

**FOOT-AND-MOUTH DISEASE
RESPONSE PLAN**
THE RED BOOK

FAD PReP

Foreign Animal Disease
Preparedness & Response Plan



**United States
Department of
Agriculture**

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By the end 2015, the United States experienced its largest Foreign Animal Disease (FAD) outbreak—highly pathogenic avian influenza (HPAI)—in history. Subsequent to the 2015 HPAI outbreak, APHIS has tested its response capabilities with FAD outbreaks in 2016, 2017, 2018 and 2019, as well as the planning and execution of the 2018 ARMAR (Agriculture Response Management and Resources foot-and-mouth disease (FMD) functional exercise. This version of the *USDA APHIS FMD Response Plan: The Red Book (Updated October 2020)* reflects knowledge and lessons learned during these activities. Additionally, this version incorporates changes made in related Foreign Animal Disease Preparedness and Response Plan (FAD PReP) materials.

The following list highlights important revisions that were made to this version of the FMD Response Plan.

- Reflects policy that explicitly recognizes vaccine as a likely response tool in an FMD outbreak.
- Reflects the new National Response Framework, released June 2019.
- References and includes the latest text of the World Organization for Animal Health (OIE) *Terrestrial Animal Health Code*.
- Includes new surveillance sections, revised by the Center for Epidemiology and Animal Health.
- Provides revised templates for epidemiology questionnaires and State FMD vaccine planning.
- Streamlines content into four chapters specific to FMD: 1) general information; 2) national roles, responsibilities, and authorities; 3) response goals and strategy; and 4) critical response activities.
- Includes critical activity “Essentials” sidebars, highlighting available training resources and often overlooked planning considerations.
- Incorporates policy guidance prepared for ARMAR on managing a National movement standstill.
- Corrects comments made on, and any errors identified in, the prior version.

This version of the FMD Red Book is being distributed as an early draft to assist in the preparation for the next cycle of FMD response planning and exercises. Links to appendices in the body of the document are internal and do not require an internet connection; however, connectivity is needed to access other links in the body and in the Essentials sidebars. It is our hope that those involved in preparing for the Southern Animal Health Association FMD functional exercise (scheduled in November 2021) will find the updated material and format useful. Future updates of this plan will incorporate new National policy guidance and/or lessons learned from FAD response experiences and exercises.

We invite comments on the FMD Response Plan for incorporation into the next version. Please email all comments to FAD.PReP.Comments@usda.gov with the subject line of “Comments to Updated FMD Response Plan.”

Additional policy guidance documents for FMD, as well as general response topics, are available at www.aphis.usda.gov/fadprep. These documents, alongside the FMD Response Plan: The Red Book, should be consulted in an FMD outbreak.

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:
<http://www.aphis.usda.gov/fadprep>
or e-mail FAD.PReP.Comments@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 (October 2020)* updates the FMD Response Plan (September 2014) and replaces previous versions of 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 **October 2020**. Please send questions or comments to:

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Chapter 1

Introduction and FMD Information

1.1 INTRODUCTION TO RESPONSE PLAN

This updated *Foot-and-Mouth Disease (FMD) Response Plan Draft: The Red Book (October 2020)* incorporates comments received on the *FMD Response Plan: The Red Book (2014)*, lessons learned from animal disease response exercises, and reflects updates to 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 the time-frames for these activities. In an outbreak situation, these critical activities are the responsibility of a unified Incident Command (IC) per the National Incident Management System (NIMS).

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 key 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 FAD PReP documents such as FMD standard operating procedures (SOP), National Animal Health Emergency Management System (NAHEMS) Guidelines, and existing Animal and Plant Health Inspection Service (APHIS) and Veterinary Services (VS) Guidance. (**Appendix A** provides a list of documents related to FMD outbreak response and an overview of FAD PReP).

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 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 93.6 million cattle, 72.4 million

swine, and 8.0 million sheep and goats.¹ Although FMD does not typically kill adult livestock, it does have highly 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 be additional costs for any vaccination or control program implemented, and heavy production losses.

1.2 AUDIENCE AND PURPOSE OF DOCUMENT

This document is intended for animal health emergency responders at all levels of government, as well as industry partners. It provides strategic guidance, current policy information, and response strategies for the control and eradication of FMD, should an outbreak occur in the United States. It also offers additional resources for responding individuals on tactical information needed to respond during an FMD outbreak in domestic livestock.

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.

1.3 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 *FAD PReP FMD Overview of Etiology and Ecology SOP* available at <http://www.aphis.usda.gov/fadprep>. See **Chapter 4** of this plan for the case and laboratory definitions for FMD.

¹ Data retrieved from National Agricultural Statistics Service, 2017 Census of Agriculture: <https://www.nass.usda.gov/Publications/AgCensus/2017/index.php>.

1.3.1 Etiology

1.3.1.1 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; each containing numerous strains. 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, fièvre aphteuse, and maul-und-klauenseuche.

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

The 2019 OIE *Terrestrial Animal Health Code* (***Terrestrial Code***, see **Appendix B**)² “defines the occurrence of infection with FMDV as:

1. FMDV has been isolated from a sample from an animal; or
2. viral antigen or viral ribonucleic acid (RNA) specific to FMDV has been identified in a sample from an animal showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed 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 detected in a sample from an animal showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed outbreak of FMD, or giving cause for suspicion of previous association or contact with FMDV.

1.3.2 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.

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

²OIE. (2019). *Terrestrial Animal Health Code*, Chapter 8.8. Retrieved from https://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_fmd.htm.

1.3.2.1 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.

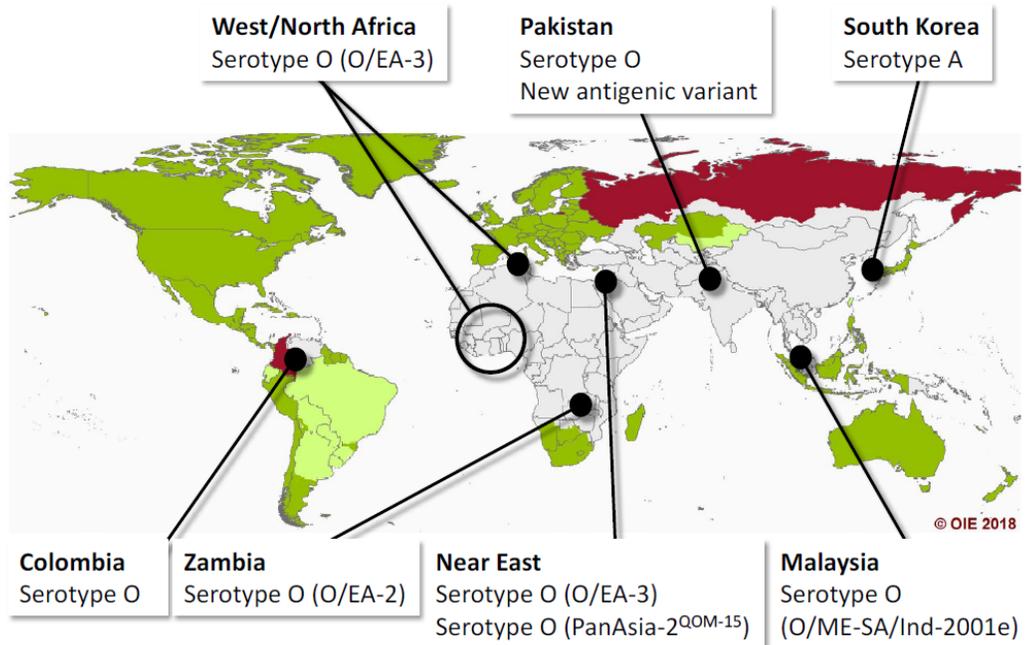


Figure 1-1. Worldwide FMD Events in 2018³

1.3.2.2 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 country's 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.

³ OIE/Food and Agriculture Organization (FAO) Foot-and-Mouth Disease Reference Laboratory Network. (2018). *Annual Report*. Retrieved from: <https://www.foot-and-mouth.org/sites/foot/files/user-files/research-paper/pdf/11-19/OIE-FAO%20FMD%20Ref%20Lab%20Network%20Report%202018.pdf>.

1.3.3 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 at its APHIS website, [Animal Health Status of Regions](#).

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 and ovine meat under specific conditions. Additional information on the products eligible for importation into the United States from other countries is posted on the Food Safety and Inspection Service (FSIS) website, [Countries Eligible for U.S. Export](#).

1.3.4 Impact of an FMD Outbreak

1.3.4.1 ECONOMIC

The 2001 FMD outbreak in the United Kingdom had an estimated economic impact between \$12 and \$18 billion⁴. A U.S. outbreak contained to California could cost \$6–14 billion; a nation-wide agroterrorism attack could reach \$228 billion.⁵ Modeled costs for a hypothetical, accidental release of FMDV from the National Bio and Agro-Defense Facility (NBAF) (under construction in Kansas) exceed \$180 billion, but were lowered by more than half with the implementation of a vaccination campaign.⁶ The estimated economic impact depends primarily on three things: the duration and geographic extent of the

⁴ Thompson, D., Muriel, P., Russell, D., Osborne, P., et al. (2002). Economic costs of the foot and mouth disease outbreak in the United Kingdom in 2001. *Revue scientifique et technique-Office international des epizooties*, 21(3), 675-687; Grubman, M.J., & Baxt, B. (2004). Foot-and-mouth disease. *Clinical Microbiology Reviews*, 17(2), 465-493. DOI: 10.1128/CMR.17.2.465-493.2004; USDA FAS. (2007). U.K. foot-and-mouth disease – recovery timetable, the economic impact and who pays? Global Agriculture Information Network, UK7020. Retrieved from <https://apps.fas.usda.gov/gainfiles/200708/146292150.pdf>.

⁵ Modeling estimates vary, and will depend on the factors listed in this section. These estimates are based on information provided in Ekboir, J.M. (1999). Potential Impact of Foot-and-Mouth Disease in California: the Role and Contribution of Animal Health Surveillance and Monitoring Services. *Agricultural Issues Center*. Retrieved from <https://aic.ucdavis.edu/pub/fmd.html>; and Oladosu G., Rose A., Lee, B. (2013). Economic Impacts of Potential Foot and Mouth Disease Agroterrorism in the USA: A General Equilibrium Analysis. *J Bioterr Biodef S12*: 001.

⁶ Pendell, Dustin L., Marsh, Thomas L., Coble, Keith H., Lusk, Jayson L., Szmania, Sara C. (2015). Economic Assessment of FMDv Releases from the National Bio and Agro Defense Facility. *PLoS One* 10(6). Retrieved from <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0129134>.

outbreak; the extent of trade embargoes on U.S. products; and the reaction of consumers to the disease and control measures.

The value of lost exports would be a substantial detriment to the economy. In addition, an FMD response effort would involve direct costs for depopulation, indemnity payments, animal disposal, disinfection, and movement control measures, as well as vaccine, if chosen as a disease control measure. 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.

1.3.4.2 ZOO NOTIC POTENTIAL AND 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.⁷ FMD differs from hand, foot, and mouth disease of humans. FMD may be able to 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.

Mass depopulation and disposal of animals in an FMD outbreak may create public health implications for personnel and individuals associated with the response effort. The 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.

1.3.5 Ecology

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

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

⁷ Spickler A.R., Roth, J.A., Galyon, J., Lofstedt, J., eds. (2010). *Emerging and Exotic Diseases of Livestock*, 4th ed. Ames, IA: Iowa State University, College of Veterinary Medicine; UK Department for Environment, Food, and Rural Affairs (DEFRA). *Summary Profile for Foot and Mouth Disease*. Retrieved from <http://adlib.everysite.co.uk/resources/000/116/112/fmd.pdf>.

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.

1.3.5.1 CARRIERS

There is a “carrier state” in many FMD-susceptible species. FMDV carriers have historically been defined as “recovered or vaccinated and exposed animals in which FMDV persists in the oropharynx for more than 28 days.”⁸ Carriers of FMD can include cattle, sheep, and goats, though sheep and goats seem to become carriers less often and for shorter periods than cattle. A carrier state has not been documented in swine. The duration of the carrier state in cattle can range from several months to several years. Persistent infections have also been reported for a limited period in some experimentally infected wildlife, including white-tailed deer, kudu, and fallow deer. Animals can become carriers regardless of their vaccination status or whether they showed clinical signs of the virus. The only wildlife reservoir of FMD proven to actually transmit the disease occurs in the African buffalo (*Syncerus caffer*).⁹

How an animal develops the carrier state and the role of FMD carriers in the infection of susceptible cattle are not well understood.¹⁰ However, a 2018 laboratory study in which susceptible animals were exposed to oropharyngeal fluid of carrier animals demonstrated transmission of FMDV, causing full clinical infection in naïve cattle.¹¹ Allowing carrier animals to persist in an FMD outbreak will increase the risk for further infection and new outbreaks.

1.3.5.2 INTRODUCTION AND TRANSMISSION OF FMD

FMDV is thought to be introduced through infected animals, contaminated fomites, and possibly carrier animals. As indicated above, there is no clear evidence on the conditions in which specific species of carrier animals can transmit FMDV to naïve animals, and wildlife does not appear to be a common means of introduction. Historically, meat products have been an important mode of introduction.

⁸ Fernández, P.J. and White, W.R. (2010). *Atlas of Transboundary Animal Diseases*. Paris: OIE.

⁹ OIE. (2019). Chapter 8.8, Article 8.8.1. *Terrestrial Animal Health Code*. Retrieved from <https://www.oie.int/en/standard-setting/terrestrial-code/access-online/>.

¹⁰ For more information on carrier animals, see Tenzin, Dekker, A., Vernooij, H., Bouma, A., Stegeman, A. (2008). Rate of Foot-and-Mouth Disease Virus Transmission by Carriers Quantified from Experimental Data. *Risk Analysis*. 28(2): 03–309.

¹¹ Arzt, J., Belsham, G.J., Lohse, L., Bøtner, A., Stenfeldt, C. (2018) Transmission of Foot-and-Mouth Disease from Persistently Infected Carrier Cattle to Naïve Cattle via Transfer of Oropharyngeal Fluid. *mSphere*; 3(5) DOI: 10.1128/mSphere.00365-18.

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 close 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 may shed FMDV from 1 to 4 days prior to the onset of clinical signs. Fomites contaminated with secretions and excretions from infected animals 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 (especially cattle, due to their large inspiratory capacity) 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. Multiple sources suggest FMDV may spread to distances well over 10 kilometers over land in favorable conditions and much greater distances over water. The conditions for long distance spread are thought 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.

1.3.5.3 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 > 9.0.¹² FMDV is preserved by refrigeration and freezing, but progressively inactivated by temperatures above 50°C. In cool laboratory conditions, FMDV has been found to survive in cattle and swine slurry as long as 10 and 14 weeks, respectively.¹³ FMDV is resistant to many disinfectants, such as iodophores and phenol, particularly when organic matter is present.

FMDV can survive in frozen bone marrow or lymph nodes for long periods. Meat must be subjected to heat treatment at 70°C for 30 minutes to ensure FMDV deactivation. Typical industrial processes for salami inactivate the virus. FMDV 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

¹² OIE. (2013). *Foot-and Mouth Disease*, Technical Disease Card. Retrieved from <https://www.oie.int>.

¹³ Bøtner, Anette, Belsham, Graham J. (2012). Virus survival in slurry: Analysis of the stability of foot-and-mouth disease, classical swine fever, bovine viral diarrhoea and swine influenza viruses. *Veterinary Microbiology* 157(1–2). Retrieved from <https://www.sciencedirect.com/science/article/pii/S037811351100650X?via%3Dihub>.

minimum temperature of 132°C for at least 1 second, 2) if the milk has a pH less than 7.0, a sterilization process applying a minimum temperature of 72°C for at least 15 seconds, or 3) if the milk has a pH of 7.0 or over, applying the process in 2) twice.¹⁴

FMDV can also persist in wool, hair, and other products for substantial periods. Please refer to the *FMD Overview of Etiology and Ecology SOP*, as well as the OIE *Terrestrial Code* for further information (www.aphis.usda.gov/fadprep and www.oie.int).

1.3.6 Diagnosis

Producers as well as veterinarians may be the initial detectors of an FMD outbreak, so they should be familiar with signs of vesicular disease. The incubation period is 2–14 days, and varies by species, on the dose of the virus, and on the route of infection. The OIE *Terrestrial Code* (2019) defines the incubation period as 14 days.

1.3.6.1 MORBIDITY & MORTALITY

The morbidity and mortality of FMD varies depending on the species affected, as well as the serotype and strain of the virus. Generally, morbidity is significant, and can approach 100 percent. Mortality is typically low in adult animals (1–5 percent), and higher in very young animals.

1.3.6.2 CLINICAL SIGNS

FMD is usually recognized by vesicular signs, although animals infected with FMD show a variety of clinical signs. Clinical signs are generally more prominent in cattle and pigs than in sheep and goats, and vesicles are indistinguishable from other vesicular diseases.

1.3.6.2.1 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;

¹⁴ OIE. (2019). Chapter 8.8, Article 8.8.35. Procedures for the inactivation of the FMD virus in milk and cream for human consumption. *Terrestrial Animal Health Code*. Retrieved from https://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_fmd.htm.

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- ▶ lameness, stamping, or kicking caused by vesicles on buccal and nasal mucous membranes or between the claws and coronary band;
 - ▶ vesicles on mammary gland; and/or
 - ▶ ruptured vesicles
 - ◆ 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.

1.3.6.2.2 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;
 - ▶ lesions on snout, muzzle, gums, and interdigital spaces; and/or
 - ▶ less severe oral lesions than in cattle (so no drooling)
- ◆ High mortality in piglets
- ◆ Possible abortion.

1.3.6.2.3 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.

1.3.6.3 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 the EuFMD (European Commission for the Control of FMD) resource available [online](#) (pp. 32–33) and the Iowa State University: Center for Food Safety and Public Health images, also available [online](#).

1.3.6.4 DIFFERENTIAL DIAGNOSES

Vesicular stomatitis, swine vesicular disease, Senecavirus A (SVA), 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.

1.3.7 Immunity

1.3.7.1 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.

1.3.7.2 VACCINATION

Vaccination against FMDV has been practiced with relatively positive immunity results, mostly in cattle. 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

-
- ▶ 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 4–5 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 protected against disease until 21–28 days after vaccination.
 - ◆ No currently available vaccine provides “sterilizing immunity” which will prevent subsequent infection.
 - ◆ It is possible that individual vaccinated cattle, sheep, and goats infected with FMDV could still become asymptomatic virus carriers.
 - ◆ In very young animals, a high level of maternal antibodies inhibits the immune response to vaccines.

Differentiating infected animals from vaccinated animals, known as a “DIVA” strategy, would be critical to a successful emergency vaccination strategy in an FMD outbreak. DIVA diagnostic techniques typically use tests for antibodies against viral nonstructural proteins (NSP) 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 is important for an effective vaccination campaign, business continuity processes, and FMDV surveillance.

Emergency vaccination and DIVA are discussed in the *NAHEMS Guidelines: Vaccination, Appendix A: FMD*. This document is available at www.aphis.usda.gov/fadprep.

Chapter 2

National Coordination for FMD Preparedness and Response

2.1 FOUNDATIONS OF PREPAREDNESS AND RESPONSE

Successful emergency preparedness for, and response to, FMD is based on the principles found in the National Response Framework (NRF) and NIMS.

2.1.1 National Response Framework

The NRF is a guide to how the Nation conducts response activities, through a whole community approach.¹⁵ It describes core capabilities for response, defines specific authorities, and establishes a comprehensive approach for responding to domestic incidents that range from serious local events to large-scale terrorist attacks or catastrophic natural disasters. It emphasizes private response efforts that support community lifelines to maintain or restore critical government operations. The NRF builds on NIMS, which provides a template and consistency in roles and responsibilities for those managing incidents.

The most recent update to the NRF retains the Emergency Support Function (ESF) annexes for coordination of Federal government resources and capabilities, but adds support annexes inclusive of private sector, non-governmental organizations, in addition to governmental entities. The NRF is available at <https://www.fema.gov>.

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 community and government to prepare for, prevent, respond to, recover from, and mitigate the effects of incidents, regardless of its size or complexity. A key concept is unified command for joint management of incidents under a single action plan. NIMS provides a common framework and a shared vocabulary, and describes systems and processes, that allow a large variety of organizational elements to achieve

¹⁵ As defined in the Federal Emergency Management Agency (FEMA) National Preparedness Goal, the whole community is a focus on enabling the participation in a wider range of players from the private and nonprofit sectors, including nongovernmental organizations and the general public, in conjunction with the participation of all levels of government in order to foster better coordination and working relationships. For more information visit [fema.gov](https://www.fema.gov).

common response and recovery goals. NIMS information is available at <https://www.fema.gov>.

NIMS consists of three major components:

- ◆ Resource Management
 - This section describes standard mechanisms to systematically manage resources, including personnel, equipment, supplies, teams, and facilities, both before and during incidents in order to allow organizations to more effectively share resources when needed.
- ◆ Command and Coordination
 - This section describes leadership roles, processes, and recommended organizational structures for incident management at the operational and incident support levels and explains how these structures interact to manage incidents effectively and efficiently. It describes four NIMS Command and Coordination structures in common use at USDA:
 - Incident Command System (ICS)
 - Emergency Operations Centers (EOC)
 - Multiagency Coordination Group (MAC)
 - Joint Information System (JIS)
- ◆ Communications and Information Management
 - This section describes systems and methods that help to ensure that incident personnel and other decision makers have the means and information they need to make and communicate decisions.

2.1.3 USDA Roles and Responsibilities Overview

The Departments of Agriculture and Interior share the primary agency role in ESF #11—Agriculture and Natural Resources—under the NRF; USDA is the coordinating agency. As stated in ESF #11, USDA responds to agriculture disease and pest incidents under its own statutory authority. USDA is responsible for implementing an integrated Federal, State, tribal, and local response to an outbreak of a highly contagious or economically devastating animal/zoonotic disease. This includes detecting animal disease anomalies, assigning FAD Diagnosticians (FADD) to conduct investigations, and coordinating tasks with other ESFs, State veterinary emergency response teams, and voluntary animal care organizations. ESF #11 ensures, in coordination with ESF #8 – Public Health and Medical Services, that animal/veterinary issues in natural disasters are supported. The USDA also plays a supporting role in other ESFs.

During a foreign animal disease (FAD) event of livestock, like an FMD outbreak, USDA deploys National Incident Management Teams (NIMT), coordinates the 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 or euthanasia of affected livestock, carcass disposal, cleaning and disinfection, active surveillance for additional cases, diagnostics, and, potentially, emergency vaccination.

During the course of an FMD outbreak response, USDA may request Federal-to-Federal 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 under a unity of effort concept for coordinating Federal resources. USDA would maintain the lead for 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 FAD Framework: Roles and Coordination (FAD PReP Manual 1-0)* and *APHIS FAD Framework: Response Strategies (FAD PReP Manual 2-0)*. These documents are available at www.aphis.usda.gov/fadprep.

2.2 USDA AUTHORITIES AND ACTIVITIES

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 to control, contain, and eradicate FMD. USDA is also 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.

APHIS produces FAD PReP documentation and materials, including this FMD-specific plan, to provide detailed response guidance for an animal disease outbreak in the United States. FAD PReP documents are consistent with both NRF and NIMS.

APHIS implements necessary mitigations to reduce risk prior to entry of animals or animal products into the United States. While the priority is always prevention, the agency is also active with domestic and international partners in preparedness efforts. These exclusionary and preparedness and activities for foreign animal diseases, generally, and FMD, specifically, are described in this section.

2.2.1 Authorities

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.

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 the State’s governor or Tribe’s chief official— 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). This extraordinary emergency declaration allows the Secretary to impose restrictions within a State or Territory.

7 *U.S. Code* 8306 further directs the Secretary to compensate the owner for animals (and articles, facilities, and conveyances) taken under these provisions. Payment is not to exceed fair market value less any compensatory payments received from a State or other payer. Regulations at 9 CFR §53.2 are applicable to FMD and authorize the APHIS Administrator to pay 50 percent of fair market value for takings in a disease control and eradication effort. The Secretary has authority to increase compensation to 100 percent. These are general provisions; exceptions are specified in the regulations, and additional sections may apply, e.g., 9 CFR §71.14.

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.

For further information on USDA APHIS authorities, see the *APHIS Foreign Animal Disease Framework: Roles and Coordination (FAD PReP Manual 1-0)* at www.aphis.usda.gov/fadprep and relevant regulatory language at www.govinfo.gov/help/uscode and www.govinfo.gov/help/cfr.

2.2.2 Foreign Animal Disease Preparedness and Response Plan

APHIS VS and its stakeholders established FAD PReP to provide guidance for preparing and responding to a FAD emergency. The precursor to FAD PReP was the NAHEMS, which offered a functional veterinary framework for responding to FADs. Now incorporated into FAD PReP, the NAHEMS Guidelines join strategic concept of operations documents, disease response plans (such as this FMD-specific plan), SOPs, and other materials to create a comprehensive approach to FADs that is consistent with NRF and NIMS. These documents aim to ensure a successful response commensurate with the severity of the outbreak. Federal, State, and local agencies; Tribal nations; and other stakeholders involved in animal health emergency management activities should integrate the information found in these documents into their preparedness and response planning activities and processes.

FAD PReP offers

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

These documents provide the foundation for coordinated National, regional, State, Tribal, and local activities in an emergency situation. They also serve as a practical guide and complement non-Federal preparedness activities.

Building on existing planning and response knowledge and relationships, FAD PReP efforts raise awareness of critical issues in FAD response and foster further collaboration between Federal partners, States, Tribes, industry, academia, and other stakeholders.

Appendix A provides more information on FAD PReP and associated materials.

Typically, documents are cleared by APHIS Legislative and Public Affairs (LPA) and posted on the FAD PReP website at www.aphis.usda.gov/fadprep. The APHIS website also hosts critical policy updates relating to ongoing or recent FAD outbreaks.

2.2.3 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.

APHIS VS has conducted multiple preparedness exercises to simulate an FMD outbreak and associated 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. Multistate exercises, like ARMAR (Agriculture and Response Management and Resources) held in 2018, have enhanced coordination and collaboration among States, and between State and Federal governments.

The National Veterinary Stockpile (NVS) has also conducted exercises to assess and test its ability to deliver supplies and services—and State and Tribal ability to receive and stage these items—in the event of an FMD outbreak. These exercises have incorporated States and Tribes, as well as industry and academia, to train together and simulate a response effort (even down to the conducting minor maintenance and troubleshooting of equipment).

2.2.4 Domestic Activities

USDA conducts 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 for suspected cases or reported vesicular conditions. The following list details a selection of ongoing USDA activities:

- ◆ *Import and export services.* APHIS 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. As an example, all cattle and breeding swine eligible for entry into the United States 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.
- ◆ *Prohibited items screening.* APHIS works directly with Federal partners, including DHS's Customs and Border Protection, to screen cargo and prevent travelers from bringing any products of concern into the United States. Travelers must declare all food items and materials of plant or

animal origin in their possession upon entry, as well as recent visits to farms and livestock facilities prior to their arrival back into the country.

- ◆ *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.
- ◆ *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.
- ◆ *Modeling, Assessments & Geospatial Analyses*. The USDA Center for Epidemiology and Animal Health (CEAH) uses complex disease spread simulation models, such as Interspread Plus and the Animal Disease Spread Model, to develop computer-generated outbreak scenarios for FMD. The results of these models can be further analyzed using economic modeling tools. Other modeling tools are used to examine within-herd spread, wind dispersion, and geospatial risk factors. Risk assessments can also inform decision-making processes. Additionally, geographic information systems are used to support preparedness and response activities. Together, various models, assessments, and analyses are used to explore possible control strategies and evaluate the consequences of FMD incursions in the United States. They may also help to estimate the countermeasures, materials, and personnel needed for control and eradication.
- ◆ *Emergency assistance*. After the 2014–2015 highly pathogenic avian influenza outbreak (HPAI), APHIS created the Voluntary Emergency Ready Response Corps (VERRC) to further increase the agency’s capacity to respond to an emergency. Additionally, APHIS may use term and temporary hires, and volunteers from other USDA agencies or Federal entities.
- ◆ *Animal Care*. APHIS Animal Care works with the American Zoological Association (AZA) on FMD planning. USDA and the AZA support the Zoo and Aquarium All Hazards Preparedness, Response, and Recovery (ZAHP) Fusion Center. More about this organization may be found at its website: <https://zahp.aza.org/>. Among the resources found at the ZAHP fusion center is the Secure Zoo Strategy (<https://securezoostrategy.org/>).

2.2.5 International Activities

In addition to the domestic activities discussed above, USDA conducts ongoing 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.* USDA 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. In addition, because some countries in South America are considered to be FMD-infected, USDA supports programs to maintain a buffer zone between Panama and Colombia in an effort to keep North and Central America FMD-free.
- ◆ *International coordination.* USDA APHIS collaborates with inter-departmental and international partners to mitigate, prevent, and control animal health threats outside the United States through the sharing of expertise and information, and development of infrastructure.
- ◆ *Global Foot-and-Mouth Disease Research Alliance (GFRA).* USDA's Agricultural Research Service 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 sent veterinarians to participate in international FMD training activities and to assist in FMD response efforts, at the request of foreign governments. In providing this assistance, USDA gains a bank of valuable expertise in FMD response and control efforts.
 - The United States is also a signatory country—with Australia, Canada, Ireland, New Zealand, and the United Kingdom—in the International Animal Health Emergency Reserve (IAHER). While not specific to FMD, the IAHER arrangement supports ready mobilization of personnel in case of an emergency animal disease event.

2.2.6 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 detection. These efforts focus on cases where bans are inconsistent with OIE standards, or with any U.S. bilateral agreements.

OIE member countries, like the United States, are to “immediately” notify the OIE of any confirmed FMDV infection, as defined in the OIE *Terrestrial 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 on the APHIS [Animal Health Status of Regions](#) web page.

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

2.3 USDA ORGANIZATIONAL STRATEGY

In the event of an FMD outbreak, effective and efficient whole community situation management and clear communication pathways will be critical for a successful response effort. A synchronized management and organizational structure will help to support the necessary control and eradication actions. Accordingly, APHIS has adopted NIMS and the ICS organizational structures to manage FAD outbreak response. The ICS is designed to enable efficient and effective incident management by integrating facilities, equipment, personnel, procedures, and communications operating within a common organizational structure.

2.4 APHIS INCIDENT MANAGEMENT STRUCTURE

The [APHIS Emergency Mobilization Guide](#) recognizes that the initial response to an incident is handled at the local level, with the lead APHIS program establishing the scope and scale of the incident, assessing local resources that may be available, and identifying when the response requires support from additional APHIS units.

The APHIS Administrator is the Federal executive responsible for implementing APHIS policy during an FMD outbreak. The Administrator is supported by the APHIS Management Team (AMT) and Emergency Preparedness Committee (EPC) which will consider how to best address resource requests for the response through a Multi-program Committee (MPC) established at the APHIS level, based on the specific incident.

2.4.1 Multi-Program Committee

The APHIS MPC serves as the senior level leadership group to support incident coordination and program area senior leaders when responding to significant

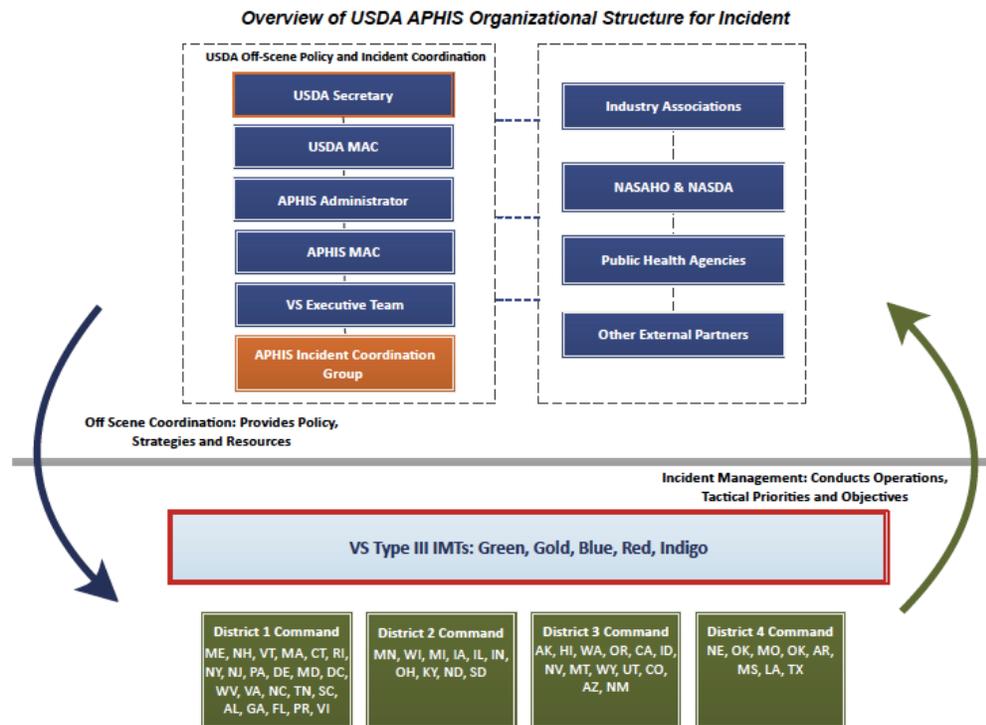
agricultural emergencies. Its structure is adaptable and easily expands and contracts to provide flexibility. The MPC establishes supportive relationships among the various units preparing for and responding to an FMD outbreak.

The APHIS MPC 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. The MPC may also include subject matter experts who can reach across the agency to achieve an effective coordination structure.

If the emergency response becomes too complex for an APHIS MPC to handle efficiently—for example, a large multistate FMD incident with numerous response activities—cooperation with other agencies or committees will be implemented, and a USDA or other MAC would likely be stood up. These groups, comprised of representatives from across USDA agencies or other government agencies, would make decisions regarding the sharing and use of critical resources. MPC and MAC groups are not part of the on-scene IC; therefore, they do not command activities in the field.

In addition to policy and incident coordination, the APHIS Administrator, AMT, Veterinary Services Deputy Administrator (VSDA), and VS Executive Team (VSET) communicate, collaborate, and coordinate with relevant industry associations, the National Assembly of State Animal Health Officials (NASAHO) and National Association of State Departments of Agriculture (NASDA), public health agencies (Federal and State), and other partners in a whole community approach. Figure 2-1 provides a visual example of the relationship among these entities.

Figure 2-1. APHIS Multiagency Coordination Structures and APHIS Emergency Operations: Relationship to Incident Management Team



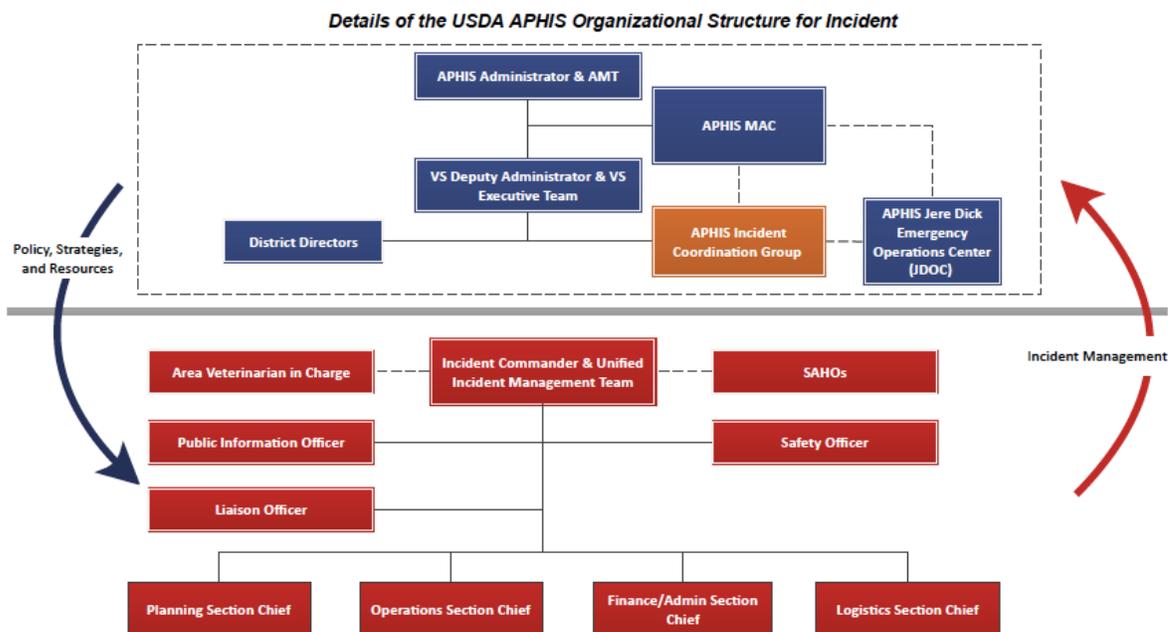
2.4.2 APHIS Incident Coordination Group

The VSDA, supported by the VSET, will coordinate many aspects of the response through an APHIS National Incident Coordination group (ICG) and NIMT. Led by a National Incident Coordinator (NIC) and a deputy NIC (or National Operations Coordinator), the ICG oversees the functions and response activities associated with the incident. Flexible and scalable to the size and scope of the incident, the ICG works closely with the unified (State/Federal) IC and the APHIS multiagency groups.

The ICG is responsible for requesting resources, formulating policy options, and assisting in implementing response and recovery strategies for an FMD outbreak. Another significant function of the ICG is to provide situational awareness, through daily or weekly reporting. (For additional information, see *APHIS FAD Framework: Roles and Coordination (FAD PReP Manual 1-0)* available at www.aphis.usda.gov/fadprep.)

Figure 2-2 provides a visual of the relationship of the ICG with response entities, including the NIMT, in the APHIS organizational structure.

Figure 2-2. Details of USDA APHIS Multiprogram Coordination, Incident Coordination Group, and a Unified Incident Management Team



2.4.3 Organization at the Field Level

At the beginning of an incident, the State Animal Health Official (SAHO) and the VS Area Veterinarian in Charge (AVIC), or their designees, may initially serve as Co-Incident Commanders in a unified IC structure. In an FMD response, one of five VS NIMTs would deploy and further develop the IC structure, jointly with the State.

The Unified IC establishes an Incident Command Post (ICP), which serves as the base of deployment for field personnel. In a large incident, multiple ICPs may exist, but each will still remain unified State-Federal IC organizational structures. (For additional information, see the *FAD PReP Incident Information Management and Reporting (FAD PReP Manual 3-0)* available at www.aphis.usda.gov/fadprep.)

When more than one incident is occurring at the same time, more than one IC may be established. Under an Area Command (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. The ICG may assume the role of AC. An AC should not be confused with the functions performed by MPC, as an AC oversees management coordination of the incident(s), while a MPC element (such as a communications/dispatch center or EOC) coordinates support.

The actual organizational structure for a given incident will be specific to the needs of that incident. As required, APHIS will consider various strategies to supplement response personnel, applying either novel concepts or those utilized in recent animal disease outbreak responses. For details on the internal structure of IMTs and ACs, please see *APHIS Foreign Animal Disease Framework: Roles and Coordination (FAD PReP Manual 1-0)*.

2.5 DIAGNOSTIC RESOURCES AND LABORATORY SUPPORT

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

2.5.1 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 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. NVSL-FADDL also assists in testing currently available vaccines.

By 2023, NVSL-FADDL is scheduled to move from Plum Island to the NBAF, currently under construction, in Manhattan, Kansas.

2.5.2 National Animal Health Laboratory Network

As of November 2019, the NAHLN consists of 59 laboratories, and coordinates the veterinary diagnostic laboratory capacity of State animal health laboratories and their extensive infrastructure, including facilities, equipment, and professional expertise. The great majority of these laboratories—including NVSL-Ames and NVSL-FADDL—are currently approved to conduct FMD preparedness and surge testing. (See **Appendix C** for a list of approved laboratories).

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 the NAHLN. Please see **Chapter 4** for more information.

2.5.3 Center for Veterinary Biologics

APHIS' 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 3

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 critical activities and tools required to achieve the response goals;
- ◆ discusses the epidemiological principles for any FMD response strategy;
- ◆ defines and describes key response strategies, including vaccine strategies;
- ◆ reviews factors that may influence the response strategies and scope of regulatory intervention;
- ◆ identifies types of FMD outbreaks and phases of FMD response; and
- ◆ addresses recovery and reviews the international standards from the OIE for FMD-free status.

3.1 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 protect public health and the environment, and stabilize animal agriculture, the food supply, and the economy; 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. The objective is to allow the United States to regain FMD-free status without the response effort causing more disruption and damage than the disease outbreak itself.

3.2 PRINCIPLES AND CRITICAL ACTIVITIES OF AN FMD RESPONSE

3.2.1 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 3-1 lists these critical activities and tools. A science- and risk-based approach that protects public health, animal health, and the environment and stabilizes animal agriculture, the food supply, and the economy will be employed at all times. Please see **Chapter 4** for more information on these critical activities and tools, (i.e., movement control, disposal, and epidemiological investigation and tracing).

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 (virus elimination) measures
- Effective and appropriate disposal procedures
- Mass depopulation and euthanasia (as response strategy indicates)
- Emergency vaccination (as response strategy indicates)

Box 3-1. Critical Activities and Tools for and FMD Response

3.2.2 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) (IZ) and Buffer Zone(s) (BZ) (the CAs), biosecurity procedures, and rigorous cleaning and disinfection protocols 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 people, materials, 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 (virus elimination) measures.
2. *Stop the production of FMDV in infected or exposed animals.* This is accomplished by timely slaughter (and processing) 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.

3.2.3 Coordinated Public Awareness Campaign

One of the most important critical activities is a public awareness campaign. Box 3-2 details the importance of a coordinated public awareness campaign in an effective response strategy.

Importance of Response Communication

Regardless of the response strategy or strategies selected, a public awareness campaign must be effectively coordinated with audience-appropriate information. 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, the environment, 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.

Box 3-2. Coordinated Public Awareness Campaign

APHIS LPA periodically updates a detailed set of FMD message maps and participates in the industry Cross-Species Communications Working Group. In addition, the livestock industry maintains a “dark” FMD website that can quickly be made visible to the public. These coordinated efforts will contribute to consistent messaging to producers and the public in case of an FMD outbreak.

3.2.4 FMD Vaccination Strategy

The use of emergency vaccination strategies may be considered in any 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 IC, the SAHO(s), and the VSDA, who is also the U.S. Chief Veterinary Officer (VSDA/CVO).

3.2.5 Incident Management

The outbreak response effort should be implemented in a manner consistent with NIMS and ICS with an appropriate span of control and delegation of authority, as described in **Chapter 2**. Incident Management includes conducting critical activities in accordance to Federal and State response plans, policies, and procedures to prevent further spread of FMD. Cooperative Federal, State, Tribal, local and industry response measures will be carried out with extreme urgency using the most appropriate geographic and jurisdictional scopes required to manage the situation. Response information must utilize the coordinated public awareness campaign (see **Section 3.2.3**) to clearly, and frequently relay consistent information to the whole community throughout the duration of the outbreak.

3.2.6 Authorization for Initial Response Activities

When the criteria for a presumptive FMD case has been met, the APHIS Administrator or VSDA/CVO can authorize APHIS personnel—in conjunction with State, Tribal, and Federal personnel—to initiate activities on the index premises. These activities may include, but are not exclusive to, depopulation, cleaning and disinfection, and epidemiological investigations of associated Contact Premises (CP)¹⁶. Concurrently, SAHOs or Tribal officials will immediately issue a quarantine or hold order for the relevant zones, areas, or premises. A Federal quarantine may be issued when requested by SAHOs or as directed by the Secretary of Agriculture.

State, Federal, and Tribal officials will also immediately discuss the issuance and specifications of initial movement standstill(s) in the United States for relevant regions or zones. In the event a National Movement Standstill is needed, USDA APHIS will provide specific guidance via Federal Register Order.

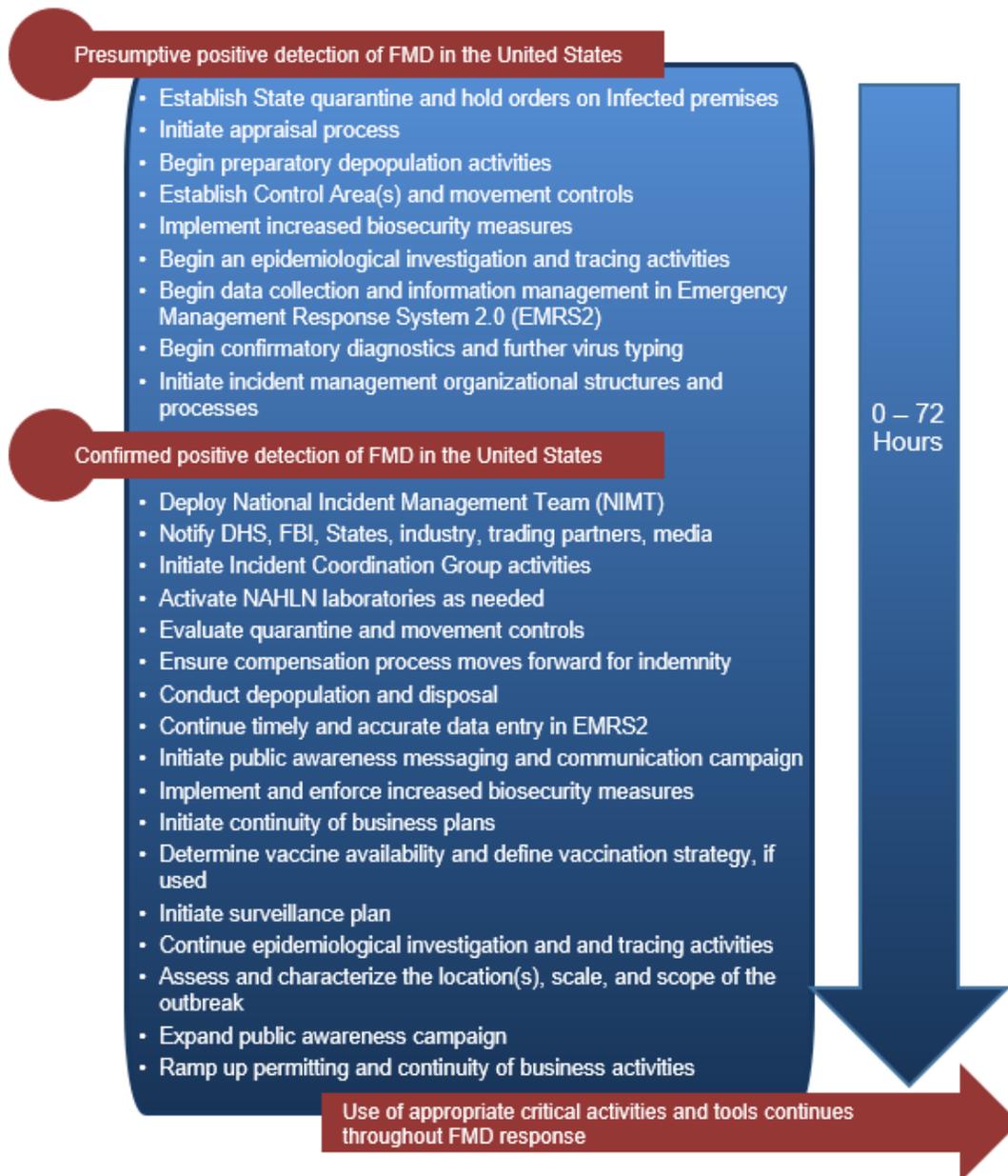
¹⁶ Contact Premises that are depopulated because of epidemiological risk factors are often termed as “dangerous Contact Premises (DCs)”.

Additionally, an ICG NIC and an IC should be identified as soon as possible to coordinate initial activities of an FMD detection.

3.2.7 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 3-1 highlights these tasks.

Figure 3-1. Critical Activities in the First 72 Hours of a U.S. FMD Outbreak



3.3 RESPONSE STRATEGIES FOR CONTROL AND ERADICATION OF FMD IN DOMESTIC LIVESTOCK

There are several generally accepted strategies for the control and eradication of FMD in domestic livestock following an outbreak, as described below and in Table 3-1.

- ◆ *Stamping-out*. Depopulation of clinically affected and in-contact susceptible animals.
- ◆ *Stamping-out modified with emergency vaccination-*
 - *to-kill*. Depopulation of clinically affected and in-contact susceptible animals and vaccination of at-risk animals, with subsequent depopulation and disposal of vaccinated animals. Depopulation and disposal of vaccinated animals may be delayed until logistically feasible, as determined by IC and the VSDA/CVO.
 - *to-slaughter*. Depopulation of clinically affected and in-contact susceptible animals and vaccination of at-risk animals, with subsequent slaughter and processing of vaccinated animals, if animals are eligible for slaughter under USDA FSIS authority and rules and/or State and Tribal authority and rules.
 - *to-live*. Depopulation of clinically affected and in-contact susceptible animals and vaccination of at-risk animals, without subsequent depopulation of vaccinated animals. Vaccinated animals intended for breeding, slaughter, milking, or other purposes live out their useful lives.
- ◆ *Emergency vaccination to-live without stamping-out*. Vaccination used without depopulation of infected animals or subsequent slaughter or depopulation of vaccinated animals.
- ◆ *No action*. A course of action where FMD would run through an affected population paired with control and containment measures. This is an unlikely option for domestic animals; however, if FMD does encroach into wildlife this may be a likely strategy.

Depending upon the circumstances and scale of the outbreak, one or a combination of these strategies can be applied. In some cases, the intended disposition of vaccinated animals (kill, slaughter, live) may be affected by epidemiological, logistical, and other considerations during an outbreak.

Table 3-1. Overview of Traditional FMD Response Strategies¹⁷

Strategy or Strategies	Definition of Strategy	Likelihood of Use	Example of Application
Stamping-Out (No Emergency Vaccination)	Depopulation of clinically affected and in-contact susceptible animals.	Possible (if outbreak is contained in jurisdictional areas in which FMD can be readily contained and further dissemination of the virus is unlikely).	Stamping-out Infected Premises.
Stamping-Out Modified with Emergency Vaccination to Kill	Depopulation of clinically affected and in-contact susceptible animals and vaccination of at-risk animals, with subsequent depopulation and disposal of vaccinated animals. Depopulation and disposal of vaccinated animals may be delayed until logistically feasible.	Possible (if outbreak is contained in jurisdictional areas in which FMD can be readily contained and further dissemination of the virus is unlikely).	Stamping-out Infected Premises, emergency vaccination to kill within the selected areas of the Buffer Zone in Containment Vaccination Zones.
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 if animals are eligible for slaughter under USDA FSIS and/or State and Tribal authority and rules.	Highly likely (depending on the type of the FMD outbreak).	Stamping-out Infected Premises; emergency vaccination to slaughter within the Control Area in Containment Vaccination Zones.
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 depopulation of vaccinated animals. Vaccinated animals intended for breeding, slaughter, or other purposes live out their useful lives.	Highly likely (depending on the type of the FMD outbreak).	Stamping-out Infected Premises; emergency vaccination to live outside of the Control Area in Protection Vaccination Zones.
Combination of Stamping-Out Modified with Emergency Vaccination to Kill, Slaughter, and Live	Combination of emergency vaccination to kill, slaughter, and live.	Highly likely (depending on the type of the FMD outbreak).	Stamping-out Infected Premises; emergency vaccination to slaughter within the Control Area in Containment Vaccination Zones and emergency vaccination to live outside.
Vaccination to Live (without Stamping-Out)	Vaccination used without depopulation of infected animals or subsequent depopulation or slaughter of vaccinated animals.	Less likely (unlikely to be implemented at start of outbreak).	No stamping-out Infected Premises; Vaccination to live outside of the Control Area in Protection Vaccination Zones.
No Action	FMD would take its course in the affected population; other measures may be implemented to control and contain FMD spread.	Unlikely in domestic animals.	Quarantine and movement control measures; biosecurity measures; cleaning and disinfection measures implemented. No stamping-out and no vaccination.

¹⁷ Extracted from FAD PReP Ready Reference Guide—Overview of Emergency Vaccination available at www.aphis.usda.gov/fadprep.

3.3.1 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. (See Box 3-3.) Stamping-out, is currently defined in the *OIE Terrestrial Code (2019)*, as

a policy designed to eliminate an outbreak by carrying out under the authority of the Veterinary Authority the following: a.) the killing of the animals which are affected and those suspected of being affected in the herd or flock and, where appropriate, those in other herds or flocks which have been exposed to infection by direct animal to animal contact, or by indirect contact with the causal pathogenic agent; . . .

Box 3-3. Critical Elements of Stamping Out

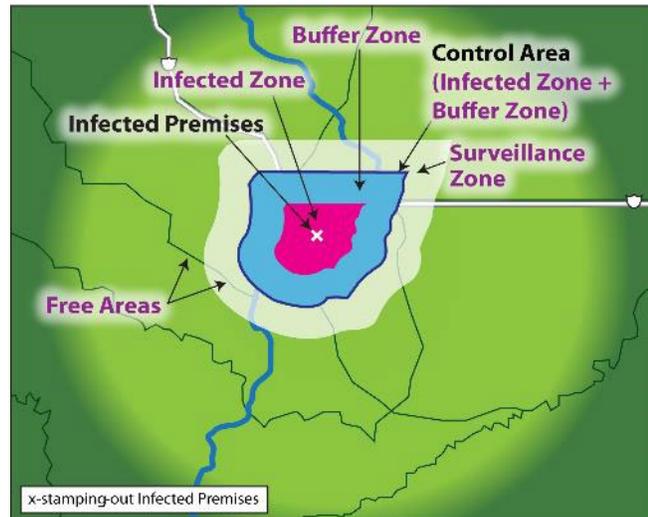
Stamping-Out: Critical Elements

- As soon as possible after classification of premises as an 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, 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.

3.3.1.1 ZONES AND AREAS IN RELATION TO STAMPING-OUT

Figure 3-2 shows an example of a stamping-out strategy, where IP are depopulated. See **Section 4.5** for more information on zones, areas, and premises for FMD outbreak response.

Figure 3-2. Example of Zones and Areas in Relation to Stamping-Out (Infected Premises Would be Depopulated)



Note: Figure is not to scale.

3.3.2 Stamping-Out Modified with Emergency Vaccination to-Kill or to-Slaughter

These strategies are similar in implementation but differ in the final disposition of vaccinated animals. Vaccination to-kill involves the depopulation of clinically affected, in-contact susceptible animals, and vaccination of at-risk animals, *with* subsequent depopulation and disposal or slaughter of vaccinated animals. Vaccination to-slaughter requires that animals are eligible for slaughter under USDA FSIS authority and rules, and/or State and Tribal authority and rules.

These suppressive vaccination strategies involve the following:

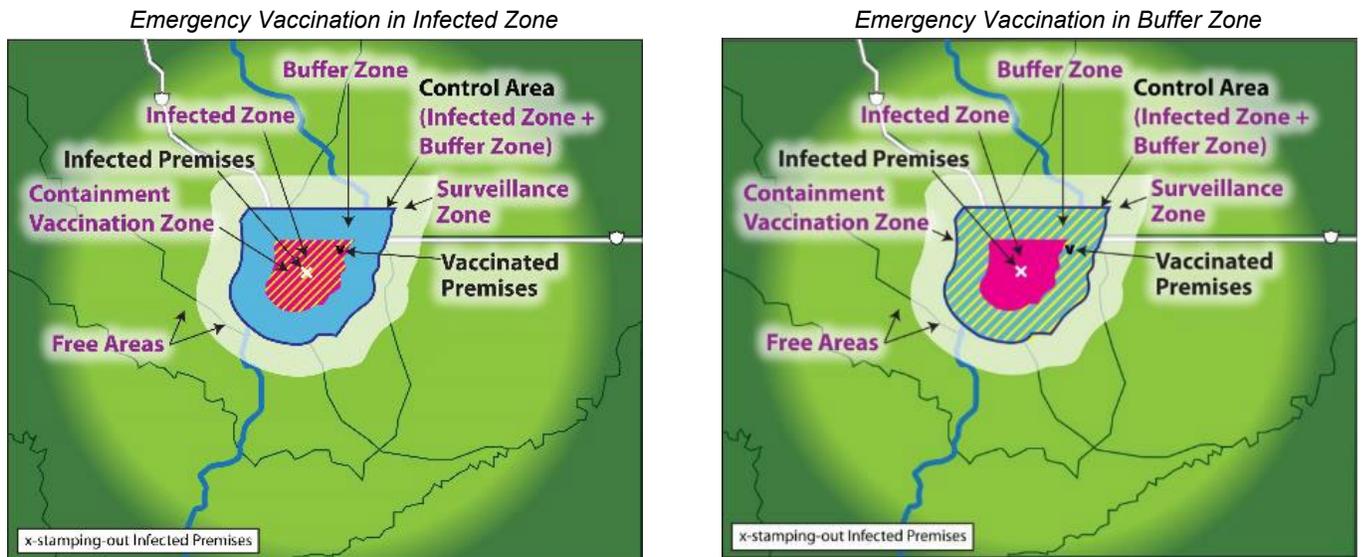
- ◆ The goal is to suppress virus replication in high-risk susceptible animals by using emergency vaccination and then depopulate or slaughter vaccinates at a later date as determined by IC and the VSDA/CVO.
- ◆ The targeted vaccination of high-risk susceptible animals in an IZ, BZ, or Vaccination Zone (VZ). Ring or regional vaccination around an IP or IZ is a frequently cited example of this strategy.
- ◆ Vaccinated animal identification, movement controls, traceability, and an effective, scalable permitting system may be necessary.

- ◆ Additionally, for movement to slaughter, DIVA testing may be necessary for movement between zones, interstate commerce, and international trade.¹⁸

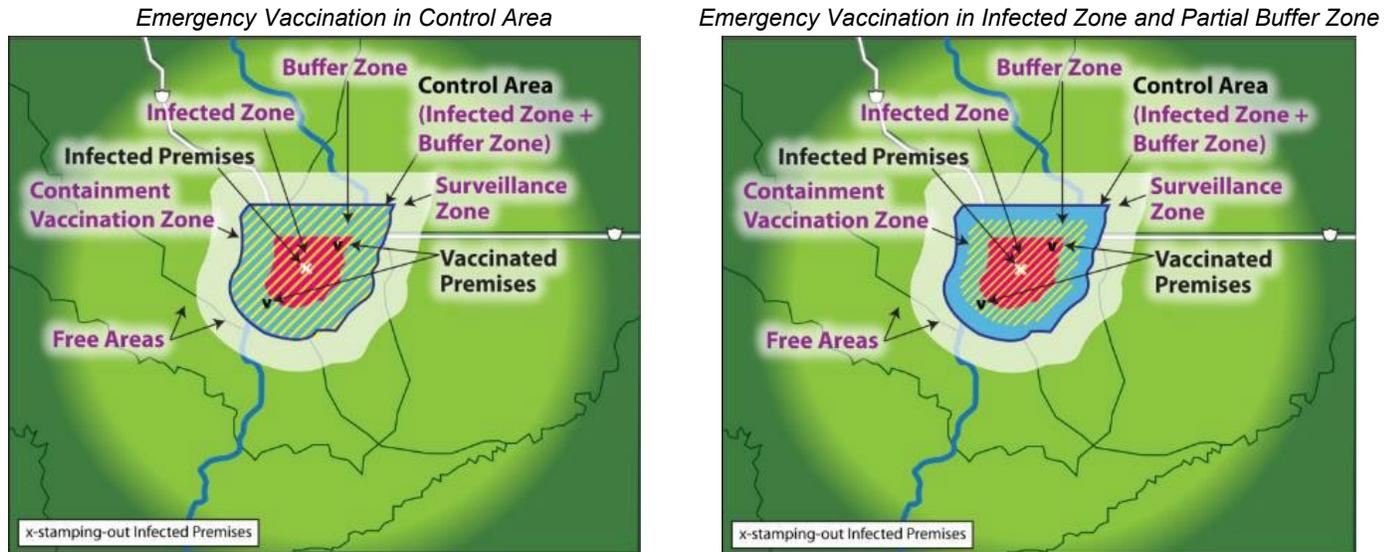
3.3.2.1 ZONES AND AREAS IN RELATION TO STAMPING-OUT MODIFIED WITH EMERGENCY VACCINATION TO-KILL OR TO-SLAUGHTER

Figure 3-3 shows four examples of how a stamping-out modified with emergency vaccination to-kill or to-slaughter strategy might be implemented. Animals on IP would be depopulated, while other animals in a Containment Vaccination Zone (CVZ) may be vaccinated.

Figure 3-3. Examples of Zones and Areas Utilizing Stamping-Out: Modified with Emergency Vaccination to-Kill or Slaughter (Infected Premises Would be Depopulated in Either Case)



¹⁸ Detailed information on vaccine selection and vaccination strategies can be found in [National Animal Health Emergency Management System \(NAHEMS\) Guidelines: Vaccination for Contagious Diseases, Appendix A: FMD.](#)



Note: Figures are not to scale.

3.3.3 Stamping-Out Modified with Emergency Vaccination to-Live

This strategy involves the depopulation of clinically affected and in-contact susceptible animals and vaccination of at-risk animals, *without* subsequent slaughter or depopulation of vaccinated animals because of their vaccination status. Stamping-out modified with emergency vaccination to-live is used when vaccinated animals intended for breeding, slaughter, milking, or other purposes live out their useful lives.

This protective vaccination strategy involves the following:

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

3.3.3.1 ZONES AND AREAS IN RELATION TO STAMPING-OUT MODIFIED WITH EMERGENCY VACCINATION TO-LIVE

Figure 3-4 shows an example of 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 depopulated or slaughtered solely on the basis of vaccination status.

Figure 3-4. Example of Zones and Areas for Stamping-Out Modified with Emergency Vaccination to-Live (Infected Premises Would be Depopulated)



Note: Figure is not to scale.

3.3.4 Emergency Vaccination to-Live without Stamping-Out

This strategy involves *no* depopulation of infected animals and the emergency vaccination of susceptible animals, with the intention of not slaughtering or depopulating these animals at a later date because of their vaccination status. This strategy might be used in 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, in the course of an outbreak, the decision might be made to switch to this strategy if the disease becomes widespread.

This protective vaccination strategy involves the following:

- ◆ The goal is to protect susceptible animals from infection with emergency vaccination, with the intention of not depopulating or slaughtering vaccinates at a later date because of vaccination status.

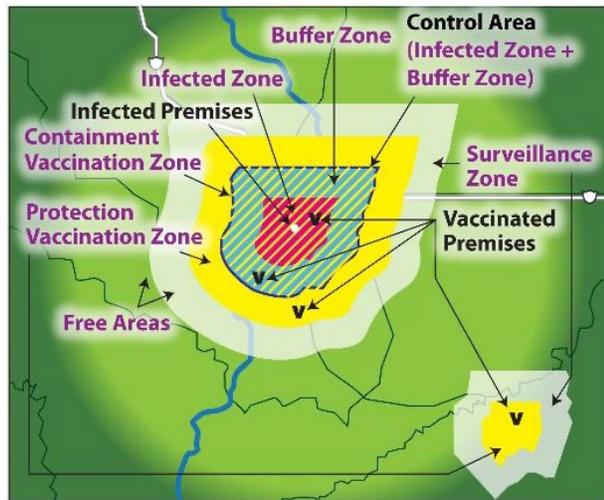
- ◆ Requires the establishment of one or more VZs free of FMD, the establishment of one or more CAs for infected animals, and movement controls to keep infected animals out of VZs free of FMD.
- ◆ DIVA testing may be necessary for movement between zones, interstate commerce, and international trade.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

3.3.4.1 ZONES AND AREAS IN RELATION TO EMERGENCY VACCINATION TO-LIVE WITHOUT STAMPING-OUT

Figure 3-5 provides an example of emergency vaccination to-live without stamping-out. There would be no stamping-out under this response, only emergency vaccination to-live.

Figure 3-5. Example of Zones and Areas for 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.

3.4 FACTORS INFLUENCING THE SELECTION OF RESPONSE STRATEGY OR STRATEGIES

Depending upon the circumstances and scale of the outbreak, a combination of one or more of the response strategies can be applied. Choosing an initial response strategy or modifying strategies as an outbreak unfolds is an important, but complex decision process. Thus, it is not possible to delineate *a priori* the specific factors that might signal the need to modify the response to an FMD

outbreak, but multiple factors must be considered and their favorable or undesirable impacts weighed.

3.4.1 General Factors that Influence a Response Strategy

Detection of FMD will result in emergency intervention by State, Tribal, Federal, and local authorities; 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, interstate commerce, international trade, 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 susceptible animals, types of susceptible animals; this is the rate at which each IP “reproduces” or results in other, additional IPs.
- ◆ *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.

3.4.2 Emergency Vaccination Sourcing and Availability

The acquisition and use of FMD vaccine is a complicated issue including the amount of vaccine available, production limitations, and the availability of the appropriate type/subtype(s) of the FMDV. The most commonly used FMD vaccine is inactivated or killed vaccine. Manufacture of this product requires starting with live virus and processing until completion to finished vaccine. Vaccine may be stored as vaccine antigen concentrate (VAC) for up to 5 to 12 years depending on the manufacture. Per 21 *U.S. Code* 133a, no live FMDV may be introduced for any purpose into any part of the mainland of the United States by commercial manufacturers or Federal entities. Therefore, conventional inactivated vaccine must be manufactured abroad then shipped to the United States for use.

There are currently two mechanisms by which the United States is supplied with FMD vaccine, the North American Foot-and-Mouth Disease Vaccine Bank (NAFMDVB) and the National Animal Vaccine and Veterinary Countermeasures Bank (NAVVCB). These Banks contain quantities of vaccine stored as VAC encompassing a range of representative FMD types/subtypes that will be converted into finished vaccine at the time of the outbreak. Current quantities of VAC in the Banks are only sufficient to address small to moderate outbreaks. Vaccines produced from the VAC are high-potency inactivated vaccines (meaning they do not contain live virus), are DIVA capable, and are shown to be effective in cattle, swine, sheep and goats. This section reviews current vaccine capabilities for an FMD outbreak in the United States.

3.4.2.1 THE NORTH AMERICAN FOOT-AND-MOUTH VACCINE BANK

The NAFMDVB is a trilateral entity that it is jointly administered by the CVOs of Mexico, Canada, and the United States. If one or more of the three countries has an outbreak and needs to use FMD vaccine, the Bank will be activated and vaccine will be shipped to the affected country(s) assuming an appropriate match is available. Allocation of the vaccine will be in accordance to the contribution ratio to the Bank—70 percent for the United States, 20 percent for Mexico and 10 percent for Canada. Any or all countries may opt to take a portion of their finished vaccine, irrespective of whether they have animals infected with FMD. However, vaccine availability is not strictly limited by this ratio since countries may decide to reallocate all or a portion of their vaccine to the affected country(s). Each country is responsible for replenishing the VAC which they choose to reformulate into vaccine.

3.4.2.2 THE NATIONAL ANIMAL VACCINE AND VETERINARY COUNTERMEASURES BANK

The Agricultural Improvement Act of 2018 (The “Farm Bill”) included the establishment of the National Animal Vaccine and Veterinary Countermeasures Bank (NAVVCB), otherwise known as the National Bank. The National Bank has sufficient resources to acquire greater quantities more quickly, and more strains of FMD vaccine, as compared to the NAFMDVB, for exclusive use in the United States. Vaccine acquisition is currently underway to complete this new National Bank. The goal is to have between 10 and 25 million doses of each of the 10-12 highest risk strains included in the NAVVCB.

3.4.2.3 BANK ACTIVATION AND SURGE CAPACITY

In the event FMD is introduced to the United States, vaccine would likely be requested by USDA APHIS after confirmatory testing, approximately 24-48 hours after sample submission.

- Activation of the NAFMDVB provides the U.S. access to an allocation of 70%, between 1.75 and 2.5 million doses (depending on the manufacturer), that would be received within 10-14 days post-order.

Based on the unique epidemiology of the outbreak, Canada and Mexico could also elect to donate their vaccine allotment to the U.S., if appropriate, to support rapid containment. The reverse also applies if Mexico or Canada experience an outbreak.

- With NAVVCB activation, it is anticipated that a minimum of 2.5 million doses would come to the U.S. within 10-14 days post-order, all of it available for domestic use, with subsequent shipments arriving every 10-14 days as available.

In a moderate to large scale outbreak, the banks are likely to be activated to exhaust all available VAC for rapid receipt of finished vaccine, prior to soliciting continuous production. The production cycle for inactivated vaccine, starting with master seed and finishing with completed vaccine, is 14 weeks. This means there may be a gap in vaccine receipt even if surge capacity production is requested and orders are immediately placed for future vaccine. Vaccine manufacturers also have other customers which must be served as well as meeting the surge capacity needs of the United States, so quantities may be somewhat restricted. For example, one of the primary FMD vaccine suppliers to the United States can only commit a portion of their production to North America, totaling one million doses per week up to 80 weeks.

3.4.2.4 FUTURE TECHNOLOGIES

Novel vaccine technologies on a variety of different platforms are currently being investigated by commercial, academic and governmental research institutions. To date, only one novel vaccine (an adenovirus-vectored A24 topotype) has been licensed by the APHIS Center for Veterinary Biologics for use in the United States.

Additionally, restrictions on research of FMD vaccines on the U.S. mainland have been relaxed. In 2018, the Secretary of Agriculture authorized the movement of a genetically modified, non-infectious version of the FMDV into the U.S. mainland for continued vaccine development and study. Having access to efficacious vaccines would enable USDA to more quickly source and acquire FMD vaccine in the event of an outbreak of this devastating disease.

3.4.3 Determining an Appropriate FMD Response Strategy

Table 3-2 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.

Table 3-2. 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 kill	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	Available
Resources for stamping-out (such as disposal)	Adequate	Adequate	Moderately limited	Limited	Limited
Resources for vaccination (such as diagnostic testing, tracing efforts, and permitting activities)	Limited	Moderately limited	Adequate	Adequate	Adequate
Population density of susceptible animals at high risk of becoming infected	Low	Moderate	High	High	High
Population density of virus amplifying animals	Low	Moderate	Moderate	High	High
Movement of infected animals, products, or fomites out of Control Area	No evidence of extensive movement	Evidence of movement	Evidence of extensive movement	Evidence of extensive movement	Evidence of extensive movement
Origin of outbreak	Known	Known	Unknown	Unknown	Unknown
Location of initial outbreak	Isolated premises	Livestock producing area	Livestock producing area	Livestock producing area	Livestock producing area
Spread of outbreak	Slow	Rapid	Rapid	Rapid	Rapid
Distribution of outbreak	Limited or restricted	Regional	Widespread	Widespread	Widespread
Risk of infection in valuable, rare, endangered, or high-value genetic livestock	High	High	High	Moderate	Low
Likelihood that FMD could become prevalent in feral swine, deer, or other wildlife	High	High	High	Moderate	Low
Public acceptance of stamping-out strategy	Neutral reaction or weak opposition	Neutral reaction or weak opposition	Weak opposition	Strong opposition	Strong opposition
Surveillance, diagnostic, and laboratory resources for serosurveillance after vaccination	Limited	Limited	Limited	Available	Available

Domestic stakeholders' acceptance of regionalization with stamping-out or vaccination to kill	Yes	Yes	No	No	No
Domestic stakeholders' acceptance of regionalization with vaccination to live or vaccination to slaughter	No	No	Yes	Yes	Yes
Trading partner acceptance of regionalization with stamping-out or vaccination to kill	Accepted	Accepted	Not accepted	Not accepted	Not accepted
Trading partner acceptance of regionalization with vaccination to slaughter or vaccination to live	Not accepted	Not accepted	Accepted	Accepted	Accepted
Assessments and economic analysis of competing control strategies	It is likely that a control strategy with emergency vaccination will lead to significantly higher economic losses, or longer duration of the outbreak	It is likely that a control strategy without emergency vaccination to kill will lead to significantly higher economic losses or longer duration of the outbreak	It is likely that a control strategy without 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 emergency vaccination to live will lead to significantly higher economic losses or longer duration of the outbreak	It is likely that a control strategy with stamping-out will lead to significantly higher economic losses or longer duration of the outbreak

3.4.4 Phases and Types of FMD Outbreaks

An FMD outbreak in the United States will be a complex event. Having pre-defined phases and types¹⁹ may be useful to facilitate the development of adaptable emergency response plans and processes. The phase (temporal) and type (extent) of the FMD outbreak is expected to change over time and could be designated by the authorities responsible for managing the response. Types are loosely defined as follows:

- ◆ Type 1–2 Focal to Moderate Regional
- ◆ Type 3 Large Regional
- ◆ Type 4–6 Widespread/ National outbreak to catastrophic North American outbreak.

¹⁹ This is one approach to describing a response to an FMD outbreak in the United States. USDA APHIS. (2013). *FAD PReP Strategy Document: Classification of Phases and Types of a Foot-and-Mouth Disease Outbreak*. Retrieved from: <http://www.cfsph.iastate.edu/pdf/phases-and-types-of-an-FMD-outbreak>.

Figure 3-6 describes the phases of FMD response, which progress from confirmation through recovery to declaration of freedom.

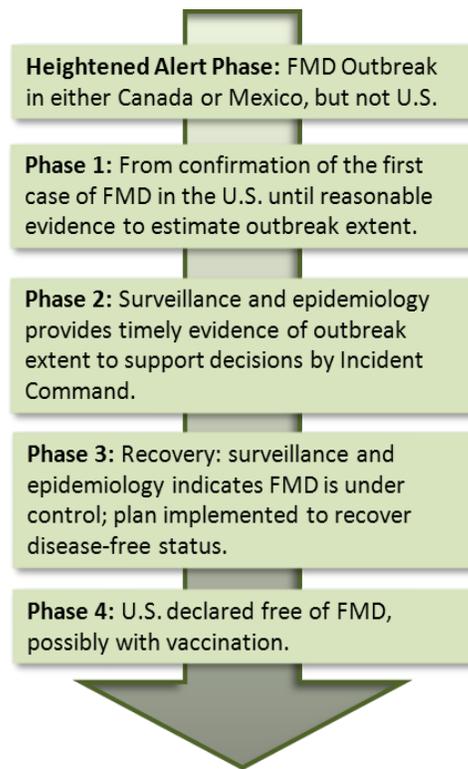


Figure 3-6. Phases of FMD Response

For detail on the Types and Phases of a response with respect to associated zones, see the [FAD PReP Ready Reference Guide—Understanding Response Strategies](#).

3.5 RECOVERY AFTER AN FMD OUTBREAK

USDA APHIS will attempt to implement response strategies that are expedient in allowing the United States to return to FMD-free status, preferably FMD-free without (continued) vaccination. The OIE recognizes FMD-free status with and without vaccination in countries and in zones.

3.5.1 FMD-Free Designations

- ◆ *FMD-free country where vaccination is not practiced.* The OIE recognizes about 70 countries FMD-free without vaccination. Stamping-out is the most efficient strategy for achieving this status, though vaccination to-kill could also achieve this status. Vaccination to-slaughter and vaccination to-live strategies could be employed to achieve this status over a longer period.
- ◆ *FMD-free country where vaccination is practiced.* The OIE recognizes one country 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.²⁰ Vaccination to slaughter and vaccination to-live strategies could be used to achieve this status over time.

- ◆ *FMD-free zone where vaccination is not practiced.* The OIE recognizes several member countries with FMD-free zone without vaccination. The United States recognizes two of these zones as FMD-free for import purposes.²¹ This is a possible interim goal for the United States if FMD-free country status is not obtainable. Stamping-out, vaccination to-kill, vaccination to-slaughter, or vaccination to-live strategies could all be used to achieve this status.
- ◆ *FMD-free zone where vaccination is practiced.* The OIE recognizes several member countries with zones 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. Vaccination to slaughter and vaccination to-live strategies could be used to achieve this status.

The remaining OIE member countries 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 classifications listed, per OIE standards. The *OIE Terrestrial Code* for FMD lists the detailed criteria for recognition.

3.5.2 OIE Minimum Time to FMD-Free Designations

For the United States to recover its free status after an outbreak, the summarized minimum time requirements herein will apply, in coordination with surveillance efforts and other documentation. These time requirements apply to both free countries and free zones where vaccination is not practiced:

- ◆ Three months after disposal of the last animal killed, if a stamping-out strategy without emergency vaccination is employed.
- ◆ Three months after disposal of the last animal killed or the slaughter of all vaccinated animals, whichever occurred last, if a stamping-out modified with emergency vaccination to-kill or -slaughter strategy is employed.
- ◆ Six months after the disposal of the last animal killed or the last vaccination, whichever occurred last, if a stamping-out modified with emergency vaccination to-live strategy is employed.

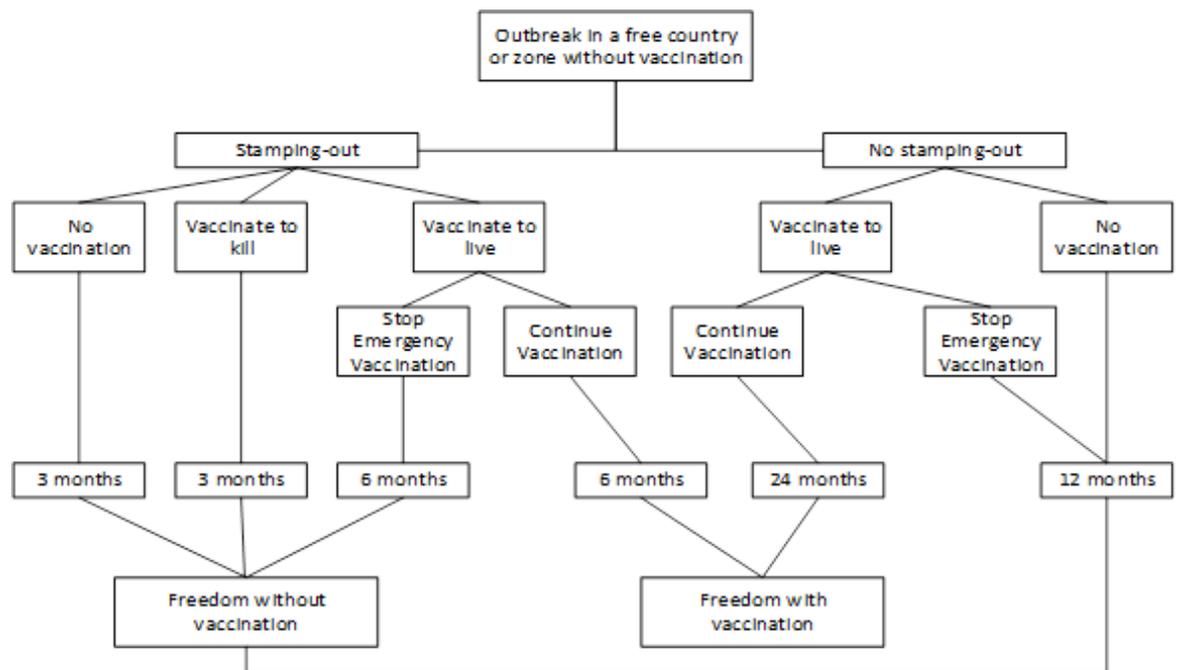
²⁰ Under specific conditions: Code of Federal Regulations. *Title 9, §94.29. Restrictions on importation of fresh (chilled or frozen) beef and ovine meat from specified regions.* <https://www.ecfr.gov>.

²¹ USDA APHIS. (2019). *Animal Health Statuses of Regions: Foot-and-Mouth Disease.* Retrieved from: <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions>.

- ◆ Twelve months after the last vaccination, if stamping-out is not applied or is discontinued, and a continued vaccination to-live strategy has been adopted.
- ◆ FMD freedom with vaccination can be applied for 24 months after the last positive detection, if stamping-out is not employed and vaccination is continuing.

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 the circumstances of the outbreak. Figure 3-7 visualizes and references OIE articles with respect to the minimum time requirements.

Figure 3-7. Minimum OIE waiting periods and pathways for recovery of FMD free status after an outbreak where vaccination is not practiced ²²



3.5.3 Surveillance for Recognition of Disease-Freedom

Surveillance is fundamental in proving disease freedom after an FMD outbreak in hopes to regain disease-free status. The *OIE Terrestrial Code* specifies surveillance procedures for members re-applying for recognition of freedom from

²² OIE. (2019). Article 8.8.42. *Terrestrial Animal Health Code: Foot-and-Mouth Disease*. Retrieved from: <https://www.oie.int/en/standard-setting/terrestrial-code/access-online/>

FMD for the whole country or zone where vaccination is either practiced or not practiced, following an outbreak. These general surveillance conditions and methods for FMD are found in Articles 8.8.40 through 8.8.42 (2019).

The use and interpretation of serological tests is addressed in the *OIE Terrestrial Code* and in the *OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (Terrestrial Manual²³). These sections discuss serological tests for both structural proteins and NSP. Tests for structural proteins are serotype specific and include structural protein antigen enzyme-linked immunosorbent assays (ELISA) and the Virus Neutralization Test (VNT). Tests for NSP antibodies include the 3ABC ELISA, which is conducted by NVSL-FADDL.

Specific information on surveillance and diagnostic testing is provided in **Chapter 4**.

3.5.4 Release of Control Area Restrictions

Quarantine and movement controls will be maintained until at least 28 days (two OIE incubation periods) 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).

3.5.5 Disposition of Vaccinates

If vaccination was used in the outbreak, FMD vaccinates may still be subject to movement controls and monitoring measures after the release of the CA.

3.5.6 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.

While the OIE lists minimum time requirements for recovering FMD-freedom after an outbreak in a previously free country, it should again be acknowledged that re-establishing international trade with trading partners may take longer than these minimum time periods.

²³ OIE Terrestrial Manual. (2018). *Chapter 3.1.8 Foot and Mouth Disease (Infection with Foot and Mouth Disease Virus)*. Retrieved from: https://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/3.01.08_FMD.pdf.

Chapter 4

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 (COB) in an outbreak. This chapter describes key components of these critical activities and tools.

The FAD PReP SOPs and NAHEMS Guidelines referenced in this chapter can be found at www.aphis.usda.gov/fadprep.

4.1 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 FAD PReP FMD Overview of Etiology and Ecology SOP contains additional information.

4.2 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 *FAD PReP Case Definition Development Process SOP* available at www.aphis.usda.gov/fadprep.

The following sections are the APHIS-VS Center for Epidemiology and Animal Health (CEAH) definitions for FMD. For further information on the diagnostic tests conducted by NVSL-FADDL in the event of an FMD outbreak, please see **Section 4.4**.

4.2.1 Laboratory Criteria

Agent identification: Virus isolation (VI), ELISAs and rRT-PCR assays are used to detect FMDV-infected animals. Samples to collect for testing include vesicular epithelium, vesicular fluid, epithelial tissues, esophageal-pharyngeal fluid, 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 ELISA or rRT-PCR 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 stand-alone 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 the 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.

Serological tests: The sample to collect for testing is serum. The following serological assays detect FMDV-exposed animals and some help to discriminate vaccinated from infected animals.

- a. Structural protein-based assays: 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. 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.

4.2.2 Case Definitions

The *FAD PReP 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 CEAH, in cooperation with VS Strategy & Policy. CEAH coordinates review with SAHOs, subject matter experts, stakeholders, and VS units. Case definitions are approved by the VSDA/CVO and VS Executive Team. Case definitions enhance the usefulness of animal disease data by providing uniform criteria for reporting purposes.

At the start of an FMD outbreak, the case definition will undergo review and will continue to be evaluated as the outbreak progresses. Any modifications will supersede what is mentioned in this Redbook on the basis of additional information or changing requirements of the eradication effort. For example, the positive predictive value of clinical signs will increase if the FMD prevalence increases.

The below presumptive positive and confirmed positive case definitions are for the index case and may change as an outbreak progresses. *Suspect case*: An FMD-susceptible animal that has either:

1. Clinical signs consistent with FMD; OR

Inconclusive or positive laboratory test results performed on a sample taken during routine surveillance, with or without the presence of clinical criteria; OR

Epidemiological information indicative of FMD.

Presumptive positive case: A suspect case that has positive laboratory test results (see laboratory criteria above):

1. 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 rRT-PCR; OR

Identification of FMDV serotype by antigen ELISA.

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

4.3 SURVEILLANCE

Surveillance is a critical activity during an FMD outbreak. The following are surveillance goals during an FMD outbreak:

- ◆ Implement a surveillance plan within 48 hours of the outbreak’s confirmation.
- ◆ Implement a surveillance plan that will 1) define the size and extent of an FMD outbreak and 2) detect unknown IPs quickly.
- ◆ Provide evidence to demonstrate FMD absence on a premises, or demonstrate FMD absence in an area during the outbreak (e.g., in the Surveillance Zone [SZ]) or after eradication (e.g., in the CA).
- ◆ Provide evidence that premises are free of FMD at a nominal level, thereby setting the stage to conduct additional testing or apply predefined conditions to permit animal and animal product movements within and/or out of the CA.

Surveillance activities should be developed to achieve desired outcomes by leveraging available resources, satisfying jurisdictional requirements, and supporting implementation of COB measures. The surveillance plan should consider the susceptible wildlife population in the area, and planners should coordinate with representatives from APHIS Wildlife Services, DOI, State wildlife agencies, and State agriculture departments to perform appropriate FMD surveillance in these populations.

The surveillance plan should also provide guidance on who is responsible for surveillance data summaries and analysis. Generally, the ICG will coordinate with CEAH and the NIMT for surveillance data summary and analysis needs, at intervals specified by the IC. The surveillance plan should also supply information to assess and modify outbreak response activities in conjunction with the Epidemiology Group.

4.3.1 Surveillance Planning for FMD Outbreak

4.3.1.1 GENERAL CONSIDERATIONS

A surveillance plan will have to be customized to the size and scope of an outbreak, which may take many forms. The epidemiologic picture will guide the response and surveillance activities, including species affected, location of outbreak, number of infected premises, number and size of animal operations, incubation period, number of potential contacts from the index premises, and

many other factors. The IC will guide response efforts to account for these differences.

Parameter settings were developed based on transmission characteristics of serotype O FMDV described in literature by species, see Table 4-1. When developing an initial surveillance plan, planners should give additional consideration to the number and types of species on a premises and in a zone. Cattle tend to show clinical signs more readily than other species, while sheep and goats tend less to show clinical signs. Swine are replicators of FMDV and can shed large quantities of virus through respiration. If swine and cattle are raised near each other or on the same premises, there is opportunity for spread between species even if neither is showing clinical signs.

Table 4-1. Descriptive statistics of serotype O FMDV infection periods by species

Species	Latent Period ¹	Subclinical ¹	Incubation ¹	Infectious ¹
Cattle	3.6, 3 (2,5)	2.0, 2 (1, 3)	5.9, 5 (5, 6)	4.4, 4 (3,6)
Pig	3.1, 2 (2,4)	2.3, 2 (1,3)	5.6, 4 (3, 9)	5.7, 5 (5, 6)
Small ruminant	4.8 5 (3, 6)	2.2, 2 (1, 3)	6.6, 6 (4, 8)	3.3, 2 (2, 4)
¹ Mean, Median, 25th-75th%				

Appendix F of this document outlines more details on how to customize the surveillance plan after initial response efforts have begun. CEAH is available to provide additional consultation.

4.3.1.2 DEFINITIONS

Active observational surveillance (AOS) is a purposeful effort to detect evidence of disease through observation of clinical signs following these criteria:

- ◆ Observations are ongoing, frequent (e.g., once or twice a day in confinement facilities or once every 2 to 3 days in large grazing operations), and follow a pre-planned schedule.
- ◆ Observer is specifically tasked with monitoring for evidence of disease, toxicity, or other causes of morbidity, mortality and decreased production.
- ◆ The group of animals undergoing AOS is clearly defined.
- ◆ A set of guidelines exist describing expected production parameters and corresponding investigation triggers.
- ◆ A communication plan is created for a response to the investigation triggers, including when to contact regulatory animal health officials or their designees.

- ◆ Observer is aware of and understands the production parameters, investigation triggers, and communication plan.

Observation of clinical signs or other changed consistent with the disease of interest during AOS serves as the screening “test.” Confirmatory testing is laboratory-based.

Utility of AOS is highest for diseases that show overt clinical signs such as HPAI or FMD. Vesicular diseases such as FMD in a naïve population are particularly amenable for AOS in many U.S. animal populations. Most confinement livestock operations have standard management practices with the above criteria and, in fact, already conduct AOS.

High Probability of Disease (HPD) – see Table 4-2 for examples. HPD animals are animals which fit into one of the categories listed but do not have clinical signs consistent with FMD infection. In the case of endemic SVA infection in swine, other clinical signs (fever, lameness, etc.) may still be used to differentiate the two diseases.

Table 4-1. Examples of animals with a Higher Probability of Disease (HPD) during an FMD outbreak¹

Health Indicators	Immunosuppressed	Exposure Risk
<ul style="list-style-type: none"> ◆ Poor-doers ◆ Lethargic ◆ Decrease feed intake ◆ Decrease in production (e.g. milk or rate of gain) 	<ul style="list-style-type: none"> ◆ Young animals ◆ Old animals ◆ Pregnant animals ◆ Animals undergoing treatment for another disease ◆ Animals under high stress (high production or recent movement) 	<ul style="list-style-type: none"> ◆ Recent introduction to premises ◆ Housed in pastures adjacent to farms with FMD susceptible species (airborne spread) ◆ Housed near entry/exit points ◆ Housed near another infected premises

¹ This list is not meant to be exhaustive. It provides guidance on prioritizing animals for diagnostic testing.

Intensively managed – operations with a high stocking density. Examples may include: feedlots, dairies, indoor housed swine, and some seed stock or show stock production.

Observational surveillance – observation of all, or a subset, of the animals on an operation. Includes disease reporting of suspected clinical signs by livestock producers or animal health professionals to regulatory officials.

4.3.1.3 ASSUMPTIONS

Several assumptions are embedded in the design of surveillance plans and analyses of surveillance data. The accuracy of these assumptions impacts the strength of conclusions drawn from surveillance activities. For the example of

FMD surveillance schemes discussed in **Appendix F**, the following assumptions apply:

1. FMD virus causes severe clinical signs in most livestock species; however, in some species like sheep, goats, and cervids, clinical signs are less severe.
2. The proportion of FMD infected animals is highest among animals with clinical signs, followed by HPD animals, relative to apparently healthy animals in the same pen or premises.
3. Observational surveillance activities are routine and ongoing in all FMD susceptible animals, both inside and outside of the CA, including at slaughter plants, markets and shows.
4. Production parameters (milk production, feed consumption, etc.) will be monitored to detect FMD incursions quickly on intensively managed operations.
5. The producer separates poor-doing animals into a group and these are the animals to be sampled for surveillance.
6. Outbreak response field personnel visiting premises will suspect FMD if compatible signs are present, and will initiate testing and implement a quarantine if necessary.
7. The rRT-PCR test sensitivity for detection is 95 percent.

4.3.1.4 SURVEILLANCE ACTIVITIES 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 and for re-establishing disease freedom status after the outbreak. For more information on the zone, area, and premises designations referred to in this section, please refer to **Section 4.5** in this chapter.

1. The initial 72 hours post FMD outbreak declaration. The initial surveillance objectives in the CA and SZ are to detect infected animals and premises as quickly as possible, and to determine the size and extent of the FMD outbreak. During this period, the goals of the IC include the following:
 - a. Create the initial IZ and BZ designation and the boundary of the CA.
 - b. Create a list of known premises with FMD susceptible animals in the CA and SZ. If possible, gather additional information for each premises including production type, estimated population size, and

whether the premises must move animals and/or product or whether it can function under quarantine for an extended time period.

- c. Determine CP (this includes direct and indirect exposure, per the definition of a CP) to known IP.
 - d. Evaluate surveillance guidance below (**Section 4.3.2**) and FMD response and policy information on surveillance (available from www.aphis.usda.gov/fadprep). Modify existing surveillance guidance with outbreak-specific information to create a surveillance plan for the CA.
 - e. Initiate surveillance within the CA as soon as possible. Carry out active observation and diagnostic testing on all premises, starting with those premises that will need to move FMD susceptible animals or their products. Ensure active outreach to all premises and investigate those deemed high-risk.
 - f. Determine the boundary of the SZ and start developing a surveillance plan to be used in the SZ based on existing FMD response and policy information and surveillance guidance below (**Section 4.3.2** and **Appendix F**). The objective of surveillance in the SZ is to determine the size and extent of the FMD outbreak and provide evidence of DF in this zone.
2. The control and eradication period (from the initial 72-hour period until the last case is detected and eradicated). Multiple key surveillance activities need to be performed simultaneously during this period.
 - a. Continue CA surveillance. The objectives are to detect new IPs so that control measures can be immediately implemented and the CA boundaries can be adjusted as needed.
 - b. Conduct surveillance in the SZ sufficient to demonstrate that the FMD virus does not extend beyond the CA.
 - c. As part of investigation and surveillance activities, gather information related to the epidemiology of the outbreak virus (virulence, incubation period, etc.) through observation and communication with other agencies, researchers, and partners (see **Section 4.5** for additional information).
 - d. Revise or prioritize ongoing control and surveillance activities based on surveillance results and available epidemiologic information. Information may support modification of sampling frequency, movement restrictions, risk factor mitigations, vaccination decisions, or targeted sampling, as examples.

- e. Provide evidence that premises are free of FMD virus at a nominal level, thereby setting the stage for movement of permitted FMD susceptible animals and their products into, within or out of the CA.
 - f. Provide evidence that the Free Area (FA) is free of disease, thereby facilitating unrestricted animal and animal product movement from the FA.
3. Post-eradication. The objective of this segment is to provide evidence that the CA and FA are free of disease (using OIE recommendations and requirements on surveillance).
- a. Establish a containment zone as defined by OIE, which includes all outbreaks, to minimize the impact on the entire country.
 - b. Prove DF on depopulated premises.
 - c. Prove DF on at-risk premises (ARP) in the CA by random or targeted sampling (choosing populations based on risk) of selected premises and herds.
 - d. Prove DF in the FA, following OIE guidelines to restore international trade.

4.3.2 Surveillance Sampling

A surveillance plan will indicate the number and frequency of premises to be investigated, the number of animals to be sampled for each investigation, and the duration of the surveillance needed to meet the surveillance objectives. Initial surveillance plans and guidelines are provided for 1) detecting new infected premises in the CA, and 2) determining the size and extent of the FMD outbreak with SZ surveillance. For 3) demonstrating FMD absence in the CA after eradication, surveillance plans in the zones should be developed according to OIE guidelines and will depend on the control strategies used during the outbreak.

Throughout this section, an investigation is defined as a veterinarian traveling to a premises, examining/observing FMD-susceptible animals on the premises, collecting diagnostic specimens on clinical animals, and completing an epidemiology investigation (e.g., forward and backward tracing, identifying on-farm visitors/deliveries, etc.). Observational surveillance is one part of an investigation, but could be the main form of diagnosing FMD during very large outbreaks.

These initial plans and guidelines apply to all species when possible. Recommended adjustments by species are provided after the description of the initial plan. These initial plans presume a Type 1 or Type 2 outbreak (See Figure

3-6). It is critical to note that during an outbreak, parameter estimates and surveillance plans may change as new information about viral characteristics, epidemiology, or outbreak size become available. Further information on surveillance parameters, factors and modifications are provided in **Appendix F**.

4.3.2.1 RECOMMENDED INITIAL DESIGNS

1. CA surveillance - Surveillance objectives in the CA during the outbreak include detecting FMD quickly and providing evidence that premises are free of FMD at a nominal level to set the stage to conduct additional testing or apply predefined conditions for the movement of permitted FMD susceptible animals and their products into, within or out of the CA.
 - a. In the CA, all CP, SP, and ARP are subject to surveillance. Exemptions may be allowed for small, non-commercial, low-risk animal operations where the premises can maintain an appropriately secure quarantine and emergency response officials have adequately informed producers about their obligations for reporting as soon as possible after establishing a CA.
 - b. All other premises should be investigated as soon as possible, but preferably within 3-5 days (approximately one latent period) after establishment of the CA. Surveillance of CPs and SPs should occur first followed by a prioritized list of ARPs.
 - c. Diagnostic testing should preferentially occur in animals with clinical signs consistent with FMD, followed by those with a higher probability of disease (HPD). See Table 4-2 for examples of animals that might be classified as HPD.
 - d. Specimens for testing (See **Section 4.2.1**, Laboratory Criteria) should be collected from sick and HPD animals. For medium to large premises, specimens from at least 100 sick and HPD animals should be submitted for diagnostic testing. For operations with less than 100 sick and HPD animals, all of the animals identified as sick and HPD should be tested. See **Section 4.3.2.2**, Animal Sample Size, for an explanation of initial sample size choice and guidance for adjusting this value.
 - e. Investigations on CPs should occur twice within 5 days for cattle and swine and twice within 7 days for sheep and goats and then every 5-10 days thereafter, depending on species and type of contact, until 56 days, then test as an ARP.
 - f. Investigations on all non-exempt ARP premises should occur every 10 days after the initial investigation until 56 days after the last detected case.
2. SZ surveillance – The primary surveillance objective in the SZ during the outbreak is to demonstrate that the virus has not extended beyond the boundary of the CA.

- a. All premises may be tested or a subset of premises (initially 300 to 500 premises is recommended) for investigation. Preferentially target premises with the highest probability of exposure to FMD. Small, non-commercial, low-risk animal operations that can maintain a secure quarantine should be excluded from the list frame. See Section 4.3.2.2 for explanation of premises samples sizes and for guidance on adjusting the number premises selected for investigation.
- b. Similar to the CA, specimens for testing (See **Section 4.2.1**, Laboratory Criteria) should be collected from HPD animals. See Table 4-2 for examples of animals that might be classified as HPD.
- c. For medium to large premises, specimens from at least 100 HPD animals should be submitted for diagnostic testing. For operations with less than 100 HPD animals, all animals identified as HPD should be tested. (See Section 4.3.2.2 Animal Sample Size for explanation.)
- d. Investigations should begin around 72 hours after index case confirmation and the first round of investigations should be completed as soon as possible, keeping in mind the latent period of the disease.
- e. A new subset of premises should be investigated at least every 21 days until 56 days after the last detected case.

3. DF surveillance after the last detected case

DF surveillance plans will vary widely depending on the size of the outbreak and the control strategies implemented. The OIE *Terrestrial Code* specifies waiting periods before a country can re-declare freedom from a disease outbreak based on the control strategy, including implementation of stamping out and/or different vaccination strategies (vaccinate to-kill or to-slaughter vs. vaccinate to-live). Regardless of the control strategy used, the animal sample size and premises sample size can be determined in the same way they were calculated for the outbreak CA and SZ.

4.3.2.2 EXPLANATION OF DETAILS ON RECOMMENDED INITIAL DESIGNS

Targeting animals with a higher probability of being diseased

Table 4-2 provides other factors that may indicate FMD susceptible HPD animals. If the premises is infected with FMD, these high-risk-for-exposure or sick animals should have a higher prevalence than the general population of animals on the premises in the early stages of an FMD infection. Therefore, prioritizing these animals for testing increases the probability of detecting disease.

Animal sample sizes

When infection in a small population, subpopulation, or target group is of interest, it is helpful to consider the actual number of infected animals rather than a prevalence level. When only one animal in the group is infected, testing all animals in the group results in a probability of detection equal to the sensitivity of the test. If the group contains two infected animals, the probability of detection increases to more than 0.95 as long as the test has sensitivity of 80 percent or more. (See Table F-1 in **Appendix F**.)

As the number of animals in the group increases, testing all of the animals becomes cost-prohibitive. With a sample size of 100, a prevalence of at least 3 percent can be detected (with 0.95 probability) using a 95 percent sensitivity test regardless of the size of the group. As outbreak size increases, reducing the sample size to 60 will enable detecting a prevalence of at least 5 percent. See Table F-2 in **Appendix F**. For a Type 2 or larger outbreak, observation of clinical signs may become the primary surveillance tool in place of diagnostic testing.

Premises sample sizes

Surveillance zones may contain several hundred to tens of thousands of premises, depending on the size and location of the outbreak. For small localized outbreaks, testing animals from all of the premises in the SZ would define the extent of the outbreak rapidly and allow faster implementation of control actions.

In most cases, a sample of premises will need to be selected for testing because of limited resources. Testing 500 premises will result in 0.95 probability of detecting at least one infected premises if at least 0.6 percent of the premises are infected, while testing 300 premises has a detection threshold of 1 percent premises prevalence. Alternatively, 60 to 100 premises could be sampled, which will result in 0.95 probability of detecting at least one infected premises if at least 3 to 5 percent are infected. Selection of any of these sample sizes will depend on the acceptable level of prevalence to be detected. Note that a surveillance design that allows for sampling of a subset of premises, rather than testing all premises, will not detect all infected premises. See Table F-3 in **Appendix F** for more information.

Frequency and duration of sampling

The frequency and duration of sampling is related to disease transmission characteristics. Testing of potentially exposed premises should occur as soon after the latent period as possible to prevent spread of infection. During an outbreak, the actual date of exposure is often unknown, so the length of the latent period is used as a guide for an ideal response time for the first visit. Of course, resource limitations may not allow an ideal response time, so these are provided as guidance. Sampling frequency thereafter is related to the approximate length of the incubation period, as listed in Table 4-3. The duration of sampling is related to

the length of the incubation period and length of viral persistence in infected animals.

Table 4-2. Sampling Frequency Guidelines by Premises Designations

Premises Type	Sampling Frequency	Sampling Duration
Contact Premises (CP)	Every 5 days	14 days, then as ARP/MP
Suspect Premises (SP)	Once	Temporary designation
At Risk Premises (ARP)	Every 10 days	Until 56 days after the last detected case
Monitored Premises (MP)	Every 10 days or more often for movement	Until 56 days after the last detected case 5 rounds minimum or more often for movement for duration of quarantine
Premises in the SZ	Every 21 days	Until 56 days after the last detected case 2-3 rounds minimum for duration of quarantine

Addressing resource limitations

Diagnostic testing is recommended unless laboratory or personnel resources are severely strained. If the outbreak grows in size, observational surveillance may be used to diagnose FMD and determine the premises status, especially for ARP.

Species-specific details

- ◆ Additional considerations for outbreaks involving primarily cattle:
 - Cattle tend to show clinical signs of disease more readily than other types of ruminants; for this reason, observation of clinical signs would be more effective as a potential surveillance tool during an extensive outbreak.
 - Cattle operations may vary considerably in housing styles and therefore risk of exposure to FMD may differ (i.e., cattle raised in intensive management systems, such as feedlots and dairies, are more likely to be exposed while extensively operated cattle, such as cow-calf or range cattle operations, are not).
- ◆ Additional considerations for outbreaks involving primarily swine:
 - Swine amplify FMD virus and shed large quantities of virus with their respirations. An outbreak in swine may have a greater chance for airborne spread, especially if other FMD-susceptible species are located near the infected operation.
 - Since most commercial swine are raised in confinement barns, their risk of exposure to FMD in the environment may be less,

assuming good biosecurity practices are followed, and therefore may be sampled less frequently.

- Swine operations tend to be located near other operations that may be contractors of the same company. This is important to note when identifying indirect contacts in disease spread.
- ◆ Additional considerations for outbreaks involving primarily small ruminants (e.g., sheep, goats, cervids):
 - Small ruminants tend to show less severe clinical signs, making reliance on observation of clinical signs a less effective strategy for these species. Due to this, increased sampling may be appropriate in these operations if they are suspected in the epidemiology of the outbreak.
 - Small ruminant operations vary in their density, from more intensively managed feedlot operations to extensive farmed cervid operations or range sheep/goat operations.

Aggregate sampling

Validated aggregate sampling techniques, such as bulk-tank milk sampling, water trough sampling, or oral fluid sampling from ropes for swine or beef cattle, are economical and efficient for testing large numbers of animals. Without aggregate sampling, early detection requires testing individual animal samples using rRT-PCR. Consideration should be given to validating such sampling techniques and/or deployed to laboratories, particularly for swine, dairy, and beef, so that additional diagnostics can supplement and amplify visual observation and individual animal sampling in the case of an outbreak. To date, some validation work performed on the bulk tests has yielded favorable results when applied to certain uses.

4.3.2.3 ADDITIONAL INFORMATION

At the APHIS level, CEAH is responsible for and assists the unified IC and NIMT in surveillance planning for the CA and SZ. CEAH is also available to advise, construct, or review outbreak surveillance plans for other stakeholders on request to VS. Field Operations is responsible for surveillance implementation.

Appendix F of this FMD Response Plan contains active surveillance strategies and introduces assumptions and methods that influence surveillance decisions. Online calculators are available to assist with certain aspects (e.g., FreeCalc). However, development of a detailed plan should either follow the templates and guidance in existing surveillance documents or involve the help of field or program teams with surveillance planning expertise.

The FAD PReP 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 (2019) is available at www.aphis.usda.gov/aphis/ourfocus/animalhealth/ceah-toolbox/home.

4.4 DIAGNOSTICS

Effective and appropriate sample collection, diagnostic testing, surge capacity, and reporting are critical in an effective FMD response. These activities may 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) provide clear direction to responders on sample collection and processing procedures, if modification from routine standards is required, 2) meet the surge requirements for diagnostic testing at specific intervals, starting at time zero and at 24-hour intervals as the response escalates, and 3) report all diagnostic test results to appropriate personnel and information management systems as soon as possible and within 4 hours of diagnostic test completion. The Emergency Management Response System 2.0 (EMRS2) is the official system of record for an FMD response.

The FAD Investigation Manual (*FAD PReP Manual 4-0*) offers detailed information on sample collection, diagnostic testing, surge capacity, and reporting. In particular, this manual provides additional guidance on who is responsible for diagnostic testing, sample collection, processing, packaging and shipping, and roles in FAD investigations. The APHIS website at <https://www.aphis.usda.gov/nvsl> has information on packaging and labeling laboratory submissions.

See **Appendix D** for VS Guidance Document 12001 (previously VS Memorandum 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.

4.4.1 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 sample type and priority. Virus isolation is used to confirm an FMD diagnosis, but this can take up to 7 days.

4.4.1.1 DIAGNOSTICS FOR INITIAL FMD INVESTIGATION

Figure 4-1 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 Guidance Document 12001 (in **Appendix D**). While simultaneous, preliminary testing may be ongoing at a NAHLN laboratory, the confirmation of an FMD outbreak will only be made by NVSL-FADDL. If FMDV is detected, sequencing will be completed to reveal the strain and toptotype to conduct vaccine matching.

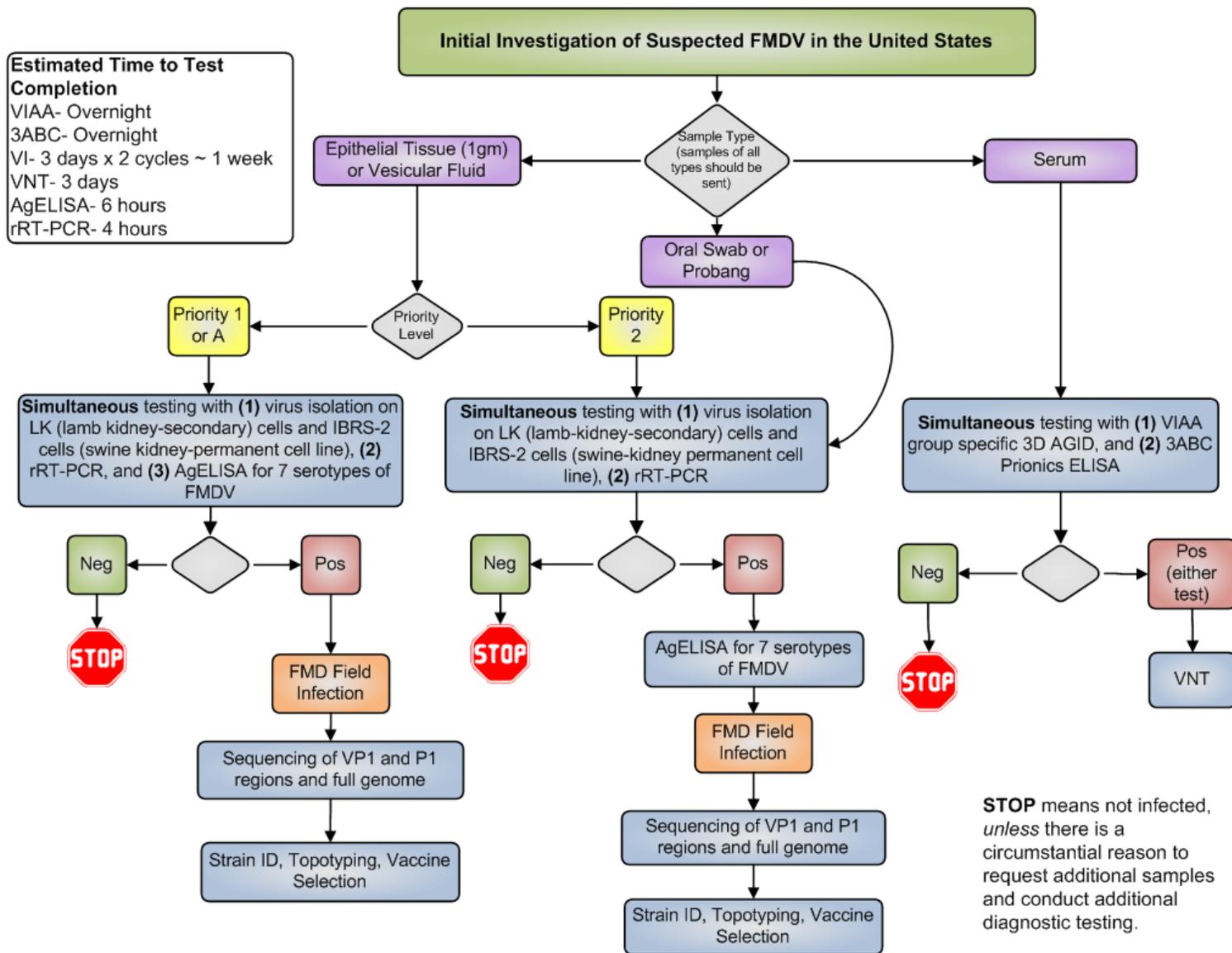


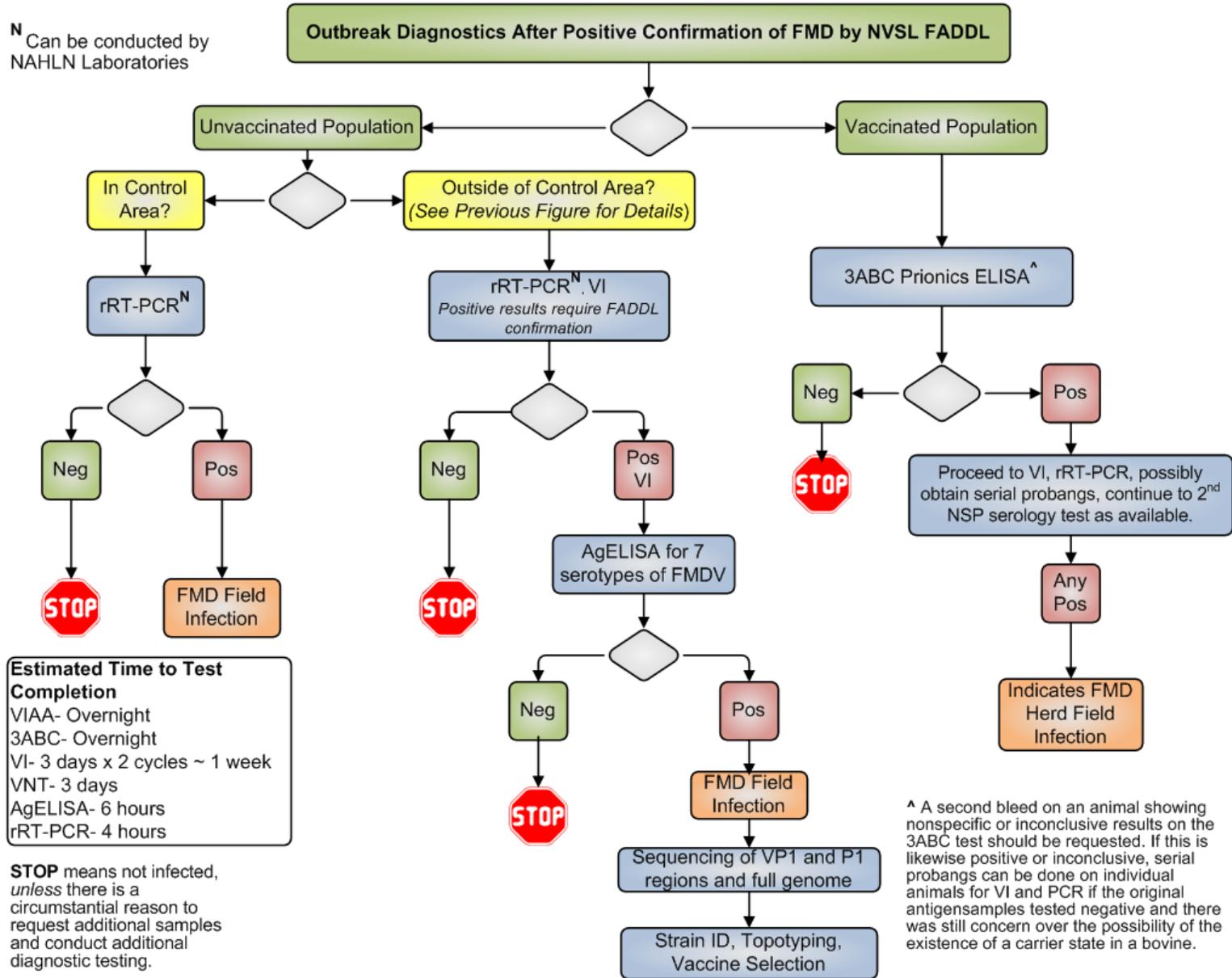
Figure 4-1. Diagnostic Flowchart for Initial Investigation of FMD

4.4.1.2 DIAGNOSTICS AFTER FMD DETECTION

NVSL-FADDL will confirm detections of FMD on any premises not currently in an FMD CA. After NVSL confirmation of FMD on a premises (index case), subsequent swab samples for rRT-PCR may be sent to USDA-approved laboratories that are part of the NAHLN network. (**Appendix C** lists NAHLN laboratories approved for FMD testing.) Figure 4-2 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. All presumptive positive samples from NAHLN laboratories will be forwarded to NVSL for confirmation and subtyping.

Figure 4-2. Outbreak Diagnostics after Positive Confirmation of FMD in United States



4.4.2 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 COB for non-infected premises. In the event that the affected State(s) NAHLN lab(s) and NVSL-FADDL are overwhelmed by the diagnostic testing requirements, NAHLN laboratories from across the country may 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 receiving samples and handle personnel requirements 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 above. 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.

4.4.3 Reporting

Box 4-1 clarifies reporting and notification of presumptive FMD cases. See APHIS VS Guidance Document 12001 and the FAD Investigation Manual (FAD PReP Manual 4-0) for further information on FMD investigation and reporting. This Guidance Document and a link to the manual are available at www.aphis.usda.gov/fadprep.

Box 4-1. Reporting and Notification

Reporting and Notification

- Cases of clinical illness that are confirmed positive by National Veterinary Services Laboratories—Foreign Animal Disease Diagnostic Laboratory (NVSL-FADDL), based on the current case definition, are reported to the affected States, other States, Tribal Nations, industry, other Federal agencies, trading partners, and the World Organization for Animal Health (OIE).
- Appropriate Federal-State-Tribal-industry response and containment measures will be initiated during FMD investigations.

4.5 EPIDEMIOLOGICAL INVESTIGATION AND TRACING

4.5.1 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 an FMD outbreak, and 2) re-evaluate these designations as needed throughout the outbreak based on the epidemiological situation. 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 PRoP Manual 2-0).

Table 4-4 summarizes the premises designations that would be employed in an FMD outbreak response. Table 4-5 summarizes the zone and area designations that would be used in an FMD outbreak response. Figure 4-3 illustrates these premises, zone, and area designations.

Table 4-3. Summary of Premises

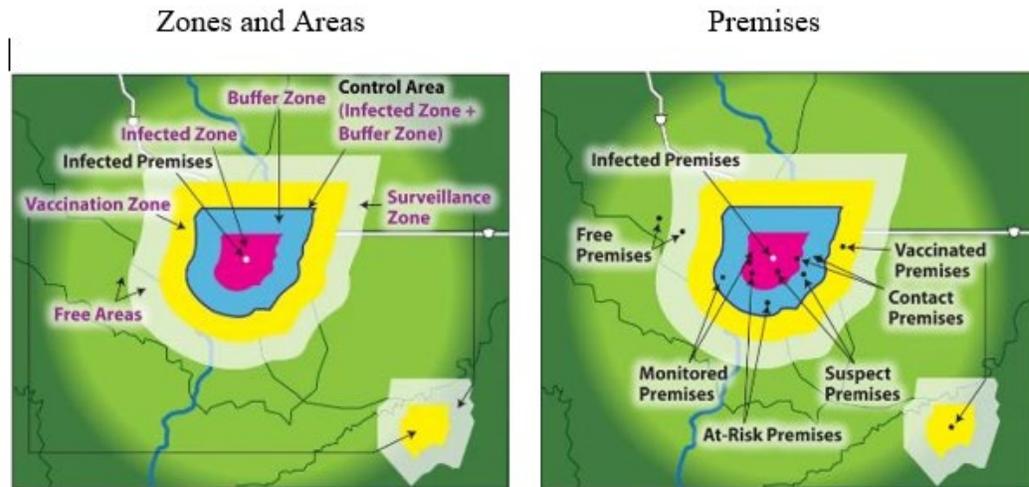
Premises	Definition	Zone
Infected Premises (IP)	Premises where presumptive positive case or confirmed positive case exists based on laboratory results, compatible clinical signs, FMD case definition, and international standards.	Infected Zone
Contact Premises (CP)	Premises with susceptible animals that 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

Premises	Definition	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 4-5: 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 4-3. 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.



4.5.2 Epidemiological Investigation

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

- ◆ Assign a premises classification and a priority of investigation within 6 hours of identifying potential IP or CP through tracing activities.
- ◆ Identify all CP within 24 hours of identifying the IP or initial CP.
- ◆ Determine, within 96 hours of identifying the index case, the nature of the FMD outbreak, identify the risk factors for transmission, and develop mitigation strategies.
- ◆ Collect trace-back and trace-forward information for at least 28 days before the appearance of clinical signs in FMD infected animals.
- ◆ Analyze epidemiological data at routine intervals so that information gathered can apply to response activities to rapidly and effectively control, contain, and eradicate FMD.

These measures will aid in the control of FMD and lessen the impact of the response effort. **Appendix G** contains a sample template of an epidemiological questionnaire. The scope of any such questionnaire should be based on the circumstances of the outbreak, and is at the discretion of IC and epidemiological

subject matter experts. It is likely that any epidemiological questionnaire will need to be modified and tailored to the specific outbreak.

The FAD PReP Epidemiological Investigation and Tracing SOP and the NAHEMS Guidelines: Surveillance, Epidemiology, and Tracing both provide more information.

4.5.3 Tracing

Box 4-2 explains the fundamental importance of movement tracing in an FMD response effort.

Box 4-2. Importance of Movement Tracing in an 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 infected premises (IP). This tracing will aid in the control of the spread of FMD virus 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 wildlife.

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 that quarantine was imposed.

When resources or personnel are limited in a widespread outbreak, movements considered high-risk by the unified IC should be traced first, so that any necessary action can be rapidly taken to control and contain the spread of FMD. Recent trace-forwards involving semen or live animals are typically the first priority.

Tracing information will be obtained from many sources (such as reports from field veterinarians, producers, industry, farm service providers, or the public). EMRS2 will be used to collect and report epidemiological data, including movement tracing information, locally and nationally. Again, EMRS2 is the official system of record for an FMD response.

4.5.4 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 4-6 provides a description of the minimum sizes of areas and zones. Table 4-7 reviews the factors used to determine the size of the CA.

Table 4-4. 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 4-7 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 4-5. Factors to Consider in Determining Control Area Size for FMD

Factors	Additional Details
Jurisdictional areas	<ul style="list-style-type: none"> ◆ Effectiveness and efficiency of administration ◆ Multi-jurisdictional considerations: local, State, Tribal, and multistate
Physical boundaries	<ul style="list-style-type: none"> ◆ Areas defined by geography ◆ Areas defined by distance between premises
FMD epidemiology	<ul style="list-style-type: none"> ◆ 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	<ul style="list-style-type: none"> ◆ Number of contacts ◆ Transmission pathways and transmission risk <ul style="list-style-type: none"> ▪ 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	<ul style="list-style-type: none"> ◆ 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	<ul style="list-style-type: none"> ◆ 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	<ul style="list-style-type: none"> ◆ Prevailing winds ◆ Humidity

Factors	Additional Details
General area, region, or agricultural sector biosecurity	<ul style="list-style-type: none"> ◆ Biosecurity practices in place prior to outbreak ◆ Biosecurity practices implemented once outbreak detected
Number of non-commercial or transitional premises	<ul style="list-style-type: none"> ◆ Types of premises, animal movements, and network of animal and fomite movements
Continuity of business (COB)	<ul style="list-style-type: none"> ◆ COB 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

4.6 INFORMATION MANAGEMENT

Rapidly functional, robust, and scalable information technology infrastructure is needed in an FMD outbreak. Field personnel should be provided with access to the mobile technology devices necessary for collecting, monitoring, and sharing information. The Incident Information Management and Reporting manual (FAD PReP Manual 3-0) provides details on the information systems and functionality for disease and response management, as well as training resources.

Information management and reporting during an FMD incident or outbreak ensures that responders, stakeholders, and decision-makers have access to accurate and timely critical emergency response information. Ideally, Federal, State, Tribal, and local information management systems are compatible for information and data sharing.

4.6.1 EMRS2

EMRS2 is the official system of record for animal health incidents in the United States.²⁴ Having accurate premises data in EMRS2 significantly facilitates response efforts, reporting, and resource tracking.

In an FMD outbreak, the goal is to have EMRS2 data entry processes performed in 12-hour or shorter intervals. Data should be entered as quickly as possible. Data must be entered in both an accurate and consistent manner across widespread field operations: this is particularly important when there is more than one ICP. If possible, it may be necessary and/or beneficial to centralize certain data-entry

EMRS Essentials

1. Obtain USDA eAuthentication Level 2 access and EMRS2 access at link in first footnote, this page).
2. Access training at AgLearn, search terms: *EMRS Intro* and *EMRS Advanced*
<https://aglearn.usda.gov/>
3. Access additional training and drill materials at EMRS **Home tab** under Training
<https://emrs2.aphis.usda.gov>
4. Practice using EMRS2 at <https://emrs2t.aphis.usda.gov>
5. View Gateway and EMRS2Go videos at the **TEP video gallery**, link below.^o
6. States should consider whether they want to import premises data into EMRS2 before an incident occurs.

²⁴EMRS 2.0. August 20, 2020. Retrieved from https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/emergency-management/sa_emrs/ct_emrs

^o TEP Video Gallery. Retrieved from <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/training-and-development/video-gallery>

capabilities, particularly when field resources are stretched.

Because it is built on a Microsoft platform, EMRS2 easily interfaces with other Microsoft programs that are used frequently, such as Word and Excel; however, the user interface is quite different from those familiar products. Training prior to an incident is highly recommended for both Federal and State responders. Details may be found in the sidebar.

Having accurate premises data in EMRS2, prior to an incident, reduces errors and saves valuable time during an animal disease response. In preparation for an animal health incident, States may request that premises data is imported into EMRS2 so that information is available to APHIS in an outbreak.²⁵

EMRS2 also offers the Customer Permit Gateway, an interactive, secure web-application, where registered producers can create a permit request for movement. For further information, see FAD PReP Manual 6-0, Permitted Movement. In addition, EMRS2GO is an app that allows authorized users to collect new premises data off-line, then upload it into EMRS2 when re-connected online.

4.7 COMMUNICATION

The APHIS EPC Emergency Communications Plan provides guidance on communications activities during an FMD outbreak, covering the responsibilities of personnel and internal and external communication procedures. APHIS 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 will operate from the JIC. The JIC will also ensure that all State and

Comms Essentials

- The APHIS [EPC Emergency Communications Plan](#) is available to APHIS employees.
- APHIS public resources:
 - [FMD Site](#)
 - [FAD PReP FMD Communications RRG](#)
 - [FAD PReP Manual 5-0, Partial List of FAD Stakeholders](#)
www.aphis.usda.gov/fadprep

[Report broken link](#)

²⁵*EMRS 2.0: Premises Data Transfer to EMRS from External/State-Based Systems*. July 2020. Retrieved from https://www.aphis.usda.gov/animal_health/emergency_management/downloads/emrs_premisesdatatransfer.pdf

IMT Public Information Officers (PIO) share information on their activities with each other and the JIC.

Effective communication during an 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;
- ◆ coordinating 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.

- [Cross-species Communication Working Group](#) materials available at footandmouthdiseaseinfo.org
- In advance of an outbreak, States will want to
 - establish lines of communication for their industry, academia, and governmental agency partners
 - identify spokespersons for animal health issues

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4.7.1 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.

4.7.2 Key Messages

Eight key messages will be conveyed in an FMD outbreak (Box 4-3).

Box 4-3. 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.
5. Meat and meat products from vaccinated animals are safe to eat.
6. Milk and dairy products from vaccinated animals are safe to eat.

For producers:

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

4.7.3 Social Media

All personnel involved in an incident—from executive leadership to field responders—must be cognizant of the impact of social media. While it can be a useful tool in disseminating information or even gathering intelligence, it can also put a spotlight on a single aspect or episode of an event that misrepresents the whole of the effort. This threatens the intended public message, as well as the safety of responders and the progress, if not the success, of the response operation.

Any Agency-initiated social media for the incident must be done thoughtfully and coordinated through the on-site PIO and LPA. Responders should not use personal social media accounts to discuss the incident.

4.8 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.

To ensure responders are safe and physically prepared for the rigors of their deployment assignment, it is necessary that they receive medical clearance and, depending on the causative disease agent or disinfectant used, respirator fit testing prior to deployment.

- ◆ Medical clearance is the overall baseline clearance of an employee's fitness based on a medical exam. The exam, for example, may include assessing your general health, eyesight, hearing, medical history, pulmonary health, etc. It may take 90 days to obtain a medical clearance. APHIS responders should receive an Emergency Qualifications System (EQS) notice as a reminder to initiate the medical clearance process via APHIS Form 29.
- ◆ Fit testing is the process of confirming that employees are medically able to wear a respirator and that they have been properly fitted with the different kinds of respirators that they may need to wear. This may be done in conjunction with a medical exam, or it may be available at the incident site.

Safety Essentials

- APHIS emergency response employees may need a current medical clearance, and will need to have current status of defensive driver training.
- PPE will be provided at the incident. Any extreme weather conditions should be among the considerations in the hazard assessment.
 - Learn the appropriate donning and doffing procedures.
- APHIS employees must report accidents and injuries through the Online First Report Tool at the my.APHIS Portal.
- States may have specific training requirements for their response employees.
- The unified incident command may need to contract with a mental health provider which can offer services, to both State and Federal employees.
- Water *can* be purchased via purchase card for responders; it requires a waiver approved by MRP/AAMD.

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4.8.1 Personal Protective Equipment

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 when leaving.

For further information, see the FAD PReP 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; and
- ◆ a protocol for staff field safety in an FMD response.

4.8.2 Mental Health Concerns

The health and safety of all personnel is affected by the mental state of those involved in the FMD response effort. Therefore, preserving health and safety of those involved in a disease response effort includes addressing their mental states. APHIS employees may call the Employee Assistance Program (1-800-222-0364) at any time for help with emotional issues. Additionally, APHIS EMSSD can contract with Federal Occupational Health for onsite federal responder counseling.

FMD depopulation efforts can significantly affect the health of responders, livestock owners, and others impacted by the outbreak and response efforts. HHS has developed resources specifically for emergency and disaster responders, States and local planners, health professionals, and the general public (<https://emergency.cdc.gov/coping/index.asp>); additional general mental health information may be found at www.cdc.gov/mentalhealth.

4.9 BIOSECURITY

To prevent or slow the spread of FMD strict biosecurity measures need to be implemented. Some level of biosecurity procedures should already be in place at large operations; enhanced biosecurity should be implemented within 24 hours of the identification of an index FMD case. 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 FAD PReP 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.

4.9.1 Biosecurity Hazards and Mitigating Measures

Box 4-4 shows biosecurity hazards and biosecurity measures to mitigate these risks during an FMD outbreak.

Biosecurity Essentials

- Site Managers act as biosecurity specialist for their assigned sites and can halt operations on the site, if necessary.
- Contracting Officers and Contracting Officer Representatives are responsible for contractor biosecurity compliance.
- Biosecurity includes site security; download signage from http://www.cfsph.iastate.edu/Infection_Control/Sign/.

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Box 4-4. FMD Biosecurity Hazards and Appropriate Biosecurity Measures

Biosecurity Hazards	Biosecurity Measures to Mitigate Risk
<ul style="list-style-type: none">• 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.	<ul style="list-style-type: none">• 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).

4.9.2 Closed Herds

In the event of an FMD outbreak, an important biosecurity measure is closing herds to new livestock. Box 4-5 provides guidance on employing closed herds as a critical biosecurity measure.

Box 4-5. Biosecurity for Closed Herds

Biosecurity: Closed Herds
<ul style="list-style-type: none">• 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.

4.9.3 Waiting Period

Another important biosecurity measure is to ensure personnel are not traveling between IP and unknown or non-infected 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 4.15**). 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).²⁶ Team members should not travel from IP or SP to unknown or non-infected premises. However, they may travel between IPs, 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.

4.10 QUARANTINE AND MOVEMENT CONTROL

By restricting the movement of infected animals, animal products, and contaminated fomites, quarantine and movement control (QMC) 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 members need to strictly adhere to movement control procedures, which are based on the best scientific information available at the time. Refer to FAD PReP Manual 6-0, Permitted Movement, for a complete treatment of that topic.

Upon report of a highly suspicious or presumptive positive case of FMD, the State or Tribal Animal Health Official will immediately issue a quarantine or hold order on the premises. (**Appendix H** contains an example of a State quarantine order.) The Incident Commander, Disease Surveillance Branch (Operations Section), and Situation Unit (Planning Section), or

QMC Essentials

- See Section 4.1 in this chapter for premises and zone/area definitions.
- At the beginning of an outbreak, be prepared for a national, regional, or State movement standstill of 24-72 hour duration and changes in zone and CA designations.
- *NAHEMS Guidelines: Quarantine and Movement Control* provides information on measures to prevent the spread of FMD through movement.
- States' animal health emergency response plan should describe the implementation of QMC, including a permit system.
- States should consider their authorities for and enforcement of movement restrictions.

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²⁶ Department for Environment, Food, and Rural Affairs (DEFRA). 2008. Biosecurity Guidance to Prevent the Spread of Animal Diseases. http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/documents/biosecurity_guidance.pdf.

other appropriate personnel, will coordinate to establish an IZ and a BZ within 6 hours of the identification of an index case. These initial zone designations may be modified at any time based on new information. Refer to **Section 4.5.1** for premises and zone/area terminology and definitions.

4.10.1 Movement Standstill

Controlled movement orders and 24- to 72-hour standstill notices are likely to be implemented upon detection of FMD in the United States in relevant regions or zones. A State may require a movement standstill under its own authority or at the request of USDA, or in some cases, USDA may impose a Federal quarantine or other movement control by Federal Order when requested by SAHOs or as directed by the Secretary of Agriculture. (**Appendix H** contains an example of a Federal Order for a movement standstill.)

A national (or regional) standstill includes stopping the sending and receiving of all live susceptible animals as well as semen and embryos from susceptible animals. The applicable geographic region may be adjusted based on the location and any known information about introduction and transmission. In general, the following concepts apply:

- ◆ All movements of susceptible animals that are in progress when a national/regional movement standstill is announced should continue to move to their intended destinations. Destination premises should accept all movements of susceptible animals that are in progress at the time of the national standstill notice; this should be supported by States and industry. Reverting animals or returning them to the origin poses serious animal welfare and logistical issues.
- ◆ Exceptions may be made for critical movements. APHIS and State officials will determine the characteristics and requirements for these movements (an example would be animals scheduled to move to slaughter within 4 hours of the movement standstill being announced). APHIS and State officials may also approve critical movements of personnel or vehicle movements in a CA or onto and off of an infected premises for delivery of feed or veterinary care, for example.
- ◆ A national/regional movement standstill notice does not affect movement of milk. Premises may continue moving milk to processing. All premises moving milk must implement, monitor, and enforce their premises biosecurity plans to reduce the risk of FMD introduction. States may choose to implement additional or alternative guidance for premises needing to move milk.

In the event of a movement standstill, the USDA will provide clear concise policy guidance on the implementation and provisions of, made easily accessible to all stakeholders. Specifications of issuance will at least be defined for

1. a specific geographical area or boundary (e.g., Nationwide or other);
2. a specific requirement that all live swine in transit at issuance must reach a destination;
3. a specific time indicating the duration of a standstill (e.g., 72 hours);
4. a specific list of what items are restricted from movement (e.g., live swine and germplasm); and
5. a specific list of what items are exempt from movement restrictions (e.g., negligible risk Food Safety and Inspection Service [FSIS]-inspected products).

If a Federal quarantine or standstill notice is implemented under existing USDA authorities, States may be asked to provide resources to maintain and enforce these requirements; reimbursement formulas for these activities would be established between the States and USDA via cooperative agreement.

The release of this standstill, and costs associated with it, will be weighed carefully by APHIS officials against the risk of further disease transmission from premises that are infected but not yet detected. Additional national-level guidance will be provided when the national/regional movement standstill is lifted. All premises with susceptible animals should continue to implement elevated biosecurity.

4.10.2 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 non-infected 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.

The NAHEMS Guidelines: Quarantine and Movement Control provides information 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 non-infected livestock in areas where FMD exists.

4.10.2.1 PERMIT GUIDANCE TO MOVE INTO A CONTROL AREA, WITHIN A CONTROL AREA, AND OUT OF A CONTROL AREA

Each State’s animal health emergency response plan should describe the implementation of quarantine and movement controls, including a permit system.

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).

During an FMD outbreak, the following guidance in Table 4-8 (movement into a CA), Table 4-9 (movement within a CA), and Table 4-10 (movement out of a CA) will be used to issue permits in movement control efforts. The Secure Food Supply plans at www.cfsph.iastate.edu/secure-food-supply/ promote COB and provide permit guidance. For milk and milk products, see the Secure Milk Supply (SMS) Plan, <http://securemilksupply.org>. The Secure Pork Supply (SPS) Plan offers guidance for pork and pork products, www.securepork.org. The Secure Beef Supply (SBS) Plan is also developing COB guidance, <http://securebeef.org/>, as is the Secure Sheep and Wool Supply (<https://seuresheepwool.org/>).

See **Section 4.16** for additional guidance for movement control of vaccinates.

Table 4-6. 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 (COB) plans for information on susceptible animal products, or guidance and processes as determined by the IC. Please see the OIE <i>Terrestrial Code</i> for specific guidance for inactivating FMDV.				
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.			
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 4-7. 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 COB plans for information on susceptible animal products, or guidance and processes as determined by the IC. Please see the OIE <i>Terrestrial Code</i> for specific guidance for inactivating FMDV.				
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 4-8. 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 COB plans for information on susceptible animal products, or guidance and processes as determined by the IC. Please see the OIE <i>Terrestrial Code</i> for specific guidance for inactivating FMDV.				
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.

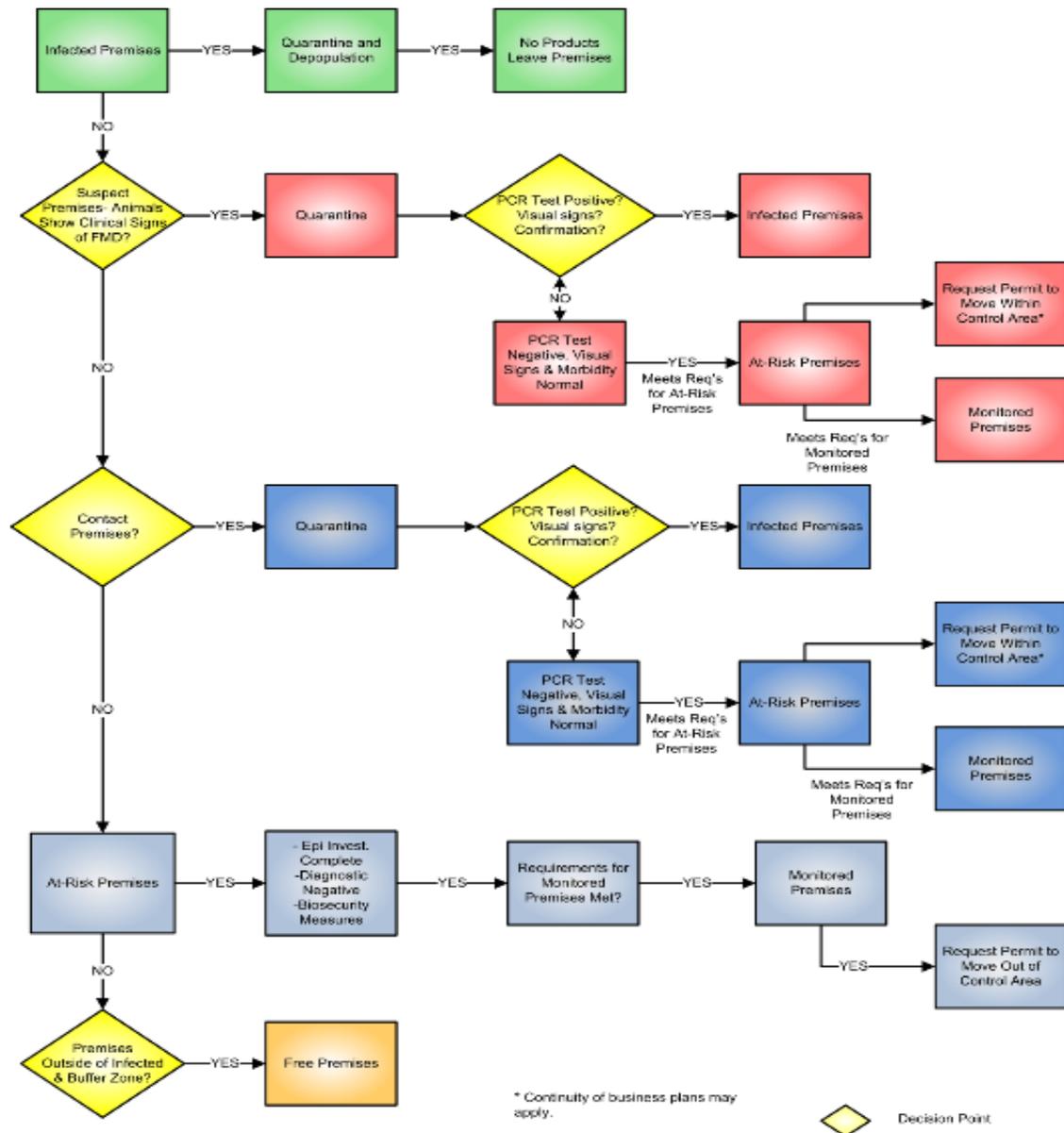
a Movement control and permit processes will change over time depending on situational awareness and operational capabilities.

^ 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, COB plans, movement and marketability plans, and compartmentalization plans will also be considered. Figure 4-4 illustrates movement control and permitting in relation to premises designation.

Figure 4-4. Premises Designations in Relation to Permitting and Movement Control



4.10.2.2 OIE TREATMENT GUIDELINES FOR FMD

The OIE *Terrestrial Code* provides guidance for the importation of animals, products, and commodities from FMD-infected countries or zones, as well as processes for inactivating FMDV. Specifically, Section 8.8 of the *Terrestrial Code* (2019) for guidance on the inactivation of FMDV in meat, wool and hair, bristles, raw hides/skins, and milk/cream, as well as other items, such as skins, trophies, and casings.

4.10.2.3 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 may include visual surveillance and/or 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 disease monitoring for dairy cattle, <http://securemilksupply.org>; the SPS Plan for swine, www.securepork.org; the SBS Plan for cattle, <http://securebeef.org>; and the Secure Sheep and Wool Supply Plan (<https://securesheepwool.org/>).

4.10.3 Repopulation

4.10.3.1 RESTOCKING GUIDANCE

Following appropriate cleaning and disinfection procedures, IPs 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 IPs 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.

4.10.3.2 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.

4.10.3.3 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.

4.11 CONTINUITY OF BUSINESS (COB)

COB is the management of non-infected premises and non-contaminated animal products in the event of an FMD outbreak. COB provides science- and risk-based approaches and systems as a critical activity in an FMD response. This helps agriculture and food industries facilitate routine business, or a return to business, during a disease response while the risk of disease spread is effectively managed. COB 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 COB. The NAHEMS Guidelines: Continuity of Business covers topics such as

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

The SMS Plan (<http://securemilksupply.org>) offers additional COB information for milk and milk products; the SPS Plan (www.securepork.org) offers additional COB information for pork and pork products, particularly applicable to interstate trade. See also the Secure Beef Supply (SBS) Plan, <http://securebeef.org/>, and the

Secure Sheep and Wool Supply Plan (<https://seuresheepwool.org/>). See **Section 4.16.3** for additional guidance for movement control of vaccinates.

4.12 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 COB 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, which 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.

4.12.1 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 veterinary authorities to demonstrate and maintain DF 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.

4.12.2 Further Guidance

The OIE *Terrestrial Code* offers specific guidelines for an FMD-free compartment in Chapter 8.8 (2019).

4.13 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. Mass depopulation methods that may be considered include

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

In an FMD outbreak, euthanasia or mass depopulation should be conducted on 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

Depop Essentials

- See the [*NAHEMS Guidelines: Mass Depopulation and Euthanasia*](#).
- In 2019, AVMA published [*Guidelines for the Depopulation of Animals*](#).
- States should prepare in advance for the depopulation method(s) it will use and the resources it will need.
 - VS has a limited supply of captive bolt equipment.
 - NVS contractors are *not* on contract to perform, nor are they capable of performing, large animal depopulation; however, they can provide labor and transport.

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circumstances. Mass depopulation is employed in an FMD response to prevent or mitigate the spread of FMD through the elimination of infected or potentially infected animals. The mass depopulation guidance document²⁷ issued in 2019 from the American Veterinary Medical Association (AVMA) recognizes the need for emergency destruction of animals in disease situations, and stresses adherence to strong ethical standards throughout depopulation to ensure animals experience minimal pain and distress. In short, 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.

Sufficiency of available personnel or materials should be assessed before an outbreak occurs. Reliance on NVS contractors is not necessarily an option, as—despite contract solicitations—it does not have the capability to deliver resources for depopulation of large animals. VS holds several captive bolt units and has a roster of trained State and Federal responders on their use. Expertise in euthanasia and mass depopulation may also be available within particular industries.

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

4.14 DISPOSAL

Appropriate disposal of animal carcasses and materials is a critical component of a successful FMD response. FMDV can survive for long periods on both organic and inorganic materials. The FAD PReP Disposal SOP discusses how to dispose of carcasses, animal products, contaminated and potentially contaminated 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.

Planning in advance for carcass management is strongly advised, as coordination among State and local agriculture emergency response and environmental agencies and waste authorities will be necessary for timely disposal of contaminated materials. The APHIS Carcass Management Dashboard is available (see sidebar on next page) to guide States and producers through carcass management options for planning or response purposes.

Disposal must be conducted 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

²⁷ American Veterinary Medical Association. (2019). *Guidelines for the Depopulation of Animals*. Retrieved from: <https://www.avma.org/KB/Policies/documents/AVMA-Guidelines-for-the-Depopulation-of-Animals.pdf>.

clinically normal animals to a slaughter facility within the CA may be possible, though they may have been exposed to FMDV on IP or CP. IC must permit any movement required for disposal. Local and State regulations must be observed and memorandums of understanding may need to be obtained to ensure disposal capabilities. Cost effectiveness and stakeholder acceptance must also be considered.

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.

On-site burial, which has been a commonly accepted means of disposal, may be an inexpensive and biosecure method of disposal that minimizes the transportation of infected materials. However, on-site methods may be significantly limited by several factors and the potential for environmental contamination, such as topography, soil type, soil depth to bedrock, seasonal high-water table, and environmental regulations.

Other disposal methods such as composting, incineration, and rendering may also be employed, as indicated by the circumstances of the outbreak and disposal requirements. These methods may address the need to minimize negative environmental impact while also mitigating virus spread; they are also considered viable alternatives for both large and small ruminants. Please note, written verification that disposal operations are approved by the state environmental regulatory agency will be required if APHIS pays for disposal. For the disposal of syringes and unused but opened vaccine vials, disposal through routine medical waste service provider is recommended.

In the event that available personnel are insufficient for disposal requirements in an FMD outbreak, the IC can request emergency 3D contractor support from the

Disposal Essentials

- APHIS resources include
 - [NAHEMS Guidelines: Disposal](#) and detailed [FAD PReP Disposal SOP](#).
 - The [Carcass Management Dashboard](#)
 - [Carcass Management Basics](#) webinar on the TEP site, search term: *disposal*
- A website search may reveal useful resources, such as the Veterinary Compliance Assistance [Carcass Disposal State Resource Locator](#) which summarizes and cites State disposal regulations.
- Work with all relevant agencies when developing site-specific carcass management plans.

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NVS. *NAHEMS Guidelines: Disposal* contains further guidance on preparation for disposal activities.

4.15 CLEANING AND DISINFECTION

Because of FMDV'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 FAD PReP 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 IC can request emergency 3D contractor support from NVS.

NAHEMS Guidelines: Cleaning and Disinfection contains additional information.

C&D Essentials

- See [*NAHEMS Guidelines: Cleaning and Disinfection*](#) for C&D preparedness.
- A list of EPA-approved disinfectants may be found [here](#), and product labels may be found at EPA's [Pesticide Product and Label System](#).
- APHIS' [Disinfectants](#) website provides letters of exemption and concentrations for use of citric acid or bleach when an EPA-registered product is not available.

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4.16 VACCINATION

The use of emergency vaccination in the event of FMD is discussed in Chapter 3. This section explains important additional details in the event emergency vaccination is approved for use in an FMD outbreak.

In addition to having a sufficient quantity of vaccine that can be delivered quickly, effectively implementing a vaccination strategy and plan requires other significant resources and infrastructure, including the following:

- ◆ Regulatory infrastructure (for procurement, licensing, permitting, distribution, and use).
- ◆ Logistics capabilities, including vaccination teams and cold chain management
- ◆ Animal identification (per requirements for FMD emergency vaccine use).
- ◆ Communication (strategy and messaging).
- ◆ Information management.
- ◆ Incident management system capabilities.
- ◆ Resources to continue execution other critical activities, including surveillance, biosecurity, and cleaning and disinfection.

Vaccination Essentials

- APHIS will likely solicit States for vaccine requests, even prior to a decision to vaccinate.
- Vaccine selection will be made at the national level.
- A well-defined State plan is a prerequisite for vaccine receipt.
- Appendices E and I of this publication provide additional information.

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4.16.1 Vaccination Plan

Limited quantities of vaccine will be available early in the response, and APHIS VS may receive requests for vaccine from multiple States. A well-defined State vaccination plan will assist decision makers in prioritizing and distributing vaccine to States that are ready and able to handle the vaccine appropriately and rapidly administer doses based on well-grounded epidemiological principles.

The State vaccine request should include an estimate of the number of vaccine doses desired in the first shipment (first two weeks), and for subsequent shipments (3 months and beyond). The projection may be made based on all

susceptible animals in the State, or of the population for which vaccine is planned, dairy cattle, for instance.

In plan development, consult Table 4-11 for assumptions used to calculate vaccine quantity needed:

Table 4-9. Projected Vaccine Dose Need

Projected vaccine dose needs

Species	Dose	Booster	Repeat
Cattle	2 ml IM	-	6 mos.
Feeder pigs	2 ml IM*	-	-
Sows & Boars	2 ml IM	10-14 days	6 mos.
Sheep & Goat	1 ml IM	-	6 mos.
Zoo – TBD			

*Feeder pigs—3 mos. immunity, to slaughter

The vaccination plan should contain this request, as well as describe the vaccination strategy and schedule; policies for identification and movement of vaccinates; and logistics for receipt and proper administration of vaccine. See **Appendix E** for an example of information that should be included in a State vaccination plan.

4.16.2 Zone, Area, and Premises Designations

Vaccination strategies are presented in Chapter 3 of this document. This section provides additional detail and figures to illustrate the use of emergency vaccination in an FMD outbreak.

4.16.2.1 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 often observed with stamping-out modified with emergency vaccination to kill or to slaughter. Figure 4-5 shows examples of a CVZ.

Figure 4-5. Examples of Containment Vaccination Zones (Figures are not to scale.)

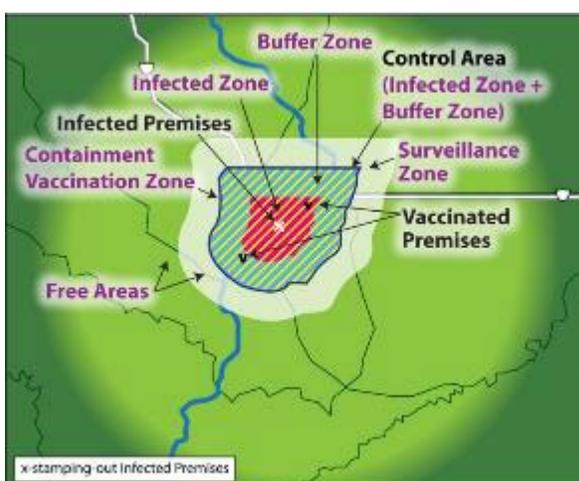
Emergency Vaccination in Infected Zone



Emergency Vaccination in Buffer Zone



Emergency Vaccination in Control Area



Emergency Vaccination in IZ and Partial BZ



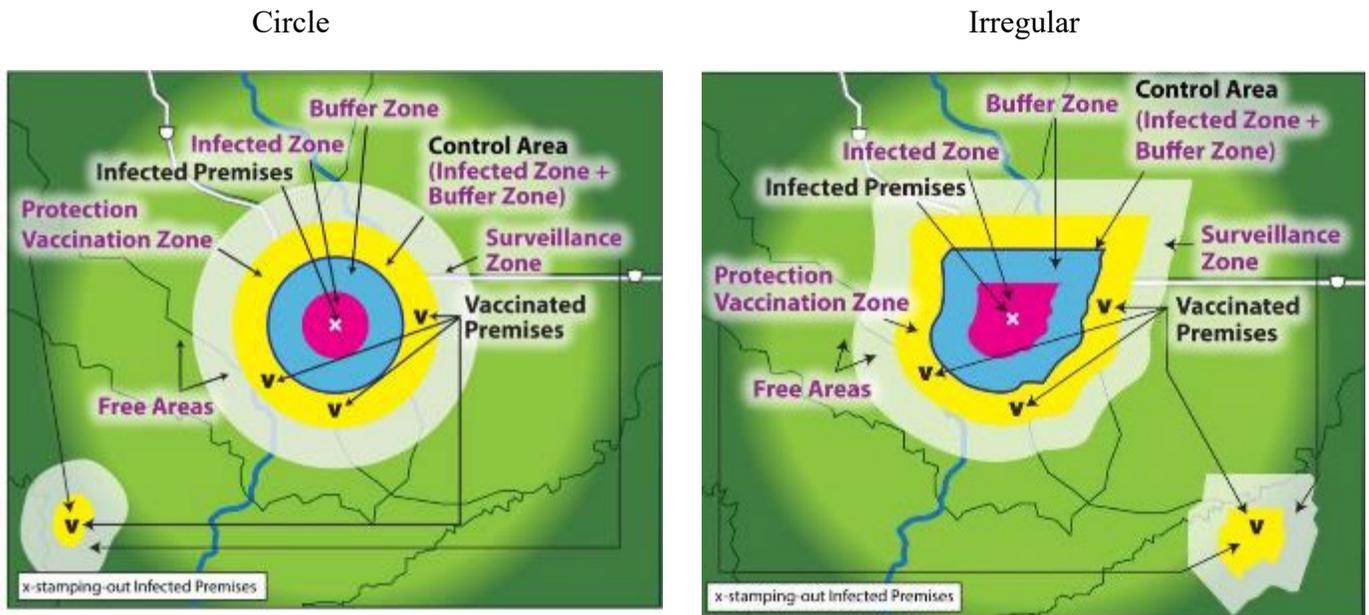
4.16.2.2 PROTECTION VACCINATION ZONE

The PVZ is an emergency vaccination zone typically in the FA. It is consistent with the OIE *Terrestrial Code* (2019) definition for a Protection Zone:

A zone where specific biosecurity and sanitary measures are implemented to prevent the entry of a pathogenic agent into a free country or zone from a neighboring country or zone of a different animal health status.

Typically, a PVZ would be observed with stamping-out modified with emergency vaccination-to-live. Figure 4-6 shows examples of a PVZ.

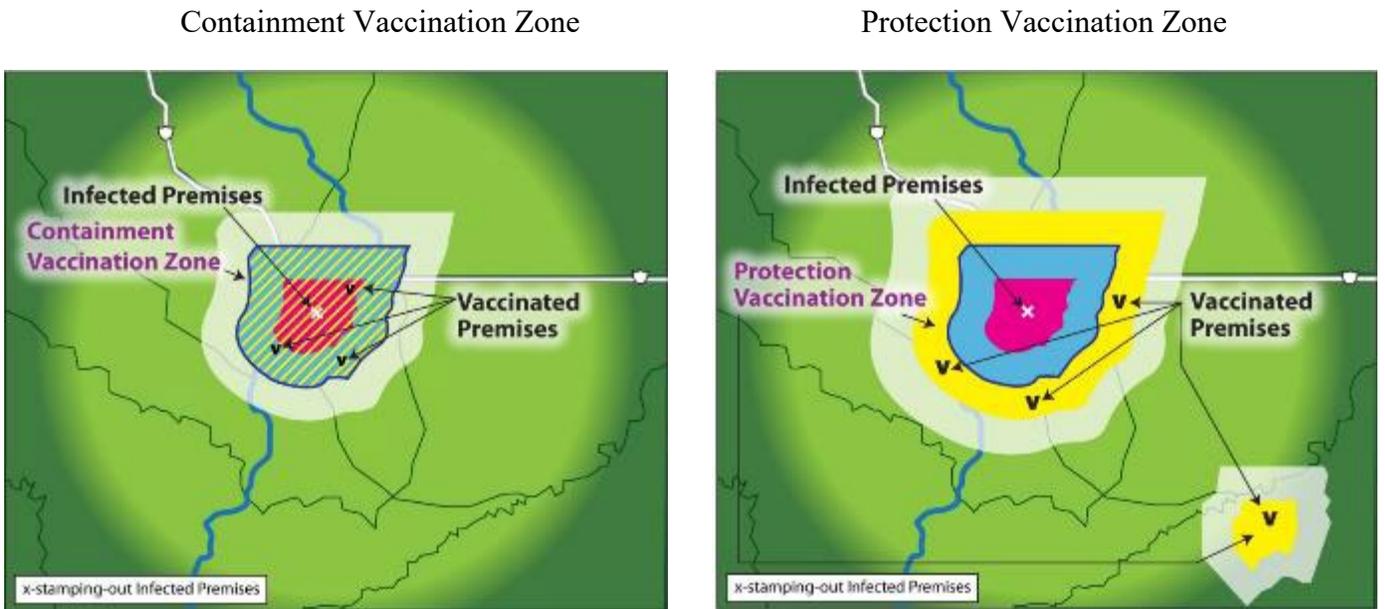
Figure 4-6. Examples of Protection Vaccination Zones (Figures are not to scale.)



4.16.2.3 Vaccinated Premises (VP)

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, typically inside a CA (IZ or BZ) or in a PVZ, typically in the FA. Figure 4-7 shows VP in a CVZ (left) and in a PVZ (right).

Figure 4-7. Vaccinated Premises (Figures are not to scale.)



4.16.3 Movement Restrictions for Vaccinates

If emergency vaccination is used in a response to an FMD outbreak, 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 vaccinates will 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 the movement restrictions of their primary premises designation.
- ◆ Animals receiving emergency vaccination on the VP may be subject to vaccinated animal identification, 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.

4.16.4 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. The decision to cease emergency vaccination will be made by the IC, SAHO, and VSDA/CVO, who will consider national and international standards for movement in making this determination.

4.17 LOGISTICS

The NVS provides veterinary countermeasures—supplies, equipment, vaccines, and response support services—that States, Tribes, and Territories need to respond to damaging animal disease outbreaks. Its website provides information on NVS capabilities and overviews the required steps to request countermeasures from the NVS. It also provides materials which State preparedness officials and responders can download 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.

In addition to physical countermeasures, the NVS maintains contracts with all-hazard response companies that are capable of supporting depopulation, disposal, and decontamination (3D) activities. 3D represents activities commonly demanding rapid deployment of response personnel and equipment. NVS contractors are trained in emergency response, and are self-sufficient with their own equipment and supplies. The contractors can deploy within 24 hours, and are capable of providing large numbers of personnel over time (weeks); however, in a widespread outbreak, personnel shortages can still occur.

4.18 WILDLIFE MANAGEMENT AND VECTOR CONTROL

USDA APHIS will work in close collaboration, communication, and coordination with DOI and other Federal, State, Tribal, and local 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 MPC.

The NAHEMS Guidelines: Wildlife Management and Vector Control for an FAD Response in Domestic Livestock also discusses personnel and equipment required for wildlife management, quarantine and movement control for wildlife, wildlife risk assessment, wildlife surveillance, and related activities.

NVS Essentials

- Visit the APHIS [NVS website](#) for details.
- Contact the NVS:
 - For routine questions, NVS@USDA.gov
 - For emergencies, 800-940-6524

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4.18.1 Wildlife Management

A wildlife management plan that addresses transmission of FMD in 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 in the first week of an outbreak. 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.

4.18.2 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.

4.19 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 FAD PReP Overview of Animal Welfare SOP available at www.aphis.usda.gov/fadprep and the AVMA mass depopulation guidance document referenced in **Section 4.13** contain additional information.

4.20 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.

Presently, CEAH is conducting modeling work associated with FMD control strategies for detected feedlots. A few of the initial scenarios to be evaluated follow:

- ◆ Total depopulation of feedlot with no animals moved to controlled slaughter.
- ◆ Segmented harvest: targeted animals moved to controlled slaughter.

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- ◆ Selective and/or welfare depopulation followed by controlled slaughter of recovered animals.
 - ◆ Vaccination followed by controlled slaughter of vaccinated animals.
 - ◆ Vaccination with selective depopulation and controlled slaughter of remaining vaccinated animals.
 - ◆ Controlled burn through with no depopulation of infected animals.

The FAD PReP Overview of Modeling and Assessment Tools SOP provides information on modeling and risk assessment, covering

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

4.21 APPRAISAL AND COMPENSATION

The AHPA gives APHIS authority to establish and implement an indemnification program to prevent or eradicate an FMD outbreak (See **Section 2.2**). Indemnity payments are made 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 best practices for containment and eradication of FMD will in many instances require depopulation, disposal, and decontamination to be carried out 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. In this case, APHIS will require that the livestock owner/producer sign an appraisal and indemnity request form, which captures basic information and confirms that the producer will accept fair market value for depopulated animals. 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.

APHIS may also reimburse owners for materials that cannot be cleaned and disinfected and must be destroyed, e.g. feed. Payment processing for materials destroyed requires receipts or documents to substantiate fair market value. Incident personnel—Case Managers and Federal Reimbursement Specialists—will be available to assist owners with appraisal and compensation processes.

4.22 FINANCE

During an FMD outbreak, a funding source will need to be identified quickly. 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).

4.22.1 Federal Funding Sources

The two most common sources are the APHIS Contingency Fund (CF) and the Commodity Credit Corporation (CCC). During an emergency, the Secretary is authorized to transfer funds from the CCC. 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.

The APHIS CF is available for 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.

For funds in excess of \$1 million, CCC funding is typically requested. The funds are provided to APHIS as no-year funds. APHIS considers the total estimated amount of funding needed to address the issue and the degree of political support for funding before deciding whether or not to seek a CCC transfer.

The FAD PReP 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.

4.22.2 Supplemental Cooperative Agreements

In an animal disease response, USDA APHIS will engage in supplemental or emergency cooperative agreements with States for conducting disease control measures. The following guidelines on types of reimbursements under a supplemental agreement provide details on what costs are covered during an animal health disease response.

Staffing. Salaries of existing State employees working on the response will not be covered by supplemental funds, but overtime worked in association with the disease event is eligible for reimbursement. Travel, housing, and per diem costs incurred by State employees responding to the event outside their normal districts are also covered. New staff brought on to assist in response activities should be term or temporary staff working directly on the response.

Supplies. PPE, cleaning and disinfection materials, shipping materials and costs, swabs and biological media, outreach materials, and office supplies needed to handle the response are covered by a supplemental agreement. Approval would be needed in advance for single purchases costing over \$5000.

Expenses. A variety of other expenses may also be covered, but it is important to note that one State being reimbursed for something does not ensure that another State will be covered for the same expense.

Communications and Information Technology. Communication and information technology needs will be covered if they are directly related to the response and require resources beyond the normal expenses already undertaken by the cooperator. However, procurements of new IT systems or investments in major upgrades for existing State systems will not be provided. If a State needs to set up an emergency operations center, the cost of leasing and outfitting a space with the appropriate information technology equipment needed would be covered. Similarly, while APHIS will not pay the cost of cell phones or lines already in place for normal use, additional lines, phones, or usage costs associated with the outbreak would be paid for.

Additional information may be found in the FAD PReP Finance SOP available at www.aphis.usda.gov/fadprep.

4.23 INCIDENT MANAGEMENT

In any FAD 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.

In an FMD outbreak, in particular a widespread one, national policy guidance will be distributed to NIMTs, the SAHOs of affected States, all States via NASAHO, and the APHIS FAD PReP website (www.aphis.usda.gov/fadprep).

Appendix A

FAD PReP Materials to Support FMD Response

This appendix provides a broad overview of the Foreign Animal Disease Preparedness and Response Plan (FAD PReP), and lists the FAD PReP documents that support this Foot-and-Mouth Disease (FMD) Response Plan (2019). The document list below may be useful for all stakeholders in preparedness and response planning related to FMD. The documents listed within may be found at www.aphis.usda.gov/fadprep.

Appendix A

FAD PReP Materials to Support FMD Response

This appendix provides a broad overview of the Foreign Animal Disease Preparedness and Response Plan (FAD PReP), and lists the FAD PReP documents that support this *Foot-and-Mouth Disease (FMD) Response Plan (2019)*. The documents list below may be useful for all stakeholders in preparedness and response planning related to FMD. These resources are found online at www.aphis.usda.gov/fadprep.

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 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 deconflict preparedness and response capabilities as much as possible before an outbreak by providing goals, guidelines, strategies, and procedures that are clear, comprehensive, easily readable, easily updated, and that comply with the National Incident Management System.

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

FAD PReP Documents and Materials

FAD PReP is a comprehensive U.S. preparedness and response strategy for FAD threats, both zoonotic and non-zoonotic. Types of FAD PReP documents include:

- ◆ Strategic Plans—Concept of Operations

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- ◆ National Animal Health Emergency Management System (NAHEMS) Guidelines
 - ◆ Industry Manuals
 - ◆ Disease Response Plans
 - ◆ Standard Operating Procedures (SOP) for Critical Activities
 - ◆ Ready Reference Guides.

Lessons Learned from Past Outbreaks

The foundation of FAD PReP is lessons learned in managing past FAD incidents. FAD PReP is based on the following:

- ◆ Providing processes for emergency planning that respect local knowledge.
- ◆ Integrating State-Federal-Tribal-industry planning processes.
- ◆ Ensuring that there are clearly defined, obtainable, and unified goals for response.
- ◆ Having a Unified Command with a proper delegation of authority that is able to act with speed and certainty.
- ◆ Employing science and risk-based management approaches to FAD response.
- ◆ Ensuring that all guidelines, strategies, and procedures are communicated effectively to responders and stakeholders.
- ◆ Identifying resources and trained personnel required for an effective incident response.
- ◆ Trying to resolve competing interests prior to an outbreak and addressing them quickly during an outbreak.
- ◆ Achieving rapid FAD detection and tracing.

FMD STANDARD OPERATING PROCEDURES (SOP)—CRITICAL ACTIVITIES

These documents (numbered corresponding to the 23 critical activities) 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
5. Epidemiological Investigation and Tracing

7. Communications
8. Health and Safety and Personal Protective Equipment
9. Biosecurity
14. Disposal
15. Cleaning and Disinfection
16. Vaccination
17. Overview of the National Veterinary Stockpile
19. Overview of Animal Welfare
20. Overview of Modeling and Assessment Tools
22. Overview of Finance
23. Overview of the National Response Framework and National Incident Management System

READY REFERENCE GUIDES

- ◆ FMD Response
 - Etiology and Ecology
 - Communications
 - Overview of the FMD Response Plan
 - Overview of Emergency Vaccination
 - Common Operating Picture
 - Overview of FMD Vaccination Issues
 - Overview of FMD Freedom and Vaccination
 - Comparing United States and United Kingdom FMD Response Planning
 - Quarantine, Movement Control, and Continuity of Business
 - Surveillance
 - Overview of Diagnostics
 - Additional Information
- ◆ General Response for all FADs
 - Introduction to FAD PReP
 - Introduction to the Emergency Management Response System (EMRS) 2
 - FAD Framework: Roles and Coordination

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- FAD Framework: Response Strategies
 - Critical Activities and Tools During an FAD Response
 - Zones, Areas, and Premises in an FAD Outbreak
 - Movement Control in an FAD Outbreak
 - Defining Permitted Movement
 - Permitting Process
 - VS Guidance 12001.3: Procedures and Policy for the Investigation of Potential FAD/Emerging Disease Incidents

INDUSTRY MANUAL

- ◆ Swine
- ◆ Cow-Calf
- ◆ Dairy
- ◆ Beef Feedlot

NAHEMS GUIDELINES

- ◆ Biosecurity
- ◆ Cleaning and Disinfection
- ◆ Continuity of Business
- ◆ Disposal
- ◆ Health and Safety
- ◆ Mass Depopulation and Euthanasia
- ◆ Personal Protective Equipment
- ◆ Surveillance, Epidemiology, and Tracing
- ◆ Quarantine and Movement Control
- ◆ Vaccination for Contagious Diseases
- ◆ Wildlife Management and Vector Control for an FAD Response in Domestic Livestock

STRATEGIC PLANS-CONCEPT OF OPERATIONS

- ◆ APHIS FAD Framework: Roles and Coordination (FAD PReP Manual 1-0)
- ◆ APHIS FAD Framework: Response Strategies (FAD PReP Manual 2-0)

- ◆ Incident Information Management and Reporting (FAD PReP Manual 3-0)
- ◆ FAD Investigation Manual (FAD PReP Manual 4-0)
- ◆ A Partial List of FAD Stakeholders (FAD PReP Manual 5-0)
- ◆ Permitted Movement (FAD PReP Manual 6-0)

Appendix B

OIE Terrestrial Animal Health Code for FMD (2019)

The World Organization for Animal Health (OIE) updates chapters in its *Terrestrial Animal Health Code (Terrestrial Code)* as needed on an annual basis. Planners and responders will want to refer to the OIE Code frequently. The 2019 update for foot-and-mouth disease (FMD) is available at www.oie.int or direct: https://www.oie.int/fileadmin/Home/eng/Health_standards/tahc/current/chapitre_asf.pdf

Appendix C

Laboratory Network List for FMD

The list of laboratories in the National Animal Health Laboratory Network (NAHLN) embedded in this document is found here: http://www.aphis.usda.gov/animal_health/nahln/downloads/fmd_lab_list.pdf. This list was last updated in August 2020.

The following laboratories can currently perform testing for foot-and-mouth disease (FMD) virus after National Veterinary Services Laboratories (NVSL) confirmation of FMD.

NAHLN Laboratories approved for FMD Preparedness and Surge Testing

	State	Laboratory
1	Alabama	Thompson-Bishop-Sparks State Diagnostic Laboratory 890 Simms Road Auburn, Alabama 36832-2026 Phone: 334-844-4987
2	Arizona	Arizona Veterinary Diagnostic Laboratory 2831 North Freeway Tucson, Arizona 85705-5021 Phone: 520-621-2356
3	Arkansas	Arkansas Livestock & Poultry Commission Laboratory #1 Natural Resources Drive Little Rock, Arkansas 72205-1539 Phone: 501-907-2430
4	California	California Animal Health & Food Safety Laboratory University of California, School of Veterinary Med 620 West Health Science Drive Davis, California 95616 Phone: 530-752-8709
5	Colorado	Colorado State University Veterinary Diagnostic Laboratory 300 West Drake Road, Building C Fort Collins, Colorado 80523-1644 Phone: 970-297-1281
6	Colorado	Colorado State University Veterinary Diagnostic Laboratory-Rocky Ford 27847 County Road 21 Rocky Ford, Colorado 81067-9466 Phone: 719-254-6382
7	Connecticut	Connecticut Veterinary Medical Diagnostic Laboratory University of Connecticut, Unit 3089 61 North Eagleville Road Storrs, Connecticut 06269-3089 Phone: 860-486-3738
8	Florida	Bronson Animal Disease Diagnostic Laboratory Florida Department of Ag and Consumer Services 2700 N. John Young Parkway Kissimmee, Florida 34741-1266 Phone: 321-697-1400
9	Georgia	Athens Veterinary Diagnostic Laboratory The University of Georgia 501 D.W. Brooks Drive Athens, Georgia 30602-5023 Phone: 706-542-5568
10	Georgia	University of Georgia Tifton Veterinary Diagnostic Laboratory 43 Brighton Road Tifton, Georgia 31793-3000 Phone: 229-386-3340

NAHLN Laboratories approved for FMD Preparedness and Surge Testing

	State	Laboratory
11	Hawaii	State Laboratories Division 2725 Waimano Home Road Pearl City, Hawaii 96782-1401 Phone: 808-453-6650
12	Illinois	University of Illinois Veterinary Diagnostic Laboratory Veterinary Diagnostic Laboratory 2001 S. Lincoln Ave Urbana, Illinois 61802-6178 Phone: 217-333-1620
13	Indiana	Indiana Animal Disease Diagnostic Laboratory at Purdue University 406 South University St West Lafayette, Indiana 47907-2065 Phone: 765-494-7440
14	Iowa	Iowa State University Veterinary Diagnostic Laboratory 1800 Christensen Dr Ames, Iowa 50011-1134 Phone: 515-294-1950
15	Kansas	Kansas State Veterinary Diagnostic Laboratory Kansas State University, CVM L232 Mosier Hall, 1800 Dennison Ave Manhattan, Kansas 66506-5611 Phone: 785-532-5650
16	Kentucky	Breathitt Veterinary Center Murray State University 715 North Drive Hopkinsville, Kentucky 42240-2620 Phone: 270-886-3959
17	Kentucky	University of Kentucky, Veterinary Diagnostic Laboratory 1490 Bull Lea Rd Lexington, Kentucky 40511-1264 Phone: 859-257-8283
18	Louisiana	Louisiana Animal Disease Diagnostic Laboratory Veterinary Med Diag. Laboratory, LSU River Road Room 1043 Baton Rouge, Louisiana 70803-0001 Phone: 225-578-9777
19	Michigan	Michigan State University Veterinary Diagnostic Laboratory College of Veterinary Medicine 4125 Beaumont Rd, Ste 201H Lansing, Michigan 48910-8103 Phone: 517-353-1683

NAHLN Laboratories approved for FMD Preparedness and Surge Testing

	State	Laboratory
20	Minnesota	University of Minnesota Veterinary Diagnostic Laboratory 1333 Gortner Ave, 244 Vet D L St. Paul, Minnesota 55108-1098 Phone: 612-625-8787
21	Mississippi	Mississippi Veterinary Research & Diagnostic Laboratory 3137 Hwy 468 West Pearl, Mississippi 39208-9007 Phone: 601-420-4700
22	Missouri	Veterinary Medical Diagnostic Laboratory University of Missouri 901 E. Campus Loop Columbia, Missouri 65211-0001 Phone: 573-882-6811
23	Missouri	Missouri Department of Agriculture Veterinary Diagnostic Laboratory 701 North Miller Avenue Springfield, Missouri 65802-6460 Phone: 417-895-6861
24	Montana	Montana Veterinary Diagnostic Laboratory Marsh Laboratory, 1911 W Lincoln St Bozeman, Montana 59771-0997 Phone: 406-994-4885
25	Nebraska	University of Nebraska Veterinary Diagnostic Center 4040 East Campus Loop North Lincoln, Nebraska 68583-0907 Phone: 402-472-1434
26	New Jersey	New Jersey Department of Agriculture, Division of Animal Health - Animal Health Diagnostic Laboratory, NJPHEAL 3 Schwarzkopf Drive Ewing, New Jersey 08628 Phone: 609-406-6999
27	New Mexico	New Mexico Department of Agriculture Veterinary Diagnostic Services Veterinary Diagnostic Services 1101 Camino de Salud NE Albuquerque, New Mexico 87102-4519 Phone: 505-383-9299
28	New York	Animal Health Diagnostic Center College of Vet Med, Cornell University 240 Farrier Road Ithaca, New York 14853-8002 Phone: 607-253-3900

NAHLN Laboratories approved for FMD Preparedness and Surge Testing

	State	Laboratory
29	North Carolina	Rollins Diagnostic Laboratory North Carolina Department of Agriculture 2101 Blue Ridge Rd Raleigh, North Carolina 27607-6432 Phone: 919-733-3986
30	North Dakota	Veterinary Diagnostic Laboratory North Dakota State University NDSU Dept. 7691 Fargo, North Dakota 58108-6050 Phone: 701-231-8307
31	Ohio	Animal Disease Diagnostic Laboratory Ohio Department of Agriculture 8995 East Main St., Bldg. # 6 Reynoldsburg, Ohio 43068-3399 Phone: 614-728-6220
32	Oklahoma	Oklahoma Animal Disease Diagnostic Laboratory Oklahoma State University, College of Vet. Med. Farm & Ridge Road Stillwater, Oklahoma 74078-0001 Phone: 405-744-6623
33	Oregon	Oregon State University Veterinary Diagnostic Lab Magruder Hall 134 700 SW 30 th St Corvallis, Oregon 97331-8628 Phone: 541-737-3261
34	Pennsylvania	Pennsylvania Veterinary Laboratory Pennsylvania Department of Agriculture 2305 N Cameron Street Harrisburg, Pennsylvania 17110-9405 Phone: 717-787-8808
35	South Carolina	Clemson Veterinary Diagnostic Center 500 Clemson Road Columbia, South Carolina 29229-4306 Phone: 803-788-2260
36	South Dakota	Animal Disease Research & Diagnostic Laboratory South Dakota State University Box 2175, N. Campus Dr. Brookings, South Dakota 57007-0001 Phone: 605-688-5171
37	Tennessee	Kord Animal Disease Diagnostic Laboratory TN Dept of Agriculture 436 Hogan Road Nashville, Tennessee 37220-2014 Phone: 615-837-5125

NAHLN Laboratories approved for FMD Preparedness and Surge Testing

	State	Laboratory
38	Texas	Texas A&M Veterinary Medical Diagnostic Laboratory - Amarillo 6610 Amarillo Blvd West Amarillo, Texas 79106-1706 Phone: 806-353-7478
39	Texas	Texas A&M Veterinary Medical Diagnostic Laboratory 483 Agronomy Road College Station, Texas 77843-4471 Phone: 979-845-3414
40	Utah	Utah Veterinary Diagnostic Laboratory 950 E. 1400 North Logan, Utah 84341-2877 Phone: 435-797-1895
41	Virginia	VDACS Harrisonburg Regional Animal Health Laboratory 261 Mt. Clinton Pike Harrisonburg, Virginia 22802-2551 Phone: 540-209-9130
42	Washington	Washington Animal Disease Diagnostic Laboratory Bustad Hall, Rm 155-N Pullman, Washington 99164-7034 Phone: 509-335-9696
43	Wisconsin	USGS National Wildlife Health Center 6006 Schroeder Road Madison, Wisconsin 53711-2531 Phone: 608-270-2400
44	Wisconsin	Wisconsin Veterinary Diagnostic Laboratory 445 Easterday Lane Madison, Wisconsin 53706-1253 Phone: 608-262-5432 ext 2227
45	Wyoming	Wyoming State Veterinary Laboratory 1174 Snowy Range Road Laramie, Wyoming 82070-6752 Phone: 307-766-9925

Appendix D

Procedures for FMD Investigation and Specimen Submission

VS Guidance Document 12001.x provides Veterinary Services (VS) policy for the field investigation and communication of a potential Foreign Animal Disease/ Emerging Disease Incident (FAD/EDI). Specific communication and operational procedures are provided in the Foreign Animal Disease Investigation Manual.

Policy for the Investigation of Potential Foreign Animal Disease/Emerging Disease Incidents (FAD/EDI)

1. Purpose and Background

This document provides Veterinary Services (VS) policy for the field investigation and communication of a potential Foreign Animal Disease/Emerging Disease Incident (FAD/EDI). Specific communication and operational procedures are provided in the *Foreign Animal Disease Investigation Manual*.

This guidance document represents the Agency's position on this topic. It does not create or confer any rights for or on any person and does not bind the U.S. Department of Agriculture (USDA) or the public. The information it contains may be made available to the public. While this document provides guidance for users outside VS, VS employees may not deviate from the directions provided herein without appropriate justification and supervisory concurrence.

2. Document Status

A. Review date: 07/10/2020

B. This document replaces VS Guidance 12001.2 (June 5, 2014).

3. Reason for Reissuance

Expiration of prior VS Guidance 12001.2.

4. Authority and References

A. Authorities (*Code of Federal Regulations* (CFR)):

[7 CFR part 331](#)

[7 CFR 371.4](#)

[9 CFR part 53](#)

[9 CFR part 71](#)

[9 CFR part 82](#)

[9 CFR part 94](#)

[9 CFR part 121](#)

[9 CFR part 122](#)

[9 CFR part 161](#)

[49 CFR part 173](#)

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B. References:

- [VS Guidance 12000, "Foreign Animal Disease Diagnostician Certification Requirements,"](#)
- [Foreign Animal Disease Investigation Manual](#)
- [Emerging Animal Disease Preparedness and Response Plan \(Draft\)](#)

C. Definitions:

- 1) An FAD is a terrestrial animal disease or pest, or an aquatic animal disease or pest, not known to exist in the United States or its territories. An FAD may be a World Organization for Animal Health (OIE) listed terrestrial and aquatic animal disease (www.oie.int); additionally, at any time, the Secretary of Agriculture, or designee, may designate a disease or pest as an FAD. An emerging disease is defined in the VS *Emerging Animal Disease Preparedness and Response Plan*. An EDI is any incident, involving an emerging disease, that requires field investigation. An FAD/EDI may involve livestock, poultry, other animals, or wildlife.

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

- 2) A Foreign Animal Disease Diagnostician (FADD) is a Federal or State employed veterinarian who has successfully completed specialized FAD diagnostician training at the National Veterinary Services Laboratories (NVSL); as well as any other specialized training and continuing education as required and administered by VS, including requirements as specified in VS Guidance Document 12000.

The Professional Development Services in VS maintains a national roster of currently available or active FADDs. VS District Directors or designees will maintain District rosters of currently available and equipped FADDs. Assistant District Directors (AD) will maintain a roster of currently available and equipped FADDs in the jurisdiction(s) for which they are responsible.

5. Audience

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

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

A. Objectives

- 1) Provide a veterinary medical assessment that consists of the following:
 - a. Differential diagnosis;
 - b. Classification of investigation, which is necessary to rank and prioritize the differential diagnosis in terms of the magnitude of suspicion for an FAD, in relation to the magnitude of suspicion for an endemic disease or condition; and
 - c. Designation of diagnostic sample priority, which is necessary to rank and prioritize the speed at which diagnostic samples are to be collected, transported, and tested; the FADD, AD, and SAHO must concur on the designation of diagnostic sample priority.
- 2) Provide presumptive and confirmatory diagnostic testing results as rapidly as required by the designation of diagnostic sample priority, in order to rule out or confirm a suspected FAD/EDI agent.
 - a. The FADD, as part of the required site visit or field investigation, will determine if diagnostic sample testing or studies are necessary to rule out or confirm the FAD/EDI. The AD and SAHO retain the right to request diagnostic sample collection during an FAD/EDI investigation. The AD and SAHO along with the FADD, NVSL, and laboratory director of the State National Animal Health Laboratory Network (NAHLN) laboratory will determine a diagnostic sample submission plan that may include a duplicate set of samples being submitted to a NAHLN lab.
- 3) Ensure the appropriate veterinary medical countermeasures, regulatory actions, and communications are recommended and implemented during the investigation period, as necessary, to prevent and/or mitigate the dissemination of an FAD/EDI agent by interstate or international commerce of animals, animal products, meat, articles, or conveyances. Examples of interstate or international commerce include but are not limited to slaughter or harvest facilities; processing or packing facilities; auction markets; exhibitions or shows; and interstate or international import-export-facilities. The appropriate veterinary medical countermeasures, regulatory actions, and communications will depend on factors such as:

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- a. The epidemiology of the suspected FAD/EDI agent (such as a highly contagious disease).
- b. The clinical and epidemiological findings obtained during the investigation as they correspond to the case definition for the suspected FAD/EDI disease agent (before obtaining presumptive or confirmatory diagnostic testing results).
- c. The State, Federal, territory, and Tribal jurisdictions and authorities as applied to the specific situation.

B. Critical Elements

Critical elements of an investigation include but are not limited to: interviewing persons for incident history; observing clinical signs; performing physical examination of animals; collecting and analyzing epidemiological information; collecting diagnostic samples as necessary; performing necropsy studies as necessary; investigating trace backs and trace forwards of animals, animal products, meat, articles, or conveyances as necessary; recommending and establishing intrastate quarantine as necessary (the authority of the SAHO); and recommending and establishing interstate quarantines during the investigation period as necessary (the authority of the Secretary of Agriculture).

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

C. Classification of Investigations and Correlation to Designation of Diagnostic Sample Priority**1) Classification of FAD/EDI investigations and definitions**

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

Table 1: Classification of FAD/EDI Investigations and Definitions

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

2) Diagnostic sample priority designations

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

- a. Samples designated as Priority 1 are only used for investigations where there is a High Suspicion of an FAD/EDI. Sample collection, transportation, and diagnostic testing are completed using rapid to extraordinary rapid methods. NVSL and NAHLN personnel will perform diagnostic testing and studies as rapidly as possible on sample arrival at the laboratory, whether during regular business hours, nights, weekends, and holidays. NVSL will use overtime as necessary to begin and complete diagnostic testing and studies. The NAHLN laboratories will perform testing as requested. Payment of overtime to NAHLN laboratory personnel will vary by State. Extraordinary collection and transportation methods will be required when the Priority 1 investigation includes a highly contagious FAD/EDI in the differential diagnosis, or when animals, animal products, meat, articles, or conveyances are involved or engaged in interstate or international commerce. This includes but is not limited to animals, animal products, meat, articles, or conveyances currently held in slaughter or harvest facilities, processing or packing facilities, auction markets, exhibitions or shows, and interstate or international import-export facilities. Telephone notification to the National Preparedness and Incident Coordination (NPIC) Center is required for High Suspicion classification.

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- b. Priority 2 sample designations are used for investigations where there is an Intermediate Suspicion of an FAD/EDI. Rapid methods must be used to collect, transport, and study diagnostic samples. NVSL and NAHLN personnel will perform diagnostic testing and studies immediately if the samples arrive at the laboratory before the close of the work day. NVSL will use overtime to complete testing and studies. The NAHLN laboratories will perform testing as necessary. Payment of overtime to NAHLN laboratory personnel will vary by State. Diagnostic samples arriving after the close of the work day will be examined first thing the following day. Diagnostic samples received Saturday will be tested or studied on Saturday only with prior notification and discussion with NVSL and NAHLN laboratory personnel. Telephone notification to NPIC is not required for Intermediate Suspicion classification.
- c. The Priority 3 designation is only used for investigations where there is a Low Suspicion of an FAD/EDI. Investigations with this designation will use routine methods of collection, transport, and diagnostic study. NVSL and NAHLN personnel will perform diagnostic testing and studies in accession order as received. NVSL and NAHLN overtime services will not be used for Priority 3 investigations. The Priority 3 designation is also used for routine surveillance samples. Telephone notification to NPIC is not required for Low Suspicion classification.
- d. The Priority A designation is only used for Intermediate Suspicion of an FAD/EDI classification or Low Suspicion of an FAD/EDI classification when animals, animal products, meat, articles, or conveyances in interstate or international commerce are involved and/or are potentially held, delayed or quarantined pending the results of diagnostic testing or studies for an FAD. It is also used when other known or potential circumstances associated with the investigation indicate it is prudent to obtain diagnostic sample testing results as rapidly as possible. Telephone notification to NPIC is required for Priority A designation. Rapid to extraordinary methods must be employed to collect, transport, and study diagnostic samples. NVSL and NAHLN personnel will perform diagnostic testing and studies as rapidly as possible upon sample arrival at the laboratory, whether during regular business hours, nights, weekends, and holidays. NVSL will use overtime as necessary to begin and complete diagnostic testing and studies. The NAHLN laboratories will perform testing as necessary. Payment of overtime to NAHLN laboratory personnel will vary by State.
- e. Extraordinary transportation methods include the use of hand carried samples, couriers, counter-to-counter services, and contracted commercial services. Rapid transportation methods include express shipping services such as FedEx® priority overnight. Routine transportation methods include express shipping services such as FedEx® priority overnight (to ensure preservation of diagnostic sample quality).

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

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

Priority	Investigation Classification	Speed of Sample Collection, Transportation, and Diagnostic Study
Priority 1	High Suspicion	Rapid to extraordinary methods.
Priority 2	Intermediate Suspicion	Rapid methods.
Priority 3	Low Suspicion	Routine methods.
Priority A	Intermediate or Low Suspicion	Rapid to extraordinary methods.

The FADD, AD, and SAHO must concur on the classification of investigation, and designation of diagnostic sample priority 1, 2, 3, or A. and if a duplicate sample will be collected and sent to an approved NAHLN laboratory in addition to NVSL. If there are questions, concerns, or disagreements regarding the classification of an investigation or the designation of diagnostic sample Priority 1, 2, 3, or A by the FADD, AD, and the SAHO, then there must be an immediate conference call of the FADD, AD, and SAHOs with the District Office, NVSL Director, and NPIC staff. The NPIC staff and the District Office will provide the capability to host and coordinate conference calls.

D. Diagnostic Case Definitions

For more information on diagnostics, please see the Foreign Animal Disease Investigation Manual.

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

E. National Veterinary Services Laboratories (NVSL)

The NVSL safeguards U.S. animal health and contributes to public health by ensuring that timely and accurate laboratory support is provided by their nationwide animal-health diagnostic system.

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NVSL is the official reference laboratory for FAD/EDI diagnostic testing and study in the United States. NVSL must perform or officially confirm the results of all diagnostic testing and studies related to FAD/EDI investigations in the United States unless otherwise specified by the Animal and Plant Health Inspection Service (APHIS) Administrator, or as delegated to the VS Deputy Administrator.

NVSL has two locations for FAD/EDI diagnostic testing: Ames, Iowa (NVSL Ames) and Plum Island, New York (NVSL FADDL). The transport and shipping of FAD/EDI diagnostic samples to NVSL Ames or NVSL FADDL by species or suspected disease is found in the Foreign Animal Disease Investigation Manual.

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

F. National Animal Health Laboratory Network (NAHLN)

The NAHLN, created in 2002, is a comprehensive, coordinated, and modernized network of Federal and State animal health laboratories and public agricultural institutions that address emergency biological and chemical threats to animal agriculture and the security of the food supply.

The purpose of the NAHLN is to enhance early detection of FAD agents and newly emerging diseases and to better respond to animal health emergencies (including bioterrorist events) that threaten the nation's food supply and public health.

Personnel in NAHLN laboratories are trained, proficiency tested, and approved to test for multiple FADs of high consequence. With the approval of the SAHO and AD, FAD samples can be collected in duplicate to send one to the local NAHLN laboratory and the other to NVSL.

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

The AD and SAHO along with the FADD and NAHLN laboratory director will determine a diagnostic sample submission plan that may include a duplicate set of samples being submitted to the NAHLN lab.

G. Guidelines for Diagnostic Testing

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

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

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- a. The first set of diagnostic samples must always be sent to the appropriate NVSL Laboratory (NVSL Ames or NVSL FADDL).
 - b. The second set of diagnostic samples will be sent to an approved NAHLN laboratory to provide preliminary FAD/EDI diagnostic information before NVSL receives the diagnostic samples.
 - c. If a second set of diagnostic samples cannot be collected, the samples that can be collected must be sent to the appropriate NVSL laboratory, not the NAHLN laboratory.
- 2) In the event of an emergency situation in which the appropriate NVSL Laboratory cannot perform FAD/EDI diagnostic testing, one set of diagnostic samples may be sent to the other NVSL Laboratory, and a second set of samples may be obtained for testing at a NAHLN Laboratory, or sent to another international reference laboratory.
 - 3) If the decision is made to submit a second set of diagnostic samples to the NAHLN laboratory, then the AD and/or SAHO must instruct the FADD to follow the procedures for submitting a second set of diagnostic samples to the NAHLN laboratory. The AD, SAHO, and/or FADD will notify the NAHLN Laboratory Director if there is a change in the NAHLN laboratory submission plan after the FADD performs the investigation.

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

H. Packaging and Labeling

Packaging and labeling of biological substances for shipment requires familiarity with and training in current rules and regulations, which frequently change. Shippers are responsible for proper packaging, marking, labeling, documentation, classification, and identification of each shipment. **Failure to follow regulations can result in substantial financial penalties.**

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

I. State-Federal-Tribal Communication and Cooperation

The coordinated State-Federal-Tribal response to a potential FAD/EDI requires close communication and cooperation among all stakeholders and jurisdictions. The AD and the SAHO (or designee) must closely communicate and cooperate on all aspects of an FAD/EDI investigation from initiation to completion.

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All FAD/EDI investigations must be initiated by the AD and/or the SAHO. All FAD/EDI investigations must be assigned by the AD and/or the SAHO to an FADD. The AD and/or the SAHO is responsible for initiating a timely investigation of all credible reported or suspected FAD/EDI, including assigning an FADD to complete a site visit or field investigation as a required part of the investigation.

The AD and/or SAHO will assign an FAD/EDI Case Coordinator(s) to assist with investigation support, communications, and Emergency Management Response System (EMRS) data entry, as required by the location, scale, complexity, or urgency of the investigation.

J. Emergency Management Response System (EMRS)

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

The AD, or their designee, will ensure the EMRS Referral Control Number is assigned and transmitted to the FADD and the SAHO. EMRS must be used for all FAD/EDI investigations.

[EMRS](#) is accessed through the internet and permits approved State, VS, and NAHLN Laboratory personnel access to enter and view investigations from their State or territory. All entries are confidential. EMRS database access at the State or Territory level is controlled and maintained by approval of the AD and the SAHO.

K. Requirements

Situation reports, spot reports, diagnostic updates, and regulatory assessments will be produced as required by the urgency or complexity of the investigation, or at intervals requested by the Field Office, the VS Associate Deputy Administrator for NPIC, and the VS Chief Veterinary Officer (CVO).

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

7. Inquiries

Any questions regarding these procedures or instructions should be directed to the National Preparedness and Incident Coordination (NPIC) staff.

Main Office

(NPIC, One Health Coordination Center, SPRS Logistics Center)
Please refer to the FAD Investigation Manual for contact numbers.
Fax: 301-734-7817

Normal Business Hours: Monday – Friday 8:00 a.m. to 4:30 p.m. ET

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

Acronyms

ADA	Associate Deputy Administrator
AD	Assistant District Director
APHIS	Animal and Plant Health Inspection Service
CFR	Code of Federal Regulations
CVO	Chief Veterinary Officer
EDI	emerging disease incident
EMRS	Emergency Management Response System
FAD	foreign animal disease
FADD	Foreign Animal Disease Diagnostician
FADDL	Foreign Animal Disease Diagnostic Laboratory
NAHLN	National Animal Health Laboratory Network
NPIC	National Preparedness and Incident Coordination
NVS	National Veterinary Stockpile
NVSL	National Veterinary Services Laboratories
OIE	World Organization for Animal Health
SAHO	State Animal Health Official
SPRS	Surveillance, Preparedness, and Response Services
USDA	United States Department of Agriculture
VS	Veterinary Services

Appendix E

Emergency Vaccine Request and Vaccination Priorities

The use of emergency vaccination to respond to a foot-and-mouth disease (FMD) outbreak within a State will be determined by the Unified Command, the State (or Tribal) Animal Health Officials (SAHO), and the APHIS VS Deputy Administrator. This guidance is intended to assist in the rapid assessment of any request(s) for FMD vaccine use that are made to the APHIS VS Deputy Administrator.

Given the highly populated nature and mobility of livestock in the United States, it is unlikely that enough FMD vaccine will be available to vaccinate all (or most) susceptible animals, even in a moderate FMD outbreak. APHIS provides general guidance for determining which premises and animal groups should be prioritized for vaccination.



Emergency FMD Vaccine Request And Initial Plan for Vaccination Campaign

FMDvacc_v8_05.03.18

Animal and Plant Health Inspection Service

Veterinary Services

Surveillance, Preparedness, and Response Services

National Preparedness and Incident Coordination Center

4700 River Rd.

Riverdale, MD 22737

The use of emergency vaccination to respond to a foot-and-mouth disease (FMD) outbreak within a State will be determined by the Unified Command, the State (or Tribal) Animal Health Officials (SAHO), and the APHIS VS Deputy Administrator. This guidance is intended to assist in the rapid assessment of any request(s) for FMD vaccine use that are made to the APHIS VS Deputy Administrator.

Part I of this form documents SAHO approval for the use of FMD vaccine within an affected State. SAHO approval should accompany the first 213RR request for APHIS VS to provide FMD vaccine through the National Veterinary Stockpile (NVS).

Once the Unified Command, the SAHO, and APHIS VS agree to the use of emergency vaccination, the State may anticipate an initial allotment of finished vaccine to be shipped within 2 weeks; however, that timeframe may vary due to vaccine availability. Limited quantities of vaccine will be available early in the response, and APHIS VS may receive requests for vaccine from multiple States. A well-defined State vaccination plan will assist decision makers in prioritizing and distributing vaccine to States that are ready and able to handle the vaccine appropriately and rapidly administer doses based on well-grounded epidemiological principles.

Part II provides an outline of a State vaccination plan, including the purpose, strategy, and logistics of the vaccination campaign. During the interval between decision to vaccinate and availability of finished vaccine, the State's initial vaccination plan should be completed. The vaccination plan should be in place before finished vaccine is shipped from NVS to the requesting State.

Subsequent vaccine orders will be placed via 213RR.
Include a revised version of this document with each 213RR request for vaccine.

Part I – Emergency FMD Vaccine Authorization and Request

The SAHO authorizes the use of FMD vaccine as part of the emergency response to an outbreak of FMD in the State (or for the Tribe) of State [\(Click here to enter text.\)](#).

Projected vaccine dose needs

Species	Dose	Booster	Repeat
Cattle	2 ml IM	-	6 mos.
Feeder pigs	2 ml IM*	-	-
Sows & Boars	2 ml IM	10-14 days	6 mos.
Sheep & Goat	1 ml IM	-	6 mos.
Zoo - TBD			

*Feeder pigs--3 mos. Immunity, to slaughter

State (Click here to enter text.) | Date (Click here to enter text.) | State Request # (Click here to enter text.)

Given the table above:

- 1) Estimate the number of FMD vaccine doses needed for an initial 2-week campaign: 1st 2 wks (Click here to enter text.).
- 2) Estimate the number of FMD vaccine doses needed to conduct a 3-month vaccine campaign in your State, if a type 2 FMD Outbreak (moderate regional outbreak) occurs: 3 mos. regional (Click here to enter text.).
- 3) Estimate the number of FMD vaccine doses needed to conduct a >6-month vaccine campaign in your State, if a type 4 FMD Outbreak (national outbreak) occurs: 6 mos. national (Click here to enter text.).

State (Click here to enter text.) | Date (Click here to enter text.) | State Request # (Click here to enter text.)

Part II – Emergency FMD Vaccination Plan for the State of

The emergency FMD Vaccination Plan should contain the following elements:

Strategy

- 1) Describe the FMD response strategy including vaccination, such as:
 - Stamping-out modified with emergency vaccination to kill
 - Stamping-out modified with emergency vaccination to slaughter
 - Stamping-out modified with emergency vaccination to live
 - Emergency vaccination to live without stamping-out

FMD Response Strategy (Click here to enter text.)

- 2) What estimated number of animals, by type and group, will be vaccinated, such as:
 - Species and age of animals
 - Industries or industry segments
 - Number of farms
 - Vulnerable or valuable groups or types of animals or industry segments

Animal vaccinates (Click here to enter text.)

- 3) What is the location on the animals of vaccine administration (rt. neck, lt. neck)?

Anatomical loc. (Click here to enter text.)

- 4) What is the geographic location of the animals to be vaccinated? Describe the types of zones (protective, suppressive, etc.), their epidemiological objectives, and their locations.

Vaccination zones (Click here to enter text.)

- 5) What is the vaccination schedule for individual animals, by species?
 - Booster doses and intervals between doses.
 - Slaughter or milk withdrawal period.

Vaccination schedule (Click here to enter text.)

- 6) Describe the State policies and enforcement strategy for permanent identification, traceability, movement restrictions, surveillance, and disposition of vaccinated animal.

Enforcement strategy (Click here to enter text.)

State (Click here to enter text.) | Date (Click here to enter text.) | State Request # (Click here to enter text.)

Logistics

- 1) Provide a name and contact information for the person authorized to receive the vaccine from National Veterinary Stockpile.

Logs contact (Click here to enter text.)

- 2) Describe cold chain maintenance and physical security for the vaccine.
 - a. How the vaccine will be stored, handled, and transported from receipt by the POC to administration in the animal?
 - b. How will proper storage temperatures be maintained?
 - c. How will chain of custody for the vaccine be maintained and documented?

Cold chain & security (Click here to enter text.)

- 3) Describe the process for vaccine administration.
 - a. Who is authorized to administer the vaccine?
 - b. How many vaccination teams are available to administer vaccine?
 - c. How is vaccination verified and documented? Documentation records must include the date, location, and description of the vaccinated animals.
 - d. What type of permanent identification will be used on the vaccinated animal?
 - e. How are unused eartags managed/controlled?
 - f. How and when is permanent identification applied to the vaccinated animal?
 - g. How are animal owners notified of their restrictions and responsibilities for movement and disposition of vaccinated animal and of not removing the animal's permanent identification?

Documentation/ID (Click here to enter text.)

- 4) Describe the State's vaccination capacity per day, by species and type for the requested number of vaccine doses for the initial 2-week, 3 month, and 6 month campaigns.
 - a. How many animals are able to be vaccinated and identified per day, by species and type? Specify how many vaccination teams are available to meet this capacity.
 - b. How will the requested vaccine doses be distributed over the initial 2-week time period (and 3 and 6 month time periods, if requested)?

State (Click here to enter text.) | **Date** (Click here to enter text.) | **State Request #** (Click here to enter text.)

Vaccine capacity (Click here to enter text.)

- 5) Describe the disposal plan for expired, temperature-abused, or otherwise unusable vaccine.

Vaccine disposal (Click here to enter text.)

STATE/TRIBAL ANIMAL HEALTH OFFICIAL SIGNATURE

DATE

FMD Vaccine Authorization and Vaccination Plan

State (Click here to enter text.) | **Date** (Click here to enter text.) | **State Request #** (Click here to enter text.)



Please note: This information may be revised or updated at any time.

INTRODUCTION

Vaccination during an FMD outbreak is an inherently complex activity. There are many tenets that dictate the rational application of FMD vaccine. This document provides guidance on how States and APHIS officials may elect to implement emergency vaccination.

BASIC INFORMATION

In order to understand how emergency vaccination will impact an FMD response effort, it is critical to know the following:

- ◆ How the virus behaves in each species that may be vaccinated;
- ◆ The epidemiology of the situation (to the best knowledge available);
- ◆ Risk of exposure to the virus;
- ◆ Age of animals and how the production sector works;
- ◆ Amount of vaccine that is available to use (both in the short and, if available, longer-term).

GUIDANCE

In general, APHIS recommends a **protective emergency vaccination strategy** to protect susceptible animals from infection.

This will require the establishment of one or more Vaccination Zones, to ensure that infected animals are not comingled, in close proximity, or in-contact with vaccinated animals. Testing to differentiate infected animals from vaccinated animals (DIVA), once available, may be required for interstate commerce and international trade. Additionally, vaccinated animal identification must be applied, with movement controls.

States should focus on animals in close proximity to the incident, but not those in-contact with, or with any known or suspected epidemiological links to the incident. When considering what premises are good candidates for vaccination, review the “specific information” below, and weigh the following:

- ◆ How likely it is that the premises has already been exposed (if high, vaccination may not be appropriate);
- ◆ Environmental conditions (wind, humidity), that may increase probability of introduction;
- ◆ Husbandry conditions and health of the animals;
- ◆ Biosecurity on the premises (guarding against the risk of introduction prior to protection); and
- ◆ Ability to physically vaccinate (logistics, personnel, identification) in a safe and effective manner.

SPECIFIC INFORMATION

In order to use the extremely limited quantity of vaccine most effectively, the following priorities are recommended.

Cattle

- ◆ Vaccinate cattle preferentially – *they are very easily infected due to low viral threshold of infection. If the number of infected cattle can be minimized through preventative measures and/or lower the viral shed if exposed, then other at-risk species can be spared from vaccination and protected through biosecurity. This approach is especially recommended when supplies of vaccine are limited.*
- ◆ Vaccinate calves preferentially – *calves are particularly vulnerable and less likely to survive infection, while adult cattle typically do not experience severe clinical signs. This is especially crucial in situations such as calf ranches housing dairy-heifer replacement and bull dairy calves for beef production.*
- ◆ Prioritize dairy operations – *feedlots and cow-calf operations are more likely to recover from FMD infection. Additionally, dairy cattle that do recover rarely achieve pre-infection levels of milk production. Dumping milk from infected dairies is incredibly challenging and not an efficient use of resources. With the narrow profit margins in the dairy industry, this is paramount to financial disaster. Infected dairies also complicate the job of the responders because not only do the cattle have to be managed through depopulation and disposal, but the milk has to be dumped which is especially challenging in states like California that have strict EPA regulations.*

Swine

In the event that there is sufficient vaccine to effectively protect dairy operations, particularly calves, swine can be considered for vaccination. Swine have a higher threshold of infection and might be protected through increase biosecurity. The swine sector should be prioritized as follows (again, assuming limited vaccine doses are available):

- ◆ Farrow operations and Genetic Founder Stock:
 - Farrow operations and genetic founder stock should be prioritized, as it ensures that weaned pigs will have adequate maternal immunity when initially moved into transit.
 - These sows and boars in farrow operations should receive one full dose, followed by a booster in 10 to 14 days and then every 6 months thereafter. This protects this multiplier stock and ensures that the weaned pigs will have adequate maternal immunity when they are moved into transit or grow-out.
 - Genetic operations may want to be vaccinated; these producers need to carefully consider long-term export consequences of implementing emergency vaccination. Vaccinated animals may not be eligible for export of their germplasm or offspring if zoning agreements can be achieved during an outbreak, or export resumes after recovery. If vaccination is elected, then these animals should be vaccinated in the same manner as farrowing operations.
- ◆ Feeder pigs:
 - Feeder pigs may be considered, but only should receive a single dose which should provide adequate protection for 3 months. Before immunity wanes, the animal will hopefully be slaughtered. This is an especially relevant recommendation if vaccine supplies are limited.

Sheep and Goats

At this time, implementation of emergency vaccination for FMD is not recommended in sheep and goats, however they are considered the silent spreaders of FMD for their sub-clinical infections. If additional doses of vaccine become available, or the epidemiology of the outbreak changes significantly, this recommendation will be reconsidered:

- The sheep industry is largely concentrated in the west, and while these animals respond to FMD vaccination well, their economic contribution to the economy may not warrant the use of precious vaccine. So if exposed, a managed outbreak followed by harvest (sheep demonstrate minimal clinical signs and clear the infection quickly) may be the best option. However if vaccination is elected, a single dose of 1ml is sufficient to protect for 6 months
- Goats are more problematic. They widely distributed and are found virtually in every state and while there is some large scale goat farming for milk, cheese, and meat, they are largely a cottage industry and found with hobbyists. They have the same response to infection by FMD and the same vaccine dosing regimen as sheep, but whether it is really cost effective to vaccinate goats would depend on the epidemiology of the situation and may be better to allow to recover and harvest as with sheep.

Zoological Species

Zoological species, at this time, are not recommended for vaccination. In particularly extraordinary circumstances, this may be reconsidered. However, these animals should be protected by biosecurity and other appropriate precautions.

SUMMARY

Tools that may inform vaccine application or even wholesale distribution to States would include this guidance and measures such as national modeling of the outbreak, Such an approach could expose pathways that could result in expansion of the outbreak and suggest where vaccines could be preferentially applied to block further spread. Modeling on a region or State can help inform local responders but may be insufficient for national responders seeking to prevent outbreak expansion. Therefore, it is important to have as much information as possible prior to modeling including age, production sector, movement networks (including feed commodities), dangerous contacts, and other factors influencing spread.

ADDITIONAL INFORMATION

In the event that there is new epidemiological information or other new data, this guidance will be reviewed and revised accordingly. States should carefully consider this information in formulating their vaccine requests that are submitted to APHIS.

Appendix F

FMD Outbreak Surveillance Guidance and Rationale

These are guidelines and example sampling schemes for foot-and-mouth disease (FMD) outbreak surveillance, prepared by the Center for Epidemiology and Animal Health, Veterinary Services (VS), Animal and Plant Health Inspection Service (APHIS). These guidelines may periodically be updated to reflect new knowledge about the epidemiology of FMD or changes in approved diagnostic tests or other response tools.

Appendix F

FMD Outbreak Surveillance Guidance and Rationale

FMD OUTBREAK SURVEILLANCE GUIDELINES

These are guidelines and example sampling schemes for foot-and-mouth disease (FMD) outbreak surveillance, prepared by the Center for Epidemiology and Animal Health, Veterinary Services (VS), Animal and Plant Health Inspection Service (APHIS). These guidelines may periodically be updated to reflect new knowledge about the epidemiology of FMD or changes in approved diagnostic tests or other response tools.

Purpose

During an outbreak, surveillance will be conducted at intervals as specified by the Incident Coordinator (IC), based on the most current scientific information and best practice guidance available. Logistical and resource considerations will also be taken into account when forming surveillance recommendations. The guidance in this appendix expands on the base information presented in Section 4.3 and offers recommendations for adapting the design of FMD surveillance as new information becomes available during an outbreak.

In addition to surveillance for disease detection or demonstrating disease freedom, surveillance may be required to permit FMD susceptible animals and/or their products to move for continuity of business. When testing and sampling methods comply, test results from continuity of business surveillance may contribute to surveillance testing requirements to obtain disease freedom. The current document does not address surveillance for continuity of business. Continuity of business guidelines, known as the [Secure Food Supply Plans](#), may allow animals and/or their products to move from farms within the control area provided there is sufficient evidence to ensure very low risk of FMD virus transmission. The Secure Food Supply Plans include *Secure Milk Supply Plan* (www.securemilksupply.org), *Secure Beef Supply Plan* (www.securebeef.org), *Secure Pork Supply Plan* (www.securepork.org), and *Secure Zoo Strategy* (<https://securezostrategy.org/build-facility-plan>). These plans provide additional guidelines that are not discussed in detail here. See also Section 4.11 of the main document for general guidance.

Surveillance Factors

As described in Chapter 4, a surveillance plan indicates the number and frequency of animals and premises to be sampled as well as the duration of surveillance. Specifying these values requires information about six surveillance factors, listed below. Initially, values are specified using preliminary information collected about the outbreak and best estimates. During an outbreak, surveillance plans will change as new information becomes available. Ideal outbreak surveillance is resource intensive, and the speed at which disease can be detected and/or the level of disease that can be detected may be limited by test type or resources.

Factors that guide surveillance design

1. *Surveillance purpose.* The surveillance purpose guides the intensity, frequency, and type of diagnostic tools used for surveillance. If the purpose is early detection of cases prior to clinical signs, the frequency and intensity of sampling is high and an appropriate diagnostic tool (sample type and test to detect circulating antigen) must be used. If surveillance is meant to demonstrate disease freedom at a regional or national level post-outbreak, the frequency and intensity of sampling can be reduced. During this period, information to declare disease freedom can accumulate using both passive and active surveillance with diagnostic tools detecting both antigen and antibodies. Conversely, disease freedom for an individual premises during the outbreak would require frequent and intense sampling with appropriate diagnostic tools.
2. *Design (threshold) prevalence.* The threshold is a tolerance limit used to design the surveillance sampling intensity. If the proportion of animals or premises infected exceeds the design prevalence, the surveillance will detect at least one case with the stated confidence. The choice of design prevalence depends on the transmission characteristics of the pathogen and the objective of the surveillance. The design prevalence can be higher when demonstrating freedom for a highly infectious disease in which disease remains at a low prevalence for only a short time. For early detection, a lower prevalence is required to detect disease before spreading. Sample size calculations are typically based on detecting at least one of an actual specified number of infected animals or premises instead of the prevalence. The prevalence threshold is computed from the number of infected animals or premises and the size of the animal groups or premises of interest. Considering the number infected instead of the prevalence is often very useful in determining the choice of an appropriate threshold.
3. *Confidence level.* Also called surveillance system sensitivity, the confidence level is the probability that disease can be detected at or above the design prevalence expressed as a percent (e.g. 95 percent confidence in detecting a 0.10 design prevalence). The confidence level is typically set

at 95 percent. When consequences of failing to detect infection are particularly high, the confidence level may be set at 99 percent. If the sampling scheme is not carried out according to plan, the actual confidence derived through surveillance (a function of sample size, population size, test accuracy and the selected design prevalence) may not reach the desired level. Alternatively, one can determine the actual design prevalence the sampling scheme is capable of detecting at 95 percent confidence.

4. *Risk-based sampling.* Sampling from subpopulations of animals within a premises which may have a higher proportion of infected animals (e.g. sick animals) or from a premises with higher risk of exposure (e.g. contact or suspect premises) allows surveillance to be designed at a higher design prevalence. This reduces the required number of animals or premises to be sampled.
5. *Population or target group size.* Sample sizes are a function of the size of the population (or target group) from which the sample is selected. The population may comprise premises within a zone (infected zone, buffer zone), pens within a premise, animals on a premise, or animals within a pen. The population or target group size is a less influential factor compared to other factors. If unknown, a sample size based on the largest population or target group expected will be conservative in that it detects the desired prevalence threshold or even a lower prevalence for a smaller population or group.
6. *Types of tests.* Diagnostic test choice, test sensitivity and specificity, and the combination of tests used to make the final determination (called the testing protocol), influence the number and frequency of animals or premises to be sampled. Test choices are varied and can be clinical signs, real-time reverse transcription polymerase chain reaction (rRT-PCR), virus isolation, ELISA, etc., individually or in combination. When series testing is used to determine disease status, such as for initial infected premises confirmatory testing, it is the sensitivity of the testing protocol that serves as an input for the sample size calculation. Lower test or protocol sensitivity requires a larger sample size relative to a test or testing protocol with a higher sensitivity to achieve the same detection capability.
7. *Pathogen and host characteristics.* The number and frequency of animals and premises to sample is dependent on the serotype/strain, host susceptibility to FMD virus, and whether the host displays clinical signs. These influence the transmission factors such as incubation period, infectious period, length of apparent clinical signs, and ability to detect clinical signs. Choice of design prevalence, and thus sampling intensity, is a function of the infectious epidemiology curve. Testing frequency is dependent on the length of the latent period; therefore we use information about the incubation period to help guide choice of testing frequency. The

duration of surveillance sampling is related to the length of the incubation period and length of viral persistence in infected animals and the environment. To initiate freedom of disease testing, no new FMD cases can occur for two incubation periods. This indicates that the pathogen is no longer being actively transmitted.

Additional Details on Adjusting Surveillance Factors

After initial surveillance plans are developed according to the objectives and designs provided in Chapter 4, further modifications may be necessary to adjust for the factors outlined above. Since the disease characteristics will dictate which adjustments are necessary, consideration to the unique outbreak characteristics should guide adjustments. Premises selection, animal selection for sampling, and frequency of sampling can all be adjusted based on the surveillance factors and outbreak size.

SCALING SURVEILLANCE EFFORTS AS AN OUTBREAK PROGRESSES

Some general considerations as the size of an outbreak grows include resource limitations, number of animals, and number of premises involved in the outbreak. It is a possibility that larger outbreaks may exceed resource capacities. In such instances, surveillance plans will be modified to work within the confines of the resource limitations. Resources, both financial and personnel, may become limited i.e. laboratory testing capacity, depopulation, disposal, and vaccination. Vaccine may take days to weeks to be produced and distributed. If laboratory diagnostic sampling becomes a limitation, greater reliance on clinical signs for surveillance may be implemented.

Outbreak types:

Refer to Chapter 3.4 for descriptions and definitions of different outbreak types. General guidelines for adjusting to the outbreak type can be found in Table F-1. The IC should adjust the response efforts as new outbreak information becomes available.

Surveillance efforts in the free area: Communication outreach via media outlets should help educate livestock owners the importance of observational surveillance including instructions on monitoring their herd or flock for clinical signs of FMD and reporting consistent clinical signs promptly to veterinary authorities. Additional surveillance efforts and adjustments may occur depending on international trade requirements. It is likely that at least some diagnostic testing will need to be performed in the free area to reassure trading partners.

Table F-1. Considerations for different outbreak sizes, progressing from small to catastrophic outbreak sizes.

Size of outbreak	Control Area (CA) surveillance strategies	Surveillance Zone (SZ) surveillance strategies
Type 1 – 2 Focal to Moderate Regional FMD outbreak	Follow guidance in Chapter 4 and Appendix F, including conducting a sampling of all operations in the CA.	
Type 3 – Large regional FMD outbreak	<p>Surveillance activities may need to be modified if sampling all operations in the CA is not feasible (i.e. if the CA is a whole State, or multiple States).</p> <p>Consider prioritizing testing in the CA – start with direct and indirect contact premises (CP), then those which request permits for continuity of business, followed by those with less urgent needs for movements.</p> <p>Response may start with a large CA, then progressively reduce the size as true outbreak extent is established through surveillance testing. This may include active observational surveillance with or without diagnostic testing. Sampling should provide confidence that the animals being re-designated are truly not infected. When resources are limited, diagnostic testing on all premises may not be possible. Testing should demonstrate lack of FMD antigen and antibodies at a high level of confidence (95%) at no more than a 5% design prevalence.</p>	<p>Greater reliance on clinical signs for detection of suspect premises (SP), with additional testing as specified in plans. Surveillance efforts should be targeted towards high probability of disease animals and premises with a greater concern for exposure or transmission.</p> <p>Consider reducing sample size or number of observations by using a higher design prevalence or lower probability of detection if the SZ is extremely large and resources are limited rather than reducing the number of premises sampled.</p>
Type 4 – 6 Widespread/national outbreak to Catastrophic North American outbreak	<p>Sampling all premises in the CA would likely be burdensome. Prioritize testing to contacts (direct and indirect) of infected premises, and monitoring needed for continuity of business permitting from the area around infected premises.</p> <p>If vaccination is employed for any outbreak type, surveillance strategies should be shifted to reflect those plans.</p>	<p>Greater reliance on clinical signs for detection of SP, with additional testing as specified in plans.</p> <p>Consider using a higher design prevalence or lower probability of detection if the SZ is extremely large and resources are limited rather than reducing the number of premises sampled.</p>

Selection of Premises

The surveillance purpose in the control area is early detection until 28 days after depopulation of the last Infected Premises in the control area. The surveillance purpose for the surveillance zone is proving FMD has not expanded outside of the control area. Sampling is more intense and frequent than proving OIE disease free country status.

As an outbreak progresses in size or scale, additional consideration may be given to modify the premises selected for surveillance sampling in both the control area and surveillance zone. As outlined in Chapter 4, small premises with no animal movement requirements may be excluded from the sampling frame. Information on biosecurity to limit the spread of the virus, and the importance of active observational surveillance must still be provided to the producer. This includes instructions on monitoring their herd or flock for clinical signs of FMD and their obligation for reporting promptly to veterinary authorities.

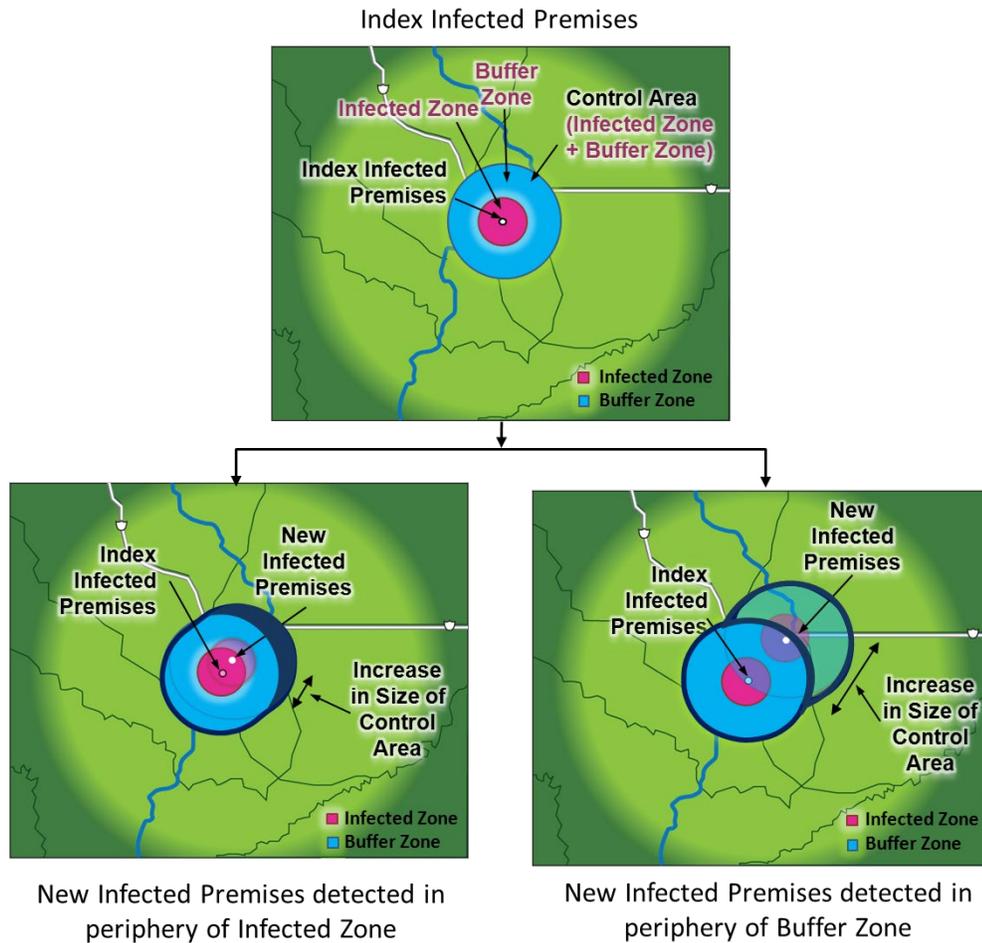
Selection of Premises in the Control Area

Ideally, include all premises within the control area in active surveillance, prioritizing by knowledge gained from epidemiologic investigations. Continuity of business plans may also influence the prioritization of premises sampled, as more frequent movements will require more frequent monitoring. Information gained from continuity of business diagnostic testing may be incorporated into the surveillance data summaries to meet surveillance plan objectives.

As the size of an outbreak increases or resources become limited, sampling can be prioritized to suspect premises and contact premises, as these have higher probability of being positive. At-risk premises may be monitored by active observational surveillance unless testing is already being performed for continuity of business purposes. Utilizing active observational surveillance or aggregate sampling (once validated for use) for the control area would reduce the number of diagnostic samples to be tested if lab capacity becomes an issue. Regardless of the method used to monitor, the goal is to survey all premises in the control area until it becomes impractical to do so. Diagnostic testing in the control area may be discontinued except for continuity of business purposes if resources are severely limited.

As additional infected premises are discovered, the size of the control area may increase accordingly. If the newly detected infected premises is located on the periphery of the buffer zone, the size of the control area may increase to encompass the new infected zone and buffer zone as shown in Figure F-1 below.

Figure F-1. Infected Premises' Effect on Size of Control Area



Selection of Premises in the Surveillance Zone

Select a subset of premises within the surveillance zone for active surveillance, prioritized by epidemiological investigation or other requirements.¹ The number of premises to sample will vary by total number of premises in the zone and the premises design prevalence or number of infected premises to detect. It is preferable to conduct surveillance on as many premises as possible using a higher design prevalence or lower probability of detection when allocating limited resources.

Table F-1 provides sample sizes to achieve 95 percent confidence of detection based on the number of premises in the zone and the premises design prevalence. It also provides the number of infected premises for each zone size and design prevalence value. The default design in Section 5.3 recommended sampling either 300 or 500 premises from the surveillance zone based on Table F-1, assuming a

¹ In a disease outbreak, permits are issued to move FMD susceptible animals and/or their products into, within, and out of a regulatory control area. Movement exclusively in a FA are not managed by the IC, though affected State(s) may have additional surveillance and/or testing criteria in FAs.

zone with large numbers of premises. For example, a zone with 10,000 premises requires a sample of 298 premises to detect 100 or more infected premises (1 percent design prevalence).

Table F-1. Minimum number of infected premises and samples sizes¹ for three prevalence values and a range of zone sizes. Sample sizes achieve 0.95 probability of detecting at least one infected premises in the zone for the chosen premises level design prevalence.²

No. Premises in zone	No. infected premises in zone at 0.6% prevalence	Sample size	No. infected premises in zone at 1% prevalence	Sample size	No. infected premises in zone at 2% prevalence	Sample size
250	1	238	2	194	5	112
500	3	315	5	224	10	128
1000	6	392	10	258	20	138
2500	15	451	25	281	50	144
5000	30	474	50	289	100	146
>10,000	-- ³	498	-- ³	298	-- ³	148

¹ Sample sizes computed using Cannon, 2001

² This statement assumes that a sufficient number of samples are collected and tested within each premises to detect at least one or more infected animals on the premise with 0.95 probability of detection.

³ Number of infected premises at the given design prevalence depends on group size

Table F-2 provides similar information for zones with smaller numbers of premises. For example, in a zone with 150 premises and a 10 percent premises level design prevalence, 27 premises would be sampled. At a 10 percent premises level design prevalence in a 150 premises zone, up to 14 infected premises may go undetected. If having 14 premises undetected is too high, a lower design prevalence can be selected, e.g. 5 percent (up to 7 undetected premises), requiring 51 premises be sampled.

Table F-2. Minimum number of premises to sample¹ from a zone to achieve 95 percent confidence in detecting at least one infected premises for the chosen premises level design prevalence.²

No. premises in zone	Premises Level Prevalence				
	1%	3%	5%	10%	15%
11 or less	3	3	3	11 ⁴	9 ³
12 to 15	3	3	3	13 ⁴	11
16 to 40	3	40 ⁴	32 ⁴	21 ⁴	16
41 to 50	3	45 ⁴	36	23	16
51 to 75	3	58	43	25	17
76 to 100	3	66	47	26	18
101 to 150	136 ⁴	76	51	27	18
151 to 200	163 ⁴	82	53	28	19
201 to 500	236 ⁴	94	58	29	19
>500	309	103	61	30	20

¹ Sample sizes computed using Cannon, 2001

² This statement assumes that a sufficient number of samples are collected and tested within each premise to detect at least one or more infected animals on the premises with 0.95 probability of detection.

³ Prevalence multiplied by the number of premises in the zone is less than one infected premises.

⁴ Select all premises if number of premises within the zone is less than the value given. Prevalence multiplied by the number of premises in the zone is less than one infected premise for some combinations.

If infected premises are detected in the surveillance zone from initial testing efforts, consideration should be given to increasing the surveillance zone size to include more premises in the sampling frame. Also consider decreasing the premises level design prevalence, allowing more intensive sampling to ensure the control area boundaries encompass all infected premises. As the outbreak size increases, utilizing active observational surveillance or aggregate sampling (once validated for use) for the surveillance zone would reduce the number of diagnostic samples to be tested, since lab capacity may become a limitation in extremely large outbreaks.

Sampling of Animals within Selected Premises

Guidance for the number of animals to sample on selected premises will vary by pathogen and host characteristics. Figure F-2 illustrates the range of values that might exist for the percentage of infected animals in small ruminant, cattle, and swine herds using disease modeling (SEIR model) parameterized from the literature (Mardones et al. 2010, Chis Ster 2012, de Rueda et al. 2014). Rapid spread in swine allows a smaller sample size because disease detection will occur shortly after exposure or clinical signs will become apparent quickly. If spread is slower, such as in cattle, then sampling may lead to earlier detection. For small ruminants, a larger sample size and regular active surveillance is important because of the slower spread and the lack of apparent clinical signs.

The design prevalence or number of infected animals to detect has the greatest impact on sample size and thus resource needs. It also impacts what the surveillance can achieve on each premises. This value should be selected with careful thought given to meeting the surveillance objectives and with an understanding of the host and pathogen characteristics.

Early detection requires a smaller design prevalence and therefore a larger sample size, but how small the design prevalence should be depends on the pathogen and host characteristics. For example, note the difference in the percentage of infectious cattle compared to sheep in Figure F-3. If infectious animals are typically detectable by rRT-PCR testing, then a sampling scheme with a design prevalence of 5 percent should detect infection (with 0.95 probability) 19 to 26 days post-exposure for cattle, but not until 32 to 47 days post exposure for sheep. Thus a 5 percent design prevalence may be too high for a sampling scheme with an early detection objective for sheep.

If the disease spread among animals is very rapid and the surveillance objective is disease freedom, a higher design prevalence may be adequate. A 5 percent design prevalence requires a sample size of approximately 60 animals (Table F-3 for group size >5000) and should detect infection in swine 10 to 16 days post exposure (Figure F-3). On the other hand, a 15 percent design prevalence requires

only a sample size of 20 (Table F-3 for group size >5000) animals and should detect infection only a day later or 11 to 18 days post-exposure in swine (Figure F-3). For disease freedom in a zone such as the surveillance zone, sampling fewer animals per premises in combination with sampling a larger number of premises can achieve the same probability of detection with fewer tests than a scheme that focuses on a smaller design prevalence and thus larger sample sizes on each premises.

If a Type 3 or greater outbreak occurs, active observational surveillance and/or aggregate sampling may become a more widely employed sampling strategy. In this case, premises with less likelihood of being infected (e.g. high biosecurity facilities, few susceptible animals, etc.) could be assigned to active observational surveillance rather than diagnostic testing.

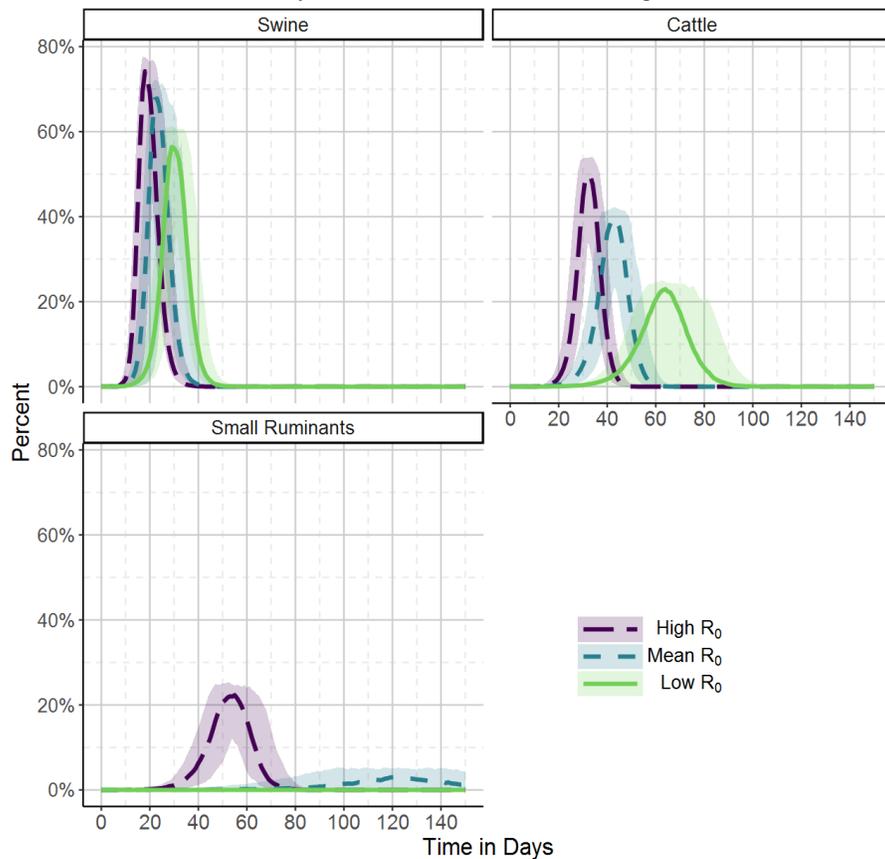


Figure F-2. Percent of animals in a small ruminant, cattle, or swine herd in the infectious stage by day for high, medium or low R_0 values. Parameters are based on information from publications by Mardones et al. 2010, Chis Ster et al., 2012, and de Rueda et al. 2014.

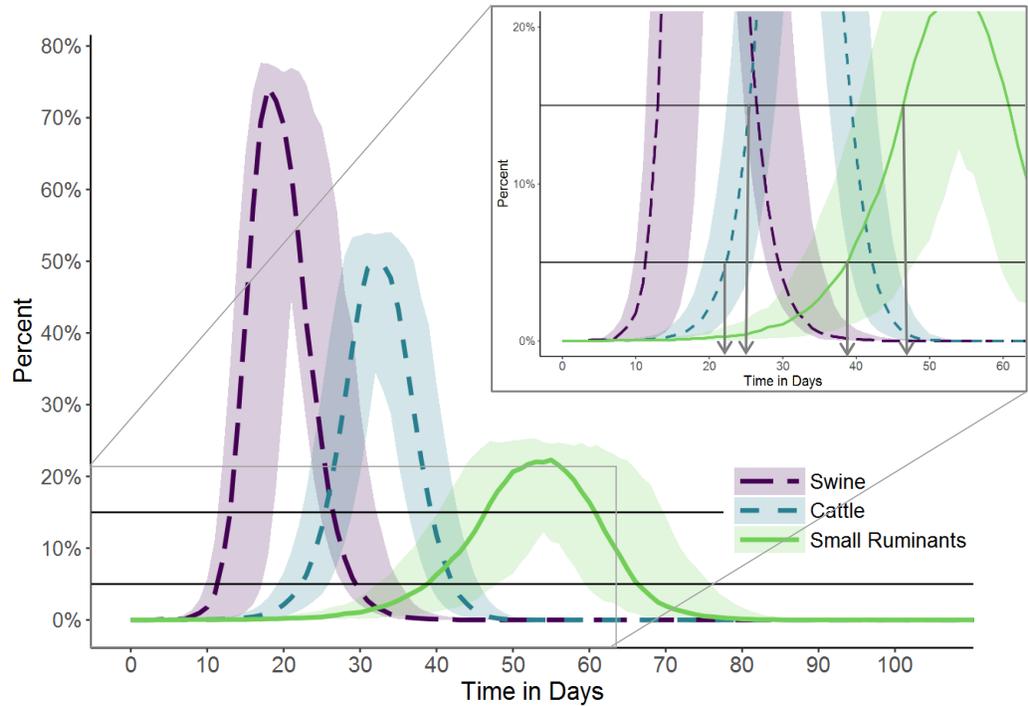


Figure F-3. Percent of animals in a small ruminant, cattle, or swine herd in the infectious stage for high R_0 values with inset showing detail of curve from 0 to 50 days and less than 15 percent infection. Parameters are based on information from publications by Mardones et al. 2010, Chis Ster et al., 2012, and de Rueda et al. 2014.

Premises/Species Likely to Manifest Clinical Signs

If the serotype or strain is expected to manifest clinically in the affected host population, sampling should primarily be targeted towards animals with clinical signs, followed by high probability of disease animals. In this case, sampling apparently healthy animals will provide less benefit than sampling those showing clinical signs or high probability of disease. This serves as risk-based sampling, which may lead to smaller sample sizes since these animals are more likely to be infected. Active observational surveillance can be utilized as an additional diagnostic tool. Collect samples from each pen or barn on the premises where clinical or high probability of disease animals are observed, or epidemiological links are found. When the number of clinical or high probability of disease animals is small, it may not be possible to detect the desired design prevalence by only sampling this group. However, if all of the animals in the group are tested and there is one infected animal in that group, the probability of detection is equal to the sensitivity of the diagnostic testing protocol (See Table F-4). If the group contains two infected animals, the probability of detection is greater than 0.95 as long as the diagnostic test sensitivity is 78 percent or higher.

Table F-3. Sample sizes¹ and number of infected animals for six prevalence values and a range of group sizes. Sample sizes achieve 0.95 probability of detection using a 95 percent sensitive test.

Group size ²	1% prevalence		2% prevalence		3% prevalence		5% prevalence		10% prevalence		15% prevalence	
	No. infected animals	Sample size										
100	1	95	2	77	3	63	5	44	10	25	15	25
150	1	143	3	94	4	78	7	51	15	26	22	26
200	2	155	4	105	6	78	10	51	20	27	30	27
250	2	194	5	112	7	86	12	54	25	27	37	27
300	3	189	6	117	9	84	15	53	30	27	45	27
400	4	210	8	124	12	87	20	54	40	27	60	27
600	6	235	12	131	18	91	30	56	60	28	90	28
800	8	249	16	135	24	93	40	56	80	28	120	28
1000	10	258	20	138	30	94	50	57	100	28	150	28
>5000	-- ³	298	-- ³	148	-- ³	98	-- ³	58	-- ³	28	-- ³	28

¹ Sample sizes computed using Cannon, 2001.

² Group size refers to the size of the population being sampled. This could be the entire herd or it could be a targeted portion of the herd such as the sick animals or animals with potential exposure.

³ Depends on group size

Table F-4. Probability of detecting at least one infected animal when all of the animals in the group are tested. Detection probabilities are given for a range of test sensitivities (or sensitivity of the testing protocol) when there are 1, 2, or 3 infected animals in the group.

Sensitivity of testing protocol (individual animal test)	Number of infected animals in the group tested		
	1	2	3
99%	0.99	>0.99	>0.99
95%	0.95	>0.99	>0.99
90%	0.90	0.99	>0.99
85%	0.85	0.98	>0.99
80%	0.80	0.96	>0.99

Premises/Species Unlikely to Manifest Clinical Signs

If the serotype or strain is less likely to manifest clinically in the affected host population, more intensive sampling may be needed. This may occur because of host characteristics, such as with sheep or goats that are less likely to show clear clinical signs, or strain specific characteristics, such as in the 1997 Taiwan outbreak which primarily affected swine.

In these cases, if animals with clinical signs and high probability of disease animals total less than the described sample size, it may be necessary to sample apparently healthy animals. If this occurs, consider increasing the sample size to meet a lower design prevalence (see Table F-3). When sampling apparently healthy animals, samples should be distributed across each group, pen or house with priority given to areas near entrances, vents (for housed animals), and areas with a high potential for fomite transmission.

Animals in zoological collections may or may not manifest obvious clinical signs, which should also be considered when designing a sampling scheme if this type

of premises is contained within a control area or surveillance zone. Review the Secure Zoo Strategy documents at <https://securezoostrategy.org/build-facility-plan/> for more information. Some tests may not be validated for use with these species, so discussion with the laboratory may be necessary prior to sample collection.

Frequency of Sampling

Frequency of sampling during an outbreak will depend on the premise designation, pathogen and host characteristics, and surveillance objectives.

For contact premises, the frequency can be further defined depending on type of contact (direct vs indirect contact with an infected premises), with direct contacts being more likely to be infected and therefore requiring more frequent sampling than indirect contact premises. For all premises designations, more frequent sampling during the outbreak is recommended for shorter incubation periods and higher exposure risks. If the disease is transmitted at such a rapid rate that it is difficult to detect disease efficiently with sampling efforts, achieving an early detection objective will be difficult. In this case, sampling may change from diagnostic testing to active observational surveillance with the reporting frequency being equivalent to diagnostic sampling frequency. If new infected premises are being discovered more rapidly than contact premises can be identified and sampled, identification of new infected premises should be the top priority.

More frequent sampling is especially important when clinical signs are not apparent. As seen in Figures F-2 and F-3, more frequent sampling would provide a benefit of detecting at a lower percent of the herd/flock infected. Detecting at this level would lead to detecting up to multiple days in advance of detecting with clinical signs.

If the surveillance objective is to demonstrate freedom from disease, frequency of sampling is dependent on the zone in which a particular premises is located. For example, demonstrating freedom for continuity of business purposes within the control area, the time period between sampling should be short, ideally less than the incubation period. Less frequent testing could be used for premises located in the surveillance zone, which have a lower level of risk or for premises in the free area, where risk is assumed to be lowest of these three examples. The frequency or level of testing in the free area may need to be modified for trade purposes.

As the outbreak increases in size, it is ideal to increase frequency of sampling. However, given the likely resource limitations associated with increased outbreak size, frequencies can be modified as necessary. Recommendations for initial frequency of sampling are summarized in Table F-5 or as directed by the IC. Table F-6 shows the incubation periods and sampling frequency.

Table F-5. Outbreak Surveillance for Disease Detection

Designation	Infected Zone and Buffer Zone	Surveillance Zone
Suspect Premises	Immediately investigate and sample. Consider repeating every other day through a full incubation period if initial test results are negative	
Contact Premises	Initially consider sampling every 5 days for 14 days. Optimum frequency depends on incubation period and exposure risk.	
Control Area (CA) - At-Risk Premises	Consider sampling every 10 days until 56 days after the last detected case. Optimum frequency depends on incubation period and exposure risk.	
CA - Monitored Premises	Consider initially sampling every 10 days until 56 days after the last detected case, or more frequently as required for movement testing. Testing should occur a minimum 5 times for the duration of the quarantine. Optimum frequency depends on incubation period and exposure risk.	
CA - Specific Animal and Product Movement	Only applies to MPs and ARPs. Refer to Secure Food Supply plans and IC recommendation.	
Surveillance Zone - Free Premises		Once to confirm lack of spread, and repeat every 21 days until 56 days after the last detected case. Or consider repeating just 2-3 times again prior to release of the control area.

Table F-6. Incubation Periods and Sampling Frequency

Incubation Period	Estimated Incubation Period Based on Field Information	
	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	

Surveillance if Vaccination Control Strategies are Implemented

See section 1.3.7.2, 3.3, 3.4, 5.16, and Appendix I for additional information on vaccination strategies and challenges. If vaccination is used, surveillance diagnostic testing will rely heavily on serum samples and testing to differentiate infected from vaccinated animals (DIVA). It is assumed that a DIVA vaccine would be used, if available, for the serotype identified in the outbreak.

If vaccination is used, surveillance plans should incorporate sampling of vaccinated premises to show proper vaccine matching to the outbreak virus is achieving immunity. This can be performed on a random sample of animals from a premises, and at a higher design prevalence than for disease detection plans. If the correct vaccine was used for the serotype, this surveillance should provide evidence that immunity to the outbreak virus is being established, sufficient numbers of animals have been vaccinated, and that the rate of spread (R_0) has decreased below 1. If this is the case, the outbreak spread should decrease.

Since vaccination does not provide complete immunity, it is possible that a vaccinated animal can still be infected, and may become a carrier. Cattle are most frequently carrier animals, harboring the virus in the oropharyngeal epithelium. If vaccinate to live strategies are employed, probang sampling will be an additional testing requirement to detect carrier animals.

Proof of Disease Freedom Surveillance

To regain a disease free country status, a number of steps are outlined in the OIE Terrestrial Code. The exact steps required to re-gain status will depend on the strategy used to control the outbreak; it is assumed for the following steps that some form of depopulation is employed. The following should be incorporated into the surveillance plan:

1. Surveillance for proof of disease freedom may start 21-28 days after depopulation of the last infected premises, to ensure enough time has passed for antibody development or adequate time for clinical signs to manifest (at least one OIE incubation period has passed).
2. Before freedom can be regained, a minimum waiting period must be observed, which differs with the control strategies used, per the OIE Code, Article 8.8.7.
 - a. A waiting period of 3 months is required after disposal of the last animal killed (if stamping out is used alone) or slaughter of all vaccinated animals (if vaccination to slaughter and stamping out controls are used).
 - b. A waiting period of 6 months after disposal of the last animal killed or last vaccination is required when a stamping out policy is combined with emergency vaccination not followed by slaughtering of all vaccinated animals.
 - c. If stamping out is not employed as a control strategy, none of the above waiting periods apply.
3. Surveillance samples will be tested to demonstrate active virus if no vaccine was used. If a DIVA vaccine was use, samples will be tested to demonstrate past exposure to the virus.

- a. Due to species differences, all vaccinated ruminants should be sampled. Vaccinated pigs should be sampled to detect 5 percent (animal level or within-herd level) prevalence with 0.95 probability of detection.
 - b. Non-vaccinated sheep and goats should be sampled to detect 1 percent of infected herds with 0.95 probability of detection and 5 percent of the animals on the farm with 0.95 probability of detection.
 - c. If the outbreak size is so great that sampling all vaccinated herds is not practical, then within herd prevalence could be set at less than 5 percent and within herd prevalence set at less than 1 percent.
4. The goal is to substantiate freedom from FMD infection or transmission and may be based on randomized or targeted clinical investigation, or sampling at an acceptable level of statistical confidence. Clinical inspections may be targeted at particular species likely to exhibit clear clinical signs (e.g. cattle and swine). If vaccination is practiced, then the goal is to demonstrate through serological survey no evidence of infection in the vaccinated population (no detection of antibodies to nonstructural proteins of FMD).
 5. Status can be regained after evidence in support of disease freedom has been submitted and accepted by OIE.

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Appendix G

Epidemiological questionnaires

Epidemiological investigation and movement tracing during an outbreak are critical in controlling and eradicating FMD. In an FMD outbreak, there are several goals, as outlined in **Section 4.5** of this publication.

The templates provided are epidemiological questionnaires that may be useful in planning. It is likely that any epidemiological questionnaire will need to be modified and tailored to the specific outbreak.

January 10, 2023: The epi questionnaires are being revised and will be posted on the FMD FAD PReP website accessible from www.aphis.usda.gov/fadprep.

Appendix H

Movement Control Notice Examples

Upon report of a highly suspicious or presumptive positive case of FMD, the State or Tribal Animal Health Official will immediately issue a quarantine or hold order on the premises. In some cases, USDA may impose a Federal quarantine or other movement control by Federal Order. Examples of these notices are attached.

Appendix H

Examples of Movement Control Notices

This appendix provides examples, both Federal and State, of halting movement of animals during a disease outbreak. Each State has different authorities and processes regarding movement controls—frequently called a “stop movement order” or a “hold order”—in response to an animal health emergency.

EXAMPLE—KANSAS (2015)

Manhattan, Kansas – In an effort to protect the Kansas poultry industry and to promote stronger biosecurity practices throughout the state, Kansas Department of Agriculture Division of Animal Health has issued a stop movement order, signed by Secretary of Agriculture Jackie McClaskey, targeting Kansas poultry and live birds, effectively cancelling all poultry-related shows and events through calendar year 2015. This includes all types of poultry activities where birds from different flocks are co-mingled.

This will include, but is not limited to: regional and county fairs, festivals, the Kansas State Fair, swap meets, exotic sales and live bird auctions. This measure is being implemented in an effort to prevent the spread of highly pathogenic H5N2 avian influenza (HPAI). Kansas experienced a positive case of HPAI in Leavenworth County in March 2015.

This decision was made after careful consideration and consultation with the K-State Research and Extension, Kansas 4-H, Kansas State Fair representatives and other poultry industry officials. Dr. Justin Smith, Deputy Animal Health Commissioner made the announcement.

“The decision to issue movement restrictions regarding poultry and bird events has been made in an effort to protect the poultry industry in Kansas and the economic contribution that the industry makes to our agricultural economy. It is a difficult decision, as I know youth and adults would soon be exhibiting their projects at local fairs,” said Smith. “This decision was not made lightly, but it is necessary we do everything possible to protect the Kansas poultry flock.”

K-State Research and Extension and Kansas 4-H, along with the Kansas State Fair, is working to identify options for youth enrolled in poultry projects to showcase their learning and participate in fairs in ways other than having their birds present.

It is important that all poultry producers continue to monitor their flocks for symptoms of the virus, and notify KDA immediately if they suspect any problems. All bird owners, whether commercial producers or backyard enthusiasts, should prevent contact between their birds and other birds including wild fowl.

If you see sickness in birds, please contact KDA Division of Animal Health at (785) 564-6601 or email HPAI@kda.ks.gov. Additional information about HPAI can be found online at www.agriculture.ks.gov/avianinfluenza.

Source: <http://agriculture.ks.gov/AllNewsItems/2015/06/09/movement-restrictions-for-poultry-events-exhibitions-and-sales-issued-in-kansas>

EXAMPLE—NORTH DAKOTA (2015)

BISMARCK, N.D. – To protect North Dakota’s poultry industry from potential exposure to H5 avian influenza virus, the State Board of Animal Health (BOAH) has halted bird movement to shows, exhibitions and public sales within the state in which birds from different locations are intermingled at an event. This does not apply to approved private sales that meet [North Dakota importation requirements](#).

“The state board is taking this precaution to reduce the risk of avian influenza exposure to North Dakota birds,” State Veterinarian Dr. Susan Keller said. “Mixing birds could unnecessarily increase the risk of exposure.”

This board action prohibits the specified poultry/bird movements until further notice. BOAH is continuing to monitor and assess the disease threat, which will be reviewed at their June 10 quarterly meeting.

North Dakota has had two confirmed cases of avian influenza in commercial poultry operations in Dickey and LaMoure counties affecting over 100,000 birds. Nationally, the outbreak has affected nearly 10 million birds in 13 states.

Bird owners should immediately report death loss to their local and state veterinarian, restrict access to their property, prevent contact between their birds and wild birds and practice enhanced biosecurity.

State Veterinarian Dr. Susan Keller is reminding anyone bringing birds into North Dakota to contact the North Dakota Department of Agriculture’s Animal Health Division at 701-328-2655 to ensure they are meeting all [importation requirements](#).

More information about avian influenza and biosecurity is available at www.nd.gov/ndda/disease/avian-influenza and from the USDA-APHIS at www.aphis.usda.gov.

Source: www.nd.gov/ndda/news/poultrybird-movements-limited-control-spread-avian-influenza.

EXAMPLE—WEST VIRGINIA (2007)

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: www.wvagriculture.org/news_releases/2007/7-9-07.html.

EXAMPLE—FEDERAL (2003)

Source: www.federalregister.gov/articles/2003/04/16/03-9322/exotic-newcastle-disease-additions-to-quarantined-area#p-3.



Rules and Regulations

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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 I

FMD Vaccines and Vaccination

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, Chapter 2 on FMD, provides extensive guidance on vaccine matching.

Appendix I

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, Appendix A: FMD*. This document can be found at www.aphis.usda.gov/fadprep.

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 (2012)* 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. 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.

$$r_1 = \frac{\text{reciprocal arithmetic titre of reference serum against field virus}}{\text{reciprocal arithmetic titre of reference serum against vaccine virus}}$$

The OIE states that the recommended standard test is the VNT; the *OIE Manual* recommends interpreting the tests as follows:

- ◆ r_1 of >0.3 : indicate the field isolate is sufficiently similar to the vaccine strain; that use of a vaccine based on this strain is likely to confer protection against challenge with the field isolate.
- ◆ r_1 of <0.3 : indicate that the field isolate is sufficiently different from the vaccine strain; a vaccine based on these strains is less likely to protect.

¹ OIE. 2012. *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, Chapter 2.1.5, “Foot-and-Mouth Disease.” <http://www.oie.int>.

Tests should always be repeated more than once; the *OIE Manual* recommends a minimum of at least three repetitions.

POTENCY

In addition to vaccine matching, the potency of the vaccine also contributes to “the range of antigenic cover.”² 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 (PD₅₀) 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.”³ The PD₅₀ is determined in a dose response study in a minimum of 15 cattle, at least 6 months of age, plus two non-vaccinated control animals. The animals are split into three groups, and administered vaccine in different volumes intradermally, into two sites on the upper surface of the tongue. The *OIE Manual* provides the example of 1 dose, ¼ dose, and 1/10 dose for the three groups.

According to the *OIE Manual*, these animals and the control group are challenged at 3 weeks (aqueous) or up to 4 weeks (oil) after vaccination, by the inoculation of 10,000 BID₅₀ (50 percent bovine infectious dose) of virulent bovine virus of the same type or subtype as that used to prepare the vaccine.

For the United States, preferred observed potency is at least 6 PD₅₀ per cattle dose; an emergency vaccine is typically considered to be 6 PD₅₀ or greater.

An alternative to this test is the PGP test (percentage of protection against generalized foot infection). Sixteen seronegative cattle, at least 6 months old, plus 2 non-vaccinated control animals, are vaccinated with a manufacturer-suggested volume. Then, these animals and the control group are challenged 4 weeks or more after vaccination with a fully virulent challenge strain, by the intradermal inoculation of a total of 10,000 BID₅₀ (50 percent bovine infectious dose) intradermally, into at least two sites on the upper surface of the tongue.

The PGP test does not provide an estimate of how many protective doses are in a single vaccine, but gives an estimated level of protection following the injection of single bovine dose.

The *OIE Terrestrial Manual* states that potency tests for other species have not yet been standardized.

² OIE. 2012. *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, Chapter 2.1.5, “Foot-and-Mouth Disease.” <http://www.oie.int>.

³ OIE. 2012. *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, Chapter 2.1.5, “Foot-and-Mouth Disease.” <http://www.oie.int>.

STRAINS

The World Reference Laboratory for FMD (WRLFMD) recommends FMDV strains that should be included in FMDV antigen banks each quarter. As of June 2014, high-priority strains, not in order of importance, include⁴

- ◆ O Manisa
- ◆ O PanAsia-2 (or equivalent)
- ◆ O BFS or Campos
- ◆ A24 Cruzeiro
- ◆ Asia 1 Shamir
- ◆ A Iran-05 (or A TUR 06)
- ◆ A22 Iraq
- ◆ SAT 2 Saudi Arabia (or equivalent, i.e. SAT 2 Eritrea).

The *WRLFMD Quarterly Report April-June 2014* also lists medium and low priority recommendations:

http://www.fao.org/fileadmin/user_upload/eufmd/docs/Pirbright_reports/April-June_2014.pdf.

DIVA

One of the most important challenges to vaccination is ensuring that infected and vaccinated animals can be successfully differentiated (a “DIVA” strategy). The Foreign Animal Disease Diagnostic Laboratory (FADDL), part of the National Veterinary Services Laboratories (NVSL), 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 National Animal Health Laboratory Network may have this capability in the future. (See [Section 5.4](#) of this response plan for diagnostic flowcharts.) Differentiating between infected and vaccinated animals on an individual rather than herd basis remains a diagnostic challenge.

Insufficiently purified vaccines may contain low levels of nonstructural proteins; vaccine purity is very important for DIVA, particularly when animals must be

⁴ World Reference Laboratory for FMD. 2014. *WRLFMD Quarterly Report April-June 2014*, http://www.fao.org/fileadmin/user_upload/eufmd/docs/Pirbright_reports/April-June_2014.pdf.

vaccinated multiple times.⁵ 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.

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 (antigenic similarity between strains) and the potency of the vaccine.

IMMUNITY

An oil adjuvanted product is likely to be used in an emergency vaccination strategy associated with an FMD outbreak in the United States.

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 clinical protection in pigs as soon as 3–4 days after vaccination; however, pigs may not be completely protected against disease until 21–28 days after vaccination.⁶

Duration of Immunity

There is relatively little information on the duration of immunity for high potency vaccines. Conventional vaccines (used in endemic countries), are expected to provide approximately 4–6 months of immunity. Some studies suggest that high potency vaccines may protect cattle, sheep, or pigs for 6–7 months.⁷ The *OIE Terrestrial Manual* states that “vaccine is usually given as a primary course consisting of one or two doses of vaccine 3–4 weeks apart (based on animal population immunological status, vaccine potency, virus-vaccine matching, virus challenge levels, and other factors), followed by revaccination every 6–12 months. The frequency of revaccination will depend on the epidemiological situation and the type and quality of vaccine used.”⁸

⁵ R. P. Kitching, 2002. “Identification of foot and mouth disease virus carrier and subclinically infected animals and differentiation from vaccinated animals,” *Rev Sci Tech*. 21(3): pp. 531–538. Also see *NAHEMS Guidelines: Vaccination for Contagious Diseases, Appendix A: FMD*.

⁶ USDA APHIS. *NAHEMS Guidelines: Vaccination for Contagious Diseases, Appendix A: FMD*.

⁷ USDA APHIS. *NAHEMS Guidelines: Vaccination for Contagious Diseases, Appendix A: FMD*.

⁸ OIE. 2012. *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*.

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Appendix J

Selected References

Note: This appendix lists documents related to foot-and-mouth disease (FMD) response. All related FAD PReP documents listed in Appendix A, the selected references listed in Appendix F, and the resources listed in document footnotes are also references for this FMD Response Plan.

Appendix K

FMD Acronyms

3D	depopulation, disposal, and decontamination	CVO	Chief Veterinary Officer	FA	Free Area
AGID	agar-gel immunodiffusion	CVZ	Containment Vaccination Zone	FAD	foreign animal disease
AHPA	Animal Health Protection Act	DEFRA	Department for Environment, Food, and Rural Affairs	FADD	Foreign Animal Disease Diagnostician
AMT	APHIS Management Team	DF	disease freedom	FADDL	Foreign Animal Disease Diagnostic Laboratory (also NVSL-FADDL)
AOS	active observational surveillance	DHS	Department of Homeland Security	FEMA	Federal Emergency Management Agency
APHIS	Animal and Plant Health Inspection Service	DIVA	differentiation of infected from vaccinated animals	FMD	foot-and-mouth disease
ARMAR	Agriculture and Response Management and Resources	DOI	Department of Interior	FMDV	foot-and-mouth disease virus
ARP	At-Risk Premises	EITB	enzyme-linked immunoelectrotransfer blot	FP	Free Premises
AVIC	Area Veterinarian in Charge	ELISA	enzyme-linked immunosorbent assay	FSIS	Food Safety and Inspection Service
AVMA	American Veterinary Medical Association	EMRS2	Emergency Management Response System 2.0	GFRA	Global Foot-and-Mouth Disease Research Alliance
BZ	Buffer Zone	EPA	Environmental Protection Agency	HHS	Department of Health and Human Services
CA	Control Area	EPC	Emergency Preparedness Committee	HPD	high probability of disease
CCC	Commodity Credit Corporation	EQS	Emergency Qualifications System	HTST	high temperature—short time pasteurization
CDC	Centers for Disease Control and Prevention	EuFMD	European Commission for the Control of FMD	IAHER	International Animal Health Emergency Reserve
CEAH	Center for Epidemiology and Animal Health	ESF	Emergency Support Function	IC	Incident Command(er)
CF	Contingency Fund			ICG	Incident Coordination Group
CFR	Code of Federal Regulations				
CP	Contact Premises				

ICP	Incident Command Post	NPIC	National Preparedness and Incident Coordination	SP	Suspect Premises
ICS	Incident Command System			SPCE	solid phase competitive ELISA
IMT	Incident Management Team	NRF	National Response Framework	SVA	Senecavirus A
IP	Infected Premises	NSP	nonstructural protein	SZ	Surveillance Zone
IZ	Infected Zone	NVS	National Veterinary Stockpile	TDD	telecommunications device for the deaf
JIC	Joint Information Center	NVSL	National Veterinary Services Laboratories	UHT	ultra-high temperature
LK	lamb-kidney secondary cells	OIE	World Organization for Animal Health	USDA	U.S. Department of Agriculture
LPA	Legislative and Public Affairs			VAC	vaccines antigen concentrate
LPAI	low pathogenicity avian influenza	PCR	polymerase chain reaction	VERRC	Voluntary Emergency Ready Response Corps
LPBE	liquid phase blocking ELISA	PD50	50 percent protective dose	VI	virus isolation
MAC	multiagency coordination	PIO	Public Information Officer	VIAA	virus infection association antigen
MP	Monitored Premises	PGP	percentage of protection	VNT	virus neutralization test
MPC	Multiprogram Committee	PPE	personal protective equipment	VP	Vaccinated Premises
NAFMDVB	North American Foot-and-Mouth Disease Vaccine Bank	PPV	positive predictive value	VS	Veterinary Services
NAHEMS	National Animal Health Emergency Management System	PVZ	Protection Vaccination Zone	VSDA	VS Deputy Administrator
NAHLN	National Animal Health Laboratory Network	QMC	Quarantine & movement control	VSDA/CVO	VS Deputy Administrator / Chief Veterinary Officer
NASAHO	National Assembly of State Animal Health Officials	RNA	ribonucleic acid	VSET	VS Executive Team
NASDA	National Association of State Departments of Agriculture	rRT-PCR	real-time reverse transcriptase polymerase chain reaction	VZ	Vaccination Zone
NIC	National Incident Coordinator	SAHO	State Animal Health Official	WRLFMD	World Reference Laboratory for Foot-and-Mouth Disease
NIMS	National Incident Management System	SAT	South African Territories (FMD serotypes)		
NIMT	National Incident Management Team	SITC	Smuggling Interdiction and Trade Compliance		
		SBS	Secure Beef Supply		
		SMS	Secure Milk Supply		
		SPS	Secure Pork Supply		
		SOP	standard operating procedure		