbreak, covering the responsibilities of personnel and internal and external communication procedures. APHIS Legislative and Public Affairs (LPA) will serve as the primary liaison with the news media in the event of an FMD outbreak. Under the ICS, a JIC is established. During an FMD outbreak, APHIS LPA and the USDA Office of Communications operate from the JIC.

Effective communication during a FMD outbreak should be carried out and maintained by

- establishing a network of stakeholders and systems for communication prior to an incident or outbreak;
- briefing the media, public, industry, Congress, trading partners, and others on the FMD outbreak status and the actions being taken to control and eradicate the disease;
- coordinate with Federal, State, and local agencies, Tribal entities, producer groups, and Land Grant University based Cooperative Extension Services to ensure consistent messaging regarding animal health, public health, and food safety; and
- assuring consumers that USDA is working on animal health issues, in an informed and timely manner.

In addition, all communications should highlight the importance of sound biosecurity measures and steps that producers and owners can take to protect against FMD infection in their own livestock herds.

5.7.1 Objectives

All FMD communications must

- furnish accurate, timely, and consistent information;
- maintain credibility and instill public confidence in the government's ability to respond to an outbreak;
- minimize public panic and fear; and
- address rumors, inaccuracies, and misperceptions as quickly as possible.

5.7.2 Key Messages

Six key messages will be conveyed in an FMD outbreak (Box 5-4).

Box 5-4. FMD Communication Messages

Key Communication Messages

For consumers:

1. FMD does not cause disease in humans.
2. Meat and meat products are safe to eat.
3. Milk and dairy products are safe to eat.
4. We are responding quickly and decisively to eradicate the virus.

For producers:

1. Protect your herds with good biosecurity practices.
2. Be vigilant about reporting signs of illness.

5.7.3 Further Communications Guidance

In addition to the FMD Communications SOP, the following resources provide guidance on communication and information about various stakeholder groups:

- APHIS Animal Health website (http://www.aphis.usda.gov/animal_health)
- FAD PReP Stakeholder Coordination and Collaboration Resource Guide.

5.8 Health and Safety and Personal Protective Equipment

During an FMD outbreak, responders are exposed to many hazards, particularly in working with heavy equipment and large animals. Taking precautions to prevent adverse human health events related to emergency response efforts is important. PPE is crucial in protecting health and safety during an FMD outbreak response effort. PPE also helps ensure response personnel are taking care to avoid transmitting FMDV to naïve premises.

PPE is fundamental in ensuring personnel are protected in the FMD response effort. All workers involved in the handling, culling, transport, or disposal of items or animals infected with FMDV must be provided with appropriate PPE. All visitors and employees, regardless of their exposure, should be provided with disposable coveralls, boots, hats, and gloves before entering a premises. Disposal of this PPE is required after leaving.

For further information on health and safety and PPE, see the FMD Health and Safety and Personal Protective Equipment SOP. It provides information on best practices to ensure the well-being and safety of all individuals involved in the response effort. Specific topics covered include the following:

- Procedures to create a site-specific health and safety plan

- Details of hazard analysis, necessary training, and medical surveillance requirements
- PPE, including Occupational Safety and Health Administration respirator fit testing
- Pre-deployment information and guidance
- A protocol for staff field safety in an FMD response.

5.8.1 Mental Health Concerns

The health and safety of all personnel is affected by the mental state of those involved in the FMD response effort. The toll an FMD outbreak may take on mental and physical health must be considered to protect the health and safety of all personnel.

FMD depopulation efforts can significantly affect the health of responders, livestock owners, and others impacted by the outbreak and response efforts. The HHS has developed resources specifically for emergency and disaster responders, States and local planners, health professionals, and the general public (www.bt.cdc.gov/mentalhealth/). The FMD Mass Depopulation and Euthanasia SOP provides further information on how personnel can effectively deal with euthanasia-related stress.

5.8.2 Further Information on Health, Safety, and Personal Protective Equipment

In addition to the resources already listed, the following documents contain information and guidance:

- *APHIS Health and Safety Manual*. Available to APHIS employees at http://inside.aphis.usda.gov/mrpbs/publications/safety_health_wellness_manual/index.shtml.
- NAHEMS Guidelines: Health and Safety
- NAHEMS Guidelines: Personal Protective Equipment.

5.9 BIOSECURITY

An FMD outbreak would seriously impact the agricultural industry; strict biosecurity measures need to be implemented to prevent or slow the spread of FMD. Biosecurity procedures should be implemented within 24 hours of the identification of an index FMD case. Accordingly, veterinarians, owners, and anyone else in contact with enterprises that have susceptible animals need to observe biosecurity measures.

Proper biosecurity measures have two functions: (1) containing the virus on IP (biocontainment), and (2) preventing the introduction of the virus via movement of personnel and material to naïve livestock and premises (bioexclusion). During an FMD outbreak, a careful balance must be maintained between facilitating response activities and ensuring personnel do not expose naïve animals and premises to FMDV.

Further information on biosecurity is provided in the FMD Biosecurity SOP, which offers guidance on how to draft a site-specific biosecurity plan and

- identifies the roles and responsibilities of key personnel,
- explains biosecurity training and briefing requirements,
- addresses site security and safety,
- discusses biosecurity practices for shipping and transportation, and
- provides a biosecurity checklist.

In addition, more information on appropriate biosecurity measures can be found in the NAHEMS Guidelines: Biosecurity.

5.9.1 Biosecurity Hazards and Mitigating Measures

Box 5-5 shows biosecurity hazards and biosecurity measures to mitigate these risks during an FMD outbreak.

Box 5–5. FMD Biosecurity Hazards and Appropriate Biosecurity Measures

Biosecurity Hazards	Biosecurity Measures to Mitigate Risk
• Movement of livestock, vehicles, equipment, and people. • Contaminated feed and water. • Contact with infected domesticated livestock and other non-susceptible animals that can act as mechanical vectors (cats, poultry, or foxes). • Contact with contaminated people, clothes, footwear, or hands.	• Clean and disinfect premises, vehicles, and equipment and dispose of materials that cannot be disinfected in an appropriate manner. • Account for the movement of all livestock, other animals, and equipment for accurate records. • Provide a location for all individuals to carry out appropriate cleaning and disinfection procedures and insist that these procedures are followed. • Prevent close or direct contact between herds (over a single fence line).

5.9.2 Closed Herds

In the event of an FMD outbreak, an important biosecurity measure is closing herds to new livestock. Box 5-6 provides guidance on employing closed herds as a critical biosecurity measure.

Box 5-6. Biosecurity Measure—Closed Herds

Biosecurity: Closed Herds

- To the fullest extent possible, close the herd to the introduction of new livestock (with population increases occurring only from offspring).
- If closing a herd is not possible, isolate newly purchased livestock (from the healthiest possible sources) and those returning from existing herds for 30 days or more.
- Do not introduce vaccinated animals to naïve herds.

5.9.3 Waiting Period

Another important biosecurity measure is to ensure personnel are not travelling between IP and unknown or uninfected premises. During an FMD outbreak, it is important that personnel wait the allotted time between premises visits in addition to following appropriate biosecurity and cleaning and disinfection protocols (see Section 5.15). *Actual waiting periods will be recommended by IC on the basis of the outbreak circumstances, and need for personnel.* Typical waiting times vary between 24 and 72 hours (for example, 72-hours was used in the United Kingdom following the 2001 FMD outbreak).[1] Team members should not travel from IP or SP to unknown or uninfected premises. However, they may travel *between* IP, if proper mitigating procedures are followed.

Extended avoidance periods for personnel may be unnecessary with stringent biosecurity practices and effective cleaning and disinfection protocols. However, until further information is available, veterinarians and other responders should adhere to the guidance provided by the local IC.

5.10 Quarantine and Movement Control

By restricting the movement of infected animals, animal products, and contaminated fomites, quarantine and movement control can be a powerful tool in controlling and containing an FMD outbreak. Movement control is accomplished through a permit system that allows entities to make necessary movements without creating an unacceptable risk of disease spread. Operational staff

[1] DEFRA, Biosecurity Guidance to Prevent the Spread of Animal Diseases, 2008, http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/documents/biosecurity_guidance.pdf.

members need to strictly adhere to movement control procedures, which are based on the best scientific information available at the time.

The Incident Commander, Disease Surveillance Branch (Operations Section), and Situation Unit (Planning Section), will coordinate to establish an IZ and a BZ within 12 hours of the identification of an index case. Controlled movement orders and 24-hour standstill notices are likely to be implemented upon detection of FMD in the United States in relevant regions or zones. (Appendix I contains examples of movement control notices.) Once the CA (IZ plus BZ) is established, quarantine and movement controls will be implemented.

Each State's animal health emergency response plan should describe the implementation of quarantine and movement controls, including a permit system. USDA will impose a Federal quarantine and restrict interstate commerce from the infected States, asking the States (or adjoining countries) to provide resources to maintain and enforce the quarantine. Reimbursement formulas will be established between the States and USDA in a cooperative agreement.

The following subsections provide further information on movement control guidelines. The FAD PReP Quarantine and Movement Control SOP provides specific, detailed guidance on measures considered necessary to prevent the spread of FMD through movement, including (1) keeping FMD out of livestock populations in areas free of FMD and (2) preventing the spread of FMD to uninfected livestock in areas where FMD exists. NAHEMS Guidelines: Quarantine and Movement Control also contains more details.

5.10.1 Zones, Areas, and Premises Designations

The Incident Commander will work with the Disease Surveillance Branch (Operations Section) and the Situation Unit (Planning Section) to determine appropriate premises designations in the event of an FMD outbreak (see Appendix B for an organizational chart). These zone, area, and premises designations will be used for quarantine and movement control efforts. Again, refer to Tables 5-1 and 5-2 and Figure 5-4 for the designations used here.

5.10.2 Permit Guidance to Move into a Control Area, within a Control Area, and out of a Control Area

During an FMD outbreak, the following guidance in Table 5-5 (movement into a CA), Table 5-6 (movement within a CA), and Table 5-7 (movement out of a CA) will be used to issue permits in movement control efforts. For permit guidance for milk and milk products, see the *Secure Milk Supply (SMS) Plan*, https://fadprep.lmi.org. See Section 5.16 for additional guidance for movement control of vaccinates.

Table 5-5. Movement into Control Area from Outside Control Area to Specific Premises[a]

Item Moving into a Control Area to a/an… →	Infected Premises	Suspect Premises^	Contact Premises^	At-Risk Premises	Monitored Premises
Susceptible animals	Prohibited, except under certain circumstances as determined by the IC, such as slaughter.	Prohibited, except under certain circumstances as determined by the IC, such as slaughter.	Prohibited, except under certain circumstances as determined by the IC, such as slaughter.	Permit for movement must be approved by the IC with appropriate biosecurity measures.	Permit for movement must be approved by the IC with appropriate biosecurity measures.
Susceptible animal products	See continuity of business plans for information on susceptible animal products, or guidance and processes as determined by the IC. Please see Subsection 5.10.5 which contains OIE FMD-specific guidance for inactivating FMD. In addition, Appendix J contains information on the SMS Plan for milk and milk product movement during an FMD outbreak.				
Other animals (non-susceptible livestock) from premises **with** susceptible species	Prohibited unless permit approved by IC and appropriate biosecurity measures.	Prohibited unless permit approved by IC and appropriate biosecurity measures.	Prohibited unless permit approved by IC and appropriate biosecurity measures.	Allowed with appropriate biosecurity measures. IC may require a permit for movement depending upon FMD epidemiology and characteristics of destination premises.	Allowed with appropriate biosecurity measures. IC may require a permit for movement depending upon FMD epidemiology and characteristics of destination premises.
Other animals (non-susceptible livestock) from premises **without** susceptible species	IC will determine movement restrictions based on FMD epidemiology and characteristics of destination premises.	IC will determine movement restrictions based on FMD epidemiology and characteristics of destination premises.	IC will determine movement restrictions based on FMD epidemiology and characteristics of destination premises.	Allowed with appropriate biosecurity measures. IC may require a permit for movement depending upon FMD epidemiology and characteristics of destination premises.	Allowed with appropriate biosecurity measures. IC may require a permit for movement depending upon FMD epidemiology and characteristics of destination premises.
Equipment, vehicles, and other fomites from premises **with** susceptible species	Allowed with appropriate biosecurity measures.	Allowed with appropriate biosecurity measures.	Allowed with appropriate biosecurity measures.	Allowed with appropriate biosecurity measures.	Allowed with appropriate biosecurity measures.
Semen, embryos from susceptible animals	Prohibited.	Prohibited.	Prohibited.	Allowed with appropriate biosecurity measures.	Allowed with appropriate biosecurity measures.

[a] **Movement control and permit processes will change over time depending on situational awareness and operational capabilities.**

^ Contact Premises and Suspect Premises are intended to be short-term premises designations. Ideally these Premises should be re-designated before movements occur.

Table 5-6. Movement within a Control Area [a]

Item Moving within a Control Area from a/an…. →	Infected Premises	Suspect Premises^	Contact Premises^	At-Risk Premises	Monitored Premises
Susceptible animals	Prohibited, except under certain circumstances as determined by the IC, such as slaughter.	Prohibited, except under certain circumstances as determined by the IC, such as slaughter.	Prohibited, except under certain circumstances as determined by the IC, such as slaughter.	Allowed to move by permit approved by the IC; surveillance, negative diagnostic tests, premises biosecurity, and risk-assessment may be required for permit.	Allowed to move by permit approved by the IC; surveillance, negative diagnostic tests, premises biosecurity, and risk-assessment may be required for permit.
Susceptible animal products	See continuity of business plans for information on susceptible animal products, or guidance and processes as determined by the IC. Please see Subsection 5.10.5 which contains OIE FMD-specific guidance for inactivating FMD. In addition, Appendix J contains information on the SMS Plan for milk and milk product movement during an FMD outbreak.				
Other animals (non-susceptible livestock) from premises **with** susceptible species	Prohibited unless specific permit granted by IC and appropriate biosecurity measures.	Prohibited unless specific permit granted by IC and appropriate biosecurity measures.	Prohibited unless specific permit granted by IC and appropriate biosecurity measures.	Allowed to move by permit approved by the IC; surveillance, negative diagnostic tests, premises biosecurity, and risk-assessment may be required for permit.	Allowed to move by permit approved by the IC; surveillance, negative diagnostic tests, premises biosecurity, and risk-assessment may be required for permit.
Other animals (non-susceptible livestock) from premises **without** susceptible species	n/a (Infected Premises have susceptible species)	n/a (Suspect Premises have susceptible species)	n/a (Contact Premises have susceptible species)	n/a (At-Risk Premises have susceptible species)	n/a (Monitored Premises have susceptible species)
Equipment, vehicles, and other fomites from premises **with** susceptible species	Prohibited unless specific permit granted by IC and appropriate biosecurity measures.	Prohibited unless specific permit granted by IC and appropriate biosecurity measures.	Prohibited unless specific permit granted by IC and appropriate biosecurity measures.	Allowed by permit approved by IC and appropriate biosecurity measures.	Allowed by permit approved by IC and appropriate biosecurity measures.
Semen, embryos from susceptible animals	Prohibited.	Prohibited.	Prohibited.	Allowed by permit approved by IC and appropriate biosecurity measures.	Allowed by permit approved by IC and appropriate biosecurity measures.

[a] Movement control and permit processes will change over time depending on situational awareness and operational capabilities.

^ Contact Premises and Suspect Premises are intended to be short-term premises designations. Ideally these Premises should be re-designated before movements occur.

Table 5-7. Movement from Inside a Control Area to Outside a Control Area from Specific Premises[a]

Item Moving out of a Control Area from a/an… →	Infected Premises	Suspect Premises^	Contact Premises^	At-Risk Premises	Monitored Premises*
Susceptible animals	Prohibited, except under certain circumstances as determined by the IC.	Prohibited, except under certain circumstances as determined by the IC.	Prohibited, except under certain circumstances as determined by the IC.	At-Risk Premises must become Monitored Premises to move susceptible livestock out of a Control Area.	Allowed to move by permit approved by IC; surveillance, negative diagnostic tests, premises biosecurity, and risk-assessment may be required for permit.
Susceptible animal products	See continuity of business plans for information on susceptible animal products, or guidance and processes as determined by the IC. Please see Subsection 5.10.5 which contains OIE FMD-specific guidance for inactivating FMD. In addition, Appendix J contains information on the SMS Plan for milk and milk product movement during an FMD outbreak.				
Other animals (non-susceptible livestock) from premises **with** susceptible species	Prohibited unless specific permit approved by IC and appropriate biosecurity measures and risk-assessment.	Prohibited unless specific permit approved by IC and appropriate biosecurity measures and risk-assessment.	Prohibited unless specific permit approved by IC and appropriate biosecurity measures and risk-assessment.	Allowed to move by permit approved by IC; surveillance and negative diagnostic tests for susceptible animals on premises, premises biosecurity, and risk-assessment may be required for permit.	Allowed to move by permit approved by IC; surveillance and negative diagnostic tests for susceptible animals on premises, premises biosecurity, and risk-assessment may be required for permit.
Other animals (non-susceptible livestock) from premises **without** susceptible species	n/a (Infected Premises have susceptible species)	n/a (Suspect Premises have susceptible species)	n/a (Contact Premises have susceptible species)	n/a (At-Risk Premises have susceptible species)	n/a (Monitored Premises have susceptible species)
Equipment, vehicles, and other fomites from premises **with** susceptible species	Prohibited unless permit approved by IC and appropriate biosecurity measures.	Prohibited unless permit approved by IC and appropriate biosecurity measures.	Prohibited unless permit approved by IC and appropriate biosecurity measures.	Allowed by permit approved by IC and appropriate biosecurity measures.	Allowed by permit approved by IC and appropriate biosecurity measures.
Semen, embryos from susceptible animals	Prohibited.	Prohibited.	Prohibited.	At-Risk Premises must become Monitored Premises to move semen, embryos from susceptible livestock out of a Control Area.	Monitored Premises only allowed by permit approved by IC and appropriate biosecurity measures.

[a] Movement control and permit processes will change over time depending on situational awareness and operational capabilities.

^ Contact Premises and Suspect Premises are intended to be short-term premises designations. Ideally these Premises should be re-designated before movements occur.

*** Continuity of business plans may apply.**

For movement of susceptible animals and susceptible animal products out of the CA to a FA, the permit process must consider national standards, any OIE standards, and conditions for such movement such as biosecurity procedures and risk assessment recommendations. In addition, commodity-specific proactive risk assessments, continuity of business plans, movement and marketability plans, and compartmentalization plans will also be considered. Figure 5-5 illustrates movement control and permitting in relation to premises designation.

Figure 5-5. Premises Designations in Relation to Permitting and Movement Control

5.10.3 Moving Commodities, Animals, and Conveyances in FMD Outbreak

Any movement of commodities, animals, and conveyances brings some level of risk of FMDV transmission from a known IP or an unknown IP to uninfected premises. The risk of moving commodities, animals, and conveyances depends on the nature of the item being moved and its ability to transmit or be contaminated with FMDV. FMDV can be transmitted via items that contain biological material (such as manure), through infected animals, or via a contaminated fomite or person.

5.10.4 Guidance for All Premises

Because of the variation in the risk of the commodities, animals, and conveyances, it is possible that premises—particularly MP and ARP—may be permitted to move one commodity, animal, or conveyance but not another. In making the decision whether movement will be allowed, substantial consideration will be given to critical movements (for example, the movement of animal feed onto premises).

5.10.5 OIE Treatment Guidelines for FMD

The OIE *Terrestrial Animal Health Code (2011)* provides guidance for the importation of animals, products, and commodities from FMD infected countries or zones, as well as processes for inactivating FMDV. The guidance for the inactivation of FMD in meat, wool and hair, bristles, raw hides/skins, and milk/cream is provided below. Chapter 8.5 of the OIE *Terrestrial Animal Health Code (2011)* also contains guidance for other items, such as skins, trophies, and casings.

5.10.5.1 Procedures for the Inactivation of FMD Virus in Meat

For the inactivation of viruses present in meat, one of the following procedures should be used:

1. Canning

   Meat is subjected to heat treatment in a hermetically sealed container to reach an internal core temperature of at least 70ºC for a minimum of 30 minutes or to any equivalent treatment which has been demonstrated to inactivate the FMD virus.

2. Thorough cooking

   Meat, previously deboned and defatted, shall be subjected to heating so that an internal temperature of 70ºC or greater is maintained for a minimum of 30 minutes.

   After cooking, it shall be packed and handled in such a way that it cannot be exposed to a source of virus.

3. Drying after salting

   When rigor mortis is complete, the meat must be deboned, salted with cooking salt (NaCl) and completely dried. It must not deteriorate at ambient temperature.

   'Drying' is defined in terms of the ratio between water and protein which must not be greater than 2.25:1.

5.10.5.2 PROCEDURES FOR THE INACTIVATION OF FMD VIRUS IN WOOL AND HAIR

For the inactivation of viruses present in wool and hair for industrial use, one of the following procedures should be used:

1. industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide (soda) or potassium hydroxide (potash);
2. chemical depilation by means of slaked lime or sodium sulphide;
3. fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours. The most practical method is to place potassium permanganate in containers (which must NOT be made of plastic or polyethylene) and add commercial formalin; the amounts of formalin and potassium permanganate are respectively 53 ml and 35 g per cubic metre of the chamber;
4. industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60-70ºC;
5. storage of wool at 18ºC for 4 weeks, or 4ºC for 4 months, or 37ºC for 8 days.

5.10.5.3 PROCEDURES FOR THE INACTIVATION OF FMD VIRUS IN BRISTLES

For the inactivation of viruses present in bristles for industrial use, one of the following procedures should be used:

1. boiling for at least one hour;
2. immersion for at least 24 hours in a 1 percent solution of formaldehyde prepared from 30 ml commercial formalin per liter of water.

5.10.5.4 PROCEDURES FOR THE INACTIVATION OF FMD VIRUS IN RAW HIDES AND SKINS

For the inactivation of viruses present in raw hides and skins for industrial use, the following procedure should be used: salting for at least 28 days in sea salt containing 2 percent sodium carbonate.

5.10.5.5 Procedures for the Inactivation of FMD Virus in Milk and Cream for Human Consumption

For the inactivation of viruses present in milk and cream for human consumption, one of the following procedures should be used:

1. a sterilization process applying a minimum temperature of 132ºC for at least one second (ultra-high temperature [UHT]), or
2. if the milk has a pH less than 7.0, a sterilization process applying a minimum temperature of 72ºC for at least 15 seconds (high temperature—short time pasteurization [HTST]), or
3. if the milk has a pH of 7.0 or over, the HTST process applied twice.

5.10.5.6 Procedures for the Inactivation of FMD Virus in Milk for Animal Consumption

For the inactivation of viruses present in milk for animal consumption, one of the following procedures should be used:

1. the HTST process applied twice;
2. HTST combined with another physical treatment, e.g., remaining a pH 6 for at least one hour or additional heating to at least 72ºC combined with dessication;
3. UHT combined with another physical treatment referred to in point 2 above.

5.10.6 Surveillance Required for Livestock and Product Movement

Surveillance measures are required for movement of livestock and animal products for premises located in the CA (IZ and BZ). These steps include visual surveillance along with diagnostic testing prior to movement. (Appendix F contains more information on surveillance for the movement of livestock and animal products.) See the *SMS Plan* for surveillance measures for movement of milk and milk products, http://securemilksupply.org or https://fadprep.lmi.org.

5.11 Continuity of Business

Continuity of business is the management of non-infected premises and non-contaminated animal products in the event of an FMD outbreak. Continuity of business provides science- and risk-based approaches and systems as a critical activity in an FMD response. This helps to facilitate agriculture and food industries maintain typical business, or return to business during a disease response, while the risk of disease spread is effectively managed. Continuity of business planning can help to minimize unintended consequences on producers and consumers impacted by FMD. During an FMD outbreak, permitting,

movement control, and prioritized disruptions—all based on science and risk-based approaches—are critical measures to ensure continuity of business. The FAD PReP Continuity of Business SOP and NAHEMS Guidelines: Continuity of Business cover topics such as

- key roles and responsibilities in continuity of business planning,
- details of developing continuity of business plans,
- potential components required for continuity of business planning, and
- preparedness and response goals.

The *SMS Plan* (http://securemilksupply.org or https://fadprep.lmi.org) offers additional continuity of business information, particularly applicable to interstate trade. (Appendix J contains information on the *SMS Plan*.)

5.12 Regionalization for International Trade (for a U.S. FMD Response)

In the event of an FMD outbreak in the United States, international trade of animals and animal products may be adversely affected for a significant period of time. This would have serious economic implications for the affected industries and the United States. Therefore, it is important to identify, prior to an outbreak, potential procedures and plans that may mitigate the consequences and reestablish international trade as rapidly as possible.

As defined by the OIE, regionalization, also known as zoning, is the concept of separating subpopulations of animals in order to maintain a specific health status in one or more disease-free regions or zones. Disease-free regions can be created to facilitate continuity of business and reestablish international trade from the regions demonstrated to be disease-free. Regionalization recognizes that risk may be tied to factors that are not reflected by political boundaries of the nation or individual states, especially when the outbreak has been confined to specific areas within an individual state or group of states. Providing information to the OIE, its member countries and our trading partners, that clearly identifies the boundaries of the disease-free areas, can be used to inform our trading partners' decisions whether to receive or reject our exports. This risk-based process, based on sound science, can mitigate the adverse economic effects of an FMD outbreak.

5.12.1 Compartmentalization

Another tool that may potentially mitigate the economic consequences of a disease outbreak is compartmentalization. Compartmentalization, which defines an animal subpopulation by management and husbandry practices related to biosecurity, could be used by the veterinary authorities to demonstrate and

maintain disease freedom in certain commercial establishments whose practices have prevented the introduction of the disease. The disease-free status of these compartments could enable trade movement of animal products. Compartmentalization has not been fully implemented by the United States for any disease agent to-date, and will depend on the recognition of the status of these compartments by international trading partners. Implementation of compartmentalization will rely on producers, industry, and State and Federal animal health authorities. By working closely together to develop and strengthen relationships and implementing the agreed upon procedures preceding an FAD outbreak, compartmentalization may be a useful tool.

5.12.2 Further Guidance

The OIE *Terrestrial Animal Health Code (2011)* also offers guidance on regionalization and compartmentalization in Chapters 4.3 and 4.4. The NAHEMS Guidelines: Regionalization for International Trade for a U.S. FAD Response contains information on regionalization as an FAD response tool.

Specific guidelines for an FMD-free compartment are found in Chapter 8.5 of the OIE *Code*. Currently there are no internationally accepted or fully implemented FMD-free compartments in the United States.

5.13 MASS DEPOPULATION AND EUTHANASIA

Depending on the FMD strategy or strategies selected, animals on an IP will be depopulated as soon as possible after declaration of an FMD outbreak. Susceptible animals on CP may also be depopulated as soon as possible after the premises are classified as CP. The FMD Mass Depopulation and Euthanasia SOP provides instructions for personnel following the declaration of an FMD outbreak and the classification of IP and CP. This SOP offers FMD-specific information on mass depopulation and euthanasia, including evaluation of various euthanasia methods, such as

- gunshot,
- penetrating captive bolt,
- electrocution,
- injectable euthanasia, and
- carbon dioxide and other gas.

In an FMD outbreak, euthanasia or mass depopulation should be provided to the affected animals as safely, quickly, efficiently, and humanely as possible. In addition, the emotional and psychological impact on animal owners, caretakers, their families, and other personnel should be minimized.

Mass depopulation and euthanasia are not synonymous, and APHIS recognizes a clear distinction. Euthanasia involves transitioning an animal to death as painlessly and stress-free as possible. Mass depopulation is a method by which large numbers of animals must be destroyed quickly and efficiently with as much consideration given to the welfare of animals as practicable, given extenuating circumstances. Mass depopulation is employed in an FMD response to prevent or mitigate the spread of FMD through eliminating infected or potentially infected animals. Best practice guidance issued in 2007 from the American Veterinary Medical Association (AVMA) states that "Under unusual conditions, such as disease eradication and natural disasters, euthanasia options may be limited. In these situations, the most appropriate technique that minimizes human and animal health concerns must be used." Qualified personnel should perform mass depopulation in the event of an FMD outbreak using the safest, quickest, and most humane procedures in accordance with AVMA guidance.

If personnel or materials are insufficient, the Incident Commander or other official should request emergency depopulation, disposal, and decontamination (3D) contractor support for FMD depopulation efforts from the NVS.

NAHEMS Guidelines: Mass Depopulation and Euthanasia contains additional information on euthanasia and mass depopulation.

5.14 DISPOSAL

Appropriate disposal of animal carcasses and materials is a critical component of a successful FMD response. FMD can survive for long periods on both organic and inorganic materials. The FMD Disposal SOP discusses how to dispose of carcasses, animal products, other materials, and items that cannot be properly cleaned and disinfected (such as manure, litter, and bedding), products of the response effort (such as PPE), and products of vaccination response. Disposal will occur as soon as possible after the depopulation of animals on premises.

Disposal must be done in a manner that does not allow FMDV to spread, minimizes negative environmental effects, and conserves meat or animal protein if logistically supportable from a biosecurity standpoint. In some cases, moving clinically normal animals to a slaughter facility within the CA may be possible, though they may have been exposed to the FMDV on IP or CP. IC must permit any movement required for disposal. Local and state regulations must be observed or memorandums of understanding must be obtained to ensure disposal capability. Cost effectiveness and stakeholder acceptance must also be considered.

On-site burial may be an inexpensive and biosecure method of disposal that minimizes the transportation of infected materials. However, on-site methods may be limited by several factors such as topography, soil type, soil depth to bedrock, seasonal high-water table, and environmental regulations. Off-site burial may be needed when on-site burial is not possible or when a number of IP must be depopulated and a common burial site would be more efficient. Other disposal

methods such as composting, incineration, digestion, and rendering may also be employed, as indicated by the circumstances of the outbreak and disposal requirements.

In addition, in any FMD outbreak, multiple methods of disposal are likely to be required, due to the large quantity of materials in need of disposal. Rendering, incineration, and composting are considered viable alternatives for both large and small ruminants. For the disposal of syringes and unused but opened vaccine vials, on-site incineration is highly recommended.

Disposal methods should always be assessed and applied appropriately, given the facility location, type of housing, premises characteristics, and other situational factors. IC will coordinate closely with local authorities in deciding how to dispose of carcasses and other items.

In the event that available personnel are insufficient for disposal requirements in an FMD outbreak, the Incident Commander can request emergency 3D contractor support from the NVS. The NAHEMS Guidelines: Disposal contains further guidance on disposal activities.

5.15 CLEANING AND DISINFECTION

Because of FMD's high survival rate on both organic and inorganic materials, aggressive cleaning and disinfection practices are required for control and eradication. Cleaning and disinfection are to be conducted within 48 hours of the disposal of depopulated animals. The FMD Cleaning and Disinfection SOP provides information on

- the FMD cleaning and disinfection effort,
- optimal cleaning and disinfection methods for FMD,
- processes used to inactivate FMD viruses from organic materials,
- how to clean and disinfect equipment and premises after FMD detection, and
- Environmental Protection Agency (EPA)-approved disinfectants for FMDV.

Because the aerosol transmission of FMD is a concern, care should be taken to reduce the generation and dispersal of potentially infective dust and aerosolized materials during cleaning and disinfection procedures. If items cannot be cleaned and disinfected adequately, they will be disposed of using burial, incineration, or other appropriate means. All disinfectants must be EPA-approved for FMD; off-label use of disinfectants is illegal.

If available personnel or materials are insufficient for cleaning and disinfection in an FMD outbreak, the Incident Commander can request emergency 3D contractor support from NVS.

NAHEMS Guidelines: Cleaning and Disinfection contains additional information.

5.16 VACCINATION

The use of emergency vaccination in the event of FMD has been extensively discussed in Chapter 4. This section explains important details in the event emergency vaccination is employed in an FMD outbreak. Box 5-7 summarizes key concerns of using emergency vaccination strategies in an FMD outbreak.[2] (Appendix E contains additional scientific information on FMD vaccines and vaccination.) The NVS Countermeasures Working Group Report on FMD (2007), the NAHEMS Guidelines: Vaccination for Contagious Diseases (and Appendix A: Vaccination for FMD) contain additional information.

[2] National Veterinary Stockpile (NVS). 2007. *National Veterinary Stockpile Countermeasures Working Group Report: Foot-and-Mouth Disease.*

Box 5-7. Challenges of Emergency Vaccination for FMD

Challenges of FMD Vaccination: Vaccine Production

- Conventional inactivated FMD vaccines cannot be manufactured in the United States.
- Growth of wild-type virus in cell culture to produce vaccine seeds requires large volumes and biosafety level (BSL)-3 facilities.
- A short shelf-life for formulated vaccines requires the banking of non-formulated antigen concentrates.
- Antigen drift results in the emergence of field isolates that may not be controlled with older vaccine antigen types and requires ongoing expense to stockpile newly emerging antigens.
- Once an outbreak is detected, the antigen(s) must be identified for vaccine matching, and vaccine must be formulated from antigen concentrates. This results in a 1-2 week delay.
- At least one serotype is less immunogenic than the others and requires a higher antigen payload; some serotypes are less stable than the others and require additional quality assurance measures to ensure potency throughout the manufacturing process and storage.
- Highly purified vaccines must be used, otherwise it is difficult to differentiate vaccinated from infected animals due to the presence of non-structural proteins in vaccines.

Challenges of FMD Vaccination: Vaccine Use

- Vaccines provide only serotype-specific protection. Vaccination against one serotype may fail to protect fully or at all against other strains within the serotype, depending on how closely the vaccine and field strain are related, and the potency of the vaccine.
- Onset of immunity is not immediate. Inactivated FMD vaccines may decrease viral shedding and clinical signs in cattle and sheep in challenge studies as early as 4 days after vaccination with protection improving for the next 2-3 weeks; swine appear to be more difficult to protect shortly after challenge, limited studies have reported some protection as soon as 3-4 days after vaccination; however, with more severe challenges, pigs may not be completely protected against disease until 21-28 days after vaccination.
- Duration of immunity depends on the type of vaccine used and varies by species of animal. No currently available vaccine provides "sterilizing immunity" which will prevent subsequent infection.
- Diagnostic testing capabilities to differentiate infected and vaccinated animals are necessary if an emergency vaccination strategy is utilized (see Subsection 5.16.1).

5.16.1 Differentiating Infected and Vaccinated Animal Testing

One of the most significant challenges to any emergency vaccination strategy is differentiating between field infected and vaccinated animals for effective surveillance of FMDV. As illustrated in Figure 5-3, a 3ABC Prionics ELISA conducted by NVSL-FADDL would typically be used to differentiate infected herds from vaccinated herds. Individual animal tests remain a diagnostic

challenge. Other NSP tests that may assist in DIVA testing are currently being validated for use in the United States.

5.16.2 North American FMD Vaccine Bank Guidelines for Use of Vaccination in FMD Outbreak

The following subsections come directly from NAFMDVB Guidelines (2007). They provide guidance for the usage of FMD vaccine in the United States in the event that an emergency vaccination strategy is employed in an outbreak. Other documents which discuss FMD vaccination include the NAHEMS Guidelines: Vaccination for Contagious Diseases with an FMD Appendix and the FMD Vaccination SOP.

5.16.2.1 Access to Vaccine Bank by Members and Other Countries

This subsection comes directly from Chapter 6 in the NAFMDVB Guidelines (2007):

1. Member countries shall have access to antigens and vaccines held by the NAFMDVB in accordance with the procedure in Chapter 6.
2. Where it is in the interests of the North American Animal Health Committee and in accordance with the procedure outlined in 19, the Commission may offer third countries access to the NAFMDVB on the condition that the use of vaccine remains under the supervision of the NAFMDVB including the serological surveys where appropriate.
3. The conditions for the use of antigen and vaccine and follow-up investigations shall be decided in accordance by the Commission by unanimous vote.
4. Following the use of antigen or formulated vaccine from the NAFMDVB, the Commission shall ensure that the used antigen or vaccine is replaced as soon as possible and according to the global epidemiological situation.
5. The Commission may also permit the sale or dispersal of vaccine not used that was ordered by a member country or of an antigen strain no longer considered a threat to allow purchase of more current strains.

5.16.2.2 Emergency Vaccine Field Usage Guide

This subsection comes directly from Chapter 7 of the NAFMDVB Guidelines (2007):

1. Each member country should establish a usage plan, including a clear policy, administrative and implementation procedures, and requirements for recording usage sufficient to meet OIE guidelines.
2. All vaccination personnel must be trained and accredited/certified by the receiving country.

3. Vaccine must be stored at 2-8°C with refrigerated ice packs and must not be frozen until the moment of usage. Individual country's vaccine usage plans must require that when boxes are opened, the temperature indicator strips must be examined to ensure that the cold chain has been maintained.
4. In the eventuality that the cold chain is broken during shipment, the vaccine will be used if there is no immediate replacement for it. The veterinarian receiving the shipment should keep a record of the status of the cold chain. The retained samples (six 20Ml vials) will be immediately forwarded to Plum Island to be evaluated for efficacy and sterility.
5. Partially used vaccine vials taken onto the farm shall be destroyed. Unopened vials brought onto high-risk premises may be disinfected off following strict biosecurity procedures. Do not retain partially empty vials overnight. Remove all vials from the premises.
6. Vaccine manufacturer's directions should be followed. Contaminated needles should not be reused. Vaccinate all ruminants over 1 day of age and pigs over 2 weeks of age or greater with the following dosages:
    a. Cattle and buffalo: 2ml deep intra-muscular in the neck;
    b. Sheep and goats: 1ml intra-muscular in the upper neck;
    c. Pigs: 2ml in neck musculature behind the ear.
7. Booster doses, if necessary, should be administered as follows:
    a. If the vaccine strain virus is homologous with the isolated field strain, re-vaccinate at 4-6 weeks and again at 6 months post vaccination;
    b. If the vaccine strain is heterologous to the isolated field strain but considered to be protective against the isolated field strain, re-vaccinate at 4-6 weeks and again at 6 months post-vaccination.

5.16.2.3 FMD VACCINATE IDENTIFICATION

This subsection comes directly from Chapter 8 of the NAFMDVB Guidelines (2007):

1. All FMD vaccinates shall have no fewer than two (2) visible external means of identification.
    a. If the animal has no official identification before vaccination, an FAD Vaccination Ear tag shall be applied in the proximal portion of each ear; OR
    b. If the animal has an existing official identification ear tag, e.g., Health of Animals, CCIA, or USA tag, TB Official Campaign

ear tag, a single FMD Vaccination ear tag should be applied to the proximal portion of the left ear.[3]

c. Should the vaccinated premises have a unique individual animal identification system in place, e.g., an electronic identification system or readily readable tattoos, only a single FMD tag may be applied to the left ear of each vaccinated animal. Use of such systems shall be at the discretion of the animal health official on site in order to allow system flexibility and greater efficiency of the vaccination crews.

d. Identification methods such as plastic tags that are numbered manually with indelible ink, brands, or ear notches are not considered acceptable unique animal identification for this circumstance.

e. In swine operations which employ all-in/all-out animal management systems, it may be acceptable to vaccinate all animals in a specific swine building without identifying the individual animals providing the competent authority controls movement.

f. Since piglet identification will be infrequent, each country will order its own piglet tags as needed.

2. FMD Vaccination tags shall be pink metal ear tags beginning with "V" followed by alphanumeric identifications. Ear tags are inserted in the proximal third of the anterior border of the animal's ear with the alpha-numeric sequence "out" i.e. the number is on the dorsal surface of the ear.[4]

3. The ear tags are

   a. To be used only for FMD vaccination identification;

   b. Are not considered official for interstate/international movement; and

   c. Do not replace or satisfy the requirements of other program identification that may be required by the country.

4. Each FMD vaccination ear tag or other official means of identification

   a. May NOT be removed from the animal until final disposition;

   b. May NOT be reused or reissued to another animal;

   c. Will be recorded at final disposition of the animal whether it be following natural death, on-farm euthanasia, rendering, or slaughter;

[3] FAD vaccination identification standards will be updated based on identification standards under current development by APHIS and stakeholders.

[4] This may be updated to reflect new animal identification technology, such as radio-frequency identification (RFID) tags for animals, particularly those that will need to be handled multiple times.

d. In the case of swine with building identification, no individual identification shall be required if an exact count of the animal is available, and the animals in the barn are under control by the competent authority with the only option for disposal being destruction.

5. Each country should have a means of enforcement such as a system of fines and penalties to ensure identification provisions.

6. Six million [5 million large (cattle) & 1 million small (sheep, swine)] fluorescent pink metal ear tags beginning with "V" followed by alphanumeric identifications; 96 large pliers and 134 small pliers are stockpiled for the NAFMDVB at the APHIS warehouse 1510 E. Bannister Road, Kansas City, Missouri, USA 64131. Telephone (816) 926-1629, and fax (816) 823-4360.

   a. In the event of an FMD outbreak, the country(ies) infected shall be allocated tags from the stockpile in quantities estimated to coincide with the initial units of vaccine being made available.

   b. A record of vaccination ear tags issued to each country shall be kept at the warehouse.

   c. Replacement ear tags shall be ordered following the outbreak at the expense of the requesting country.

7. Additional ear tags can be manufactured at a minimum rate of 300,000 tags per week. The USDA contract requires the manufacturer to have the capacity to deliver a maximum of 1,500,00 tags a week.

5.16.2.4 FMD VACCINATE RECORDS AND DISPOSITION

This subsection comes from Chapter 9 of the NAFMDVB Guidelines (2007):

1. The identity of each animal and its location at the time of vaccination must be carefully recorded. Required data record fields include:

   a. Owner

   b. Premises location

   c. Animal species

   d. FMD vaccinate ear tag(s)

   e. Officially legislated identification or tattoo

   f. Breed

   g. Sex

   h. Age

   i. Color or markings

   j. Commercial or purebred

k. Registration numbers (if purebreds). In the case of purebred animals, the information on the registration/pedigree certificates must be verified for each animal.

2. Vaccination records should take advantage of existing databases. Collaboration with livestock industry associations is critical but competent authorities in each member country must retain the official secure records for tracing vaccinates. The following fields are required in the official database:

   a. Owner;

   b. Address;

   c. Location (legal land description, +/- GIS coordinates);

   d. Telephone(s);

   e. Email if available;

   f. Vaccination date;

   g. Vaccination team;

   h. Vaccine serial number & expiry date;

   i. All on-farm records animal characteristics-species, sex, age, color, registration (if purebred; FMD Vaccinate Ear Tag; official ear tag (H or A tag, CCIP tag or tattoo); any other unofficial ear tag, brands or electronic implants;

   j. Any licensed movements (origin and destination);

   k. Disposition of animal.

3. Where possible, records should be kept electronically.

4. Vaccinated animals may be:

   a. Euthanized on the infected premises or at other approved location;

   b. Shipped to slaughter for human consumption following required vaccine withdrawal period; or

   c. Entered into the general animal population after an acceptable level of risk is determined. A proper NSP test will be recommended by the Technical Committee for use to determine the level of risk.

5. The decision will be taken by the 3 CVOs.

5.16.2.5 CONTROL MEASURES IN THE VACCINATION ZONE

This subsection is from Chapter 10 of the NAFMDVB Guidelines (2007):

1. Movement within zone during vaccination campaign: The Mexican Secretariat of Agriculture and Rural Development (SAGARPA), the Canadian Food Inspection (CFIA) Agency and the United States Department of Agriculture (USDA) shall ensure that the following

control measures are applied in the vaccination-buffer zone(s) during the period of vaccination until 30 days after last herd is vaccinated as this allows time to remove circulating virus:

a. No movement of animals is permitted onto or from vaccinated premises without appropriate licenses. Upon vaccination, premises are quarantined (under appropriate authority for each country). Movement permit conditions will require that:

   i) No animal in herd of origin has shown clinical signs of FMD within 30 days.

   ii) No additions to herd of origin for 30 days.

   iii) No clinical FMD within 10 km for 30 days.

   iv) A vaccinated animal may only move to another vaccinated premises.

   v) Transport conveyances meet C&D requirements of zone.

b. Vaccinated animals may be moved under license within the vaccination-buffer zone(s) but may not leave the zone except to slaughter.

c. In the absence of an abattoir in the vaccination-buffer or surveillance-buffer zone, vaccinated animals can exceptionally be transported to the nearest abattoir for immediate slaughter at the end of the day provided suitable cleaning & disinfection procedures were followed.

d. Since the carrier state cannot be ruled out, animal products and by-products from vaccinated animals shall be considered potentially infected and their distribution restricted to the infected zone unless treated to OIE standards for FMD destruction.

e. People and service vehicles present the greatest risk for fomite transmission of FMD to hitherto undiagnosed premises. All premises shall implement enhanced biosecurity approved by the competent authority.

f. Trucks used to transport animals or animal products or used to service a farm within the vaccination-buffer zone shall

   i) Have an external cleaning and disinfection at origin prior to departure; and

   ii) A thorough cleaning and disinfection at destination.

g. Trucks used to transport animals or animal products or used to service a farm shall not leave the vaccination-buffer zone without a thorough cleaning and disinfection under official inspection at cleaning and disinfection facility approved by the competent authority.

h. Periodic monitoring of transport carriers should be conducted to determine compliance.

i. Animal service industries personnel including veterinary practitioners, inseminators, feed delivery, transporters working on vaccinated premises in the vaccination-buffer zone shall

   i) Restrict service to that zone since a vaccinated premises can more readily mask the presence of FMD virus than non-vaccinated premises;

   ii) Strictly follow an approved cleaning and disinfection protocol.

j. Semen and embryo collection within vaccination zone shall be suspended unless it is frozen and stored separately for at least 30 days then dispatched only if the vaccinated donors meet conditions stipulated in the Code, Annex 2.1.1.14, Annex 2.1.1.16, and Annex 2.1.1.19 as appropriate.

k. Straw and forage meet conditions stipulated in the Code 2002 Annex 2.1.1.130 and move under permit.

l. All stockyards, auction markets, sales, fairs, zoos, assembly points, and other livestock concentration points shall operate under inspection by the competent authority. Only vaccinated animals under permit may enter such premises in the vaccination-buffer zone under permit.

m. Animals in zoos within the vaccination-buffer zone may be vaccinated pending risk assessment and in line with the Code, Article 2.1.1.5.

n. Any concentration points must be cleaned and disinfected after assembly of animals.

o. Transportation through the vaccination-buffer zone of susceptible (non-vaccinated) animals will be permitted if by shortest direct route and vehicles are sealed by the competent authority.

p. Susceptible wildlife in the vaccination-buffer zone will undergo a risk assessment considering information on

   i) Population density and distribution;

   ii) Social structure; habitat; contact with domestic species;

   iii) FMD virus train and length of time of potential exposure.

   These will be factored into three non-exclusive options

   i) Containment;

   ii) Surveillance and sampling; or

   iii) Population reduction.

   It should be appreciated that wildlife depopulation even on a local area basis is extremely difficult.

2. Surveillance within vaccination zone post-vaccination: The Mexican Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA), the Canadian Food Inspection Agency

(CFIA) and the United States Department of Agriculture (USDA) shall ensure that the following control measures are applied in the vaccination zone(s) during the period between at least 30 days from the time of completion of vaccination until the completion of a clinical and serological survey.

a. A clinical and serological survey shall be carried out with the aim to identify herds of animals of susceptible species that have had contact with FMD virus without clinical signs including:

   i) Clinical inspection of all animals of susceptible animals in the vaccination-buffer zone.

   ii) Serological testing for non-structural protein antibodies or other OIE approved test suitable to detect circulating virus in all vaccinated animals and their non-vaccinated offspring.

b. Any herd found infected through the confirmed presence of FMD virus or previous contact with FMD virus shall be subject to

   i) Destruction of animals positive to the approved test (above);

   ii) Slaughter of the remaining animals under controlled conditions authorized by the competent authorities;

   iii) Decontamination (=cleaning and disinfection) of the premises;

   iv) Restocking according to country's contingency plan;

   v) Tracing and treatment for FMD virus destruction of any products from the estimated time of introduction of FMD virus.

c. Movement of animals, animal products and by-products shall be as for 8.1 with the additions as described below.

d. Movement of non-vaccinated susceptible animals may be authorized at least 6 months after completion of vaccination where vaccinates are not slaughtered or not earlier than three months if vaccinates are slaughtered.

e. Movement of non-vaccinated susceptible animals, offspring of vaccinates shall be restricted to move to:

   i) A slaughterhouse outside the vaccination-buffer zone for immediate slaughter;

   ii) A feedlot from which they are sent directly to slaughter;

   iii) Any premises after a negative serological test for the detection of FMD virus antibody.

3. Movement post-surveillance: Following completion of the serological survey in paragraph 2, The Mexican Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA), the Canadian Food Inspection Agency (CFIA) and the United States Department of Agriculture (USDA) shall ensure that

the following control measures are applied in the vaccination-buffer zone(s):

a. North American trade in vaccinated animals is prohibited except under authorized conditions as outlined below;

b. Movement of animals of susceptible species out of the vaccination-buffer zone may be authorized following Annex 2.1.1.6 bis of the Code where originating and receiving zones are of equivalent Animal Health status and transportation through zones of higher status is in trucks sealed by the competent authority and travelling the shortest distance on a direct route.

4. The above conditions will apply only if all vaccinates are ear tagged, movements of vaccinates remain under veterinary service control until death, and an active program of slaughter of vaccinates is followed.

5.16.2.6 FMD VACCINE DISTRIBUTION

This subsection comes from Chapter 11 of the NAFMDVB Guidelines (2007).

1. The purpose of this Chapter is to propose the criteria for sharing and distribution if more than one Tripartite country wants to use FMD vaccine. This chapter is to be used in conjunction with the North American Guidelines for FMD Vaccine Use Consideration on page.

2. It is assumed that this decision planning would not be necessary unless there were cases of FMD in more than one country or that an outbreak in one country was very near or on the border of a neighboring country.

3. It has been suggested that it may not be in the best interests of a situation to base the availability of vaccine entirely on the 70/20/10 (US/Mexico/Canada) funding ratio.

4. It appears that most of the criteria used in the decision tree for FMD vaccination would also apply to the decision on how to distribute vaccine to more than one country. They are:

   a. Number of susceptible animals in the vaccination zone: to be defined based on the national statistical sources identified by each country. The size of the vaccination zone may vary according to local epidemiological conditions.

   b. Number of affected herds: based on the number of affected herds at the time the decision to vaccinate is taken.

   c. Rate of spread: measure of the number of new cases per week, based on the week the decision to vaccinate is taken.

   d. Geographic spread: the distance separating affected herds or clusters of affected herds provides an indication of the distribution of disease in the vaccination zone.

   e. Number of affected swine herds: swine play an important role in the spread of FMD as they are great amplifiers of the FMD virus.

f. Kind of farms—a description of the predominant species and production systems in the vaccination zone is required.

g. Ability/capacity to depopulate.

h. Density of the susceptible livestock population (herds & animals) in the vaccination zone.

i. Contact rate. Contact rates the susceptible livestock in the infected zone may have to be based on quite a bit of subjectivity. Some factors that affect contact rates would be the time of year, weather, farm crop harvesting, density of livestock, and presence of livestock markets in the area.

j. Natural barriers—well defined and easily controlled access; few or many points of entry and exit.

k. Free-ranging wildlife involvement.

l. Climate—warm and dry versus cold, a relatively high humidity, and slow/steady winds.

5. There would have to be agreement on what livestock population data are to be used and how it will be obtained. Once FMD has been diagnosed and a decision made to vaccinate, there may not be time to organize and send out survey crews to establish a current livestock population estimate.

   a. Canada would use the Statistics Canada Census of Agriculture completed every five years. The last census was carried out in 2001.

   b. The United States would base their estimates on the Department of Agriculture (USDA) National Agricultural Statistics Service (NASS) published yearly and the Census of Agriculture published every 5 years.

   c. Mexico would use data gathered by SAGARPA Delegations in each state as the most likely source of population data.

6. If the NAFMDVB will provide immediate support based on the official estimates of the susceptible livestock population in each vaccination zone, no other criterion may need to be considered. If there is not enough vaccine immediately available, then the other criteria would be used.

7. The decision criteria for vaccinate distribution should be applied when

   a. Two or more concurrent outbreaks occur in more than one country;

   b. The number of susceptible species in the vaccination zone exceeds the number of doses present in the bank and commercially produced vaccine of the appropriate subtype is not available.

8. Table 5-8 shows the proposed rating system for distribution of vaccine:

Table 5-8. Scoring System for Vaccine Distribution Decision Based on Criteria Related to Outbreak (from Chapter 11 NAFMDVB Guidelines)

Criteria in order of impact priority	High	Medium	Low
Number of susceptible animals in vaccination zone. High = >500,000 Medium = 250,00 - 500,000 Low = <250,000	25	20	15
Number of affected herds in the infected zone. High = 5 or more Medium = 3 or 4 Low = 1 or 2	25	20	15
Rate of spread in the infected zone. High = > 7 cases per wk. Medium = 3 to 7 cases per wk. Low = < 3	25	20	15
Geographic spread of affected herds. High = 2 or more outbreaks separated by > or = 10 km Medium = 2 or more affected herds less than 10 km apart Low = 1 affected herd	25	20	15
Number of affected swine herds in the infected zone. High = 2 or more infected swine herds Med. = 1 swine herd Low = 0 swine	25	20	0
Kinds of farms in the vaccination zone. High = swine predominant in the zone Medium = Bovine herds predominant in the zone Low = sheep/goats predominant in the zone	25	20	15
Ability/capacity to depopulate. High = on-farm disposal not possible; capacity of 1 small herd per day Medium = on-farm disposal possible but limited capacity of 2 small herds per day Low = on-farm disposal possible; capacity of 2 large herds per day	20	15	10
Density of livestock in the vaccination zone. High = >1 per acre (>2.5/Ha) Medium = 1/2 to 1 per acre (1.2-2.5/Ha) Low = < 1/2 per acre (<1.2/Ha)	15	10	5
Density of herds in the vaccination zone. High = 5 or more herds per 3 sq. km. (about 1 sq. mile) Medium = 1 - 4 herds per 3 sq. km. Low = < 1 herd per 3 sq. km.	15	10	5
Contact rate. High = > 10 per wk. Medium = 5 to 10 per wk. Low = less than 5	15	10	5
Natural barriers. High = affected area is in a flat mainland area with many roads and traffic Medium = some presence of barriers such as major river or major mountain range Low = very isolated area such as a desert, island, or isthmus	15	10	5
Wildlife involvement. High = wild swine in the zone Medium = wild ruminants in the zone but no swine Low = no wildlife involvement	10	5	0
Climate. High = cold, relative humidity at 60 % or above, slow/steady winds Medium = cold, relative humidity 40 to 59%, moderate/variable winds Low = warm, dry, strong/straight winds	5	3	1
Totals of Ratings	245	183	106

a. Example:

   i) Country A and Country B both have outbreaks and both want to vaccinate at the same time.

   ii) Each country is rated (scored) on each of the criterion by the same small committee of experts. Country A receives a total score of 215. Country B received a total score of 195. 215+195=410.

   iii) Country A would receive 52% (215/410) of the doses and country B would receive 48% (195/410).

   iv) It is suggested that the committee be made up of three epidemiologists, one from each of the three tripartite countries.

   v) The objective for the committee is to present objective information as an aid to the decision makers.

b. Example with more than one vaccination zones in a country:

   i) Country A and Country B both have outbreaks and both want to vaccinate at the same time.

   ii) Country B has two distinct infected zones and two distinct vaccination zones.

   iii) Each country is rated (scored) on each of the criterion by the same small committee of experts. Country A receives a total score of 215. Country B received a total score of 300 (120 for Vaccination zone 1 and 180 for Vaccination zone 2). 215+300=515.

   iv) Country A would receive 42% (215/515) of the doses and Country B would receive 58% (300/515). Within Country B, Vaccination zone 1 would receive 40% (120/300) and vaccination zone 2 would receive 60% (180/300) of the vaccine.

5.16.3 Zone, Area, and Premises Designations

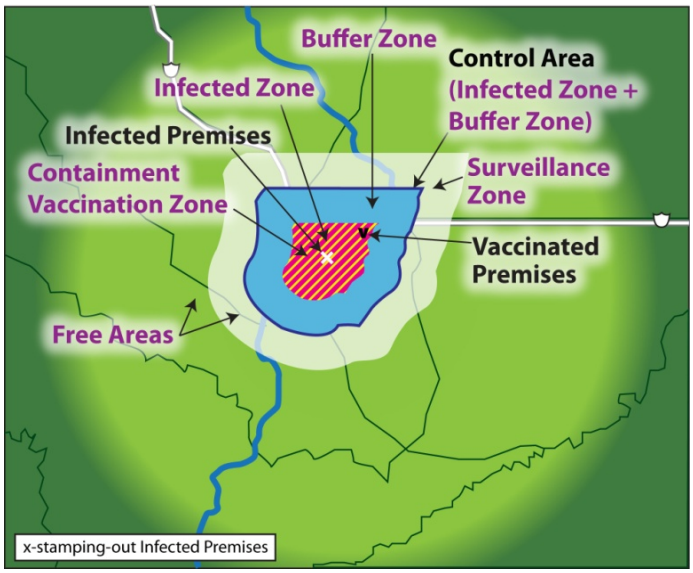
Also provided in Chapter 4 of this document, this subsection provides figures to illustrate the use of emergency vaccination in an FMD outbreak.

5.16.3.1 Containment Vaccination Zone

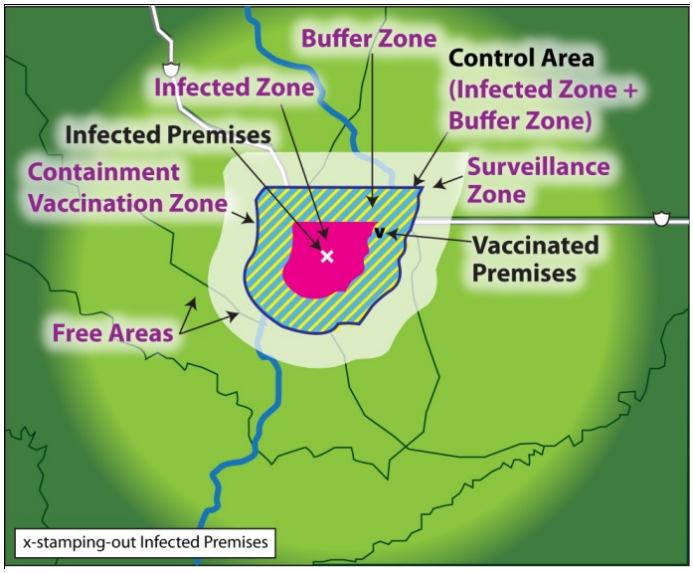
The CVZ is an emergency vaccination zone typically within the CA, and may include the IZ and/or the BZ. A CVZ is typically observed in stamping-out modified with emergency vaccination to slaughter. Figure 5-6 shows examples of a CVZ.

Figure 5-6. Examples of Containment Vaccination Zones

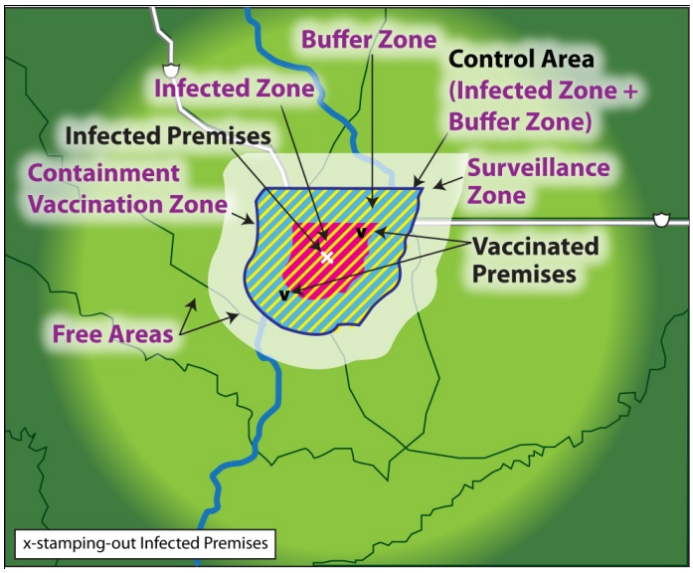
Emergency Vaccination in Infected Zone



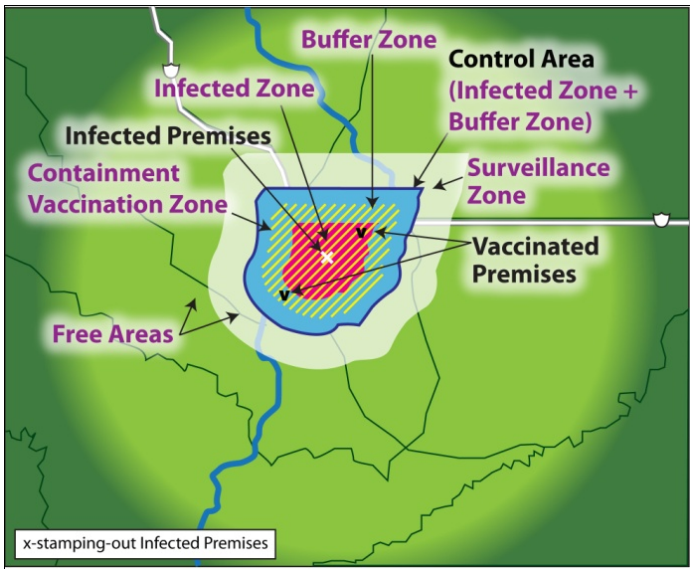
Emergency Vaccination in Buffer Zone



Emergency Vaccination in Control Area



Emergency Vaccination in IZ and Partial BZ



Note: Figures are not to scale.

5.16.3.2 PROTECTION VACCINATION ZONE

The PVZ is an emergency vaccination zone in the FA. It is consistent with the OIE *Terrestrial Animal Health Code (2011)* definition for a Protection Zone:

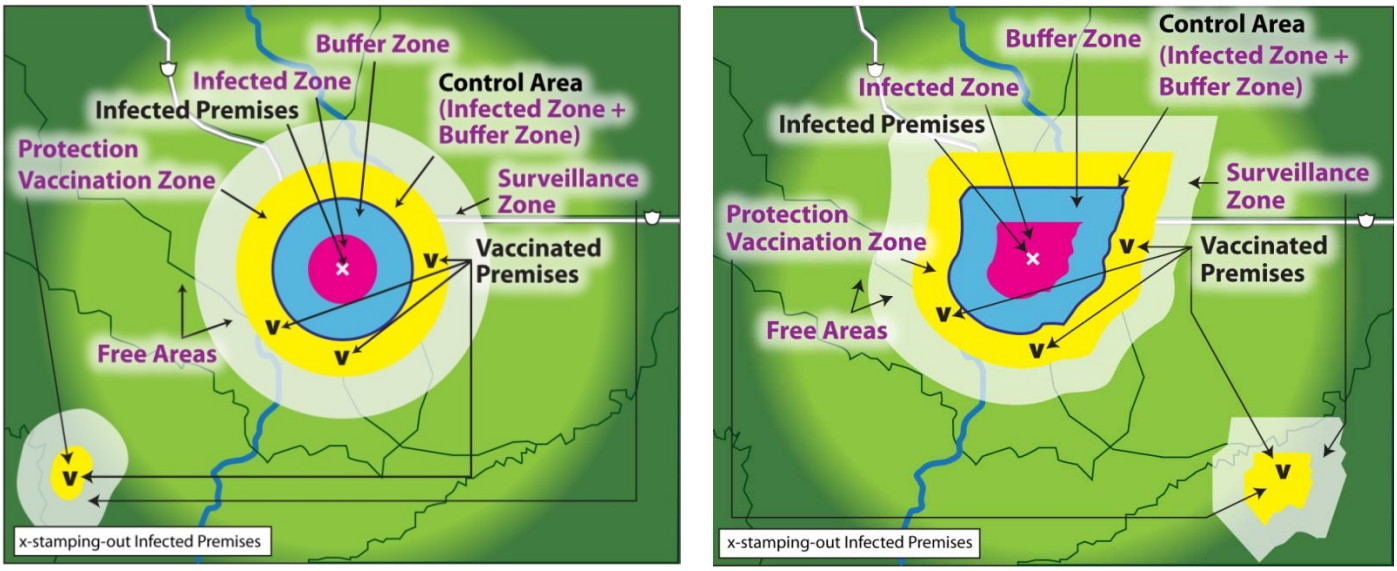
> A zone established to protect the health status of animals in a free country or free zone, from those in a country or zone of a different animal health status, using measures based on the epidemiology of the disease under consideration to prevent spread of the causative pathogenic

agent into a free country or free zone. These measures may include, but are not limited to, vaccination, movement control and an intensified degree of surveillance.

Typically, a PVZ would be observed with stamping-out modified with emergency vaccination to live. Figure 5-7 shows examples of a PVZ.

Figure 5-7. Examples of Protection Vaccination Zones

Circle *Irregular*



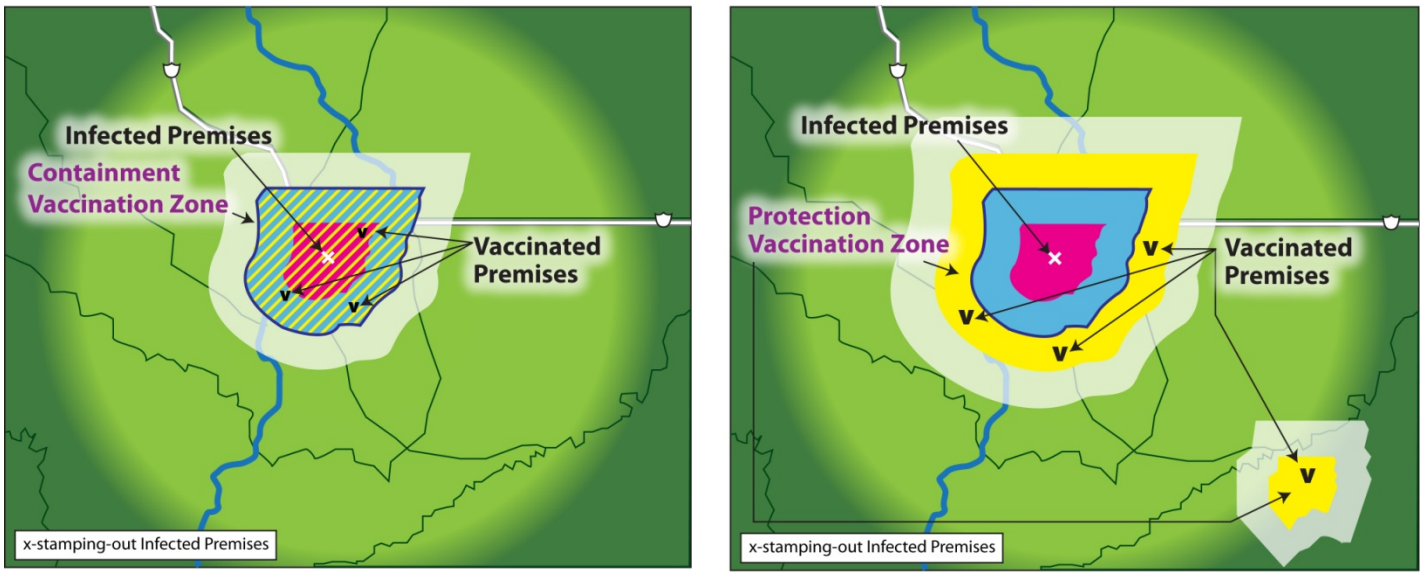
Note: Figures are not to scale.

5.16.3.3 VACCINATED PREMISES

VP may be a secondary designation to another premises designation and is only used if emergency vaccination is employed in an outbreak. A VP may be located in a CVZ within the CA (IZ or BZ) or in a PVZ in the FA. Figure 5-8 shows VP in a CVZ (left) and in a PVZ (right).

Figure 5-8. Vaccinated Premises

Containment Vaccination Zone *Protection Vaccination Zone*



Note: Figures are not to scale.

5.16.4 Movement Restrictions for Vaccinates

If emergency vaccination is used, a vaccination plan will define procedures to prevent the spread of FMD by vaccination teams. Emergency vaccination occurs within a CVZ or a PVZ. All vaccinated animals may be identified with specific and permanent (tamper-proof) identification. When vaccine is used, surveillance must continue to assess vaccination effectiveness and detect any antigenic change. Movement restrictions for vaccinates are as follows.

- VP may be subject to movement restrictions for their primary premises designation.
- Animals receiving emergency vaccination on the VP may be subject to vaccinated animal identification, vaccinated animal traceability, and DIVA testing.
- For movement of emergency vaccinated animals, consideration must be given to any national or international standards or conditions for such movement.

5.16.5 Cessation of Vaccination

FMD emergency vaccination should cease as soon as possible to allow the region or State to return quickly to a favorable trade status. No new vaccinations will be given more than 28 days after the last known new case of FMD is detected.

The NAFMDVB Guidelines, NAHEMS Guidelines: Vaccination for Contagious Diseases, and FMD Vaccination SOP contain further guidance.

5.17 National Veterinary Stockpile

The Overview of the NVS SOP provides information on NVS capabilities and lays out the required steps to request countermeasures from the NVS. It also provides a direct link to the NVS website, where State preparedness officials and responders can download important publications to help them understand the NVS. This website provides

- a planning guide for Federal, State, and local authorities;
- a template for a State NVS plan; and
- outreach and exercise programs.

The NVS also has contractor support for 3D activities, which can be requested through IC. The surge response capacity of 3D commercial responders is a response to the site within 24 hours, 500–600 people within 72 hours, and 1,000 people within a week.

5.18 Wildlife Management and Vector Control

USDA APHIS will work in close collaboration, communication, and coordination with DOI and other Federal, State, Tribal, and local wildlife agencies that have primary jurisdictional authority and subject matter expertise for wildlife. This collaboration, communication, and coordination will occur in both the Unified Command and MAC Groups.

The Overview of Wildlife Management and Vector Control SOP also discusses personnel and equipment required for wildlife management, quarantine and movement control for wildlife, wildlife risk assessment, wildlife surveillance, and related activities. Further information can also be found in the NAHEMS Guidelines: Wildlife Management and Vector Control.

5.18.1 Wildlife Management

A wildlife management plan that addresses both captive and free-ranging wildlife will be developed as soon as possible after identification of the index case in livestock. An assessment of the risk that wildlife poses for the transmission of FMDV to susceptible livestock will be conducted within 7 days of

confirmation of the index case. Assessment of the risks posed by wildlife will require information on

- density and distribution,
- social organization,
- habitat,
- contact with domestic livestock, and
- length of time wild animals could have been exposed to the virus.

If wildlife populations are determined to be infected with FMDV or otherwise pose a biological risk for transmission, appropriate wildlife management principles will be applied as needed to reduce exposure of wildlife to livestock. If wildlife populations are determined not to be infected or be a biological risk for transmission of FMDV to livestock, wildlife management tools will be implemented to keep wildlife populations from acting as mechanical vectors.

5.18.2 Vector Control

FMD can be transmitted mechanically by mice, vultures, and other vectors. To-date, there is no evidence that insects can biologically transmit the FMDV to susceptible animals. Appropriate biosecurity measures should be in place during an FMD outbreak to ensure that mechanical vectors do not have contact with infected herds or other infected material.

5.19 Animal Welfare

During an FMD outbreak, humane treatment must be provided to animals given the specific circumstances of the outbreak, particularly from the time they are identified for destruction or vaccination activities until they are depopulated, euthanized, or slaughtered, as prescribed by veterinary authorities of the affected States or Tribal nations. The Overview of Animal Welfare SOP contains additional information.

5.20 Modeling and Assessment Tools

The development of models and risk assessments are critical in a successful FMD response. These tools give decision makers valuable insight. During an outbreak, one or more multidisciplinary teams (consisting of epidemiologists, disease agent experts, economists, affected commodity experts, and others) will be established to perform risk assessments as needed. An appropriate, scientific risk assessment on an issue of concern will be provided within 72 hours after a request from the Incident Commander.

For FMDV, the Tool for the Assessment of Intervention Options (TAIO) may be used prior to an outbreak to inform strategy decisions. TAIO provides decision makers with additional information on the most efficacious, feasible, and cost-effective approach to manage the response effort. More information about TAIO is available from the CEAH (http://www.aphis.usda.gov/about_aphis/programs_offices/veterinary_services/ceah.shtml).

The Overview of Modeling and Assessment Tools SOP provides information on modeling and risk assessment, covering the following:

- Key roles and responsibilities in modeling and risk analysis
- Uses of epidemiological models
- Proactive risk assessments
- Risk assessment during and after an outbreak
- Examples of current models and assessment tools.

5.21 APPRAISAL AND COMPENSATION

Indemnity payments are to encourage disease reporting, reduce the spread of animal disease, and compensate owners on the basis of fair market value. Fair market value appraisals are provided to owners of destroyed animals and materials. The FMD Appraisal and Compensation SOP focuses on specifying personnel responsibilities, appraisal procedures, assessment of compensation eligibility, payment of indemnity, and required forms and reports during an FMD outbreak.

The AHPA gives APHIS authority to establish and implement an indemnification program to prevent or eradicate an FMD outbreak. Indemnity is a key component of APHIS's disease control programs in that the promise of fair compensation for losses helps to ensure cooperation from the owners of affected livestock. Such cooperation is important for rapid disease control and eradication.

The best practices for containment and eradication of FMD will in many instances require depopulation, disposal, and decontamination that are faster than can be achieved with slow appraisal processes. In some circumstances, appraisals will not be required to be signed prior to destruction if APHIS and the cooperating State agree that the livestock must be destroyed immediately to mitigate the potential spread or amplification of FMDV during a response to a confirmed or presumptive FMD incident. Data required to determine fair market value will be collected prior to depopulation, including a complete inventory of livestock being destroyed and any relevant value information.

The following resources offer additional guidance on appraisal and compensation:

- APHIS's Livestock Appraisal, Indemnity, and Compensation Website (http://www.aphis.usda.gov/animal_health/emergingissues/compensation/comp.shtml).
- NAHEMS Guidelines: Appraisal and Compensation.
- FMD Appraisal and Compensation SOP.

5.22 FINANCE

During an FMD outbreak, funding will be rapidly required. For responding to specific emergency situations, VS has access to a variety of sources for funding. The two most common sources are the Commodity Credit Corporation (CCC) and the APHIS Contingency Fund (CF).

During an emergency, the Secretary is authorized to transfer funds from the CCC. The funds are provided to APHIS as no-year funds. Before APHIS can ask the Secretary to transfer funds, however, it must consider whether it can redirect funds from a budget line item or if other funding sources are available. APHIS will consider the total estimated amount of funding needed to address the issue and whether the program has political support prior to deciding whether or not to seek a CCC transfer.

The APHIS CF takes care of unforeseen, unpredictable program activities. The following four conditions must exist to qualify for the release of agency contingency funds:

1. The outbreak must pose an economic threat.
2. Eradication technology must be feasible and cost-effective.
3. No program or no effective program must currently exist.
4. The proposed program must have industry support.

The Overview of Finance SOP contains additional guidance on

- key roles and responsibilities in finance,
- emergency funding processes for foreign animal disease outbreaks, and
- triggering events for APHIS emergency funding.

5.23 National Response Framework and National Incident Management System

In any FMD outbreak, the capability to rapidly scale up the size of an IC and integrate veterinary functions and countermeasures is critical for an effective response. NRF and NIMS, already discussed in this plan, allow such scalability. The Overview of NRF and NIMS SOP provides additional information on the relation of NRF and NIMS to APHIS and lists the responsibilities of Federal, State, Tribal, and local governments in an FMD outbreak.

The FAD PReP SOPs and NAHEMS Guidelines referenced in this chapter can be found, for APHIS employees, at http://inside.aphis.usda.gov/vs/em/fadprep.shtml, or, for others, at https://fadprep.lmi.org.

Chapter 6
Recovery after an FMD Outbreak

6.1 PROOF OF FREEDOM

6.1.1 Recognition of Disease-Free Status

In May 1994, the World Assembly of Delegates of the OIE requested the Foot-and-Mouth Disease and Other Epizootics Commission (now called the Scientific Commission for Animal Diseases) to develop a procedure for OIE to officially recognize the FMD-free status of members. In 1998, an official agreement (Agreement on the Application of Sanitary and Phytosanitary Measures) between the World Trade Organization and the OIE further confirmed the OIE's mandate to recognize disease-free areas for trade purposes.

Any member that wishes to be included in the list of disease-free countries or to change its status (for example, to move from the list of countries or zones free where vaccination is practiced to the list of countries or zones where vaccination is not practiced) sends a request to the OIE director general, accompanied by specific documentation and the relevant questionnaires for FMD. The director general then submits the request to the scientific commission for evaluation.

6.1.2 Criteria Needed for FMD-Free Status

There are six OIE official recognitions for FMD: (1) FMD-free country where vaccination is not practiced; (2) FMD-free country where vaccination is practiced; (3) FMD-free zone where vaccination is not practiced; (4) FMD-free zone where vaccination is practiced (this zone can be established in either an FMD-free country where vaccination is not practiced or in a country of which parts are infected); (5) FMD-free compartment; and (6) FMD-infected country or zone. The criteria for these recognitions are listed in the OIE *Terrestrial Animal Health Code (2011).*

6.1.2.1 RECOVERY OF FREE STATUS

There are separate requirements for the recovery of free status in previously FMD-free countries. These requirements, listed below, are taken from Article 8.5.9 of the OIE *Terrestrial Animal Health Code (2011)*.

1. When an FMD outbreak or FMDV infection occurs in an FMD free country or zone where vaccination is not practiced, one of the

following waiting periods is required to regain the status of FMD free country or zone where vaccination is not practiced:

a. three months after the last case where a stamping-out policy and serological surveillance are applied in accordance with Articles 8.5.42 to 8.5.49; or

b. three months after the slaughter of all vaccinated animals where a stamping-out policy, emergency vaccination and serological surveillance are applied in accordance with Articles 8.5.42 to 8.5.47 and Article 8.5.49; or

c. six months after the last case or the last vaccination (according to the event that occurs the latest), where a stamping-out policy, emergency vaccination not followed by the slaughtering of all vaccinated animals, and serological surveillance are applied in accordance with Articles 8.5.42 to 8.5.47 and Article 8.5.49, provided that a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of infection in the remaining vaccinated population.

Where a stamping-out policy is not practiced, the above waiting periods do not apply, and Article 8.5.2 or 8.5.4 applies.

2. When an FMD outbreak or FMDV infection occurs in an FMD free country or zone where vaccination is practiced, one of the following waiting periods is required to regain the status of FMD free country or zone where vaccination is practiced:

   a. 6 months after the last case where a stamping-out policy, emergency vaccination and serological surveillance in accordance with Articles 8.5.42 to 8.5.47 and Article 8.5.49 are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation; or

   b. 18 months after the last case where a stamping-out policy is not applied, but emergency vaccination and serological surveillance in accordance with Articles 8.5.42 to 8.5.47 and Article 8.5.49 are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation.

3. When a FMD outbreak or FMDV infection occurs in a FMD free compartment, Article 8.5.6 applies.

6.1.2.2 FMD-FREE COUNTRY WHERE VACCINATION IS NOT PRACTICED

The following text is taken from Article 8.5.2 of the OIE *Terrestrial Animal Health Code (2011)*:

> Susceptible animals in the FMD-free country where vaccination is not practiced should be protected from neighboring infected countries by the application of animal health measures that effectively prevent the entry of the

virus, taking into consideration physical or geographical barriers. These measures may include a protection zone.

To qualify for inclusion in the existing list of FMD-free countries where vaccination is not practiced, a Member should:

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that:
    a. there has been no outbreak of FMD during the past 12 months;
    b. no evidence of FMDV infection has been found during the past 12 months;
    c. no vaccination against FMD has been carried out during the past 12 months;
    d. no vaccinated animal has been introduced since the cessation of vaccination;
3. supply documented evidence that:
    a. surveillance for both FMD and FMDV infection in accordance with Articles 8.5.42 and 8.5.47 and Article 8.5.49 is in operation;
    b. regulatory measures for the early detection, prevention and control of FMD have been implemented.
4. describe in detail the boundaries and measures of a protection zone, if applicable.

The Member will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 2, 3, and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

6.1.2.3 FMD-FREE COUNTRY WHERE VACCINATION IS PRACTICED

The following text is taken from Article 8.5.3 of the OIE *Terrestrial Animal Health Code (2011)*:

Susceptible animals in the FMD free country where vaccination is practiced should be protected from neighboring infected countries by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a protection zone.

To qualify for inclusion in the list of FMD free countries where vaccination is practiced, a Member should:

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that:
    a. there has been no outbreak of FMD during the past two years;

b. no evidence of FMDV circulation has been found during the past 12 months;

3. supply documented evidence that:

   a. surveillance for FMD and FMDV circulation in accordance with Articles 8.5.42 and 8.5.47 and Article 8.5.49 is in operation;

   b. regulatory measures for the early detection, prevention and control of FMD have been implemented;

   c. routine vaccination is carried out for the purpose of the prevention of FMD;

   d. the vaccine used complies with the standards described in the Terrestrial Manual;

4. describe in detail the boundaries and measures of a protection zone, if applicable.

The Member will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 2, 3, and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

If a Member that meets the requirements of a FMD free country where vaccination is practiced wishes to change its status to FMD free country where vaccination is not practiced, the status of this country remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV infection has not occurred during that period.

6.1.2.4 FMD-FREE ZONE WHERE VACCINATION IS NOT PRACTICED

The following text is taken from Article 8.5.4 of the OIE *Terrestrial Animal Health Code (2011)*:

An FMD free zone where vaccination is not practiced can be established in either an FMD free country where vaccination is practiced or in a country of which parts are infected. In defining such zones, the principles of Chapter 4.3 should be followed. Susceptible animals in the FMD free zone should be protected from the rest of the country and from neighboring countries if they are of a different animal health status by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a protection zone.

To qualify for inclusion in the list of FMD free zones where vaccination is not practiced, a Member should:

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that within the proposed FMD free zone:

a. there has been no outbreak of FMD during the past 12 months,

b. no evidence of FMDV infection has been found during the past 12 months;

c. no vaccination against FMD has been carried out during the past 12 months;

d. no vaccinated animal has been introduced into the zone since the cessation of vaccination, except in accordance with Article 8.5.10;

3. supply documented evidence that:

a. surveillance for FMD and FMDV infection in accordance with Articles 8.5.42 to 8.5.47 and Article 8.5.49 is in operation;

b. regulatory measures for the early detection, prevention and control of FMD have been implemented;

4. describe in detail and supply documented evidence that these are properly implemented and supervised:

a. the boundaries of the proposed FMD free zone,

b. the boundaries and measures of a protection zone, if applicable,

c. the system for preventing the entry of the virus (including the control of the movement of susceptible animals) into the proposed FMD free zone (in particular if the procedure described in Article 8.5.10 is implemented).

The proposed free zone will be included in the list of FMD free zones where vaccination is not practiced only after the submitted evidence has been accepted by the OIE.

The information required in points 2, 3, and 4b)-c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

6.1.2.5 FMD-FREE ZONE WHERE VACCINATION IS PRACTICED

The following text is taken from Article 8.5.5 of the OIE *Terrestrial Animal Health Code (2011)*:

An FMD free zone where vaccination is practiced can be established in either an FMD free country where vaccination is not practiced or in a country of which parts are infected. In defining such zones, the principles of Chapter 4.3 should be followed. Susceptible animals in the FMD free zone where vaccination is practiced should be protected from neighboring countries or zones if they are of a lesser animal health status by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a protection zone.

To qualify for inclusion in the list of FMD free zones where vaccination is practiced, a Member should:

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE that within the proposed FMD free zone;
    a. there has been no outbreak of FMD for the past 2 years;
    b. no evidence of FMDV circulation has been found during the past 12 months;
3. supply documented evidence that:
    a. surveillance for FMD and FMDV infection/circulation in accordance with Articles 8.5.42 and 8.5.47 and Article 8.5.49 is in operation;
    b. regulatory measures for the early detection, prevention, and control of FMD have been implemented;
    c. routine vaccination is carried out for the purpose of the prevention of FMD;
    d. the vaccine used complies with the standards described in the Terrestrial Manual;
4. describe in detail and supply documented evidence that these are properly implemented and supervised:
    a. the boundaries of the proposed FMD free zone,
    b. the boundaries and measures of a protection zone, if applicable,
    c. the system for preventing the entry of the virus (including the control of the movement of susceptible animals) into the proposed FMD free zone (in particular if the procedure described in Article 8.5.10 is implemented).

The proposed free zone will be included in the list of FMD free zones where vaccination is practiced only after the submitted evidence has been accepted by the OIE. The information required in points 2, 3, and 4b)-c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

If a Member that has a zone which meets the requirements of a FMD free zone where vaccination is practiced wishes to change the status of the zone to FMD free zone where vaccination is not practiced, the status of this zone remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV infection has not occurred in the said zone during that period.

6.1.2.6 FMD-FREE COMPARTMENT

The following text is taken from Article 8.5.6 of the OIE *Terrestrial Animal Health Code (2011)*:

> An FMD free compartment can be established in either a FMD free country or zone or in an infected country or zone. In defining such a compartment the principles of Chapters 4.3 and 4.4 should be followed. Susceptible animals in the FMD free compartment should be separated from any other susceptible animals by the application of an effective biosecurity management system.
>
> A Member wishing to establish a FMD free compartment should:
>
> 1. have a record of regular and prompt animal disease reporting and if not FMD free, have an official control program and a surveillance system for FMD in place according to Articles 8.5.42 to 8.5.47 and Article 8.5.49 that allows an accurate knowledge of the prevalence of FMD in the country or zone;
> 2. declare for the FMD free compartment that:
>   a. there has been no outbreak of FMD during the past 12 months;
>   b. no evidence of FMDV infection has been found during the past 12 months;
>   c. vaccination against FMD is prohibited;
>   d. no animal vaccinated against FMD within the past 12 months is in the compartment;
>   e. animals, semen, and embryos should only enter the compartment in accordance with relevant articles in this chapter;
>   f. documented evidence should that surveillance in accordance with Articles 8.5.42 to 8.5.47 and Article 8.5.49 is in operation for FMD and FMDV infection;
>   g. an animal identification and traceability system in accordance with Chapters 4.1 and 4.2 is in place;
> 3. describe in detail the animal subpopulation in the compartment and the biosecurity plan for FMD and FMDV infection.
>
> The compartment should be approved by the Veterinary Authority. The first approval should only be granted when no outbreak of FMD has occurred within the zone in which the compartment is situated, during the last three months.

6.1.2.6.1 FMD-Free Compartments

There are no OIE-recognized FMD-free compartments in the world. An FMD compartment is unlikely to be established in an FMD outbreak in the United States.

6.1.2.7 FMD INFECTED COUNTRY OR ZONE

The following text is taken from Article 8.5.7 of the OIE *Terrestrial Animal Health Code (2011)*:

> For the purposes of this chapter, an FMD infected country is a country that does not fulfill the requirements to qualify as either an FMD free country where vaccination is not practiced or an FMD free country where vaccination is practiced.
>
> For the purposes of this chapter, an FMD infected zone is a zone that does not fulfill the requirements to qualify as either an FMD free zone where vaccination is not practiced or an FMD free zone where vaccination is practiced.

6.1.3 Surveillance for Recognition of Disease-Freedom

Surveillance is fundamental in proving DF to regain disease-free status after an FMD outbreak. The OIE *Terrestrial Animal Health Code (2011)* specifies surveillance procedures for members re-applying for recognition of freedom from FMD for the whole country or zone where vaccination is either practiced or not practiced, following an outbreak. General OIE surveillance guidelines are provided in Article 8.5.43.

The following text is taken from Article 8.5.47 of the OIE *Terrestrial Animal Health Code (2011)*:

> In addition to the general conditions described in the above-mentioned articles, a country re-applying for country or zone freedom from FMD where vaccination is practiced or not practiced should show evidence of an active surveillance program for FMD as well as absence of FMDV infection/circulation. This will require serological surveillance incorporating, in the case of a country or a zone practicing vaccination, tests able to detect antibodies to NSPs as described in the Terrestrial Manual.
>
> Four strategies are recognized by the OIE in a program to eradicate FMDV infection following an outbreak:
>
> 1. slaughter of all clinically affected and in-contact susceptible animals;
> 2. slaughter of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, with subsequent slaughter of vaccinated animals;
> 3. slaughter of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, without subsequent slaughter of vaccinated animals;
> 4. vaccination used without slaughter of affected animals or subsequent slaughter of vaccinated animals.
>
> The time periods before which an application can be made for re-instatement of freedom from FMD depend on which of these alternatives is followed. The time periods are prescribed in Article 8.5.9.

> In all circumstances, a Member re-applying for country or zone freedom from FMD with vaccination or without vaccination should report the results of an active surveillance program implemented according to general conditions and methods in this Chapter.

The use and interpretation of serological tests is covered in Article 8.5.49 of the OIE *Terrestrial Animal Health Code (2011)* and in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (2011).* These sections discuss serological tests for both structural proteins and NSP. Tests for structural proteins are serotype specific and include structural protein-ELISAs and the VNT. Tests for NSP antibodies include the 3ABC Prionics ELISA, which is conducted by NVSL-FADDL. Additional information on diagnostic testing is provided in Chapter 5, and in the aforementioned OIE documents.

6.1.4 Release of Control Area Restrictions

Quarantine and movement control restrictions will be maintained until at least 28 days have elapsed since the decontamination of all confirmed IP and negative results of surveillance activities. IC and animal health officials need to plan for a release of quarantine prior to or during the issuance of quarantine and movement controls. Such a plan would specify procedures by which quarantined premises will be evaluated for FMD freedom and how the quarantine will be released (by sections, by risk, or in its entirety).

6.1.5 Disposition of Vaccinates

If vaccination was used in the outbreak, FMD vaccinates will still be subject to movement control and monitoring measures.

6.1.6 Country Freedom Declaration

The United States will apply to the OIE after meeting OIE requirements. FMD-free status will require a formal submission detailing FMD policy, eradication procedures, surveillance, monitoring and tracing of vaccinates, and veterinary infrastructure. Acceptance of the claim for country freedom may also involve an inspection by an international panel to review the eradication program and all available information.

6.2 REPOPULATION

6.2.1 Restocking Guidance

Following appropriate cleaning and disinfection procedures, IP will remain vacant for a period of time before restocking susceptible animals onto premises. The minimum recommendation is 21 days (used by the United Kingdom in the Foot-and-Mouth Disease Order, 2006) to 28 days (two OIE incubation periods). If it is

not possible to carry out full cleaning and disinfection procedures, the premises must remain vacant for a longer period of time to be determined by the IC. It is critically important that in restocking, the IC consider the likelihood of FMDV survival based on environmental conditions, the execution of cleaning and disinfection procedures, and specific circumstances of the outbreak. In some cases, previously IP may need to remain vacant for significantly longer than 28 days.

The producer should provide a restocking plan, including details of the susceptible species, number of animals, and locations of sentinel animals. Once introduced to the previously IP, no animals may leave until all locations on that premises have been restocked and serological diagnostics are negative. Replacing the slaughtered or depopulated animals with the same species is unnecessary—any FMD susceptible species is appropriate, though the use of sheep as sentinel animals should be discouraged.

Non-susceptible species also must be restocked a minimum of 21–28 days after full cleaning and disinfection procedures, as non-susceptible species can act as mechanical vectors for FMDV. The IC has the discretion to consider the risk of non-susceptible animals and make appropriate considerations for these species.

6.2.2 Testing Requirements for Restocking

During restocking, animals will be subject to clinical inspection every 3 days for the first 14 days (one OIE incubation period), and once per week thereafter up to 28 days (two OIE incubation periods). At 28 days *after the last* animals are introduced, each animal must be clinically examined by a veterinary inspector and samples tested for the presence of FMDV antibodies.

6.2.3 Approved Sources of Livestock

Introduced livestock must be derived from areas not subject to quarantine and movement control measures. All livestock must test negative before introduction. A 24-hour pre-movement clinical inspection is also required. Animals must originate on and come from premises on which there has not been a confirmed case of FMD within 6.2 miles (10 kilometers) for at least 30 days.

Appendix A
FAD PReP Materials to Support FMD Response

This appendix lists the Foreign Animal Disease Preparedness and Response Plan (FAD PReP) documents that directly support this *Foot-and-Mouth Disease (FMD) Response Plan (June 2012)*, and also provides an overview of the goals and mission of FAD PReP. The new and revised documents listed below will be useful in preparedness and response efforts related to FMD. Many of these documents have been released; others are forthcoming. These resources are found online at https://fadprep.lmi.org, and also for Animal and Plant Health Inspection Service (APHIS) employees at http://inside.aphis.usda.gov/vs/em/fadprep.shtml.

FMD Continuity of Business Planning

Secure Milk Supply Plan

Secure Pork Supply Plan

FMD Standard Operating Procedures (SOPs)—Critical Activities

These documents are templates to provide a common picture or set of procedures for the following tools and strategies used in FMD response:

1. Overview of Etiology and Ecology
2. Case Definition Development Process
3. Surveillance
4. Diagnostics (Sample Collection, Surge Capacity, and Reporting)
5. Epidemiological Investigation and Tracing
6. Overview of Information Management
7. Communications
8. Health and Safety and Personal Protective Equipment
9. Biosecurity

10. Quarantine and Movement Control
11. Continuity of Business
12. Overview of Regionalization for International Trade
13. Mass Depopulation and Euthanasia
14. Disposal
15. Cleaning and Disinfection
16. Vaccination
17. Overview of the National Veterinary Stockpile
18. Overview of Wildlife Management and Vector Control
19. Overview of Animal Welfare
20. Overview of Modeling and Assessment Tools
21. Appraisal and Compensation
22. Overview of Finance
23. Overview of the National Response Framework and National Incident Management System.

INDUSTRY MANUAL

- Swine
- Cow-Calf
- Dairy
- Beef Feedlot.

NATIONAL ANIMAL HEALTH EMERGENCY MANAGEMENT SYSTEM (NAHEMS) GUIDELINES

- Health and Safety
- Personal Protective Equipment
- Biosecurity

- Quarantine and Movement Control
- Mass Depopulation and Euthanasia
- Disposal
- Cleaning and Disinfection
- Vaccination for Contagious Diseases
- Wildlife Management and Vector Control
- Appraisal and Compensation
- National Animal Health Emergency Response Corp (NAHERC) Deployment Guide
- Surveillance, Epidemiology, and Tracing
- Regionalization for International Trade for a U.S. FAD Response
- Continuity of Business.

STRATEGIC PLANS-CONCEPT OF OPERATIONS

- APHIS Foreign Animal Disease Framework: Roles and Coordination (FAD PReP Manual 1-0)
- APHIS Foreign Animal Disease Framework: Response Strategies (FAD PReP Manual 2-0)
- NCAHEM (National Center for Animal Health Emergency Management) Stakeholder Coordination and Collaboration Resource Guide
- NCAHEM Incident Coordination Group Plan.

OVERVIEW OF FAD PREP

FAD PReP Mission and Goals

The significant threat and potential consequences of FADs and the challenges and lessons-learned of effective and rapid FAD response have led to the development of the Foreign Animal Disease Preparedness and Response Plan, also known as "FAD PReP." The mission of FAD PReP is to raise awareness, expectations, and develop capabilities surrounding FAD preparedness and response. The goal of FAD PReP is to integrate, synchronize, and de-conflict preparedness and response capabilities as much as possible before an outbreak, by providing goals, guide-

lines, strategies, and procedures that are clear, comprehensive, easily readable, easily updated, and that comply with the National Incident Management System.

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

FAD PReP Documents and Materials

FAD PReP is a comprehensive U.S. preparedness and response strategy for FAD threats. This strategy is provided and explained in a series of different types of integrated documents, as illustrated below in Figure A-1.

Figure A-1. FAD PReP Suite of Documents and Materials

Lessons Learned from Past Outbreaks

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

- Provide a unified State-Federal-Tribal-industry planning process that respects local knowledge.
- Ensure the Unified Command sets clearly defined, obtainable, and united goals.
- Have a Unified Command with a clear and proper delegation of authority and that acts with speed and certainty.

- Employ science-based and risk-management approaches that seek to protect public health and animal health, protect animal agriculture, and stabilize the food supply and the U.S. economy.

- Ensure guidelines, strategies, and procedures are communicated to, and understood by, responders and stakeholders.

- Acknowledge that high expectations for timely and successful outcomes require the

  - rapid scale-up of resources and trained personnel for veterinary activities and countermeasures, and

  - the capability to quickly address competing interests before or during an outbreak.

- Ensure rapid detection and FAD tracing, essential for timely control of FAD outbreaks.

Appendix B
Incident Management

This appendix contains Chapter 4 from the *APHIS [Animal and Plant Health Inspection Service] Foreign Animal Disease Framework: Roles and Coordination* (FAD PReP Manual 1-0) document. This chapter explains incident management in the event of a foot-and-mouth disease outbreak. Please refer to the *APHIS Foreign Animal Disease Framework: Roles and Coordination* (FAD PReP Manual 1-0) and the *NCAHEM [National Center for Animal Health Emergency Management] Incident Coordination Group Plan* for more information (available at https://fadprep.lmi.org).

Homeland Security Presidential Directive-5, Management of Domestic Incidents, directed the development and administration of the National Incident Management System (NIMS). NIMS, in conjunction with the National Response Framework, provides the template for managing incidents and provides the structure and mechanisms for National-level policy for incident management. NIMS provides a systematic, proactive approach to guide departments and agencies at all levels of government, non-governmental organizations (NGOs), and the private sector to prevent, mitigate, respond to, and recover from the effects of incidents, regardless of cause, size, location, or complexity, in order to reduce the loss of life and property and harm to the environment.

A basic premise of NIMS is that all incidents begin and end locally. NIMS does not take command away from State and local authorities. NIMS simply provides the framework to enhance the ability of responders, including the private sector and NGOs, to work together more effectively. The Federal government supports State and local authorities when their resources are overwhelmed or anticipated to be overwhelmed.

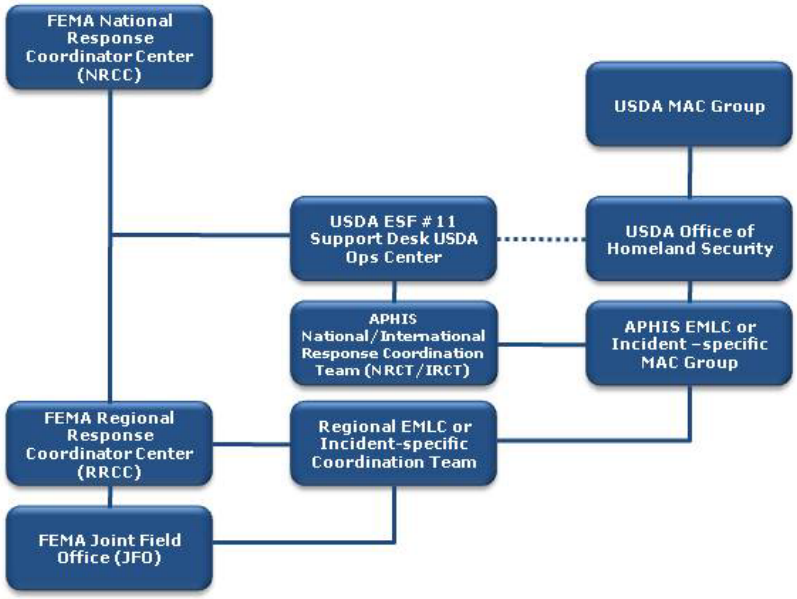
The Incident Command System (ICS) is a management system designed to enable effective and efficient domestic incident management by integrating a combination of facilities, equipment, personnel, procedures, and communication within a common organizational structure. The Animal and Plant Health Inspection Service (APHIS) has adopted NIMS and ICS organizational structures and processes to manage animal health incidents. Additional information on NIMS can be found at: http://www.fema.gov/emergency/nims/. Additional information on ICS can be found at: http://training.fema.gov/EMIWeb/IS/ICSResource/index.htm.

APHIS policy and procedures for APHIS Emergency Responder positions and APHIS Specialized Emergency Responder positions are described in the *APHIS Emergency Response Qualification Process* and *APHIS Emergency Responder Position Catalog*.[1] APHIS employees can find these documents at: http://inside.aphis.usda.gov/emergency_info/organization/resp_cat.shtml.

MULTIAGENCY COORDINATION

Multiagency coordination (MAC) is a process that allows all levels of government and all disciplines to work together more efficiently and effectively. MAC occurs across the different disciplines involved in incident management, across jurisdictional lines, or across levels of government. The *APHIS Emergency Mobilization Guide* defines APHIS coordination for major agricultural disasters and agro-terrorism responses (see Figure B-1). In the event of an animal emergency an APHIS MAC Group will be formed if the incident response needs more support. Fundamentally, the APHIS MAC Group will provide support, coordination, and assistance with policy-level decisions to the ICS structure managing an incident.

Figure B-1. Coordination Structures: U.S. Department of Agriculture and Department of Homeland Security/Federal Emergency Management Agency[2]



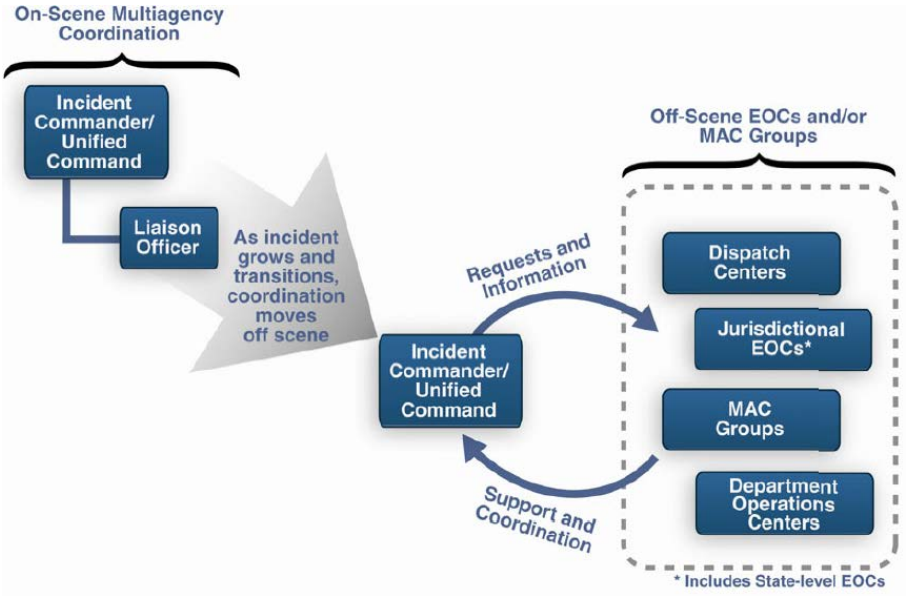
Note: EMLC = Emergency Management Leadership Council, ESF = Emergency Support Function.

[1] Information on USDA policies and procedures can be found in Departmental Manual #1800-001. Incident Preparedness, Response, and Recovery. November 2011; and Departmental Regulation #1800-001. Incident Preparedness, Response, and Recovery. November 2011.

[2] USDA APHIS, 2009, *Emergency Mobilization Guide*.

Figure B-2 illustrates an overview of a MAC system according to NIMS. The figure shows the transition over the course of an incident. The incident begins with an on-scene single Incident Command (IC); as the incident expands in size or complexity developing into a Unified Command, the incident may require off-scene coordination and support, which is when MAC Groups are activated.

Figure B-2. Multiagency Coordination System[3]



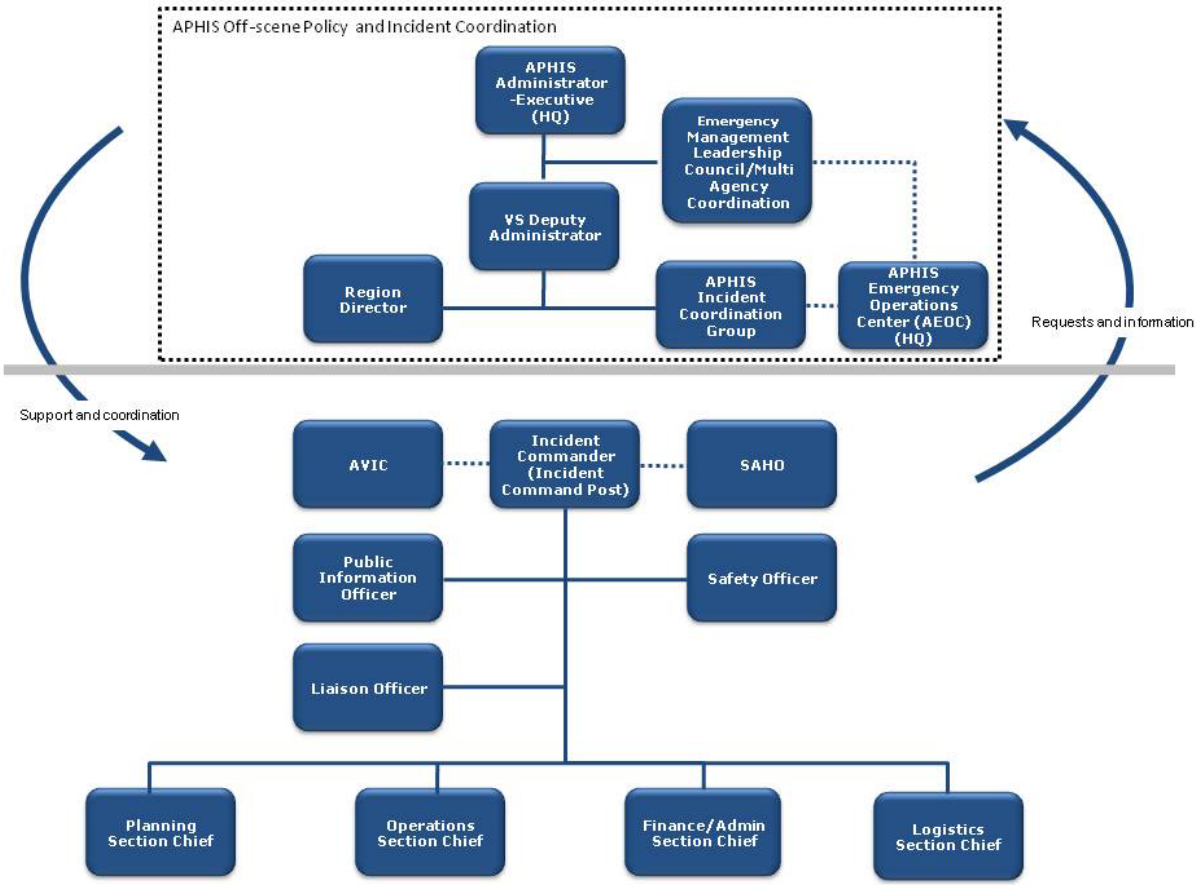
Note: EOC = Emergency Operations Center.

APHIS INCIDENT MANAGEMENT STRUCTURE

Figure B-3 displays the APHIS foreign animal disease (FAD) incident management organizational structure, starting with the APHIS Administrator.

[3] Federal Emergency Management Agency (FEMA), 2008. *National Incident Management System.* http://www.fema.gov/pdf/emergency/nims/NIMS_core.pdf.

Figure B-3. APHIS Multiagency Coordination Structures and APHIS Emergency Operations Center: Relationship to Incident Management Team (Assuming a Single Incident)



Note: SAHO = State Animal Health Official, AVIC = Area Veterinarian in Charge.

The APHIS Administrator is the primary Federal executive responsible for implementing APHIS policy during an FAD outbreak. The APHIS Administrator will delegate many of the actual MAC functions to the Veterinary Services (VS) Deputy Administrator (Chief Veterinary Officer of the United States) and the APHIS Emergency Management Leadership Council (EMLC).

The VS Deputy Administrator and the EMLC will establish an APHIS Incident Coordination Group (ICG) to oversee the staff functions associated with the incident at the APHIS headquarters level. The APHIS ICG will work closely with the personnel in charge of establishing operations for the incident response at the Area Command (AC) or Incident Command Post (ICP) in the field and coordinate with the APHIS MAC Group.

APHIS MULTIAGENCY COORDINATION GROUP

In the event of a significant FAD emergency, the EMLC typically serves as the APHIS MAC Group, unless it transfers responsibility for a specific incident. The EMLC is co-chaired by Plant Protection and Quarantine's Associate Director,

Emergency and Domestic Programs and VS' Associate Deputy Administrator, Emergency Management and Diagnostics. The EMLC is comprised of the following headquarters and regional members:

- Plant Protection and Quarantine,
- VS,
- Animal Care,
- Wildlife Services,
- International Services,
- Biotechnology Regulatory Services,
- Marketing and Regulatory Programs Business Services,
- Legislative and Public Affairs,
- Policy and Program Development,
- Investigative Enforcement Services,
- Emergency Management and Safety and Security Division, and
- APHIS Chief Information Officer.

The APHIS MAC Group may include additional members if the response requires them and may be activated if one or more of the following conditions take place:

- complex incidents that overwhelm local and regional assets;
- overlapping USDA agency jurisdictions;
- an incident that crosses international borders; or
- the existence of or potential for a high level of National political and media interest.

The APHIS MAC Group provides a forum to discuss actions that need to be taken to ensure that an adequate number of resources are available to meet anticipated needs. The APHIS MAC Group strategically coordinates the incident response, but does not typically direct the APHIS ICG.

The APHIS MAC Group offers guidance on the most efficient way to allocate resources during an animal health event. Specific responsibilities vary from disease to disease, but the general functions of the APHIS MAC Group include

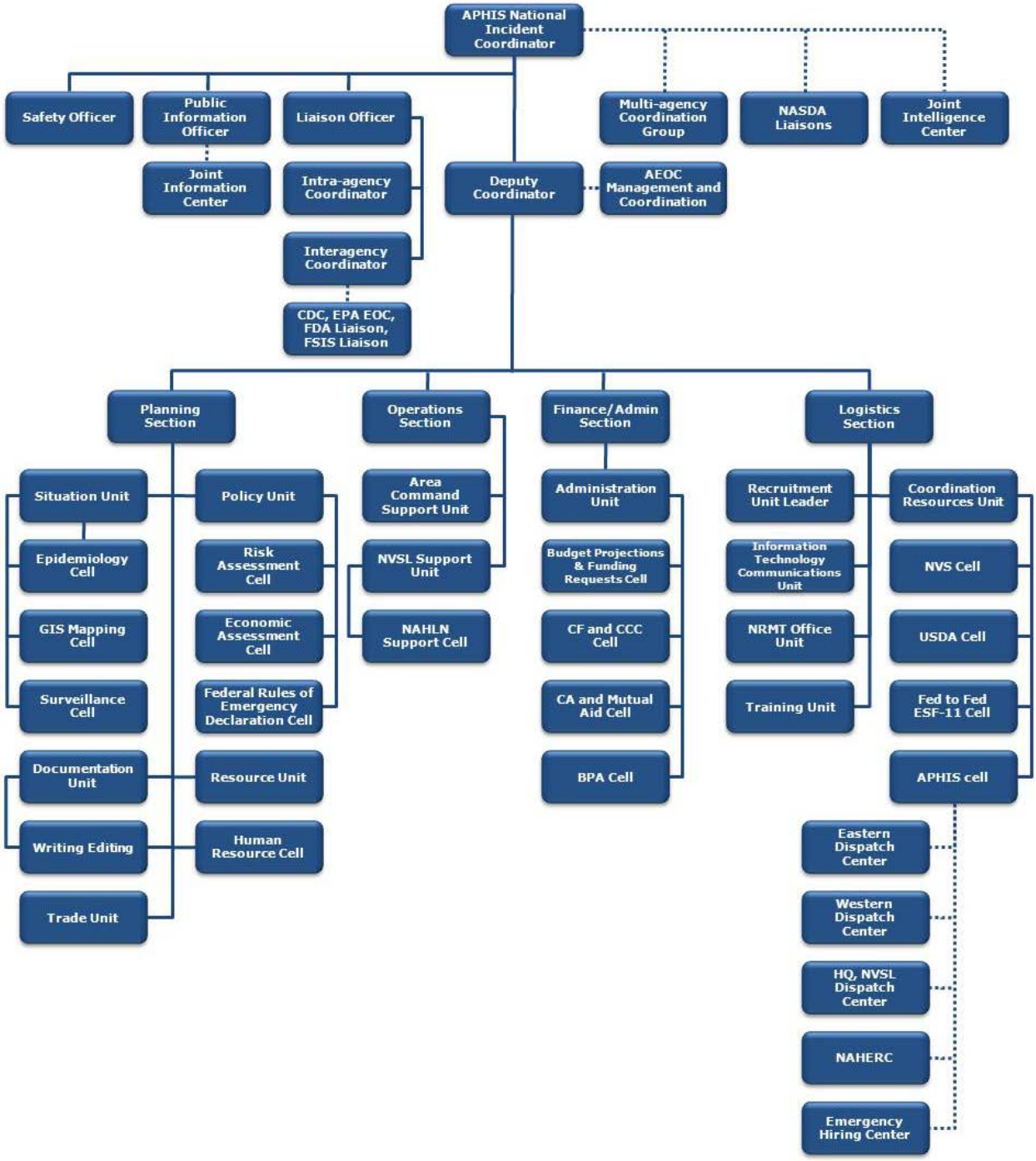
- incident prioritization,
- resource allocation and acquisition, and
- identification and resolution of issues common to all parties.

APHIS INCIDENT COORDINATION GROUP

The APHIS ICG is responsible for supporting an IC and AC in acquiring resources, formulating policy options, and assisting in developing and implementing response and recovery strategies for FAD outbreaks. For additional information and details, see the *National Center for Animal Health Emergency Management (NCAHEM) Incident Coordination Group Plan*. Figure B-4 illustrates an example organizational chart for an APHIS ICG. The group has the following responsibilities:

- providing guidelines to ensure responder and public health and safety;
- supporting IC(s) and AC(s);
- assisting in developing response policy as needed;
- coordinating effective communication;
- coordinating resources;
- assisting in establishing epidemiological priorities;
- assisting in developing incident objectives and approving response strategies for emergency vaccination as needed;
- assisting in integrating response organizations into the ICS;
- assisting in developing protocols as needed;
- providing information to the Joint Information Center for use in media and stakeholder briefings;
- providing budget requests and projections as needed; and
- assessing response progress, response strategies, and providing economic analyses as needed.

Figure B-4. Example APHIS Incident Coordination Group—Organizational Structure (for Foreign Animal Disease Outbreak)



Note: SAHO = State Animal Health Official, CDC = Centers for Disease Control, EPA = Environmental Protection Agency, EOC = Emergency Operations Center, FDA = Food and Drug Administration, FSIS = Food Safety Inspection Service, AEOC = APHIS Emergency Operations Center, NASDA = National Association of State Departments of Agriculture, GIS = Geographic Information System, NVSL = National Veterinary Services Laboratories, NAHLN = National Animal Health Laboratory Network, CF = Contingency Fund, CA = Cooperative Agreement, CCC = Commodity Credit Corporation, BPA = Blanket Purchase Agreement, ESF = Emergency Support Function, NVS = National Veterinary Stockpile, NRMT = National Response Management Team.

APHIS ORGANIZATION FOR A SINGLE INCIDENT

The ICP is a physical location that administers the on-scene IC and the other major incident management functions. An Emergency Operations Center (EOC) is a physical location that is located separately from the on-scene ICP and supports the on-scene response by providing external coordination and securing of additional resources. A MAC Group does not have any direct IC involvement and will often be located some distance from the incident site(s). EOC/MAC Groups do not command the on-scene level of the incident, but rather supports the ICP's command and management efforts.

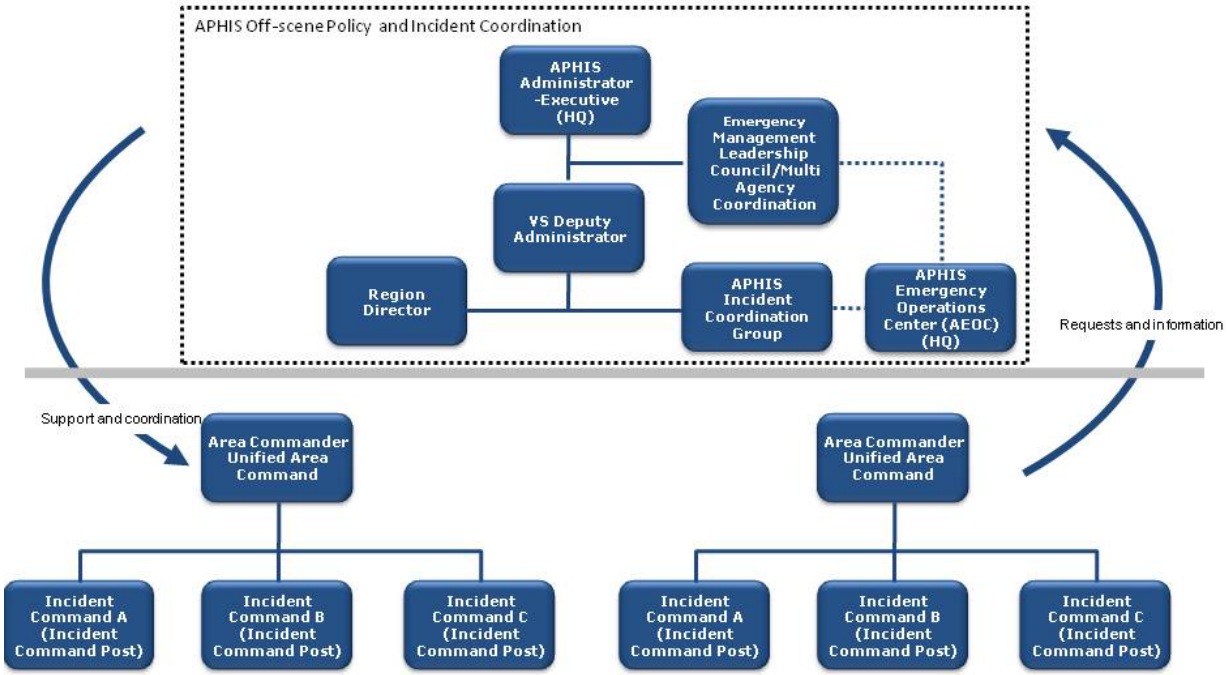
At the start of any FAD outbreak, the State Animal Health Official (SAHO), or designee, and Area Veterinarian in Charge (AVIC), or designee, will initially serve as the co-Incident Commanders for the Unified Command. The AVIC and SAHO may be relieved by an Incident Management Team (IMT) if there is a delegation of authority to the IMT. Figure B-3 is an example of an APHIS organization chart for a single incident.

APHIS ORGANIZATION FOR MULTIPLE INCIDENTS

When more than one incident is occurring at the same time, more than one IC may be established. An AC may also be established. An AC is an organization that oversees the management of multiple incidents handled individually by separate IC organizations or to oversee the management of a very large or evolving incident engaging multiple IMTs. An AC should not be confused with the functions performed by MAC as AC oversees management coordination of the incident(s), while a MAC element (such as a communications/dispatch center, EOC, or MAC Group) coordinates support.

In terms of MAC Group structures, if the emergency response becomes too large for an APHIS MAC Group to handle efficiently—for example, a large multistate incident with numerous response activities—cooperation from other agencies or committees will be implemented. MAC Groups will coordinate additional resources and make decisions regarding the prioritization of incidents and the sharing and use of critical resources, but are not a part of the on-scene IC. Figure B-5 is an example of the command structure when multiple incidents are involved.

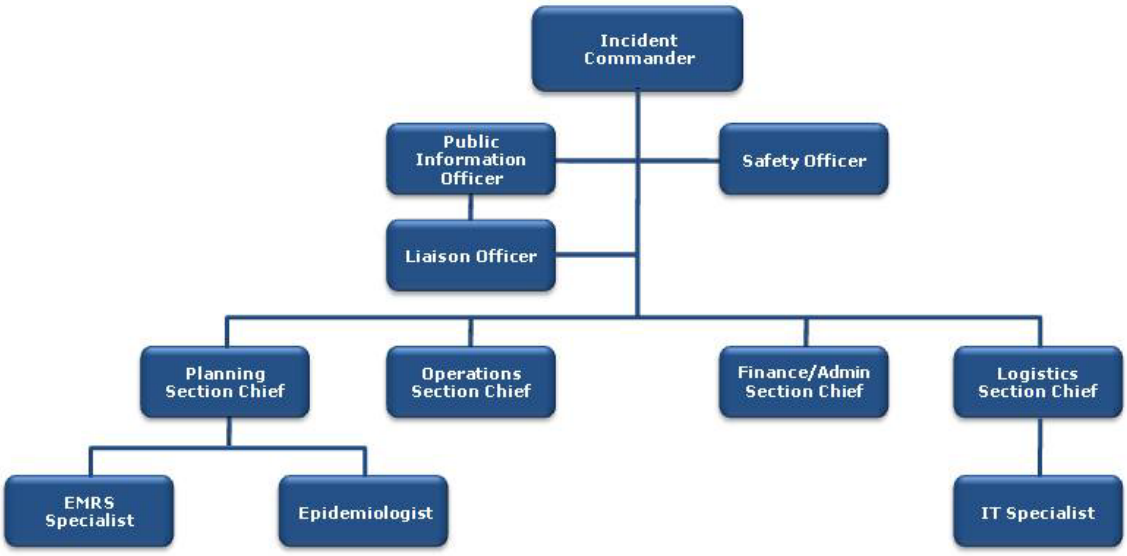
Figure B-5. APHIS Multiagency Coordination Structures and APHIS Emergency Operations Center: Relationship to Multiple Incident Management Team Structures (Assuming Multiple Incidents and a Unified Area Command)



APHIS INCIDENT MANAGEMENT TEAMS

Upon detection and confirmation of an FAD incident, the SAHO or AVIC establishes an ICP with an IMT, headed by an Incident Commander. Figure B-6 depicts the organization of the APHIS VS IMT for managing an incident.

Figure B-6. Current APHIS VS Incident Management Team—Short Team Configuration



The IMT includes an Incident Commander and staff for various types of communication, safety, and liaison purposes. This staff and the heads of the Incident Commander's line organization sections are considered the Incident Commander's general staff. The IMT also includes four line organizations to perform all of the efforts required to identify, contain, eradicate, recover, and return the situation to normal business practices. These line organizations include sections for operations, planning, logistics, and finance and administration. Within each of these sections is the capability to accomplish all of the tasks necessary to ensure a successful outcome to an FAD incident.

For single-incident outbreaks where the potential for spread is low, a short team configuration as depicted in Table B-1 will suffice.

Table B-1. List of Short Team Configuration Positions

APHIS VS IMT Short Team	APHIS Emergency Responder Position Catalog
Incident Commander	A800 Incident Commander
Deputy Incident Commander	A800 Incident Commander
Operations Section Chief	A810 Operations Section Chief
Deputy Operations Section	A810 Operations Section Chief
Planning Section Chief	A820 Planning Section Chief
Deputy Planning Section	A820 Planning Section Chief
Logistics Section Chief	A830 Logistics Section Chief
Deputy Logistics Section	A830 Logistics Section Chief
Finance Section Chief	A840 Finance Section Chief
Deputy Finance Section	A840 Finance Section Chief
Safety Officer	A805 Safety Officer (or A001)
Assistant Safety Officer	A805 Safety Officer
Public Information Officer	A803 Public Information Officer
Liaison Officer	A807 Liaison Officer
Assistant Liaison Officer	A807 Liaison Officer
Information Technology (IT) Specialist	A122 IT Specialist
Assistant IT Specialist	A122 IT Specialist
EMRS Specialist	A813 Group Supervisor (or Specialist)
Assistant EMRS Specialist	A813 Group Supervisor (or Specialist)
Epidemiologist	A813 Group Supervisor (or Specialist)
Assistant Epidemiologist	A813 Group Supervisor (or Specialist)

Note: EMRS = Emergency Management Response System.

When an outbreak occurs that is complex or large scale, a long team configuration, as listed in Table B-2, will be established. The long team consists of additional team members beyond those in the initial short team configuration.

Figure B-7 shows an example long team configuration; however, the exact makeup of the long teams will depend on the type of disease and magnitude of spread.

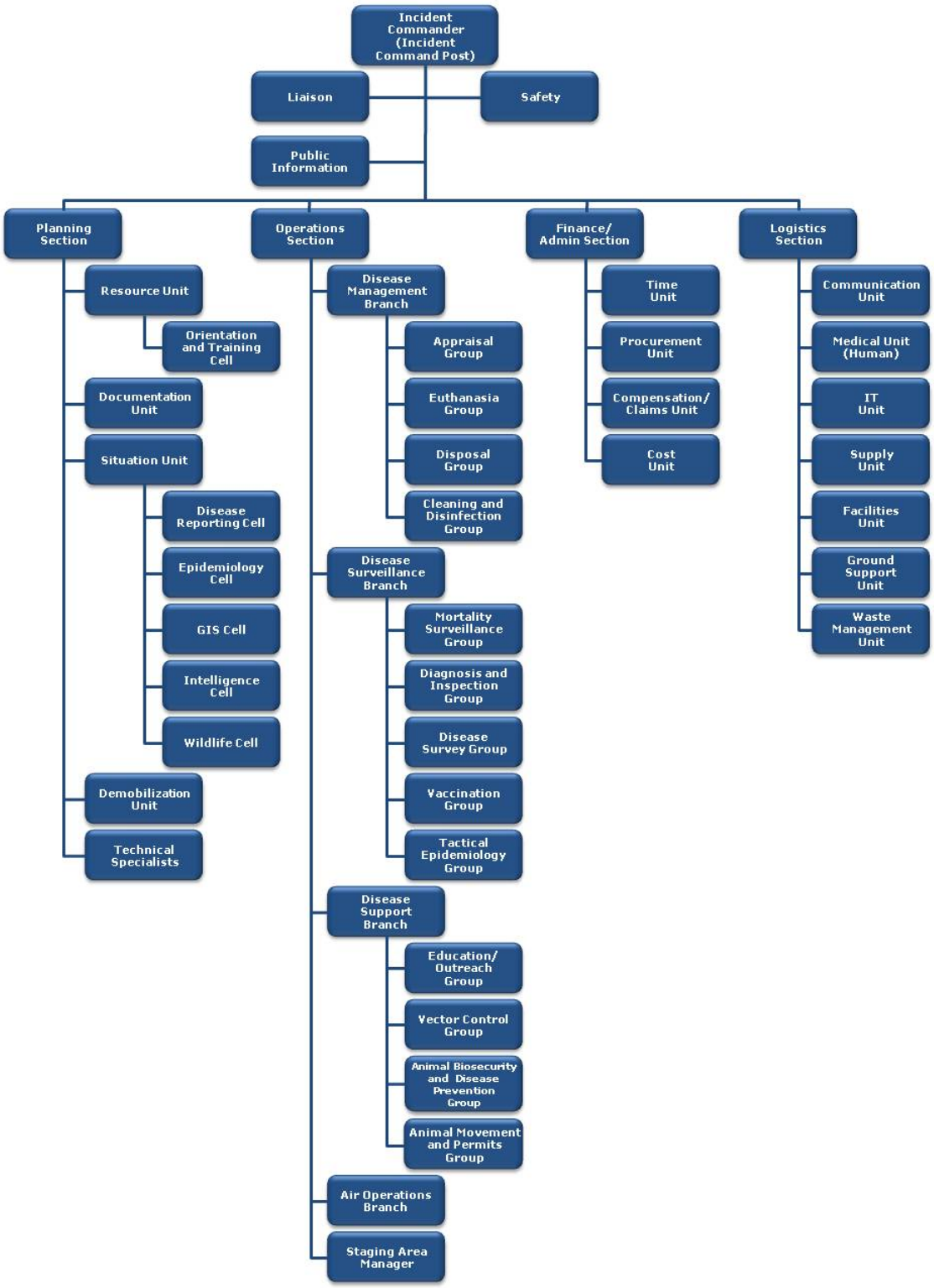
Table B-2. Typical Positions—Long Team Configuration

APHIS VS Long IMT Configuration	APHIS Emergency Responder Position Catalog
Deputy Operations Section Chief	A810 Operations Section Chief
Deputy Planning Section Chief	A820 Planning Section Chief
Deputy Logistics Section Chief	A830 Logistics Section Chief
Deputy Finance Section Chief	A840 Finance Section Chief
Disease Management Branch Director ◆ Appraisal Group Supervisor ◆ Euthanasia Group Supervisor ◆ Disposal Group Supervisor ◆ Cleaning and Disinfection Group Supervisor	A813 Group Supervisor A813 Group Supervisor A813 Group Supervisor A813 Group Supervisor A813 Group Supervisor
Disease Surveillance Branch Director ◆ Mortality Surveillance Group Supervisor ◆ Diagnosis and Inspection Group Supervisor ◆ Disease Survey Group Supervisor ◆ Vaccination Group Supervisor ◆ Tactical Epidemiology Group Supervisor	A813 Group Supervisor A813 Group Supervisor A813 Group Supervisor A813 Group Supervisor A813 Group Supervisor A813 Group Supervisor
Disease Support Branch Director ◆ Education/Outreach Group Supervisor ◆ Vector Control Group Supervisor ◆ Biosecurity and Disease Prevention Group Supervisor ◆ Movement and Permits Group Supervisor	A813 Group Supervisor A813 Group Supervisor A813 Group Supervisor A813 Group Supervisor A813 Group Supervisor
Air Operations Branch	—
Staging Area Manager (Operations)	—
Resources Unit Leader ◆ Orientation and Training Group Supervisor	A821 Resources Unit Leader A813 Group Supervisor
Documentation Unit Leader	A823 Documentation Unit Leader
Situation Unit Leader ◆ Disease Reporting Cell Supervisor ◆ Epidemiology Cell Supervisor ◆ Geographic Information System (GIS) Cell Supervisor ◆ Intelligence Cell Supervisor ◆ Wildlife Cell Supervisor	A813 Group Supervisor (or A822) A813 Group Supervisor A813 Group Supervisor A813 Group Supervisor (or A825) A813 Group Supervisor A813 Group Supervisor (or A045)
Demobilization Unit Leader	A824 Demobilization Unit Leader

Table B-2. Typical Positions—Long Team Configuration

APHIS VS Long IMT Configuration	APHIS Emergency Responder Position Catalog
◆ Communications Unit Leader	A831 Communications Unit Leader
◆ Medical Unit Leader	A815 Team Leader (or A001 or A057)
◆ Information Technology Specialist	A122 IT Specialist
◆ Supply Unit Leader	A833 Supply Unit Leader
◆ Facilities Unit Leader	A834 Facilities Unit Leader
◆ Ground Support Unit Leader	A832 Ground Support Unit Leader
◆ Waste Management Unit Leader	A003 Environmental Protection Specialist
◆ Time Unit Leader	A842 Time Unit Leader
◆ Procurement Unit Leader	A841 Procurement Unit Leader
◆ Compensation/Claims Unit Leader	A844 Compensation/Claims Unit Leader
◆ Cost Unit Leader	A843 Cost Unit Leader

Figure B-7. Example APHIS VS Incident Management Team—Long Team Configuration



RESPONSE RESOURCES

The IMT, ICG, and APHIS MAC Group can use a number of systems to aid in staffing and resourcing during an event such as the Emergency Qualification System (EQS) and the Resource Ordering and Status System (ROSS), which are discussed below. The *APHIS Emergency Mobilization Guide* and the *NCAHEM Incident Coordination Group Plan* are two planning documents that are used as response resources.

APHIS Emergency Mobilization Guide

The *APHIS Emergency Mobilization Guide* provides information and policy for mobilizing APHIS personnel for emergency events. The *APHIS Emergency Mobilization Guide* is available at: http://www.aphis.usda.gov/emergency_response/.

NCAHEM Incident Coordination Group Plan

The *NCAHEM Incident Coordination Group Plan* provides details on how the VS program unit will provide incident coordination support during FAD outbreaks.

APHIS Emergency Qualification System

The APHIS EQS is used to store the skills and qualifications of emergency response personnel and other data imported from the National Finance Center and AgLearn and to feed certification data to ROSS. It is customizable to APHIS program needs and can house training documents. Training documentation flow into EQS from AgLearn for APHIS employees. If the National Animal Health Emergency Response Corps (NAHERC) volunteers do not have access to AgLearn, their training documentation can be manually entered or imported through an Excel spreadsheet.

APHIS Resource Ordering and Status System

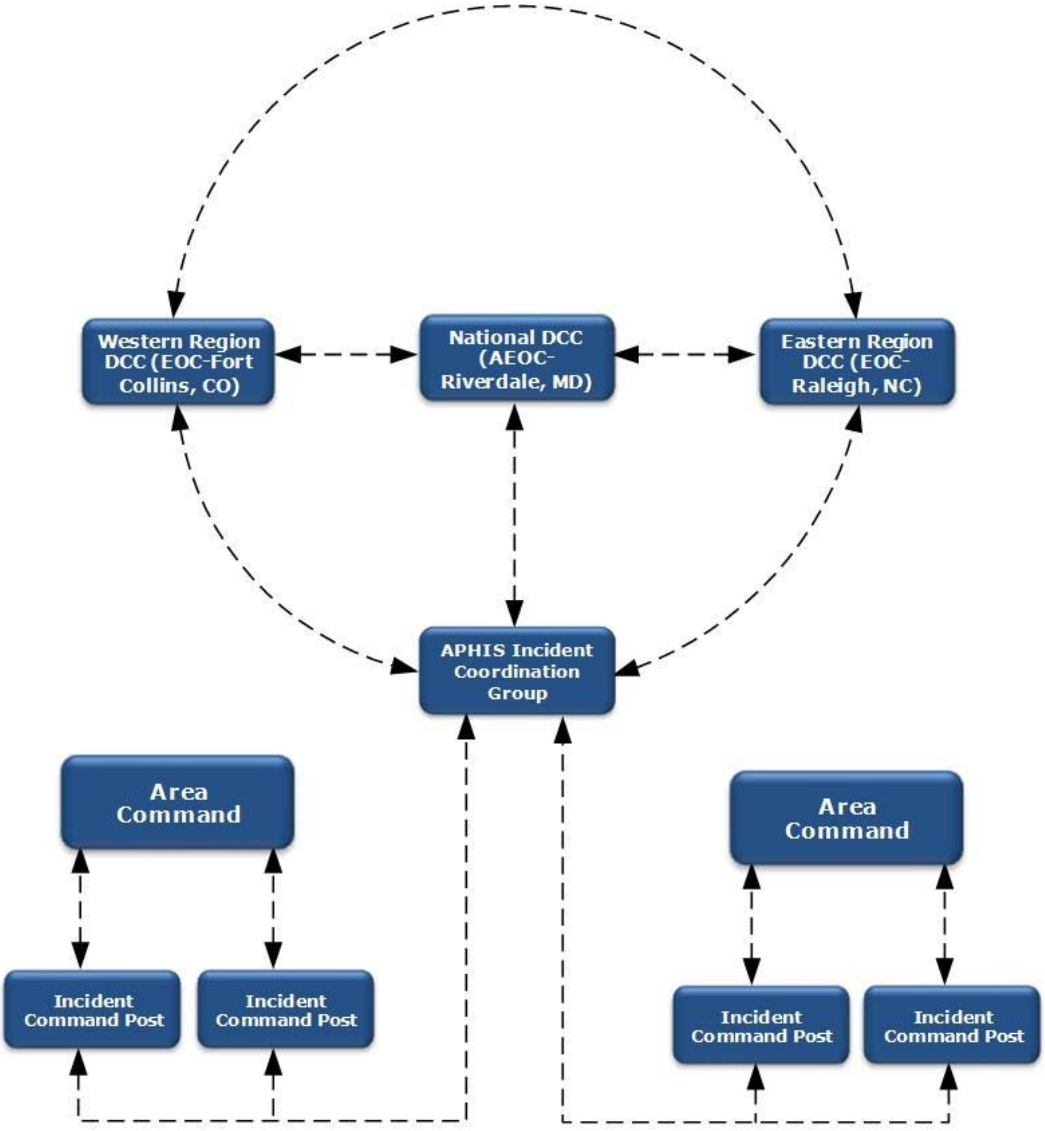
The APHIS ROSS allows APHIS to identify, track, and mobilize the resources needed to support emergency response. It provides a database of qualified emergency response personnel. The database can be searched according to personnel training levels and subject of expertise, such as procurement, epidemiology, or public information. Being able to quickly identify and dispatch appropriate personnel and supplies is a key component of emergency response, and ROSS facilitates that process. ROSS initiatives include the following:

- developing the APHIS *Emergency Responder Position Catalog*
- integrating ROSS into APHIS emergency management practices

- training and sustaining an APHIS dispatch community.

Figure B-8 illustrates the relationships among the APHIS ICG, Dispatch Coordination Centers, ACs, and ICPs.

Figure B-8. Resource Ordering Coordination[4]



Note: AEOC = APHIS Emergency Operations Center, DCC = Dispatch Coordinating Center.

[4] USDA APHIS, 2009. *Emergency Mobilization Guide*.

Appendix C
Laboratory Network List for FMD

The list of laboratories in the National Animal Health Laboratory Network (NAHLN) is found here: http://www.aphis.usda.gov/animal_health/nahln/labs.shtml. This list was last updated in March 2012. The following laboratories can currently perform testing for foot-and-mouth disease (FMD) virus after National Veterinary Services Laboratory (NVSL) confirmation of FMD.

Table C-1. FMD NAHLN Laboratories

#	State	Laboratory	Phone Numbers
1	Arizona	Arizona Veterinary Diagnostic Laboratory 2831 N. Freeway Tucson, AZ 85705	520-621-2356 Fax 520-626-8696
2	Arkansas	Arkansas Livestock & Poultry Commission Lab One Natural Resources Dr. Little Rock, AR 72205	501-907-2430 Fax 501-907-2410
3	California	California Animal Health & Food Safety Lab University of California, School of Vet Med W. Health Science Drive Davis, CA 95616	530-752-8709 (Backup 951-751-0025) Fax 530-752-5680
4	Colorado	Colorado State University Veterinary Diag. Lab 300 West Drake Rd, Bldg C Fort Collins, CO 80523-1644	970-297-1281 Fax 970-297-0320
5	Colorado	Colorado State University Veterinary Diagnostic Lab-Rocky Ford 27847 County Road 21 Rocky Ford, CO 81067	719-254-6382 Fax 719-254-6055
6	Connecticut	Connecticut Veterinary Medical Diagnostic Laboratory University of Connecticut Unit 3089, 61 N. Eagleville Rd. Storrs, CT 06269-3089	860-486-3738 Fax 860-486-2737
7	Florida	Bronson Animal Disease Diagnostic Laboratory 2700 N. John Young Parkway Kissimmee, FL 34741	321-697-1400 Fax 321-697-1467
8	Georgia	University of Georgia Tifton Veterinary Diag. Laboratory 43 Brighton Road, PO Box 1389 Tifton, GA 31793-3000	229-386-3340 Fax 229-386-3399
9	Georgia	Athens Veterinary Diagnostic Laboratory University of Georgia College of Vet Med, Building 1079 Athens, GA 30602	706-542-5568 Fax 706-542-5977

Table C-1. FMD NAHLN Laboratories

#	State	Laboratory	Phone Numbers
10	Illinois	University of Illinois Veterinary Diagnostic Laboratory 2001 S. Lincoln Urbana, IL 61802-6199	217-333-1620 Fax 217-244-2439
11	Indiana	Indiana Animal Disease Diagnostic Laboratory at Purdue University 406 South University St. West Lafayette, IN 47907	765-494-7440 Fax 765-494-9181
12	Iowa	Iowa State University Veterinary Diagnostic Laboratory 1600 S. 16th St. Ames, IA 50011	515-294-1950 Fax 515-294-3564
13	Iowa	USDA, APHIS, VS, NVSL, Diagnostic Virology Laboratory 1920 Dayton Ave Ames, IA 50010	515-337-7551 Fax 515-337-7527
14	Kansas	Kansas State Veterinary Diagnostic Laboratory Kansas State University, CVM L232 Mosier Hall, 1800 Dennison Ave Manhattan, KS 66506	785-532-5650 Fax 785-532-4039
15	Kentucky	Breathitt Veterinary Center Murray State University 715 North Drive Hopkinsville, KY 42240	270-886-3959 Fax 270-886-4295
16	Kentucky	University of Kentucky, Veterinary Diagnostic Laboratory 1490 Bull Lea Rd Lexington, KY 40511	859-257-8283 Fax 859-255-1624
17	Louisiana	Louisiana Animal Disease Diagnostic Laboratory Veterinary Med Diag. Laboratory, LSU Baton Rouge, LA 70803	225-578-9777 Fax 225-578-9784
18	Michigan	Diagnostic Center for Population and Animal Health Michigan State University 4125 Beaumont Rd, Ste 201H Lansing, MI 48910	517-353-1683 Fax 517-432-5836
19	Minnesota	University of Minnesota Veterinary Diagnostic Lab 1333 Gortner Ave, 244 Vet D L St. Paul, MN 55108	612-625-8787 Fax 612-624-8707
20	Mississippi	Mississippi Veterinary Research & Diagnostic Laboratory 3137 Hwy 468 West Pearl, MS 39208	601-420-4700 Fax 601-420-4719
21	Missouri	Veterinary Medical Diagnostic Laboratory University of Missouri 1600 East Rollins Columbia, MO 65211	573-882-6811 Fax 573-882-1411

Table C-1. FMD NAHLN Laboratories

#	State	Laboratory	Phone Numbers
22	Montana	Montana Veterinary Diagnostic Laboratory PO Box 997 Marsh Laboratory, 19th and Lincoln Bozeman, MT 59771	406-994-4885 Fax 406-994-6344
23	Nebraska	Veterinary Diagnostic Center University of Nebraska 137 VDC UNL Lincoln, NE 68583-0907	402-472-1434 Fax 402-472-3094
24	New Jersey	New Jersey Dept of Agriculture, Division of Animal Health State Diagnostic Lab, H & A Bldg Rm 201 John Fitch Plaza, P.O. Box 330 Trenton, NJ 08625	609-984-2293 Fax 609-777-8395
25	New York	Animal Health Diagnostic Center Upper Tower Road College of Vet Med, Cornell University Ithaca, NY 14853	607-253-3900
26	New York	USDA, APHIS, VS, NVSL, Foreign Animal Disease Diagnostic Laboratory PO Box 848 40550 Route 25 Greenport, NY 11857	631-323-3256 Fax 631-323-3366
27	North Carolina	Rollins Diagnostic Laboratory North Carolina Department of Agriculture 2101 Blue Ridge Rd. Raleigh, NC 27607	919-733-3986 Fax 919-733-0454
28	North Dakota	Veterinary Diagnostic Laboratory North Dakota State University Dept. 7691, PO Box 7691 Fargo, ND 58108-6050	701-231-8307 Fax 701-231-7514
29	Ohio	Ohio Department of Agriculture Animal Disease Diagnostic Lab 8995 E. Main Street, Building 6 Reynoldsburg, OH 43068	614-728-6220 Fax 614-728-6310
30	Oklahoma	Oklahoma Animal Disease Diagnostic Laboratory Oklahoma State Univ., College of Vet. Med. Farm & Ridge Road Stillwater, OK 74078	405-744-6623 Fax 405-744-8612
31	Oregon	Oregon State University Veterinary Diagnostic Lab Magruder Hall, 30th & Washington Way Corvallis, OR 97331	541-737-3261 Fax 541-737-6817
32	Pennsylvania	Pennsylvania Veterinary Laboratory Pennsylvania Department of Agriculture 2305 N. Cameron Street Harrisburg, PA 17110	717-787-8808 Fax 717-772-3895

Table C-1. FMD NAHLN Laboratories

#	State	Laboratory	Phone Numbers
33	South Carolina	Clemson Veterinary Diagnostic Center 500 Clemson Road, PO Box 102406 Columbia, SC 29229	803-788-2260 Fax 803-788-8058
34	South Dakota	Animal Disease Research & Diagnostic Lab South Dakota State University Box 2175, N. Campus Dr. Brookings, SD 57007	605-688-5171 Fax 605-688-6003
35	Tennessee	CE Kord Animal Disease Diagnostic Lab Ellington Agricultural Center 440 Hogan Rd. Nashville, TN 37220	615-837-5125 Fax 615-837-5250
36	Texas	Texas Veterinary Medical Diagnostic Laboratory 1 Sippel Road, Drawer 3040 College Station, TX 77843	979-845-3414 Fax 979-845-1794
37	Texas	Texas Veterinary Medical Diagnostic Laboratory - Amarillo 6610 Amarillo Blvd West Amarillo, TX 79106	806-353-7478 Fax 806-676-4582
38	Utah	Utah Veterinary Diagnostic Laboratory 950 E. 1400 North Logan, UT 84322-5700	435-797-1895 Fax 435-797-2805
39	Washington	Washington Animal Disease Diagnostic Laboratory P.O. Box 647034 Bustad Hall, Room 155-N Pullman, WA 99164-7034	Phone 509-335-9696/ 509-335-6190 Fax 509-335-7424
40	Wisconsin	Wisconsin Veterinary Diagnostic Laboratory University of Wisconsin-Madison 445 Easterday Road Madison, WI 53706	608-262-5432/ 608-262-5432 Fax 847-574-8085
41	Wyoming	Wyoming State Veterinary Laboratory 1174 Snowy Range Road Laramie, WY 82070	307-766-9925 Fax 307-721-2051

Appendix D
North American FMD Vaccine Bank Guidelines for FMD Vaccine Use

This appendix contains an excerpt from the North American Foot-and-Mouth Disease (FMD) Vaccine Bank Guidelines (2007) for FMD vaccine use, explaining the vaccination decision tree found in Chapter 4 of this *FMD Response Plan (2012)*.

Appendix 3 – North American Guidelines for FMD Vaccine Use

The decision tree has been updated to include changes to the Code of 2004. The change permits return to "FMD freedom without vaccination" in 6 months without slaughtering all vaccinates. This is provided serological surveillance is sufficient to detect antibodies to non-structural proteins (NSP) of FMDV indicating the absence of infection in the remaining vaccinated population for countries previously FMD free (Article 2.1.1.7). The option for slaughtering all vaccinates or if there is no accepted NSP test are also illustrated. It has also been updated with modifications made in the UK to reflect that consideration for vaccination would be made much sooner (decision box 2) than in the past, prior to other, more drastic culling strategies.

It has also been updated with modifications made in the UK to reflect that consideration for vaccination would be made much sooner (decision box 2) than in the past, prior to other, more drastic culling strategies.

The development of this decision tree and matrix resulted from a request at the Tripartite Exercise 2000 Program. It was determined to use a decision tree flowchart combined with decision matrices. The rationale for this choice was that a *decision tree* has linear reasoning and can only evaluate single factors sequentially. Thus, simple linear logic:

i.e.A→B→C→D→F→G→H = decision ie VACCINATE cannot be devised

For non-linear or multi factorial decisions, a *decision table* or *matrix* is required with the following logic,
i.e. *If* A + C +F *then* VACCINATE; or *If* A + C +F +H *then* PRE-EMPTIVE SLAUGHTER

A *decision matrix* conceptually evaluates factors in parallel, not in sequence and thus has the capacity to consider multiple factors at the same time. Connector words such as *and*, *even, if,* and *but* can be used to weight the factors.

However, a *decision matrix* also does not reflect decision making in reality because human reasoning cannot consider all factors simultaneously. Logical reasoning seeks to group related factors. Thus, a *decision tree* flowchart was developed with five decision boxes. The decision flow chart is illustrated on page 44. The decision process starts from the top left (decision box 1) and proceeds to decision box 5 in the bottom right of the figure.

Future Work

This decision matrix will be updated as results are obtained from modelling work (epidemiological and economical) [32]. These results will be used to identify the trigger points for the various control measures in the North American context.

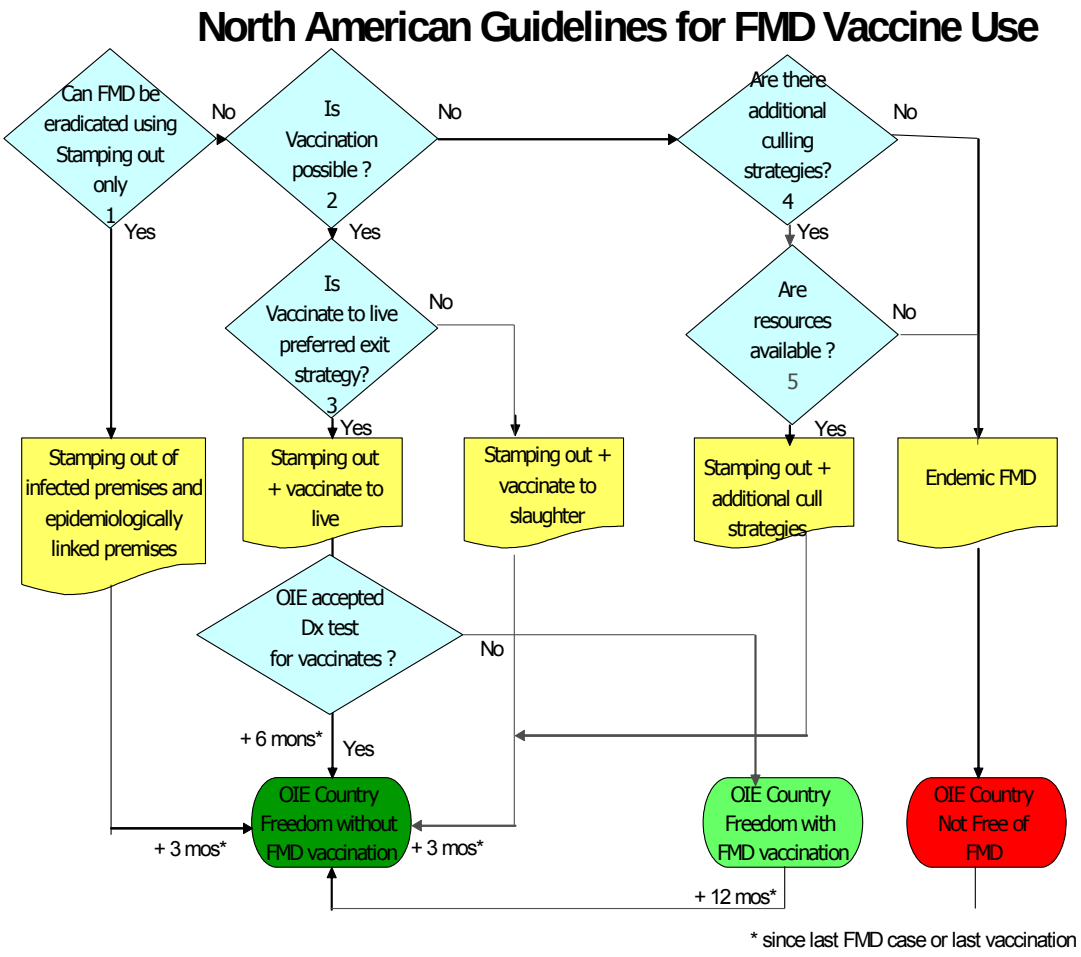


Figure 4. North American guidelines for FMD Vaccine use.

Each decision box is supported by a *decision matrix* where appropriate factors are listed for consideration. The factors have been grouped into four pivotal factors that characterize the nature of the epidemic (OUTBREAK FACTORS) and four pivotal factors which describe mitigation measures for the outbreak (MITIGATION FACTORS). Each pivotal factor has numerous sub-factors described below.

OUTBREAK FACTORS are:

Contact Rate
Host or Species affected/species at risk
Status of Outbreak
Environmental

MITIGATION FACTORS include:

Physical Resources
Human Resources
Socio-political factors
Economic considerations

Note that only factors appropriate to the specific decision box are provided. For example, *decision matrix 1* is the only matrix that contains all the outbreak factors. *Decision matrices 2-5* contain only mitigation factors in addition to stamping out of infected herds. In order to leave the decision box, one must determine the direction by deciding YES or NO considering all the factors and sub-factors in that box. Tables are available to facilitate record keeping of decisions**.**

1st Decision Box – Can disease be eradicated with stamping out alone (of infected premises and epidemiologically linked premises)?

In this decision box, *all* outbreak factors and mitigation factors must be considered. This is the point of departure from the preferred, traditional policy of stamping out of infected premises and epidemiology linked premises. In most instances, such factors will not be known at the start of an outbreak. Decisions may need to be revisited as more information becomes available. Modelling work done *a priori* based on normal movements patterns may help early in the outbreak.

1. Time to Detection

Detecting infected premises early after exposure reduces the probability of transmitting FMD to other premises. Age of oldest lesions at detection can provide an estimate of this delay between exposure and detection.

2. Contact Rate

In simulated outbreaks using the North American model for FMD, contact rate (direct, indirect) was identified as one of the most sensitive parameters. This suggests that for the same resource capacity, variations in the contact rate will influence how quickly the outbreak will be controlled. The contact rate will be influenced by the following factors:

2.1 Kind of Farms – Contact rates may vary by type and size of farms. A higher level of transmission may be expected if an outbreak is declared in premises known to have high contact rates.

2.2 Type of contact – Movement of animals (direct), people or equipment (indirect) or possible vectors such as wildlife can spread FMD. Direct movements have a higher probability of transmission of infection compared to indirect movements. Indirect movements include but are not limited to fomites such as equipment, contamination of supply delivery vehicles, veterinarians, artificial insemination technicians, and farm workers. It also includes marketing of animal products and by-products. Indirect movements that include close contacts with livestock or their products and by-products should be considered at higher risk of spreading FMD.

2.3 Movement distances – An important factor in the spread of the outbreak. Knowledge of routine movement distances will help in the implementation of the size of the control zones.

2.4 Efficacy of movement controls – this factor is critical in preventing the spread of FMDV and should include an estimate of illegal movements in the outbreak area as well as past movements.

3. Host

The species affected and species at risk must be considered. Intractability of zoo or exotic livestock must also be considered.

3.1 Domestic livestock only - Of the domestic livestock under consideration, swine are crucial because of their ability to amplify the amount of virus that can be spread by airborne means. Sheep and goats tend to be sub clinical and tend to be less likely to spread virus by aerosol but are spreading the disease following movements. Cattle are more at risk of infection by aerosol whereas swine are more susceptible through ingestion of contaminated material.

Modelling in Australia[23] suggests:

Swine:

- 100 sows put livestock at risk 10 km downwind
- 1000 swine create a virus plume in 12 hr, infecting livestock over a 200 km^2 area

Feedlot:

- 1000 cattle over 24 hr infected an area of 0.5 km^2, 3.4 km downwind
- 5000 cattle over 24 hr infected an area of 6.2 km^2, 15.2 km downwind
- 5000 cattle over 24 hr infected an area of 26 km^2, 37.2 km downwind

2.2 Game farms; zoos - Are there genetics or endangered species that will not be able to be slaughtered? How effective would quarantine or isolation methods be?

2.3 Wildlife - Are there genetics or endangered species that will not be able to be slaughtered? How effective would quarantine or isolation methods be?

2.4 Virus tropism - Tropism of the virus will not likely be immediately known. By the time it will be known, mitigation measures can be modified but they will not reduce the trade disruption. Additional surveillance testing of non-target species will be required.

4. Status of Outbreak

Estimation of FMD extent and duration of the epidemic. Sub-factors to be considered include:

4.1 # affected herds - A greater number would indicate more undiscovered or incubating herds. This observation would be of concern in that it could indicate biological terrorism.

4.2 # foci - One focus of infection would be less likely to spread before stamping out could contain the outbreak. Two or more foci separated by 10 or more km would indicate that the outbreak has already spread.

4.3 Rate of spread - Rapid spread would be reflected in increasing number of cases per day or increasing number of cases per week. Rate of spread estimates whether the outbreak is in the arithmetic (initial) or logarithmic (expansion) portion of the epidemiological curve.

5. Environment

Includes cultural and physical geography as well as climate.

5.1 Livestock density and distribution - How many herds/animals are there per square unit of area? Obviously, the more herds and the more widely distributed they are, the greater the likelihood of spread. Density of livestock and farms are key issues.

5.2 Livestock management - Whether the majority of affected producers are large corporations/owners on private land; communes; as opposed to small producers or backyard subsistence producers may have an impact on outbreak due to socio-political status and influence.

5.3 Casual access - Network of transportation corridors in outbreak area with casual human and vehicle traffic may promote spread although it is noted that the UK determined that footpaths would not be closed in future epidemics after the outbreak in 2001.

5.4 Physical barriers - Is the outbreak in a naturally isolated area, i.e. desert, island/isthmus, or protected by rivers, mountains or any other physical geographic feature that would limit spread?

5.5 Climate - Do prevailing winds, temperature and humidity conditions favour airborne spread?

6. Physical Resources

6.1 Slaughter capacity - FMD infected animals are slaughtered on-farm by policy. Thus farm technology and mustering facilities, intractability of livestock are factors. If wildlife is affected, capability to slaughter all infected animals is very difficult unless confined.

6.2 Transportation capacity - If conditions prohibit on-farm disposal, bio-secure transportation of carcasses and all animal products or any other such thing used in respect of animals is essential.

6.3 Disposal capacity - If on-farm disposal is available, heavy equipment would be required for burial or incinerator facilities for burn. If off farm disposal, rendering facilities, burn or burial sites are needed. If these are easily available, then slaughter of animals and disposal of all animal products or any other such thing used in respect of animals is facilitated.

7. Human Resources

7.1 Emergency response system /movement control - Is there sufficient trained staff for stamping out and to enforce movement control restrictions to limit FMD spread. Is the level and quality of surveillance sufficient to evaluate the effect movement controls? Is the administration able to meet the needs of the emergency response system?

7.2 Epidemic projections - potential outcomes for region, species, costs to aid in decision-making.

8. Social–Political

8.1 Legislation available - Is there legislation in place for stamping out activities?

8.2 Public opinion / legislative will / appearance of government - What is the current welfare/animal rights climate? Public perception of affected animal destruction. Public perception that the government is acting responsibly. Legislative and public attitude to vaccination, pre-emptive slaughter and compensation.

8.3 Industry acceptance - Will the producer organizations concur with the decision? Is information on which tracebacks are based credible? Will industry disclose all traceback information? What is the opinion of non-FMD affected livestock industry sectors? Is the agricultural economy in general affected by international FMD restrictions? What is their opinion?

8.4 Socio- economic status of producers and / or of a region - What is the level of sophistication of the producers in the affected region? What is their socio-political influence? Are there genetic preservation considerations against stamping out?

9. Economic

9.1 Compensation - Is there sufficient funding for the potential number of animals to be eliminated by stamping out (commercial versus purebred)? Could numbers necessary to be depopulated significantly be reduced by vaccination? Is there compensation for lost production, animal products, by-products etc.

9.2 Value of exports - Cost-benefit of country-free status versus stamping out eradication effort. Are there enough funds available for other emergency response activities and supplies?

9.3 Regionalization – Is there the ability to zone or regionalize the affected area with international acceptance without eradication of FMD? If not international, can a Tripartite agreement be reached to permit North American trade in spite of OIE restrictions without eradication of FMD in affected area?

2nd Decision Box – Is vaccination possible?

One arrives at this decision box when stamping-out of infected premises and epidemiologically linked premises is not sufficient to eradicate the disease or resources are insufficient to keep up to the volume of animals requiring slaughter and disposal. In either case, in this vaccination decision box, factors surrounding the decision to vaccinate are outlined.

1. Physical Resources

1.1 Vaccine strain available - Does the NAFMDVB have the correct strain? Does the NAFMDVB have a cross-protection strain available in the Bank? (Little or no cross-protection between 7 serological types) In cases of bio-terrorist action, more than one serotype of virus may be involved.

1.2 Vaccine doses available – Vaccine is not immediately available. The NAFMDVB has negotiated an initial standby supply to be delivered within a time period specified in the manufacturers' contract. Animals may require to be vaccinated twice (2-4 wks apart) to maximize the immunity and decrease the probability of having "carrier animals."

1.3 Vaccine logistics - Are all logistics for vaccination in place, i.e. equipment, supplies such as ear tags from NAFMDVB, taggers, record keeping system, portable corrals, head gates. Are there cold chain provisions for the vaccine to the field outbreak centre?

1.4 Vaccine distribution - Vaccine required for ring vaccination/high risk situations (feedlot or intensive swine) Australian models shows: ring vaccination decreases length of outbreak 0.1- 0.6 weeks; whereas high risk situation vaccination decreases length of outbreak 1.2 - 2.9 weeks.

1.5 Laboratory capacity- Does laboratory have diagnostic capability to distinguish vaccinates from infected animals? Does laboratory have diagnostic capability to analyse suspect and surveillance samples needed to assure trading partners that all animals at risk have been vaccinated

1.6 Time - Are there sufficient physical resources to permit vaccination of herds in the affected area prior to spread of infection from the outbreak (incubation period = 7+/- 4 d ;OIE =14d for cattle and swine)?

2. Human Resources

2.1 Emergency response system /movement control - Is there sufficient trained staff for vaccinating the numbers required, including intractable species? Are there enough resources to conduct pre-emptive slaughter if both options are being employed? And to enforce movement control restrictions to limit FMD spread? Is the administration able to meet the needs of the emergency response system? Are training staff & material available to train vaccination teams? Is competent contract staff available?

2.1 Risk of FMD introduction - Risk of vaccinating teams spreading FMD while vaccinating. Is there sufficient time and protocols in place to train vaccinating teams to minimize risk?

2.2 Epidemic projections- Potential outcomes including risk of outbreak due to early field challenge or less than 85%coverage in vaccination region. Identification of high risk herds that would seroconvert prior to field virus challenge, cattle (1-2 weeks); swine (3 weeks). Early field FMD challenge increases FMD carrier state in vaccinate cattle (3 yr), sheep (9 mos), goats (4 mos).

3. Social–Political

3.1 Legislation available - Is there legislation required for mandatory vaccination?

3.2 Public opinion /appearance of government - What is the current welfare/animal rights climate? Are there public perceptions of FMD vaccination that could lead to trade restrictions? Public perception that the government is acting responsibly.

3.3 Industry acceptance- Will the producer organizations concur with the vaccination decision? Will industry present all susceptible animals for vaccination? Will industry rather be FMD infected and be compensated at market value or vaccinate and have livestock market value reduced.

3.4 Social- economic status of producers/region -What is the sophistication of the producers in the affected area? What is their social-political influence?

4. Economic

4.1 Cost of vaccination - Cost of vaccination requires requesting country to pay $US 400,000 to the vaccine bank for vaccine finishing plus replacement cost of antigen within 60 days of request. Is this cost prohibitive for a single country?

4.2 Value of exports - Does vaccination reduce exportation from the country in general? Cost-benefit of additional time to attain country-free status after vaccination. Other vaccinates restrictions (OIE code)?

4.3 Regionalization - within country/ Tripartite? - Ability to regionalize the affected area with international acceptance with vaccination for FMD? Can a Tripartite agreement be reached to permit North American trade in spite of OIE restrictions on FMD vaccination?

4.4 Compensation for decrease value of vaccinated animals?

3d Decision Box – Is the exit strategy "Vaccinate to live"?

The disposition of vaccinates is a separate consideration from decision to vaccinate but necessary to regain "FMD free without vaccination" status. The third decision box has been split into two because the decision to slaughter vaccinates is dependent on two main criteria. The first is the economic and ethical question of slaughtering apparently healthy vaccinates that could be co-infected with a field strain of FMD. The second consideration is whether trading partners will accept the validity of a non-structural protein (NSP) test to identify vaccinates from non-clinical expressions of field FMD. At the time of writing, there is no OIE sanctioned discriminatory test.

The economic criteria here is based in the gain of 3 months trade at OIE standards since "FMD free without vaccination" status is achieved 3 months after the slaughter of the last vaccinate where as "FMD free without vaccination" status is achieved 6 months after the slaughter of the case or the last vaccination provided that a serological survey based on the detection of antibodies to nonstructural proteins

of FMD virus demonstrates the absence of infection in the remaining vaccinated population. If no such test is available OR acceptable, "FMD free without vaccination" can be achieved 12 months after the last FMD case or last vaccination. During the interim period, a country would be FMD free with vaccination.

International markets discriminate between countries that are FMD free without vaccination from those that are FMD free with vaccination. Europe, North America, Australia and New Zealand enjoy a superior status without FMD vaccination. Thus, this decision is primarily an economic consideration but other MITIGATION factors also play a role.

1. Physical Resources

1.1 Slaughter capacity - Slaughter of FMD vaccinates would likely be done off farm as it would be more efficient. On-farm slaughter may be considered under set circumstances. Thus farm technology and mustering facilities, intractability of livestock are factors.

1.2 Disposal capacity - If vaccinates are not salvaged for meat or other animal products, on-farm disposal may be considered in some circumstances. Requirements for heavy equipment for burial or incinerator facilities for burning, rendering facilities or burial sites must be located.

1.3 Time - Are there sufficient physical resources to permit slaughter and disposal of vaccinates within 6 weeks of vaccination (no 2nd dose required)?

2. Human Resources

2.1 Emergency response system /movement control -Is there sufficient trained staff for slaughter of vaccinates in addition to surveillance activities required for OIE country freedom recognition? Can movement control of vaccinates be tracked to ensure that all vaccinates are slaughtered? Is the administration able to meet the needs of the emergency response system?

2.2 Epidemic projections - Potential outcomes including risk of another outbreak once vaccinates eliminated from the region.

3. Social-Political

3.1 Legislation available - Is there legislation for mandatory slaughter of vaccinates?

3.2 Public opinion /appearance of government - What is the current welfare/animal rights climate? Public perception of slaughter of healthy FMD vaccinates. Public perception that government is acting responsibly

3.3 Industry acceptance - Besides record keeping, what are the movement restrictions of vaccinates? Will FMD vaccinates be allowed to move (under permit) to other affected tripartite countries? Will the producer organizations concur with the slaughter of vaccinates? Will industry assist in tracking all vaccinates and respect movement controls? (Influenced by 4.2 if the government compensates for loss of market share of vaccinated animals). Will industry agree to slaughter the offspring of vaccinates (maternal antibodies)? What is the opinion of non-FMD affected livestock industry sectors? Is the agricultural economy in general affected by international FMD restrictions? What is their opinion?

3.4 Social- economic status of producers/region - What is the sophistication of the producers in the affected area? What is their social -political influence?

4. Economic

4.1 Cost of vaccinate slaughter - Cost of vaccinate slaughter including tracking of all vaccinates to ensure that all are slaughtered.

4.2 Compensation- Compensation costs for vaccinated animals as well as animal products and by-products, decreased market value of vaccinates, cost of maintenance of vaccinates between vaccination and slaughter? Are compensation funds available in short term to allow rapid slaughter?

4.3 Value of Exports - Cost-benefit of country-free status versus cost of compensating for vaccinates until discrimination test of vaccinate versus infected animal is internationally accepted (OIE code)?

4.4 Regionalization - within country / Tripartite? Ability to regionalize the affected area with international acceptance with vaccination for FMD? Can a Tripartite agreement be reached to permit North American trade in spite of OIE restrictions on FMD vaccination?

4th Decision Box – Are there additional cull strategies to consider?

This fourth box deals with culling strategies other than stamping-out of infected premises and dangerous contacts (i.e. ring or contiguous cull, culling of premises in order to stop the spread outside an area, etc.). *Only* social-political and economic factors must be considered. Of particular importance is the existence of legislation to support these culling strategies. The issue of adequate resources to perform these measures at the rate required is dealt with in decision box 5.

1. Social-Political

1.1 Legislation available - Is there legislation in place for pre-emptive slaughter on traceback and peripheral herds?

1.2 Public opinion /appearance of government - What is the current welfare/animal rights climate? Public perception of healthy animal destruction based on risk. Public perception that the government is acting responsibly.

1.3 Industry Acceptance - Will the producer organizations agree to slaughter tracebacks and peripheral herds? Is the information on which tracebacks are based credible? Will industry disclose all traceback information? What is the opinion of non-FMD affected livestock industry sectors? Is the agricultural economy in general affected by international FMD restrictions? What is their opinion?

1.4 Social - economic status of producers/region - What is the sophistication of the producers in the affected region? What is their social-political influence? Are there genetic preservation considerations against pre-emptive slaughter?

2. Economic

2.1 Compensation - Is there sufficient funding for potential number of animals to be eliminated by stamping out and pre-emptive slaughter on tracebacks and peripheral herds (commercial / purebred)? Is there compensation for lost production time, animal products, by-products etc? Are animal products (including meat) salvageable for human consumption from pre-emptively slaughtered animals (unknown FMD infection status)?

2.2 Value of Exports - Cost-benefit of country-free status versus cost of eradication effort including pre-emptive slaughter costs.

2.3 Regionalization/zoning - Ability to zone or regionalize the affected area with international acceptance without eradication of FMD? Can a Tripartite agreement be reached to permit North American trade in spite of OIE restrictions without eradication of FMD in affected area?

5th Decision Box – Are resources available to perform additional culling strategies?

In this fifth decision box, *only* resource factors are considered. The social-political and economic considerations are such that other culling strategies are an option. The prime concern is whether adequate physical and human resources exist to accommodate the anticipated number of livestock to be pre-emptively slaughtered *in addition* to those slaughtered under stamping out.

1. Physical Resources

1.1 Slaughter capacity FMD infected/ high-risk animals should be slaughtered on-farm. Thus farm technology and mustering facilities, intractability of livestock are factors. However, the majority of pre-emptive slaughter would likely be done off farm as it would be more efficient. The presence of slaughter facilities within the infected zone is important.

1.2 Transportation capacity - Unless tested immediately prior to movement, peripheral / traceback herds could be incubating and thus contagious for FMD. If pre-emptive slaughter is done off farm, biosecure transportation of animals is necessary to prevent spread.

1.3 Disposal capacity - If on-farm disposal available, heavy equipment would be required for burial or incinerator facilities for burn. For off farm disposal, rendering facilities, burn or burial sites are needed. If these are easily available, then pre-emptive slaughter and stamping out are good options.

1.4 Time - Are there sufficient physical resources to permit pre-emptive slaughter of peripheral herds in addition to tracebacks and infected herds *before* peripheral and traceback herds develop FMD? (Incubation period = 7+/- 4days; OIE= 14 days).

2. Human Resources

2.1 Emergency response system /movement control - Is there sufficient trained staff for stamping out and pre-emptive slaughter without impacting on enforcement of movement control restrictions to limit FMD spread within the required time frame (see 1.4)? Is the administration able to meet the needs of the emergency response system?

2.2 Epidemic *projections* Potential outcomes including risk of another outbreak with pre-emptive slaughter for region, species, costs to aid in decision making. Identification of high-risk herds that would have priority for pre-emptive slaughter.

Appendix E
Information on FMD Vaccines and Vaccination

Foot-and-mouth disease (FMD) vaccination is a complex topic, and further information can be found in National Animal Health Emergency Management System (NAHEMS) Guidelines: Vaccination for Contagious Diseases, which has an FMD-specific Appendix A; the FMD Vaccination Standard Operating Procedure (SOP); and the National Veterinary Stockpile FMD Countermeasures Working Group document. All of these resources can be found at https://fadprep.lmi.org.

MATCHING

Vaccine matching is critical in the success of an emergency vaccination strategy for an FMD outbreak. The World Organization for Animal Health (OIE) *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (2011)* Chapter 2.1.5 on FMD provides extensive guidance on vaccine matching. As stated in this chapter, "Vaccination against one serotype of FMDV [FMD virus] does not cross-protect against other serotypes and may also fail to protect fully or at all against other strains of the same serotype."[1]

The most effective way to test the match of a vaccine is to challenge vaccinated animals with FMDV. However, this is expensive and time consuming: in vitro methods should be considered as alternatives.[2] Chapter 2.1.5 explains the serological testing that can be conducted to choose an effective vaccine strain and details the enzyme-linked immunosorbent assays (ELISAs), two-dimensional neutralization tests (VNT), or a complement fixation test (CFT). These tests assess the serological relationship between a field isolate and a vaccine virus (*r* value). In addition, it explains how to calculate the expected percentage of protection (EPP).

For the *r* value, with an ELISA test, the following guidelines are used for interpretation:

- 0.2–0.39: The field isolate is antigenically related to the vaccine strain. The vaccine strain might be suitable for use if no closer match can be found provided that a potent vaccine is used and animals are preferably immunized more than once.

- <0.2: The field isolate is only distantly related to the vaccine strain and the vaccine strain is unlikely to protect against challenge with the field isolate.[3]

POTENCY

In addition to vaccine matching, the potency of the vaccine also contributes to "the range of antigenic cover."[4] For example, vaccines that are more potent may give greater protection against heterologous strains, a quicker onset of immunity, and increased protection from viral shedding and transmission. Additional booster vaccines can also increase the antigenic cover of a given vaccine.

The most common test of potency is the 50 percent protective dose (PD_{50}) test for cattle. In this test, "the number of protective doses in a vaccine is estimated from the resistance to live virus challenge of animal groups receiving different amounts of vaccine."[5,6] The PD_{50} is determined in a dose response study in 15 cattle at least 6 months of age given primary vaccination of either one full dose, 1/4 dose, or 1/16 dose (5 cattle per group, with 2 cattle in a control group that is not vaccinated), and subsequently challenged by the inoculation of 10,000 ID_{50} (50 percent infectious dose) of virulent bovine virus of the same type or subtype as that used to prepare the vaccine. Preferred observed potency is at least 6 PD_{50} per cattle dose.[7,8]

An alternative to this test is the PGP test (percentage of protection against generalized foot infection). Seronegative cattle with the same characteristics described above are vaccinated with a manufacturer-suggested volume.[9,10] Then, these animals and a control group (two nonvaccinated animals) are challenged 4 weeks or more after vaccination with a fully virulent challenge strain, intradermally onto the surface of the tongue. Unprotected animals will show lesions at sites other than the tongue within 7 days.

[3] OIE, *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, 2011.

[4] OIE, *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, 2011.

[5] OIE, *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, 2011.

[6] NVS, *National Veterinary Stockpile Countermeasures Working Group Report: Foot-and-Mouth Disease*, 2007.

[7] OIE, *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, 2011.

[8] NVS, *National Veterinary Stockpile Countermeasures Working Group Report: Foot-and-Mouth Disease*, 2007.

[9] OIE, *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, 2011.

[10] NVS, *National Veterinary Stockpile Countermeasures Working Group Report: Foot-and-Mouth Disease*, 2007.

Potency tests for other species have not yet been standardized. However, a test similar to the cattle PD_{50} test can be adopted for pigs.[11]

STRAINS

The World Reference Laboratory for FMD (WRLFMD) recommends FMDV strains that should be included in FMDV antigen banks, most recently in June 2011. High-priority strains, not in order of importance, include[12]

- O Manisa (covers pan-Asian topotype),
- O BFS or Campos,
- A24 Cruzeiro,
- Asia 1 Shamir,
- A Iran-05,
- A22 Iraq, and
- SAT 2 Saudi Arabia (or equivalent).

The *WRLFMD Quarterly Report April-June 2011* lists the medium and low priority recommendations: http://www.wrlfmd.org/ref_labs/ref_lab_reports/FAO-OIE%20FMD%20Ref%20Lab%20Report%20Apr-Jun%202011.pdf.

DIVA

One of the most important challenges to vaccination is ensuring that infected and vaccinated animals can be successfully differentiated. NVSL-FADDL uses the 3ABC Prionics ELISA as a herd DIVA test. In the United States, NVSL-FADDL is the only laboratory that currently runs the 3ABC ELISA, though laboratories in the NAHLN may have that capability in the future. (See Subsection 5.4 of this response plan for diagnostic flowcharts.)

Differentiating infected and vaccinated animals on an individual rather than herd basis remains a diagnostic challenge. Subsection 6.4 and the FMD Diagnostics SOP provide information on the diagnostic tests, flow of these tests, and Incident Command responsibilities for DIVA and surveillance in the event of an FMD outbreak in the United States.

[11] OIE, *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, 2011.

[12] World Reference Laboratory for FMD, *WRLFMD Quarterly Report April-June 2011*, http://www.wrlfmd.org/ref_labs/ref_lab_reports/FAO-OIE%20FMD%20Ref%20Lab%20Report%20Apr-Jun%202011.pdf.

Insufficiently purified vaccines may contain low levels of non-structural proteins; vaccine purity is very important for DIVA, particularly when animals must be vaccinated multiple times.[13] The fact that individual vaccinated cattle infected with FMDV could be asymptomatic carriers without seroconverting to the non-structural proteins (which is the basis of DIVA testing with current diagnostics) is also a concern.[14]

CROSS-PROTECTION

Vaccines will not provide cross-protection among different serotypes. Cross-protection against different strains in the same serotype depends on the amount of variation and its potency.[15]

IMMUNITY

Onset of Immunity

Inactivated FMD vaccines may decrease viral shedding and clinical signs in cattle and sheep in challenge studies as early as 4 days after vaccination with protection improving for the next 2–3 weeks; swine appear to be more difficult to protect shortly after challenge. Limited studies have reported some protection as soon as 3–4 days after vaccination; however, with more severe challenges, pigs may not be completely protected against disease until 21–28 days after vaccination.[16] An oil adjuvanted product is likely to be used in an emergency vaccination strategy associated with an FMD outbreak in the United States.

Duration of Immunity

With three doses of Al(OH) adjuvanted vaccine, cattle showed immunity (via reduced clinical signs) for up to 3 years. With a single dose of oil emulsion vaccine, cattle remained seropositive with titers believed to be protective for at least 90 days post-vaccination. Swine challenged with low levels of homologous virus after one dose did not display clinical disease for 7 months.[17] The OIE

[13] R. P. Kitching, "Identification of foot and mouth disease virus carrier and subclinically infected animals and differentiation from vaccinated animals," *Rev Sci Tech*, 21(3), 2002, pp. 531–538. Also see NAHEMS Guidelines: Vaccination for Contagious Diseases, Appendix A.

[14] NVS, *National Veterinary Stockpile Countermeasures Working Group Report: Foot-and-Mouth Disease*, 2007.

[15] NVS, *National Veterinary Stockpile Countermeasures Working Group Report: Foot-and-Mouth Disease*, 2007.

[16] NVS, *National Veterinary Stockpile Countermeasures Working Group Report: Foot-and-Mouth Disease*, 2007. Also see NAHEMS Guidelines: Vaccination for Contagious Diseases, Appendix A.

[17] NVS, *National Veterinary Stockpile Countermeasures Working Group Report: Foot-and-Mouth Disease*, 2007.

suggests two inoculations, 2–4 weeks apart, with revaccination every 4–12 months.[18]

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[18] OIE, *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, 2011.

Appendix F
Updated FMD Outbreak Surveillance Guidance and Rationale

FMD OUTBREAK SURVEILLANCE GUIDELINES

These are updated recommendations for foot-and-mouth disease (FMD) outbreak surveillance, prepared by the National Surveillance Unit (NSU) of the Centers for Epidemiology and Animal Health, Veterinary Services (VS), Animal and Plant Health Inspection Service (APHIS). These guidelines may be updated periodically.

Purpose

The purpose of these guidelines is to provide recommendations for surveillance activities in domestic livestock for this *FMD Response Plan*. These are sample guidelines.

Surveillance will be conducted at intervals as specified by the Incident Command (IC) using the most current scientific information and best practice guidance available.

Objectives

The objectives of FMD outbreak surveillance are to:

- Detect FMD Infected Premises (IP) during an outbreak.
- Determine the size and extent of an FMD outbreak.
- Supply information to evaluate outbreak control activities.
- Provide information for animal and product movement within the Control Area (CA).
- Provide information for animal and product movement out of the CA.
- Prove disease-freedom (DF) to regain FMD-free status after eradication of the outbreak.

Definitions

There are two key definitions that are important in outbreak surveillance.

- *Clinically ill animals.* Animals with signs of illness compatible with FMD.
- *Detection probability.* Likelihood that the sampling scheme will detect at least one infected animal in each premises or epidemiological unit with 95 percent confidence at the selected design prevalence, population size, and sensitivity of the chosen validated test.

Rationale for Selecting a Design Prevalence

It is difficult to recommend a single surveillance sampling scheme for an FMD outbreak because many factors impact the nature and characteristics of the outbreak. Each outbreak is different; surveillance plans will need to be tailored to individual outbreaks.

General Considerations for Selecting a Design Prevalence

There are a number of general factors that impact the selection of a design prevalence to be used in an FMD surveillance plan. Some of these factors are related to the nature of the FMD outbreak itself, while others are related to the surveillance plan.

- Outbreak or disease related factors:
  - *Prevalence.* (1) proportion of infected animals on the premises, or (2) proportion of IP in the area at a specific time period.
  - *Incubation period.* Length of the period that elapses between the introduction of the pathogen into the animal and the occurrence of the first clinical signs.
  - *Transmission and generation.* Length of time between when one animal is infected, becomes infectious, and infects another animal.
  - *Ease of recognition.* The ease of recognition of clinical signs of FMD in affected species.
  - *Time.* The length of time which has passed since the disease was introduced to the premises or area.
  - *Herd size.* Number of animals on a given premises.
  - *Density of premises.* Number of IP in a given area.

- Surveillance plan factors:
  - *Resources.* Resources that are available for sample collection or visual observation, including personnel.
  - *Diagnostics.* Tests that are available, including how many animals must be tested, and what type of test (tissue, vesicular fluid, serum).
  - *Detection time.* How long it takes before a test can detect the presence of FMD virus (FMDV) in an animal. For example, does the test require the animal to be clinically ill or can it detect prior to visual signs.
  - *Test sensitivity.* The estimated proportion of true diseased or infected animals that will test positive.
  - *Test specificity.* The estimated proportion of true non-diseased or non-infected animals that will test negative.
  - *Frequency.* How often samples must be collected and diagnostic tests must be conducted for effective surveillance.
  - *Goal of surveillance.* A surveillance scheme will depend on whether the goal is to prove disease freedom or detect disease in a vaccinated or unvaccinated population.
  - *Confidence level.* The probability of accepting the null hypothesis when it is true; choosing a confidence level (for example, 90 percent, 95 percent, or 99 percent) for the surveillance plan.

All of the factors listed above are interrelated. Table F-1 lists the factors and general surveillance design in an outbreak response effort. It is important to consider all factors together, rather than independently, when developing a surveillance plan.

Table F-1. Interaction of Disease/Outbreak and Surveillance Factors, with Suggested Adaptations in Surveillance Scheme

	Surveillance Factors						
Disease/Outbreak Factor	**Design prevalence**	**Sampling frequency**	**Visual/ observational exam (lower sensitivity test)**	**Animal handling**	**Test sensitivity**	**Early detection**	**Tissue testing (higher sensitivity test)**
Shorter incubation period	Increase	Increase	Use, depending on strength of clinical signs	Decrease	Less important	Increased likelihood	Less important
Strong clinical signs	Increase	Depends	Use	Decrease	Less important	Increased likelihood	Less important
Size of epidemiological unit	Decrease	Frequent	Depends	Depends	More important	Depends	More important
Increased prevalence	Decrease	Less frequent	Depends	Depends	Less important	Depends	Less important

REASONS TO SELECT A LOW DESIGN PREVALENCE

It is impossible to select one disease factor and one surveillance factor from Table F-1 and to understand how the surveillance factor should change based on that one disease factor independently of the other factors. However, if possible, it is always desired to (1) select the test that detects FMDV as early as possible, and (2) use the lowest design prevalence. A low design prevalence is consistent with surveillance schemes used for disease detection, business continuity, and proof of DF.

The reasons for selecting the low design prevalence are as follows.

- FMDV is highly contagious. In a naïve population, the virus multiplies rapidly in multiple animals and spreads quickly throughout the population via direct contact, indirect contact (fomites), and possible aerosol transmission.
- Animals infected with FMDV may become infectious and transmit the virus early in the infectious process (1 to 7 days after exposure, depending on serotype and species); this is before clinical signs are apparent.
  - Clinical infection varies from very mild to severe; animals with mild clinical signs may not be detected.
- Low design prevalence will be exceeded rapidly, as FMD spreads quickly through an epidemiological unit, which fosters early disease detection in comparison to a high design prevalence.
- Early detection reduces the time that premises are infectious.

- The FMDV is detectable in epithelial tissue (for example, pharyngeal epithelium, teats, muzzles, and coronary bands), vesicular fluid, and tissues before animals display clinical signs.
- Samples required for approved and validated diagnostic tests—such as epithelium, vesicular fluid, serum, oral swabs—require direct contact with the animal.
- There are no approved and validated mass population or pooled sampling procedures.
- Monitoring feed intake and/or milk production in large herds may require more than a few infected animals before signs trigger additional diagnostics.
- It is not likely that the index premises is the first IP; FMDV may be widely dispersed.
  - All IP may be a source for transmission of FMDV.
  - More undetected IP (without movement controls) increases the probability that the FMD outbreak will be widespread.
  - Personnel may unknowingly transmit FMD from clinically normal but infected animals to uninfected animals.
- Following appropriate biosecurity and cleaning and disinfection requirements, surveillance teams can sample approximately 2 premises per day if taking individual samples.

Surveillance Scheme Sampling Considerations

Surveillance on susceptible premises should detect the presence of FMDV at the earliest possible moment after viral introduction. This occurs when the virus is detectable, using the lowest possible design prevalence, in tissues, serum, or vesicular fluid.

The choice of the design prevalence depends on (1) the surveillance methodology, (2) the diagnostic test sensitivity, and (3) the chosen confidence level.

At present, there are no validated mass population sampling techniques, as explained in Chapter 5 of this *FMD Response Plan*. It is a priority to validate mass population or pooled sample testing.

Currently, as explained in Chapter 5, the following diagnostic tests will be used in an FMD outbreak to detect and characterize FMDV.

- Virus Isolation (VI)
- 3ABC enzyme-linked immunosorbent assay (3 ABC ELISA)
- Virus infection association antigen (VIAA) group specific 3D agarose immunodiffusion (AGID)
- Antigen ELISA (AgELISA)
- Virus Neutralization (VNT)
- Real-time reverse transcriptase polymerase chain reaction (rRT-PCR).

The rRT-PCR test will be used in an outbreak to detect infected, unvaccinated animals because of its rapid turnaround time (approximately 4 hours).

Given that no validated mass population sampling techniques are available at this time, the following questions provide guidance to develop a surveillance sampling scheme after declaration of an FMD outbreak in a location or area.

1. Are resources limited to intensively survey premises (for example, collect tissue samples from the needed number of animals)?
2. Is it unlikely that the outbreak can be contained locally (such as on a farm or within a small geographic area)?
3. Does evidence suggest that the introduction of virus (for example, start of the outbreak) on the premises or in the zone began at least 7 days ago?
4. Is there evidence that the FMD serotype is highly pathogenic (for example, a high proportion of infected animals will show clinical signs and/or severe clinical signs)?
5. Are there limited movements of animals, vehicles, products, or personnel on and off premises (for example, it is unlikely that virus will be introduced to, or spread from, this premises or zone)?
6. Are sheep present in the zone or on the premises?
7. Are there noncommercial or feral swine in the zone?
8. Are there noncommercial or small premises in the zone?
9. Are there premises with more than one susceptible species?
10. Are there large feedlots or swine operations in the zone?

11. Are dairy cattle, feedlots, or swine operations in the zone managed to present low-risks of exposure (such as, biosecurity practices, little opportunity for fomite transmission)?

12. Are there beef cattle (cow-calf or small operations) in the zone?

Figure F-1 demonstrates how these questions should be used to inform a surveillance sampling scheme.

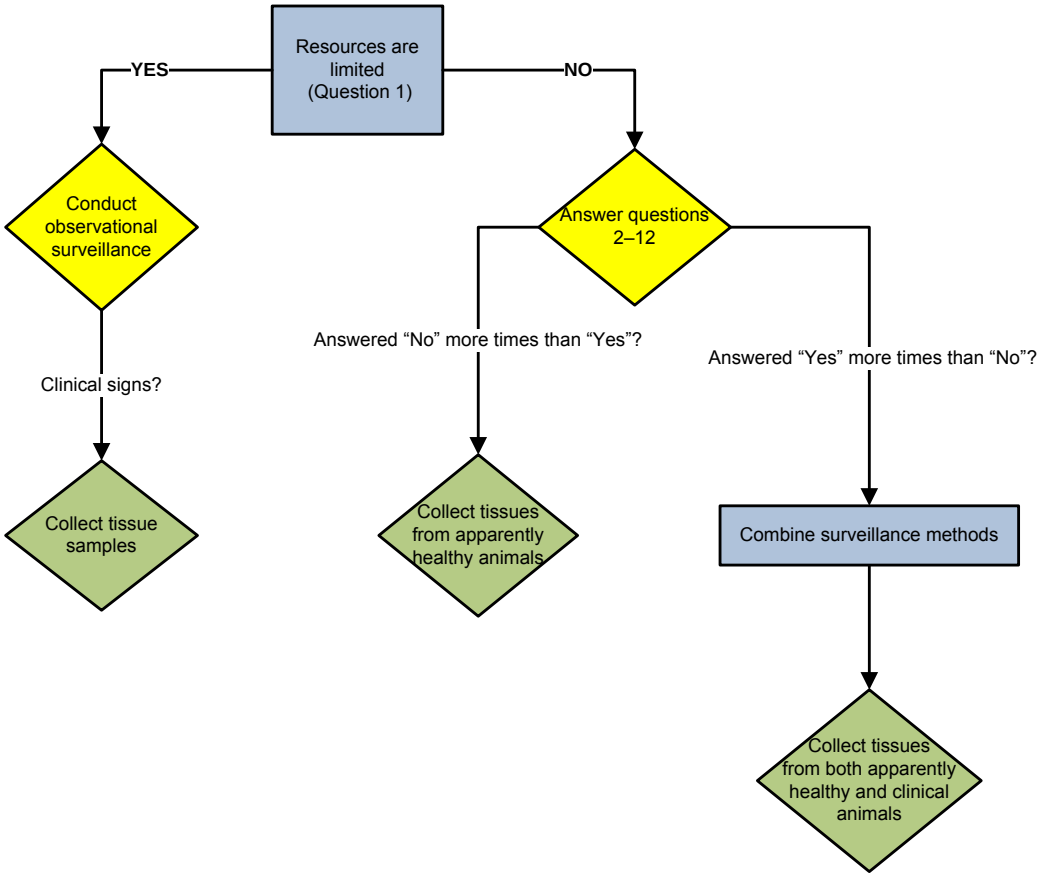
If the answer to Question 1 is "yes," the minimum surveillance to detect FMDV is observational surveillance/routine visual inspection of cattle herds for clinical signs, and targeted tissue sampling of individual animals with clinical signs.

If the answer to Question 1 is "no," and

- There are more "no" than "yes" answers for Questions 2 – 12, then surveillance may include the collection of tissue samples from herds and animals which appear to be healthy.

- There are more "yes" than "no" answers for Questions 2 – 12, then surveillance may include a combination that leads to collection of tissue samples from both animals that appear to be healthy and animals with clinical signs of FMDV.

Figure F-1. Developing an FMD Outbreak Surveillance Sampling Scheme



It is likely that individual animal sampling may quickly exceed resource capacity, and any surveillance sampling scheme may have to adjust accordingly by switching from individual animal sampling to observation with rRT-PCR confirmation. The plan may require visual inspection on premises least likely to spread the disease and individual animal sampling on premises most likely to transmit FMD.

Surveillance Test Choices

The predictive positive value (PPV) of a diagnostic test depends, foremost, on the disease prevalence in the population. The PPV also depends on test specificity and sensitivity. The PPV of any test is poor if the prevalence in the population is less than 5 percent. Early in the disease outbreak, it can be difficult to estimate the prevalence of IP in a given area, or the prevalence of infected animals on a given premises. The goal is always to detect viral presence with the *least* number of infectious animals. Subsequently, it is important to use the lowest design prevalence possible.

The negative predictive value of a test is best used when the disease is not prevalent (less than 1 percent), the specificity of the test is high, and there is little

disease clustering. These conditions, coupled with low design prevalence and negative diagnostic test results, facilitate proving DF in a given population.

As FMD viral prevalence increases, the PPV increases and the specificity of the test plays a minor role in disease detection. With FMD, the rRT-PCR has the ability to detect viral presence earlier than visual examination.

FACTORS THAT INFLUENCE DIAGNOSTIC TEST CHOICE

The choice of a diagnostic test or tests is influenced by a number of choices:

- *Resources available.*
- *FMD prevalence in the population.* The following factors increase prevalence:
  - Highly contagious animals.
  - Short incubation period (2 days vs. 2 weeks).
  - Number of contacts between infectious and susceptible animals.
  - Animals infected with FMDV may become infectious and transmit the virus early in the infectious process (1 to 7 days after exposure, depending on serotype and species); this is before clinical signs are apparent.
  - Pathogenicity of the virus.
- *Test characteristics.*
  - Prevalence at which the test can detect disease:
    - For example, visual inspection requires approximately 50–75 percent of the herd to be infected before morbidity is likely to appear abnormally high.
  - Speed of test results.
  - Sensitivity.
  - Sampling frequency.
  - Level of animal contact required.

SAMPLING ALTERNATIVES

If resources are not significantly limited, (1) use the lowest intra-premises and inter-premises design prevalence, and (2) sample at least three times per incubation period.

If mass population sampling tests become available, substitute these tests for individual animal sampling, and sample frequently.

The following are sampling scheme alternatives to individual sampling, using a 1 percent design prevalence.

- Increase the design intra-premises prevalence from 1 to 2 percent, or 5 to 10 percent. With each percent increase, fewer animals will be sampled.
- With a highly contagious FMD viral strain, there will be less time lost between infection and detection when using higher design prevalence. This is because the number of ill animals increases exponentially. If R_0=2, each animal infects 2 others, so then the number of infected animals will increase in the exposed group from 1, 2, 4, 8 etc. If R_0=5, every animal infected will infect five other animals, so the number of infected animals will increase from 1, 5, 25, 125, etc.[1]
  - Visual detection of FMD infected animals will become easier.
- If the FMDV strain has a short incubation period, there will be less time lost between infection and detection using a higher design prevalence because the animals become infectious and display clinical signs rapidly.
  - The reverse is true with an FMDV that has a longer incubation period.

SAMPLING EXAMPLES

1. *rRT-PCR.* The rRT-PCR test would be used to sample all clinically ill animals. The remainder of the samples (from the calculated total needed) would be from animals selected from the population of animals without clinical signs. In this population of animals that do not have clinical signs, the prevalence of infected animals is expected to be *less than* in the sub-population of animals with clinical signs.

2. *Visual examination.* Visual examination will occur in the sub-population of animals with clinical signs.

   For example, 5 pyretic cows may be expected each day in a group of 250 milking cows (mastitis, pneumonia, etc.). Visual observation would detect the

[1] R_0 is the basic reproduction number, or the expected number of cases produced by a single case in a susceptible population.

additional 5 clinically ill cows (based on previous outbreaks, the prevalence of FMD infected animals in the 250 cows may vary from 10 to 80 percent). The prevalence of FMD infected cows would be 50 percent in the sub-group of 10 clinically sick animals.

MINIMUM SAMPLE SIZES

Tissue collection from apparently healthy animals/herds is performed to detect subclinical animals as quickly as possible, reducing the risk of virus spread. The selection of an appropriate prevalence level in an FMD outbreak should be based on known or estimated epidemiological findings. Table F-2 presents sample sizes based on prevalence level. Five percent and 10 percent prevalence rates are also provided.

Table F-2. Minimum Sample Sizes with Various Prevalence Levels Needed to Detect FMD in Apparently Healthy Herds/Animals

Herd Size or Number of Premises	Prevalence			
	1%	2%	5%	10%
<=50	ALL	ALL	37	23
51–100	ALL	82	47	27
101–200	164	111	54	28
201–300	199	124	56	29
301–400	222	131	58	29
401–500	237	136	59	30
501–600	248	139	62	30
601–700	256	141	62	30
701–800	262	143	62	30
801–900	268	144	62	30
901–1000	272	146	62	30
1001–2000	292	157	62	30
>2000	314	157	62	30

Note: These sample sizes are based on an rRT-PCR sensitivity of 95 percent for detecting FMDV in appropriately collected samples from infected cattle. The sizes provide 95 percent confidence that the premises or area has an FMD prevalence less than the design prevalence given that the virus is there and all animals test negative. Prevalence in this table indicates:
1. If determining the number of animals in a herd, then the within herd prevalence is the level chosen.
2. If determining the number of herds in a zone to test, then the herd level prevalence is the level chosen.

Table F-3 presents sample sizes, based on prevalence level expected in the group of clinically infected animals on premises. This shows that fewer samples are required to detect FMDV with clinically ill animals because of the high prevalence of FMD infected animals in the clinically ill animal population. The provided sample sizes in the table are based on within-herd prevalence of FMD by the time cattle develop visible lesions.

Table F-3. Minimum Sample Sizes with Various Prevalence Levels Needed to Detect an Infected Animal Using Visual Observation

Herd Size or Number of Premises	Prevalence		
	40%	60%	80%
<=15	6	4	3
16–75	7	4	3
>75	8	4	3

Note: These sample sizes are based on an rRT-PCR sensitivity of 95 percent for detecting FMDV in appropriately collected samples from infected cattle with clinical signs of infection. The sizes provide 95 percent confidence of detecting infection in a herd or zone, given that it is there at the given prevalence. Prevalence in this table indicates:

1. If determining the number of animals in a herd, then the within herd prevalence is the level chosen. Thus using rRT-PCR for detection, we have 95 percent confidence of detecting an infected animal in the herd if the prevalence in the herd is 40 percent, 60 percent, 80 percent (in Table F-3).
2. If determining the number of herds in a zone to test, then the herd level prevalence is the level chosen. Thus using rRT-PCR for detection, we have 95 percent confidence of detecting an infected herd in the zone if the prevalence in the herd is 40 percent, 60 percent, 80 percent (in Table F-3).

Sampling Schemes for Commercial and Noncommercial Premises

The following definitions apply to both commercial and noncommercial premises.

1. *Sampling unit.* Premises or epidemiological unit(s) on premises (for example, feedlot pens, air management units in swine operations, milk cow groups, etc.).

2. *Sample.* (1) Visual examination of sick or dead animals followed by rRT-PCR confirmation if suspicion of FMD, (2) Collection of individual animal tissue, vesicular fluid, or oral/nasal swabs from calculated number of animals or premises and then test with rRT-PCR.

Frequency recommendations are based on the following:

- Short incubation period of FMD (2 – 14 days).
- Sufficient personnel available for surveillance activities.
- High probability of spreading FMD with frequent inspection/sampling.
- Recommendations for changing frequency of premises inspection and sampling are listed in Table F-4.

This information is summarized in Table F-5.

COMMERCIAL PREMISES

Infected Zone

1. Census of premises within zone; sample premises as prioritized by results of epidemiological investigation and continuity of business requirements.

2. Sampling frequency:

   - Contact Premises (CP), Suspect Premises (SP), and Monitored Premises (MP):

     - Collect samples from the calculated number of animals (Tables F-2 and F-3), or calculated using the Outbreak Toolbox,[2] on each premises every 5 days for 28 days.

     - Treat CP, SP, and MP that test negative as At-Risk Premises (ARP), and sample as such.

     - MP may be sampled more frequently depending on the need to move products, but must be sampled at the minimum listed above. For example, a dairy farm needing to ship milk daily will be evaluated daily. See the *Secure Milk Supply Plan* for further information. On a feedlot, premises will be evaluated on each of the 3 days prior to shipping the animals.

   - ARP:

     - Collect samples on each premises once every 7 days for duration of the area quarantine.

Buffer Zone

1. Census of premises within zone; sample premises as prioritized by results of epidemiological investigation and continuity of business requirements.

2. Sampling frequency:

   - CP, SP, and MP:

     - Collect samples from the calculated number of animals (Tables F-2 and F-3), or calculated using the Outbreak Toolbox, on each premises every 5 days for 28 days.

     - Treat CP, SP, and MP that test negative as ARP, and sample as such.

[2] For the Outbreak Surveillance Toolbox, mentioned throughout this document, please go to http://inside.aphis.usda.gov/vs/ceah/nsu/toolbox/, or e-mail National.Surveillance.Unit@aphis.usda.gov.

- MP may be sampled more frequently depending on the need to move products, but must be sampled at the minimum listed above. For example, a dairy farm needing to ship milk daily will be evaluated daily. See *Secure Milk Supply Plan* for further information. On a feedlot, premises will be evaluated on each of the 3 days prior to shipping the animals.

- ARP:

  - Collect samples on each premises once every 7 days for duration of the area quarantine.

Surveillance Zone

1. Number of premises to be sampled:

   - Calculate using the Outbreak Toolbox or Cannon formulae.

   - Premises to be sampled is based on detecting at least one IP with 95 percent confidence, where:

     - IP prevalence equals or exceeds 1 percent of all premises with susceptible animals, or

     - A census, if the number of premises in the zone is small, and

     - In order as prioritized by results of epidemiological investigation and continuity of business requirements.

2. Sampling frequency:

   - Randomly select the calculated number of premises to be sampled (as determined above, such as 60), and collect the appropriate samples on each of the selected premises once during the first 3-week period of the area quarantine. Then,

   - Randomly select in the sampling list frame the premises sampled (in the first 3-week period) and sample and equal number of premises (as calculated above) once during each additional 3-week period of the area quarantine.

     - For example, select and sample 60 premises once during the first 3-week period, then reselect (with replacement) another 60 premises to be sampled in the second 3-week period.

NONCOMMERCIAL PREMISES

The same sampling unit and sample is used.

Infected Zone

1. Census of premises within zone; sample premises as prioritized by results of epidemiological investigation and continuity of business requirements.

2. Observe the herd for FMD compatible signs.

3. If FMD compatible signs are observed, or in species that show few signs, collect appropriate samples on the premises using 1 percent design prevalence. Most noncommercial premises will have few animals, requiring a census.

4. Sampling frequency:

   - CP, SP, and MP:

     - Observe/sample entire herd/flock for FMD signs (swab any with FMD signs) every 5 days for 28 days.

       - Frequency of sampling depends on available personnel, number of premises to be sampled, owner resistance, and other factors.

       - IC must balance premises' transmission risks and detection costs in deciding sampling frequency.

       - MP may be sampled more frequently depending on the need to ship product, but at the minimum listed above.

     - Treat CP, SP, and MP that test negative in the above sampling regime as ARP, and sample as described for ARP.

   - ARP:

     - Observe/sample entire herd/flock on each premises once every 7 days for the duration of the area quarantine.

Buffer Zone

1. Census of premises within zone; sample premises as prioritized by results of epidemiological investigation and continuity of business requirements.

2. If FMD compatible signs are observed or in species that show few signs: collect appropriate samples on the premises using 1 percent design prevalence (most noncommercial premises will have few animals, thereby requiring a census).

3. Sampling frequency:

- CP, SP, and MP:
  - Observe/sample entire herd/flock for FMD signs (swab any with FMD signs) every 5 days for 28 days.
    - Frequency of sampling depends on available personnel, number of premises to be sampled, owner resistance, and other factors.
    - IC must balance premises' transmission risks and detection costs in deciding sampling frequency.
    - MP may be sampled more frequently depending on the need to ship product, but at the minimum listed above.
  - Treat CP, SP, and MP that test negative in the above sampling regime as ARP, and sample as described for ARP.
- ARP:
  - Observe/sample entire herd/flock on each premises once every 7 days for the duration of the area quarantine.

Surveillance Zone

1. Observe/sample the herd/flock for FMD compatible signs (swab any with FMD signs).
2. If FMD compatible signs are observed or in species that show few signs: collect appropriate samples on the premises using 1 percent design prevalence (most noncommercial premises will have few animals, thereby requiring a census).
3. Number of premises to be sampled:
   - Calculate using the Outbreak Toolbox or Cannon formulae.
   - Premises to be sampled is based on detecting at least one IP with 95 percent confidence, where:
     - IP prevalence equals or exceeds 1 percent of all premises with susceptible animals, or
     - A census, if the number of premises in the zone is small, and
     - In order as prioritized by results of epidemiological investigation and continuity of business requirements.
   - Sampling frequency:

- Randomly select the calculated number of premises to be sampled (as determined above, such as 60), and collect the appropriate samples on each of the selected premises once during the first 3-week period of the area quarantine. Then,

- Randomly reselect (include the premises observed/sampled in the first 3-week period in the sampling list frame) and sample an equal number of premises (as calculated above) once during each additional 3-week period of the area quarantine. For example, randomly select and observe/sample 60 premises during the first 3-week period, then reselect (with replacement) another 60 premises to be observed/ sampled in the second 3-week period.

Proof of Disease Freedom Surveillance

This information is summarized in Table F-6.

1. Surveillance samples will be tested using the 3ABC ELISA that demonstrates past exposure to the virus, thus adding a time element into the surveillance scheme. Additionally, there will be enhanced passive clinical surveillance with accepted testing protocols of suspect cases, surveillance in slaughter plants, and enhanced surveillance in markets and shows. Surveillance for proof of DF starts 21 days (World Organization for Animal Health [OIE] requirement) after depopulation of the last IP.

2. The goal is to demonstrate that all premises are disease free at the design prevalence level because diagnostic tests are negative. OIE recommends intensifying surveillance schemes in conjunction with (1) active investigation of herds/flocks with suspicious clinical signs, and (2) increased slaughter sero-surveillance.

COMMERCIAL PREMISES (DISEASE FREEDOM)

Infected Zone, Buffer Zone, and Surveillance Zone

1. Number of samples per herd:

   - Calculate using the Outbreak Toolbox or Cannon formulae.

   - Premises to be sampled is based on detecting at least one IP with 95 percent confidence, where:

     - IP prevalence equals or exceeds 5 percent where the maximum animals sampled doesn't exceed 60 animals per herd/flock.

2. Number of premises to be sampled:

   - Calculate using the Outbreak Toolbox or Cannon formulae.

- Premises to be sampled is based on detecting at least one IP with 95 percent confidence, where:
  - The IP prevalence equals or exceeds 1 percent of all premises with susceptible animals in the Infected Zone (IZ).

3. Sampling frequency:
   - Sample the number of premises calculated above (for example, 60 premises one time each) during a 3-month period after the outbreak has been eradicated.

NONCOMMERCIAL PREMISES (DISEASE FREEDOM)

Infected Zone, Buffer Zone, and Surveillance Zone

1. Number of samples per herd:
   - Calculate using the Outbreak Toolbox or Cannon formulae.
   - Number of animals to be sampled is based on detecting at least one IP with 95 percent confidence, where:
     - IP prevalence equals or exceeds 1 percent where the maximum number of animals sampled doesn't exceed 60 animals per herd/flock.
2. Number of premises to be sampled:
   - Calculate using the Outbreak Toolbox or Cannon formulae.
   - Premises to be sampled is based on detecting at least one IP with 95 percent confidence, where:
     - The IP prevalence equals or exceeds 1 percent of all premises with susceptible animals in the IZ.
3. Sampling frequency:
   - Sample the number of premises calculated above (for example, 60 premises one time each) during a 3-month period after the outbreak has been eradicated.

FURTHER SURVEILLANCE INFORMATION

Table F-4 shows the incubation periods and sampling frequency.

Table F-4. Incubation Periods and Sampling Frequency

Estimated Incubation Period Based on Field Information		
Incubation Period	**Frequency of Sampling (days between sampling)**	
	Minimum (Days)	**Maximum (Days)**
1 to 2 Days	1	1
3 to 4 Days	2	3
5 to 7 Days	4	6
8 to 14 Days	7	10
> 14 Days	10	

Table F-5 summarizes the outbreak surveillance scheme for disease detection.

Table F-5. Outbreak Surveillance for Disease Detection

Disease Detection						
FMD Outbreak Response						
	Commercial			**Noncommercial**		
Sampling	**Infected Zone**	**Buffer Zone**	**Surveillance Zone#**	**Infected Zone**	**Buffer Zone**	**Surveillance Zone#**
Number of Premises	Census	Census	1% Prevalence Threshold°	Census	Census	1% Prevalence Threshold°
Unit	Individual Animal Sample	Individual Animal Sample	Individual Animal Sample	Observation or Individual Animal Sample ^	Observation or Individual Animal Sample ^	Observation or Individual Animal Sample ^
Frequency						
Free Premises	-	-	21 Days	-	-	21 Days
Monitored Premises	Every 5 days for 28 days		-	Every 5 days for 28 days		-
At-Risk Premises	7 Days	7 Days	-	7 Days	7 Days	-
Contact and Suspect Premises#	Every 5 days for 28 days		-	Every 5 days for 28 days		-
Product Movement	Daily evaluation for daily product movement; evaluation each day, 3 days prior for non-daily movement.			Daily evaluation for daily product movement; evaluation each day, 3 days prior for non-daily movement.		

° Prevalence threshold is a predetermined proportion of Infected Premises (for example, 5 percent) used to calculate the number of premises to be sampled at a specific confidence level (for example, 95 percent) in a population of a given size (for example, 1,000 premises) based on detecting at least one IP.
^ Types of sample depend on available tests. Visual sampling followed 3ABC ELISA.
# Suspect Premises in a Surveillance Zone will be subject to surveillance procedures and diagnostic testing as indicated by relevant authorities.

Table F-6 shows surveillance requirements to prove FMD-freedom.

Table F-6. Surveillance for Proof of Disease Freedom

Proof of Disease Freedom[#]						
FMD Outbreak Response						
	Commercial			**Noncommercial**		
Sampling*	**Infected Zone[$]**	**Buffer Zone[$]**	**Surveillance Zone[$]**	**Infected Zone[$]**	**Buffer Zone[$]**	**Surveillance Zone[$]**
Number of Samples per Premises	5% Prevalence Threshold[&]	5% Prevalence Threshold[&]	5% Prevalence Threshold[&]	1% Prevalence Threshold[&]	1% Prevalence Threshold[&]	1% Prevalence Threshold[&]
Number of Premises	1% Prevalence Threshold[°]	1% Prevalence Threshold[°]	1% Prevalence Threshold[°]	1% Prevalence Threshold[°]	1% Prevalence Threshold[°]	1% Prevalence Threshold[°]
Frequency	Sample each premises of the Calculated Number of Premises once during a 3-month Period					

[#] Sero-surveillance conducted in the area to be proved disease free in addition to any other animal sampling.
[$] Infected, Buffer, and Surveillance Zones combine as one unit for proof of DF.
[&] Number of animals sero-sampled based on 5 percent prevalence in herd/flock at the 95 percent confidence level where the maximum number of animals sampled per epidemiological unit does not exceed 60 animals.
[°] Prevalence threshold is a predetermined proportion of Infected Premises (for example, 5 percent) used to calculate the number of premises to be sampled at a specific confidence level (for example, 95 percent) in a population of a given size (for example, 1,000 premises) based on detecting at least one IP. A census of the premises in a zone will be sampled if there are few premises. Sample premises in order as by epidemiological investigation and continuity of business requirements.
* Sampling Unit used in all Surveillance Schemes: Individual animals observation, appropriate individual animal sample or, if available, mass population sampling techniques (for example, bulk tank).

Assumptions for Surveillance Schemes

1. Production parameters will be monitored for indications of FMD intrusion.

2. The consequences of an infected but undetected premises is greater if it is located at the periphery of the Buffer Zone (BZ) vs. the periphery of the IZ:

   - Increased opportunity of disease spread due to less stringent movement requirements in the BZ;

   - Increased difficulty of surveillance:

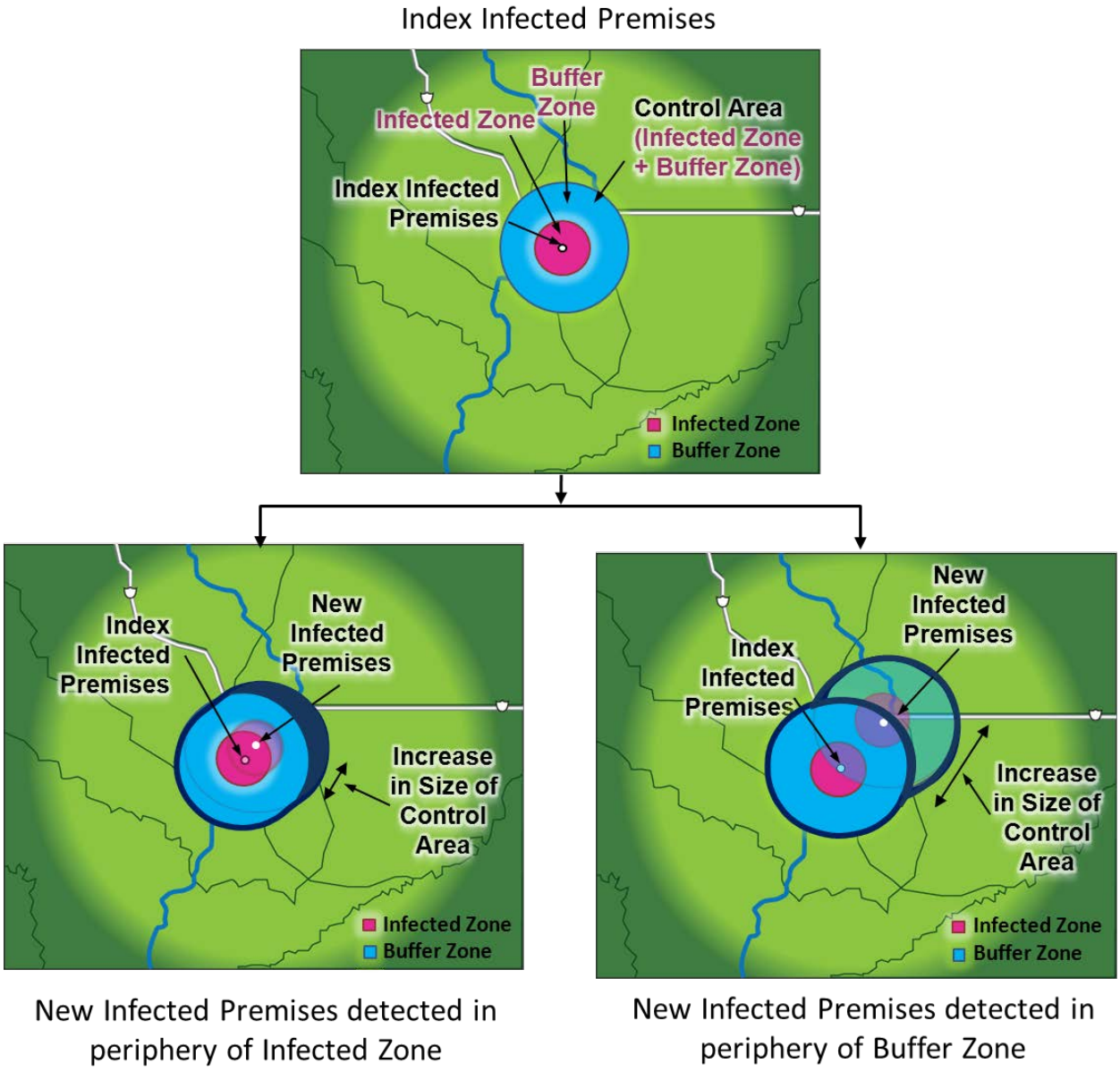
     - A larger number of ARP that require sampling.

     - A larger geographic area over which to sample ARP.

3. Increased Size of the CA: An IP will increase the size of the CA by the radius of the IZ. However, if the newly detected IP is located on the periphery of the BZ, the size of the CA will increase by the radius of the IZ and the BZ.

Figure F-2 shows that the size of the CA depends on where the new IP is located.

Figure F-2. Infected Premises' Effect on Size of Control Area



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Appendix G
Procedures for FMD Investigation and Specimen Submission

Veterinary Services (VS) Memorandum 580.4 provides guidance for the investigation of potential foreign animal disease/emerging disease incidents. VS Memo 580.4 is currently under review. The document is available at https://fadprep.lmi.org and http://inside.aphis.usda.gov/vs/em/fadprep.shtml (for APHIS employees).

Appendix H
Epidemiological Investigation Questionnaire

This appendix contains a sample epidemiological questionnaire that could be employed in the event of a foot-and-mouth disease (FMD) outbreak.

This epidemiological questionnaire is only an example template. Based on the epidemiological situation or the types of premises involved in the actual outbreak, it may be appropriate to add other questions regarding other risk factors which may play a role in transmission.

Sample FMD Epidemiology Questionnaire

Date: _____

Business/farm name: _____

Primary contact:_____

Business address: _____

Business telephone number: _____

Cell telephone number: _____

Fax number: _____

Home telephone number: _____

E-mail address: _____

Secondary contact: _____

Business address: _____

Business telephone number: _____

Cell telephone number: _____

Fax number: _____

Home telephone number: _____

E-mail address: _____

Farm address (911 and Animal Location): _____

City: _____ Zip code: _____

County: _____ Township: _____

Range: _____ Section: _____

GPS coordinates (decimal degrees): _____

Premises identification number: _____

The purpose of this epidemiological questionnaire is to help the Incident Command determine premises designations: Contact Premises, At-Risk Premises, or Monitored Premises. Additional information will be considered (for example, diagnostic tests) for movement permits.

A. General Information

1. Species on premises: _____

2. Type of premises (commercial or non-commercial): _____

3. Have you observed feral or wild animals on or near the premises?

   ☐ Yes ☐ No ☐ Don't know

4. Are there backyard premises with susceptible livestock nearby?

   ☐ Yes ☐ No ☐ Don't know

5. Do you have multiple, non-contiguous premises you travel and work between (yes/no)?

   ☐ Yes ☐ No

6. Are there contiguous premises with susceptible livestock (not owned by you)?

   ☐ Yes ☐ No

B. Animal Population on Premises

7. Please identify the animals on the premises.

Species	Males > 1 year	Females > 1 year	< 1 year
a. Swine			
b. Sheep/Goats			
c. Cattle			
d. Other Susceptible Species			

e. Non-susceptible species (type and number): _____

_____

C. Employee Risk Factors

8. Do any of your personnel work at other premises with susceptible animals or have they visited other premises, feedlots, dairy, processing plants, or livestock slaughtering facilities within the past 28 days? ☐ Yes ☐ No

   If Yes, what premises? _____

9. Do any of your workers live with someone who works at another livestock premises, feedlot, dairy, processing plant, slaughter facility or rendering plant? ☐ Yes ☐ No

10. Have you hired new personnel during the past 28 days? ☐ Yes ☐ No

    If Yes, did they work for another livestock premises before you hired them? ☐ Yes ☐ No
    If Yes, where did they work prior to coming to your premises? _____

11. Has an employee from this premises visited a slaughter/rendering facility within the past 28 days? ☐ Yes ☐ No

    If Yes, what facility?_____
    If Yes, did the person clean and disinfect his vehicle? ☐ Yes ☐ No
    If Yes, did the person change outer clothes? ☐ Yes ☐ No
    If Yes, did the person disinfect footwear or change into footwear assigned to this premises upon return? ☐ Yes ☐ No

12. Have any of your employees been overseas? ☐ Yes ☐ No

    If Yes, where? _____

D. **Biosecurity Risk Factors**

13. Have wild ruminants been seen on the property in the last 28 days? ☐ Yes ☐ No

14. Have rodents, dogs, or cats been observed in livestock housing in the past 28 days? ☐ Yes ☐ No

15. Which of the following **best** describes this farm's usual carcass (normal mortality) disposal method?
    - ☐ Rendering
    - ☐ Composting on site
    - ☐ Burial on site
    - ☐ Incineration on site
    - ☐ Other (specify: _____)

16. Do you dispose of livestock for other farms? ☐ Yes ☐ No

17. Have you maintained all requirements since your last regular biosecurity audit? ☐ Yes ☐ No

    If no, what requirements have not been met?

18. What additional biosecurity measures have been implemented? (For example, once the premises has been determined to be within a Control Area, all vehicles, including feed trucks, must now be cleaned and disinfected prior to entry to and exit from the premises.)

E. Trace Back Information

In the last 28 days, did the following movements **onto** the farm occur? If yes, please provide as much accurate information as possible for each unique source. You can add more rows by 'right clicking' in the box and selecting "Insert→Insert Rows Below".

19. **Susceptible Animals** ☐ Yes ☐ Don't know ☐ No

If yes,

a. What species? _____

b. How many animals? _____

Source/name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Animals tested for FMD prior to movement (Yes/No)	Entered in visitor log (Yes/No)

20. **Milk Products or By-Products** ☐ Yes ☐ Don't know ☐ No

If yes,

Source/name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Milk or product tested for FMD prior to movement (Yes/No)	Entered in visitor log (Yes/No)

21. **Feed trucks** ☐ Yes ☐ Don't know ☐ No

If yes,

Source/name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

22. **Fresh litter/bedding** ☐ Yes ☐ Don't know ☐ No

If yes,

Source/name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

23. **Manure** ☐ Yes ☐ Don't know ☐ No

If yes,

Source/name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

24. **Hoof Trimmers** ☐ Yes ☐ Don't know ☐ No

If yes,

Source/name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

25. **Mortality Pick Up/Renderer** ☐ Yes ☐ Don't know ☐ No

If yes,

Source/name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

a. Did the driver leave the vehicle while on this premises? ☐ Yes ☐ Don't know ☐ No

b. If Yes,
What area of the premises did he enter? _____

Was driver required to wear outer clothes
and foot wear provided by this premises? ☐ Yes ☐ Don't know ☐ No

26. **Company vet/service tech** ☐ Yes ☐ Don't know ☐ No

If yes,

Source/name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

27. **Non-company vet/consultant** ☐ Yes ☐ Don't know ☐ No

If yes,

Source/name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

28. **Construction or service person (e.g., gas, plumbing, pest control)** ☐ Yes ☐ Don't know ☐ No

If yes,

Source/name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

29. **Customer/buyer/dealer** ☐ Yes ☐ Don't know ☐ No

If yes,

Source/name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

30. **Other producer** ☐ Yes ☐ Don't know ☐ No

If yes,

Source/name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

31. **Non-business visitor (friend/neighbor)** ☐ Yes ☐ Don't know ☐ No

If yes,

Source/name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

F. Trace Forward Information

In the last 28 days, did the following movements **off** the farm occur? If yes, please provide as much accurate information as possible for each unique source. You can add more rows by 'right clicking' in the box and selecting "Insert→Insert Rows Below".

32. **Susceptible Animals** ☐ Yes ☐ Don't know ☐ No

If yes,

a. What species? _____

b. How many animals? _____

Destination/name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Animals tested for FMD prior to movement (Yes/No)	Entered in visitor log (Yes/No)

33. **Milk Products or By-Products** ☐ Yes ☐ Don't know ☐ No

If yes,

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Milk or product tested for FMD prior to movement (Yes/No)	Entered in visitor log (Yes/No)

34. **Feed trucks** ☐ Yes ☐ Don't know ☐ No

If yes,

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

35. **Fresh litter/bedding** ☐ Yes ☐ Don't know ☐ No

If yes,

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

36. **Manure** ☐ Yes ☐ Don't know ☐ No

If yes,

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

37. **Hoof Trimmers** ☐ Yes ☐ Don't know ☐ No

If yes,

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

38. **Mortality Pick Up/Renderer** ☐ Yes ☐ Don't know ☐ No

If yes,

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

a. Did the driver leave the vehicle while on this premises? ☐ Yes ☐ Don't know ☐ No

b. If Yes,
What area of the premises did he enter? _____

Was driver required to wear outer clothes and foot wear provided by this premises? ☐ Yes ☐ Don't know ☐ No

39. **Company vet/service tech** ☐ Yes ☐ Don't know ☐ No

If yes,

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

40. **Non-company vet/consultant** ☐ Yes ☐ Don't know ☐ No

If yes,

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

41. **Construction or service person (e.g., gas, plumbing, pest control)** ☐ Yes ☐ Don't know ☐ No

If yes,

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

42. **Customer/buyer/dealer** ☐ Yes ☐ Don't know ☐ No

If yes,

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

43. **Other producer** ☐ Yes ☐ Don't know ☐ No

If yes,

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

44. **Non-business visitor (friend/neighbor)** ☐ Yes ☐ Don't know ☐ No

If yes,

Destination/name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

Appendix I
Examples of Movement Control Notices

This appendix provides two examples—Federal and State—of halting movement of animals during a disease outbreak.

EXAMPLE—WEST VIRGINIA

Commissioner of Agriculture Halts Poultry Shows and Sales after AI-Positive Flock Discovered in Virginia

Commissioner of Agriculture Gus R. Douglass has ordered a halt to poultry shows and sales throughout West Virginia in response to a turkey flock that tested positive for low pathogenicity avian influenza (LPAI) in Mt. Jackson, Va., just across the West Virginia border.

The strain is not the "bird flu" that has been plaguing Southeast Asia and parts of Europe and poses no threat to human health.

The order applies to any gathering of live birds, including shows at fairs and festivals and sales of poultry. The order is effective Monday, July 9, and will be in place for 30 days unless another positive flock is discovered.

The order does not apply to the commercial industry, which tests every flock for AI before it is moved off the farm to ensure that infected birds are not trucked past other poultry farms.

"Having already dealt with a positive flock in West Virginia earlier this year, we want to take every precaution to protect our poultry industry from a potentially devastating situation," said Commissioner Douglass.

He also noted that the West Virginia Department of Agriculture is on high alert for any signs of the disease here, and that the industry has been exercising enhanced surveillance protocols since a 2002 AI outbreak that affected West Virginia and Virginia.

Poultry companies on both sides of the border have instructed their growers not to spread litter or move it from their farms until further notice.

According to the Virginia Department of Agriculture and Consumer Services (VDACS), testing over the weekend by the USDA's National Veterinary Services Laboratory (NVSL) in Ames, Iowa, confirmed the presence of AI antibodies, which indicates possible prior exposure to the virus. The turkeys did not show any signs of illness prior to testing.

Virginia is closely monitoring all poultry operations within a six-mile radius of the affected farm.

NVSL is doing further testing to help identify the virus and hopefully determine its source. VDACS, USDA and the poultry owner are working cooperatively to minimize the possibility that the virus will move beyond this farm.

The affected flock contains 54,000 birds, which will be euthanized as a precaution as soon as possible and composted on-site. While LPAI poses no risk to human health, federal and state policy is to eradicate H5 and H7 subtypes because of their potential to change into more serious types, which have a higher mortality rate among birds. .

Source: http://www.wvagriculture.org/news_releases/2007/7-9-07.html.

EXAMPLE—FEDERAL

Source: http://www.federalregister.gov/articles/2003/04/16/03-9322/exotic-newcastle-disease-additions-to-quarantined-area#p-3.

18531

Rules and Regulations

Federal Register
Vol. 68, No. 73
Wednesday, April 16, 2003

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 82

[Docket No. 02–117–5]

Exotic Newcastle Disease; Additions to Quarantined Area

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the exotic Newcastle disease regulations by quarantining El Paso and Hudspeth Counties, TX, and Dona Ana, Luna, and Otero Counties, NM, and prohibiting or restricting the movement of birds, poultry, products, and materials that could spread exotic Newcastle disease from the quarantined area. This action is necessary on an emergency basis to prevent the spread of exotic Newcastle disease from the quarantined area.

DATES: This interim rule was effective April 10, 2003. We will consider all comments that we receive on or before June 16, 2003.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 02–117–5, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 02–117–5. If you use e-mail, address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 02–117–5" on the subject line.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html*.

FOR FURTHER INFORMATION CONTACT: Dr. Aida Boghossian, Senior Staff Veterinarian, Emergency Programs Staff, VS, APHIS, 4700 River Road Unit 41, Riverdale, MD 20737–1231; (301) 734–8073.

SUPPLEMENTARY INFORMATION:

Background

Exotic Newcastle disease (END) is a contagious and fatal viral disease affecting the respiratory, nervous, and digestive systems of birds and poultry. END is so virulent that many birds and poultry die without showing any clinical signs. A death rate of almost 100 percent can occur in unvaccinated poultry flocks. END can infect and cause death even in vaccinated poultry.

The regulations in "Subpart A—Exotic Newcastle Disease (END)" (9 CFR 82.1 through 82.15, referred to below as the regulations) were established to prevent the spread of END in the United States in the event of an outbreak. In § 82.3, paragraph (a) provides that any area where birds or poultry infected with END are located will be designated as a quarantined area, and that a quarantined area is any geographical area, which may be a premises or all or part of a State, deemed by epidemiological evaluation to be sufficient to contain all birds or poultry known to be infected with or exposed to END. Less than an entire State will be designated as a quarantined area only if the State enforces restrictions on intrastate movements from the quarantined area that are at least as stringent as the regulations. The regulations prohibit or restrict the movement of birds, poultry, products, and materials that could spread END from quarantined areas. Areas quarantined because of END are listed in § 82.3, paragraph (c).

On October 1, 2002, END was confirmed in the State of California. The disease was confirmed in backyard poultry, which are raised on private premises for hobby, exhibition, and personal consumption, and in commercial poultry.

In an interim rule effective on November 21, 2002, and published in the **Federal Register** on November 26, 2002 (67 FR 70674–70675, Docket No. 02–117–1), we amended the regulations in § 82.3(c) by quarantining Los Angeles County, CA, and portions of Riverside and San Bernardino Counties, CA, and restricting the interstate movement of birds, poultry, products, and materials that could spread END from the quarantined area.

In a second interim rule effective on January 7, 2003, and published in the **Federal Register** on January 13, 2003 (68 FR 1515–1517, Docket No. 02–117–2), we further amended § 82.3(c) by adding Imperial, Orange, San Diego, Santa Barbara, and Ventura Counties, CA, and the previously non-quarantined portions of Riverside and San Bernardino Counties, CA, to the list of quarantined areas. Because the Secretary of Agriculture signed a declaration of extraordinary emergency with respect to the END situation in California on January 6, 2003 (see 68 FR 1432, Docket No. 03–001–1, published January 10, 2003), that second interim rule also amended the regulations to provide that the prohibitions and restrictions that apply to the interstate movement of birds, poultry, products, and materials that could spread END will also apply to the intrastate movement of those articles in situations where the Secretary of Agriculture has issued a declaration of extraordinary emergency (new § 82.16).

On January 16, 2003, END was confirmed in backyard poultry on a premises in Las Vegas, NV. Therefore, in a third interim rule effective January 17, 2003, and published in the **Federal Register** on January 24, 2003 (68 FR 3375–3376, Docket No. 02–117–3), we amended § 82.3(c) by quarantining Clark County, NV, and a portion of Nye County, NV, and prohibiting or restricting the movement of birds, poultry, products, and materials that

could spread END from the quarantined area. On January 17, 2003, the Secretary of Agriculture signed a declaration of extraordinary emergency because of END in Nevada (see 68 FR 3507, Docket No. 03–001–2, published January 24, 2003).

On February 4, 2003, END was confirmed in backyard poultry on a premises in the Colorado River Indian Nation in Arizona. Therefore, in a fourth interim rule effective February 10, 2003, and published in the **Federal Register** on February 14, 2003 (68 FR 7412–7413, Docket No. 02–117–4), we amended § 82.3(c) by quarantining La Paz and Yuma Counties, AZ, and a portion of Mohave County, AZ, and prohibiting or restricting the movement of birds, poultry, products, and materials that could spread END from the quarantined area. On February 7, 2003, the Secretary of Agriculture signed a declaration of extraordinary emergency because of END in Arizona (see 68 FR 7338, Docket No. 03–001–3, published February 13, 2003).

On April 9, 2003, END was confirmed in backyard poultry on a premises in El Paso County, TX. Therefore, in this interim rule, we are amending § 82.3(c) by designating El Paso and Hudspeth Counties, TX, and Dona Ana, Luna, and Otero Counties, NM, as a quarantined area and prohibiting or restricting the movement of birds, poultry, products, and materials that could spread END from the quarantined area. As provided for by the regulations in § 82.3(a), this quarantined area encompasses the area where poultry infected with END were located and a surrounding geographical area deemed by epidemiological evaluation to be sufficient to contain all birds or poultry known to be infected with or exposed to END.

Emergency Action

This rulemaking is necessary on an emergency basis to prevent the spread of END. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**.

We will consider comments that we receive during the comment period for this interim rule (see **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review under Executive Order 12866.

This rule amends the regulations by quarantining El Paso and Hudspeth Counties, TX, and Dona Ana, Luna, and Otero Counties, NM, and prohibiting or restricting the movement of birds, poultry, products, and materials that could spread END from the quarantined area. This action is necessary on an emergency basis to prevent the spread of END from the quarantined area.

This emergency situation makes timely compliance with section 604 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) impracticable. We are currently assessing the potential economic effects of this action on small entities. Based on that assessment, we will either certify that the rule will not have a significant economic impact on a substantial number of small entities or publish a final regulatory flexibility analysis.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 82

Animal diseases, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements, Transportation.

■ Accordingly, 9 CFR part 82 is amended as follows:

PART 82—EXOTIC NEWCASTLE DISEASE (END) AND CHLAMYDIOSIS; POULTRY DISEASE CAUSED BY SALMONELLA ENTERITIDIS SEROTYPE ENTERITIDIS

■ 1. The authority citation for part 82 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

■ 2. In § 82.3, paragraph (c) is amended by adding, in alphabetical order, entries for New Mexico and Texas to read as follows:

§ 82.3 Quarantined areas.

* * * * *

(c) * * *

* * * * *

New Mexico

Dona Ana County. The entire county.
Luna County. The entire county.
Otero County. The entire county.

Texas

El Paso County. The entire county.
Hudspeth County. The entire county.

Done in Washington, DC, this 10th day of April 2003.

Bobby R. Acord,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03–9322 Filed 4–15–03; 8:45 am]

BILLING CODE 3410–34–P

FARM CREDIT ADMINISTRATION

12 CFR Part 615

RIN 3052–AC05

Funding and Fiscal Affairs, Loan Policies and Operations, and Funding Operations; Capital Adequacy

AGENCY: Farm Credit Administration.

ACTION: Final rule.

SUMMARY: The Farm Credit Administration (FCA or agency) amends its capital adequacy regulations to add a definition of total liabilities for the net collateral ratio calculation, limit the amount of term preferred stock that may count as total surplus, clarify the circumstances in which we may waive disclosure requirements for an issuance of equities by a Farm Credit System (FCS, Farm Credit or System) institution, and make several nonsubstantive technical changes. These amendments update, modify, and clarify certain capital requirements.

EFFECTIVE DATE: This regulation will become effective 30 days after publication in the **Federal Register** during which either or both houses of

Appendix J
Secure Milk Supply Plan

The *Secure Milk Supply (SMS) Plan* is a public-private-academic collaboration, currently in progress. *The overall goal is to maintain business continuity for dairy producers and processors in a foot-and-mouth disease (FMD) outbreak and to provide a continuous supply of milk and milk products for consumers.*

The *SMS Plan* will develop processes and procedures that milk producers, processors, and Federal and State agencies agree are feasible. These processes and procedures will allow the safe movement of milk from dairies in an FMD Control Area through a processing plant such that the FMD virus (FMDV) does not spread and further impair U.S. ability to export agricultural products.

The Animal and Plant Health Inspection Service (APHIS) has provided funding to examine this issue in detail and develop specific response recommendations. Each group has a set of objectives that will contribute to developing a national *SMS Plan*. Communication among the researchers throughout development will ensure the final products are complementary and well coordinated. The principal academic investigators are as follows:

- Center for Food Security and Public Health, Iowa State University
- University of California, Davis
- Center for Animal Health and Food Safety, University of Minnesota.

The *SMS Plan* has also created four working groups:

1. Milk Movement Matrix
2. Premises Biosecurity
3. Milk Truck Biosecurity
4. Milk Plant Biosecurity.

Each of these groups consists of members of academia and industry, State Animal Health Officials, and APHIS officials.

Together, these groups will achieve objectives that contribute to the development of the *SMS Plan*, including the following:

- Research on the survival of FMDV in milk and potential methods to transport and process milk in a biosecure way, including the ability to detect FMDV in bulk milk tanks through diagnostic testing.
- Determination of the viability of a Federal and State transport plan for raw milk movement from non-infected premises in an FMD Control Area.
- Socialization of information with stakeholders to obtain feedback and gauge acceptance, particularly on current regulations and critical movement points to minimize FMD spread.
- Analysis of current structure and business practices of the dairy industry to see how they relate to emergency management and business continuity.
- Identification and prioritization of risk assessments for different commodities necessary to support continuity of business efforts for the dairy industry in the event of an FMD outbreak response.
- Engagement of the dairy industry in animal health emergency response planning.
- Engagement of dairy health professionals in national animal health emergency management planning for FMD response.

Please see https://fadprep.lmi.org or http://securemilksupply.org for more information.

Appendix K
Glossary

Animal product	Blood or any of its components, bones, bristles, feathers, flesh, offal, skins, and any by product containing any of those components that originated from an animal or bird.
Case	An individual animal infected by FMD virus, with or without clinical signs.
Cloven-hooved animals	Members of the order Artiodactyla. Most are susceptible to infection by FMDV. Includes pigs, deer, sheep, goats, and cattle.
Compartment (compartmentalization)	An animal subpopulation contained in one or more establishments under a common biosecurity management system with a distinct health status with respect to a specific disease or specific diseases for which required surveillance, control, and biosecurity measures have been applied for the purpose of international trade.
Confirmed positive premises	Any premises with at least one confirmed positive case (animal) as specified by the current APHIS definition for FMD; Infected Premises.
Control Area	A Control Area (an Infected Zone and Buffer Zone) has individual premises quarantine for Infected Premises, Suspect Premises, and Contact Premises and movement restrictions for At-Risk Premises and Monitored Premises.
Emergency vaccination	A disease control strategy using the immunization of susceptible animals through the administration of a vaccine comprising antigens appropriate to the disease to be controlled.
Etiology	The causes or origin of disease or the factors that produce or predispose toward a certain disease or disorder.
Euthanasia	The humane destruction of an animal accomplished by a method that produces rapid unconsciousness and subsequent death with a minimum of pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death.

FAD PReP (Foreign Animal Disease Preparedness and Response Plan)	Documents used to identify veterinary functions and countermeasures necessary to contain and control a FAD outbreak. It is also used to integrate functions and countermeasures with emergency management systems and operations conducted in joint and unified command by local, State, Tribal, and Federal personnel.
FMDV infection	For the purposes of international trade, the OIE *Terrestrial Animal Health Code* Chapter 8.5 deals with not only the occurrence of clinical signs caused by FMDV, but also with the presence of infection with FMDV in the absence of clinical signs. FMDV infection is defined by the OIE as follows: 1. FMDV has been isolated and identified as such from an animal or a product derived from that animal; or 2. Viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of FMDV has been identified in samples from one or more animals, whether showing clinical signs consistent with FMD or not, or epidemiologically linked to a confirmed or suspected outbreak of FMD, or giving cause for suspicion of previous association or contact with FMDV; or 3. Antibodies to structural or nonstructural proteins of FMDV that are not a consequence of vaccination have been identified in one or more animals showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected outbreak of FMD, or giving cause for suspicion of previous association or contact with FMDV.
Fomites	Inanimate objects that can transmit infectious agents from one animal or person to another.
Foreign animal disease	A transboundary animal disease not known to exist in the U.S. animal population.
Incident Command System	A standardized, on-scene, all-hazards incident management approach that ◆ allows for the integration of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure; ◆ enables a coordinated response among various jurisdictions and functional agencies, both public and private; and ◆ establishes common processes for planning and managing resources.

Incubation period	For the purposes of the OIE *Terrestrial Animal Health Code (2011)*, the incubation period for FMD is 14 days. The incubation period is the longest period that elapses between the introduction of the pathogen into the animal and the first clinical signs of the disease.
Index case	The first or original case identified in a disease outbreak.
Kill	Any procedure which causes the death of an animal.
Mass depopulation	Method by which large numbers of animals must be destroyed quickly and efficiently with as much consideration given to the welfare of the animals as practicable, but where the circumstances and tasks facing those doing the depopulation are understood to be extenuating.
Milk	The normal mammary secretion of milking animals obtained from one or more milkings.
Milk product	The product obtained by any processing of milk.
Modified stamping-out policy	Animal health measures for stamping-out that are not implemented in full.
Mutation (genetic)	Change in the sequence of a cell's genome caused by radiation, viruses, transposons, and mutagenic chemicals, as well as errors during meiosis or replication.
Non-susceptible animal	Animal that does not develop a particular disease when exposed to the causative infectious agent of that disease.
OIE (World Organization for Animal Health)	Organization that collects and publishes information on animal diseases from 178 countries (June 2012) and develops standards for animal health.
Outbreak	The occurrence of cases of a disease that are in excess of what is normally expected in a given population.
Personal protective equipment (PPE)	Clothing and equipment to prevent occupational injuries and diseases through control of exposure to potential hazards in the work place after engineering and administrative controls have been implemented to the fullest extent.
Preemptive slaughter	Depopulation under the competent authority of susceptible animal species in herds or flocks on premises that have been exposed to infection by direct animal-to-animal contact or by indirect contact of a kind likely to cause the transmission of FMD virus prior to the expression of clinical signs.

Premises	A geographically and epidemiologically defined location, including a ranch, farm, stable, or other establishment.
Regionalization (also known as zoning)	An animal subpopulation defined primarily on a geographical basis (using natural, artificial, or legal boundaries).
Rendering	Process by which purified fat and protein products are recovered from inedible portions of animals by cooking at high temperatures.
Ruminants	Mammal in the order Artiodactyla, including cattle, goats, sheep, bison, deer, elk, moose, antelope, and others (camelids, giraffes), but not including Suina (pigs, peccaries). For purposes of the OIE *Terrestrial Animal Health Code (2011)*, ruminants do not include the dromedary (*Camelus dromedarius).*
Slaughter	The killing of an animal or animals for human consumption, often by bleeding.
Stamping-out (OIE definition)	Carrying out under the authority of the Veterinary Authority, on confirmation of a disease, the killing of the animals which are affected and those suspected of being affected in the herd and, where appropriate, those in other herds which have been exposed to infection by direct animal to animal contact, or by indirect contact of a kind likely to cause the transmission of the causal pathogen. All susceptible animals, vaccinated or unvaccinated, on an infected premises should be killed and their carcasses destroyed by burning or burial, or by any other method which will eliminate the spread of infection through the carcasses or products of the animals killed.
Susceptible animal	Any animal that can be infected with and replicate the disease pathogen of concern.
Susceptible species	See susceptible animal.
Trace back	The identification of the origin and movements of all animals, animal products, possible fomites, people, possible vectors, and so on that have entered onto an infected premises.
Trace forward	The tracing of all animals, people, fomites, and so on that have left an infected premises. The premises that received the animals or goods should be investigated and kept under surveillance or quarantine.
Vector	An insect or any living carrier that transports an infectious agent from an infected individual to a susceptible individual or its food or immediate surroundings.

Appendix L
Abbreviations

3D	depopulation, disposal, and decontamination
AC	Area Command
AEOC	APHIS Emergency Operations Center
AgELISA	Antigen ELISA
AGID	agar-gel immunodiffusion
AHPA	Animal Health Protection Act
Al(OH)	aluminum hydroxide
APHIS	Animal and Plant Health Inspection Service
ARP	At-Risk Premises
AVIC	Area Veterinarian in Charge
AVMA	American Veterinary Medical Association
BSL-3	Biosafety Level 3
BZ	Buffer Zone
CA	Control Area
CCC	Commodity Credit Corporation
CEAH	Centers for Epidemiology and Animal Health
CF	Contingency Fund
CFIA	Canadian Food Inspection Agency
CFT	complement fixation test
CP	Contact Premises
CVO	Chief Veterinary Officer of the United States
CVZ	Containment Vaccination Zone
DEFRA	Department for Environment, Food, and Rural Affairs
DF	disease freedom
DHS	Department of Homeland Security
DIVA	differentiation of infected from vaccinated animals
DOI	Department of Interior
EITB	enzyme-linked immunoelectrotransfer blot

ELISA	enzyme-linked immunosorbent assay
EMLC	Emergency Management Leadership Council
EMRS	Emergency Management Response System
EOC	emergency operations center
EPA	Environmental Protection Agency
EPP	expected percentage of protection
EQS	Emergency Qualifications System
ESF	Emergency Support Function
FA	Free Area
FAD	foreign animal disease
FAD PReP	Foreign Animal Disease Preparedness and Response Plan
FADDL	Foreign Animal Disease Diagnostic Laboratory
FEMA	Federal Emergency Management Agency
FFS	Federal-to-Federal support
FMD	foot-and-mouth disease
FMDV	foot-and-mouth disease virus
FP	Free Premises
FSIS	Food Safety Inspection Service
GFRA	Global Foot-and-Mouth Disease Research Alliance
GIS	geographic information system
HHS	Department of Health and Human Services
HTST	high temperature—short time pasteurization
IBRS-2	swine-kidney permanent cell line
IC	Incident Command
ICG	Incident Coordination Group
ICP	Incident Command Post
ICS	Incident Command System
ID_{50}	50 percent infectious dose
IMT	incident management team
IP	Infected Premises
IZ	Infected Zone
JIC	Joint Information Center

LK	lamb-kidney secondary cells
LPA	Legislative and Public Affairs
LPBE	liquid phase blocking ELISA
MAC	Multiagency Coordination Group
MP	Monitored Premises
NAFMDVB	North American Foot-and-Mouth Disease Vaccine Bank
NAHEMS	National Animal Health Emergency Management System
NAHERC	National Animal Health Emergency Response Corps
NAHLN	National Animal Health Laboratory Network
NCAHEM	National Center for Animal Health Emergency Management
NCIE	National Center for Import and Export
NIMS	National Incident Management System
NRF	National Response Framework
NSP	nonstructural protein
NSU	National Surveillance Unit
NVS	National Veterinary Stockpile
NVSL	National Veterinary Services Laboratories
OIE	World Organization for Animal Health
PCR	polymerase chain reaction
PD_{50}	50 percent protective dose
PGP	percentage of protection
PPE	personal protective equipment
PPV	positive predictive value
PVZ	Protection Vaccination Zone
RFID	radio frequency identification
RNA	ribonucleic acid
ROSS	Resource Ordering and Status System
rRT-PCR	real-time reverse transcriptase polymerase chain reaction
SAGARPA	Mexican Secretariat of Agriculture and Rural Development
SAHO	State Animal Health Official
SATs	South African Territories (FMD serotypes)
SITC	Smuggling Interdiction and Trade Compliance

SMS	Secure Milk Supply
SOP	standard operating procedure
SP	Suspect Premises
SPCE	solid phase competitive ELISA
SZ	Surveillance Zone
TAIO	Tool for the Assessment of Intervention Options
TDD	telecommunications device for the deaf
UHT	ultra-high temperature
USDA	U.S. Department of Agriculture
VDACS	Virginia Department of Agriculture and Consumer Services
VI	virus isolation
VIAA	virus infection association antigen
VNT	virus neutralization test
VP	Vaccinated Premises
VS	Veterinary Services
VZ	Vaccination Zone
WRLFMD	World Reference Laboratory for Foot-and-Mouth Disease
WS	Wildlife Services

Appendix M
Selected References and Resources

Note: This appendix lists documents related to foot-and-mouth disease (FMD) response. All related FAD PReP documents listed in Appendix A are also references for this *FMD Response Plan.*

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