USDA
United States Department of Agriculture

FOOT-AND-MOUTH DISEASE RESPONSE PLAN

THE RED BOOK

DRAFT October 2020

The *Foot-and-Mouth Disease (FMD) Response Plan: The Red Book* (October 2020) incorporates comments received on the *FMD Response Plan: The Red Book* (September 2014) and reflects updates to Foreign Animal Disease Preparedness and Response Plan (FAD PReP) materials.

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 an FMD response.

In particular, States should develop response plans focused on the specific characteristics of the State and its livestock industry.

Outline

- Introduction and Information
- Preparedness and Response
- Response Goals and Strategy for Recovery
- Specific Response Critical Activities and Tools




FMD RESPONSE PLAN

Introduction and Information

Objectives of this Plan

- Identify the capabilities needed to respond to an foot-and-mouth (FMD) outbreak.
- Identify critical activities that are involved in responding to an outbreak and the time-frames for these activities.

In an outbreak situation, these critical activities are under the authority of an Incident Command (IC) per the National Incident Management System (NIMS).

Etiology

- FMD is also known as fiebre aftosa, fievre aphteuse, and maul-und-klauenseuche.
- It is a *highly* contagious viral disease that affects
  - domestic cloven-hoofed animals (cattle, swine, sheep, and goats) and
  - many wildlife species (deer, bison, pronghorn antelope, and feral swine).

FMD Virus Subtypes

- There are seven immunologically distinct FMD virus (FMDV) serotypes:
  - A, O, C, South African Territories types SAT-1, SAT-2, SAT-3, & Asia 1.
- More than 65 strains of FMD virus (FMDV) have been recognized.
- There is no cross protection between serotypes, and protection between strains varies depending on their antigenic similarity.

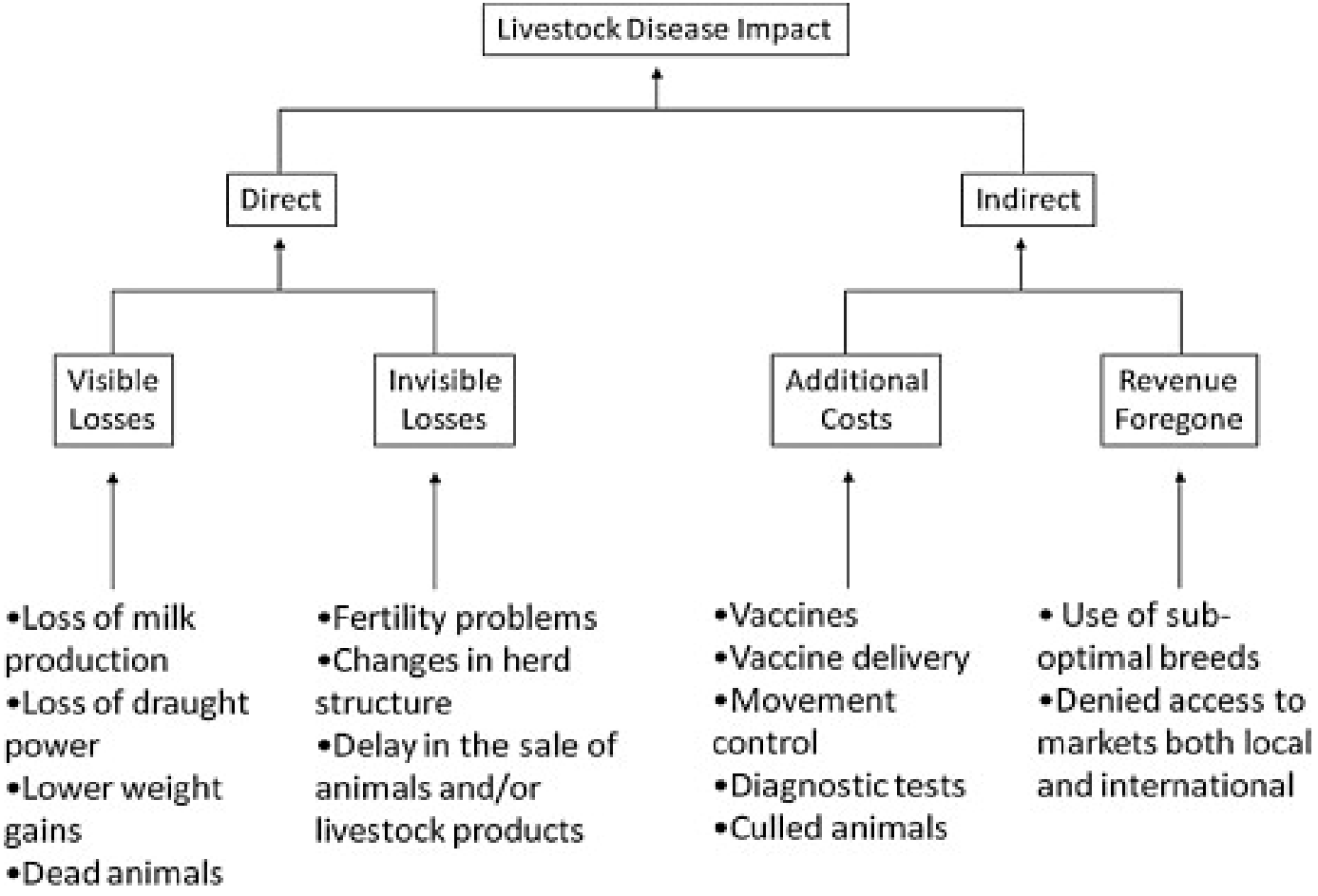
Global Distribution

- 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 last FMD outbreak in the United States was in 1929.

Threat to the United States

- International travel and trade pose a substantial risk of FMD entering the country.
- The disease is a critical threat to the United States because of the millions of susceptible cloven-hoofed livestock and wild animals.
- FMD can be transmitted over long distances by animal products, fomites, people, and other mechanical vectors.
- FMDV is also considered a potential agent for agricultural terrorism.

FMD Effects



Source: Knight-Jones, T. and Rushton. (n.d.).

Economic Impact

- The 2001 FMD outbreak in the United Kingdom cost an estimated $12-18 billion.
- A U.S. outbreak contained in California could cost between $6-14 billion; a nation-wide agroterrorism attack could range up to $228 billion.
- Economic impact estimates depend primarily on
  - the duration and geographic extent of the outbreak;
  - the extent of trade embargoes on U.S. products; and
  - the reaction of consumers to the disease and control measures.

No Zoonotic Potential

- FMD is *not* considered a public health threat.
  - FMDV infections in humans are very rare and mild: about 40 cases have been diagnosed since 1921.
  - FMD differs from hand, foot, and mouth disease (HFMD) of humans.
- The FMD virus may be able to survive in the human respiratory tract for 24 hours, allowing people to potentially serve as a source of virus exposure for susceptible animals.

Susceptible Species

- FMD affects cloven-hoofed animals.
  - Cattle, bison
  - Pigs, wild boar
  - Sheep, goats
  - Deer, elk, llamas,
- The disease is generally most severe in cattle and pigs.
- While rare, FMD has been documented in several other species including elephants and hedgehogs.

Carriers

- FMDV carriers are defined as "recovered or vaccinated and exposed animals in which FMDV persists in the oropharynx for more than 28 days."
  - Carriers can potentially infect susceptible animals.
- The duration of carrier status in cattle can range from several months to several years.
- Sheep and goats become carriers less often and for shorter periods than cattle; swine are not reported to become carriers.
- The only known natural reservoir of FMD exists in the African buffalo (*Syncerus caffer*).

Introduction and Transmission

- Animal to animal contact
- Air/Windborne
- Fomites
- Feed
- Personnel
- Wildlife

Virus Introduction and Transmission

- FMDV is thought to be introduced through infected animals, contaminated fomites, and, possibly, carrier animals.
  - The virus is present in secretions from acutely ill animals.
  - Viral shedding may occur days before signs of disease.
- Wildlife does not appear to be a common means of introduction.
- Meat products *have* been an important mode of introduction.

Aerosol Transmission

- Pigs excrete large amounts of virus through their respiratory tract, leading to infectious aerosols that can be inhaled by other animals.
- FMDV has also been known to spread through windborne transmission to distances well over 10 kilometers over land in favorable conditions.
- The conditions for long distance spread are thought to be highly specific, and include high relative humidity, steady wind, minimal convection currents, and lack of topographical obstructions.

Persistence in Environment and Animal Products

- FMD viruses are susceptible to both acid and alkaline pH and are quickly inactivated by 6.0 < pH > 9.0.
- FMDV is preserved by refrigeration and freezing; and progressively inactivated by temps above 50°C.
  - Meat must be subjected to heat treatment at 70°C for 30 minutes to ensure FMDV deactivation.
- FMDV can also persist in wool, hair, and other products for substantial periods.

Incubation Period

- Ø Incubation period ranges from 2–14 days (species-dependent).
- Ø The World Organization for Animal Health (OIE) *Terrestrial Animal Health Code (Terrestrial Code)* gives the incubation period as 14 days.

Morbidity and Mortality

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

Clinical Signs

- FMD is typically recognized by vesicles, though affected animals may show a variety of clinical signs.
- Vesicular signs are most prominent in cattle and pigs; often unpronounced in sheep and goats.
- FMD vesicles are indistinguishable from those of other vesicular diseases.

Image from EuFMD
Retrieved from:
http://www.fao.org/fileadmin/user_upload/eufmd/docs/training/KenyaManualMarch2014Final.pdf

Clinical Signs in Cattle

- Pyrexia (fever), anorexia, shivering, reduction in milk production for 2–3 days, followed by vesicular signs:
  - grinding of teeth, drooling, excess nasal mucous secretions,
  - lameness, stamping, or kicking caused by vesicles on buccal and nasal mucous membranes or between the claws and coronary band,
  - vesicles on mammary gland and tongue, and
  - ruptured vesicles.
- Abortion or sudden death in young animals.
- The infection usually resolves in 8–15 days unless there is a secondary bacterial infection.

Clinical Signs in Pigs

- Pyrexia (fever) and blanching of the coronary bands, followed by:
  - severe foot lesions,
  - severe lameness,
  - reluctance to move,
  - no drooling (fewer vesicles), and
  - lesions on snout, muzzle, gums, and interdigital spaces.

- High mortality in piglets.
- Possible abortion.

Clinical Signs in Sheep and Goats

- 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.

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.
- Necrosis may also occur.
- Lesions will vary among cattle, swine, and sheep.
- Resources exist online with extensive pictures demonstrating the aging of FMD lesions.

Differential Diagnosis

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

Immunity

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 7–14 days post-infection, protective antibodies are developed against FMDV structural proteins.

Immunity
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.

Immunity

Vaccination Limitations

Vaccines provide only serotype-specific protection. Vaccination against one serotype may fail to protect fully or at all against other strains within the serotype. This protection depends on:

- the similarity between the field strain and the vaccine, and
- the potency of the vaccine (more potent vaccines are likely to be protective against even less well-matched strains).

Immunity

In Studies

- 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.
  - With more severe challenges, pigs may not be completely protected against disease until 21–28 days after vaccination.

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 become asymptomatic virus carriers.
- 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 Vaccines

- DIVA diagnostic techniques typically use tests for antibodies against viral nonstructural proteins 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.

FMD NATIONAL

Preparedness and Response

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
- National Incident Management System (NIMS).

These documents available at
www.fema.gov

National Response Framework

- Part of the National Preparedness System.
- The NRF sets the strategy and doctrine for how the Nation conducts all-hazards response, through a whole community approach.
  - Composed of a base document, Emergency Support Function (ESF) Annexes, and Support Annexes
  - Describes specific authorities and incorporates best practices for managing incidents of any size or complexity.
  - Built on scalable, flexible, and adaptable concepts identified in the NIMS.

National Incident Management System

- NIMS helps departments and agencies at all levels of government, the private sector, and non-governmental organizations
  - to prepare for, prevent, respond to, recover from, and mitigate the effects of incidents, regardless of cause or complexity
  - providing a shared vocabulary, systems, and processes.
- A common framework to achieve common goals.

NIMS Key Components

- Ø Resource Management
  - – systematic, prior to and during incidents, and scalable
- Ø Command and Coordination
  - – roles, processes and structures, including ICS, EOCs, MAC
- Ø Communications and Information Management
  - – incident-related policies, equipment, data architecture, systems, standards, and training

USDA Responsibilities

- Under ESF-11 (Agriculture and Natural Resources), APHIS is the coordinating agency.

  APHIS is the agency responsible for detecting animal disease anomalies, assigning foreign animal disease diagnosticians to conduct investigations, and coordinating tasks with other ESFs, State veterinary emergency response teams, and voluntary animal care organizations to respond.

- USDA agencies play a role as Coordinating Agency in three ESFs and as Support Agency in the remaining twelve.

APHIS' Role

As the primary Federal agency for incident management during an FAD event of livestock or poultry, APHIS

- Ø deploys Incident Management Teams (IMT),
- Ø coordinates the incident response,
- Ø manages public messages, and
- Ø takes measures to control and eradicate disease.

USDA 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.
- The AHPA authorizes related activities with respect to exportation, interstate movement, cooperative agreements, enforcement and penalties, seizure, quarantine, and disease and pest eradication.

USDA Authorities—Cooperation

- The AHPA gives the Secretary authority to cooperate with to multiple entities to prevent, detect, control, or eradicate FMD.
  - other Federal agencies, State and foreign governments, domestic or international organizations or associations, Tribal nations, and other persons
- It allows that the Secretary may declare that an extraordinary emergency exists.
  - Provides additional flexibilities
  - Allows for restrictions *within* a State or Territory, after consultation with State or Tribal officials

USDA Authorities—Indemnity

- The AHPA 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 (FMV).
- Regulations for FMD authorize the APHIS Administrator to pay 50% of FMV for takings in a disease control and eradication effort. (9 CFR §53.2)
  - The Secretary is given authority to increase compensation to 100% of FMV.

USDA Activities—FAD PReP

- APHIS and its stakeholders established FAD PReP to provide guidance for preparing and responding to an FAD emergency.
- FAD PReP is a set of strategic concept of operations documents, disease response plans SOPs, and other materials to create a comprehensive approach to managing FADs
- FAD PReP is consistent with NRF and NIMS.

www.aphis.usda.gov/fadprep

FAD PReP offers...

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

USDA Activities—Exercises

- Multiple preparedness exercises have been conducted to simulate an FMD outbreak and response effort in the United States.
  - These exercises allow responders to discuss and practice FMD response activities and to consider the social and economic implications of an FMD outbreak.
  - They help prepare us for the difficult decisions that will be made regarding animal depopulation and business continuity.
  - Multistate functional exercises, like ARMAR (Agriculture and Response Management and Resources) held in 2018, enhance coordination and collaboration among States, and between State and Federal governments.

Domestic Activities

USDA and its Federal partners conduct a variety of ongoing FMD preparedness and response activities.

- Ø Vesicular disease surveillance
- Ø Prohibited items airport screening
- Ø Pre-export quarantines
- Ø Monitoring health of animals at import
- Ø Smuggling Interdiction and Trade Compliance (SITC)
- Ø Modeling, assessment, and geospatial analyses
- Ø Emergency veterinary assistance response corps

International Activities

USDA also conducts ongoing international activities in support of FMD eradication and to bolster preparedness planning and response capabilities.

- Hemispheric collaboration
- International coordination
- Global Foot-and-Mouth Disease Research Alliance (GFRA)
- Emergency veterinary assistance to other countries
- OIE-member country

USDA Organizational Strategy

- APHIS employs NIMS and the Incident Command System (ICS) organizational structures to manage a response to an FAD outbreak.
- ICS is designed to enable efficient and effective domestic incident management by integrating facilities, equipment, personnel, procedures, and communications operating within a common organizational structure.

APHIS Incident Management Structure

- The APHIS Administrator is the Federal executive responsible for implementing APHIS policy during an FMD outbreak, supported by
  - APHIS Management Team (AMT),
  - Emergency Preparedness Committee (EPC), and
  - VS Deputy Administrator and Chief Veterinary Officer (VSDA-CVO).
- An APHIS-level Multi-program Committee (MPC), or a USDA Multiagency Coordination group (MAC), may be established to coordinate resources.

APHIS MPC

- Likely formed early on with the expectation that an FMD response needs robust support
- To prioritize the sharing and use of critical resources
- Establishes supportive relationships among the agencies preparing for and responding to an FMD outbreak
- Could expand to a multiagency command to include representatives from USDA agencies or other government agencies in a complex response

MPC/MAC Functions

- MPC/MAC functions are executed at various levels, and typically include:
  - the coordination of policy,
  - incident priorities,
  - resource allocation and acquisition, and
  - resolution of issues common to all parties.
- The size and scope of the FMD incident dictates what levels and types of coordinating groups and functions are required.

APHIS ICG and IC Structure

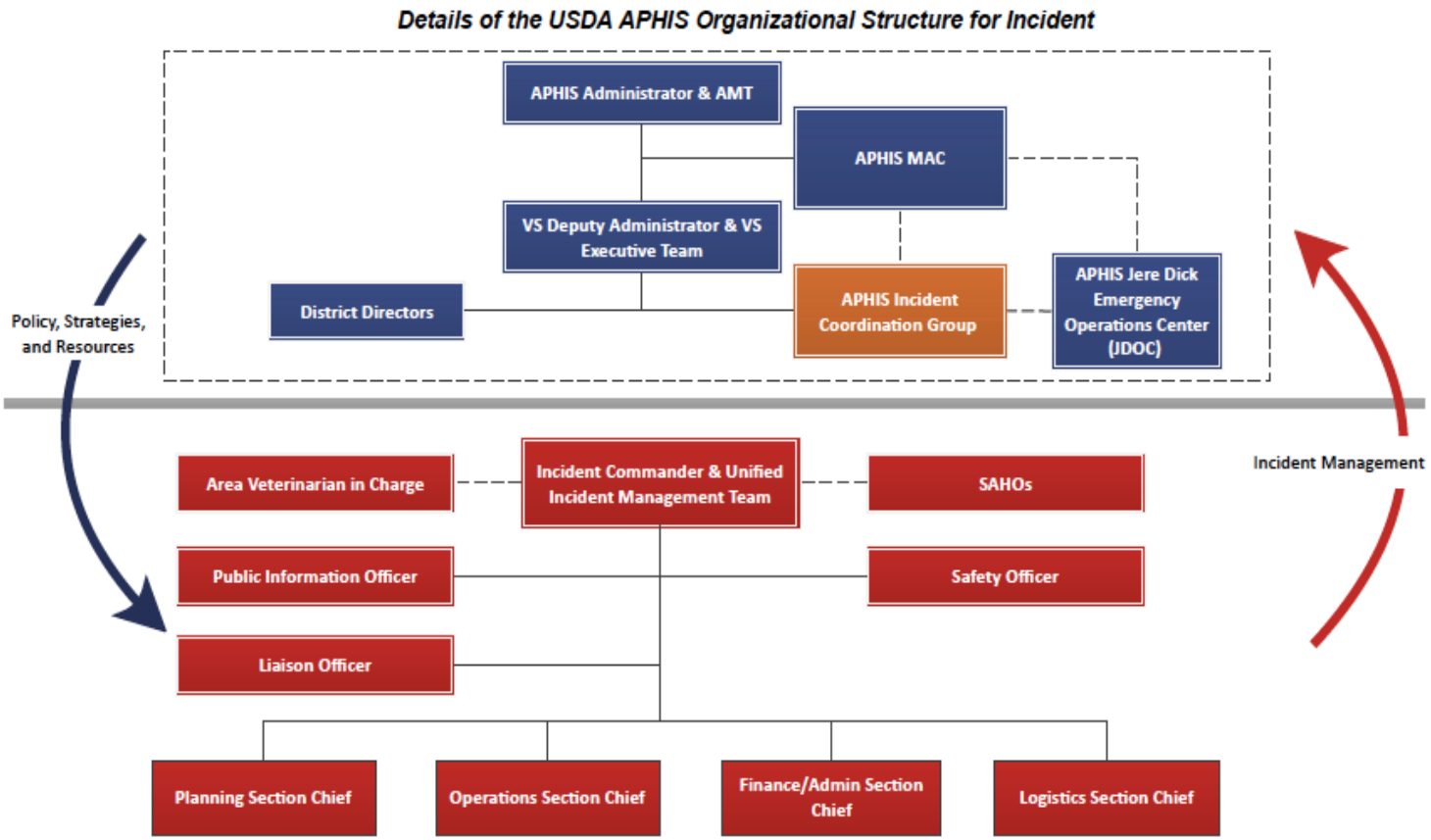
- An APHIS ICG is immediately established to oversee the functions and response activities associated with the incident.
- The ICG coordinates with any MPC or MAC established at the APHIS or USDA level.
- The ICG coordinates with Co-Incident Commanders in a unified IC structure.
  - State Animal Health Official (SAHO) and the VS Area Veterinarian in Charge (AVIC), or their designees

APHIS Incident Coordination Group

APHIS ICG responsibilities in an FMD outbreak include

- formulating policy options,
- assisting in implementing response and recovery strategies,
- providing situational awareness,
- ensuring responder and public health and safety,
- supporting IMTs and their requirements,
- assisting in coordinating resources and integrating other organizations into the ICS, and
- providing information to the Joint Information Center (JIC) for use in media and stakeholder briefings.

APHIS Multi-program Coordination, Incident Coordination Group, and Incident Command Structures



Incident Management and Organizational Structure

- The actual organizational structure for an incident will be specific to the needs of the incident.
- The field configuration would include a unified incident command and NIMT plus needed positions.
- APHIS will consider various strategies to supplement response personnel, either novel concepts or those utilized in recent animal disease outbreak responses.

Federal Coordination: USDA and DHS/FEMA

- Organization of multiple Federal Departments in support of an animal disease event depends upon the magnitude of the event.
- During the course of an FMD outbreak response, USDA may request Federal-to-Federal support as necessary from other Federal agencies.
- The Secretary could request DHS to manage coordination of Federal resources; USDA would maintain the lead of overall incident management.

Diagnostic Resources and Laboratory Support
National Veterinary Services Laboratories (NVSL)

NVSL is the official reference laboratory for FAD diagnostic testing and study in the United States.

- NVSL provides *all* confirmatory testing for FMD, including those found presumptively positive at a National Animal Health Laboratory Network (NAHLN) laboratory.
- It has two locations for FAD diagnostic testing:
  - Ames, IA (NVSL-Ames).
  - Foreign Animal Disease Diagnostic Laboratory (FADDL), Plum Island, NY (NVSL-FADDL).
- By 2023, NVSL-FADDL will move to the National Bio and Agro-Defense Facility (NBAF) in Manhattan, Kansas.

Diagnostic Resources and Laboratory Support
National Animal Health Laboratory Network

- Consists of 59 laboratories, of which 45 are approved to perform FMD diagnostic testing.
- Coordinates the veterinary diagnostic laboratory capacity of State animal health 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.

Diagnostic Resources and Laboratory Support

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.

FMD RESPONSE PLAN

Response Goals and Strategy

Response Goals

The goals of an FMD response are to:

- detect, control, and contain FMD in livestock as quickly as possible;
- eradicate FMD using strategies that seek to protect public health and the environment, and stabilize animal agriculture, the food supply, and the economy; and
- provide science- and risk-based approaches and systems to facilitate continuity of business for non-infected animals and non-contaminated animal products.

Critical Activities

- Public communication and messaging campaign
- Swift imposition of quarantine and movement controls
- Stringent and effective biosecurity measures
- Rapid diagnosis and reporting
- Epidemiological investigation and tracing
- Increased surveillance
- Continuity of business measures for non-infected premises and non-contaminated products (Secure Food Supply Plans)
- Rapid mass depopulation and euthanasia
- Effective and appropriate disposal procedures
- Virus elimination measures
- Emergency vaccination (as the response strategy indicates)

Coordinated Public Awareness Campaign

- Occurs in conjunction with any response strategy or strategies.
- Engages and leverages State-Federal-Tribal-stakeholder relationships to provide unified public messages for all audiences.
- Addresses issues and concerns relating to food safety, public health, and animal welfare.
- Addresses issues and concerns related to interstate commerce, continuity of business, and international trade.

Epidemiological Principles

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

- Prevent contact between FMDV and susceptible animals.
- Stop the production of FMDV by infected or exposed animals.
- Increase the disease resistance of susceptible animals to the FMDV or reduce the shedding of FMDV in infected or exposed animals.

U.S. FMD Vaccination Policy

- The use of emergency vaccination strategies may be considered in an FMD outbreak.
- An FMD response may use a variety of vaccination strategies in order to detect, control, contain, and ultimately eradicate FMD in domestic animals.
- The use of emergency vaccination will be determined by the VSDA/CVO, the SAHO, and the incident Unified Command.

Response Strategy for Control and Eradiation of FMD in Domestic Livestock

- There are several generally accepted strategies for the control and eradication of FMD in domestic livestock following an outbreak.
  - Stamping-out
  - Stamping-out modified with emergency vaccination to kill
  - Stamping-out modified with emergency vaccination to slaughter
  - Stamping-out modified with emergency vaccination to live
  - Emergency vaccination to live without stamping-out

Stamping-Out
Definition

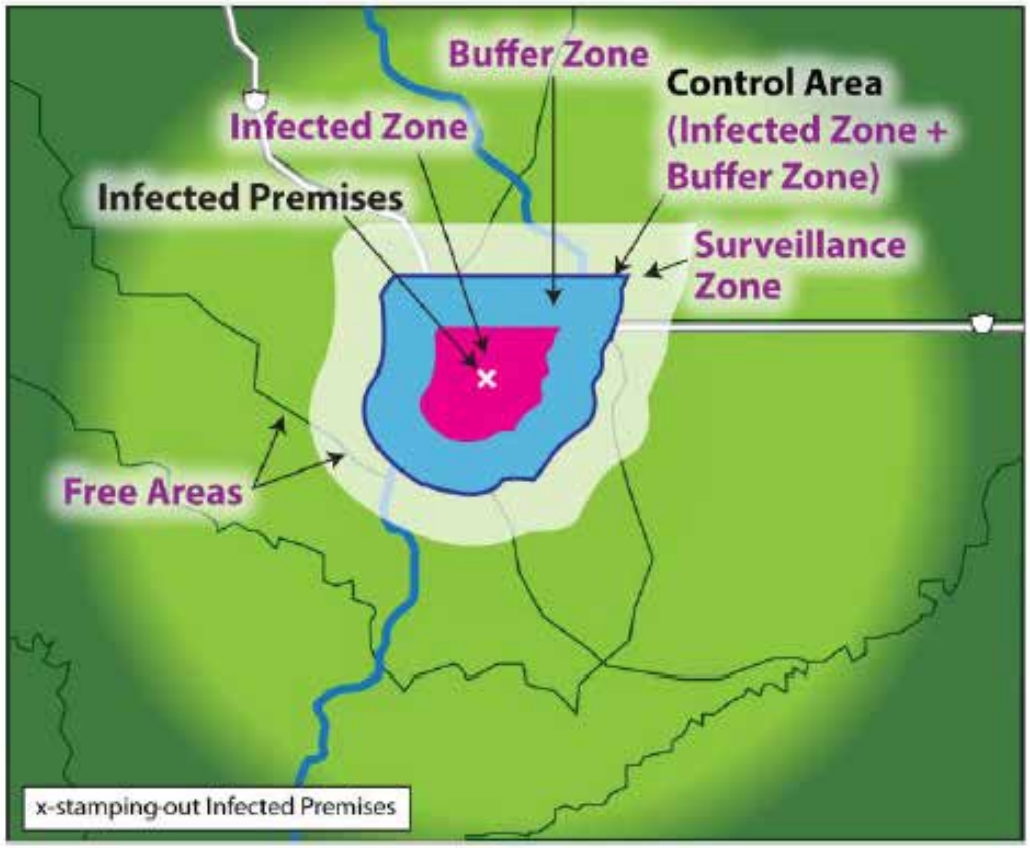
"Stamping-out" is defined in the OIE *Terrestrial Animal Health Code* as the:

killing of animals which are affected and those suspected of being affected in the herd and, where appropriate, those in other herds which have been exposed to infection by direct animal to animal contact, or by indirect contact with the causal pathogen; this includes all susceptible animals, vaccinated or unvaccinated, on infected establishments.

Stamping-Out

- The goal is to depopulate infected livestock in the quickest, safest, and most humane way possible.
  - Ideally within 24 hours after a presumptive positive classification
- Premises are prioritized so that those with the highest potential for FMD spread are stamped-out first.
- Public concerns about stamping-out require a proactive public relations and liaison campaign.
  - Stakeholders, the public, and the international community must be involved.

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



Note: Figure is not to scale.

Stamping-Out Modified with Emergency Vaccination to Kill or Slaughter

- The goal is to suppress virus replication in high-risk susceptible animals by using emergency vaccination
  - then depopulate or slaughter vaccinates at a later date, as determined by IC and the VSDA/CVO.
- Ring or regional vaccination around an infected premises or infected zone exemplifies this strategy.
- For movement to slaughter, DIVA testing may be necessary.

Examples of Zones and Areas in Relation to Stamping-Out Modified with Emergency Vaccination to Kill or Slaughter

(Infected Premises would be depopulated)

Emergency Vaccination in Infected Zone

Emergency Vaccination in Buffer Zone

Examples of Zones and Areas in Relation to Stamping-Out Modified with Emergency Vaccination to Kill or Slaughter

(Infected Premises would be depopulated)

Emergency Vaccination in Control Area

Emergency Vaccination in Infected Zone and Partial Buffer Zone

Note: Figures are not to scale.

Stamping-Out Modified with Emergency Vaccination to Live

- 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.
- It involves 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.

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

(Infected Premises would be Depopulated)

Note: Figure is not to scale.

Emergency Vaccination to Live
without Stamping-Out

- This strategy involves the emergency vaccination of susceptible animals, with no intention of slaughtering or depopulating these animals later solely because of their vaccination status.
- It is unlikely to be employed initially but might be relied upon in the course of an FMD outbreak reaching endemic status.

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

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.

Factors Influencing the Selection of Response Strategy

- Consequences of the outbreak
- Acceptance of response policy
- Scale of the outbreak
- Rate of outbreak spread
- Availability of vaccine
- Resources available to implement response strategies

Emergency Vaccine Sourcing

Two mechanisms exist by which the United States is supplied with FMD vaccine.

- Ø North American Foot-and-Mouth Disease Vaccine Bank (NAFMDVB) [U.S. has 70% share]
  - An initial order could provide 70% of 1.75-2.5M doses in 10-14 days.
- Ø National Animal Vaccine and Veterinary Countermeasures Bank (NAVVCB)
  - 2.5M doses in 10-14 days, with subsequent shipments every 10-14 days, as available.
  - Vaccine acquisition is underway, with a goal of 10 and 25 million doses of each of the 10-12 highest risk strains to North America.

Emergency Vaccine Sourcing
Vaccination Campaign Considerations

- If the matched vaccine doses available from the banks are all used and a vaccine campaign is desired, additional vaccine could be manufactured.
  - There may be a gap in vaccine receipt as the production period for newly manufactured vaccine is 14 weeks.
  - Vaccine could then be received in continuously in large batches of as much as 1M doses per week (for all of North America).
  - A contractual commitment for 40-80 million doses would be required.

Emergency Vaccine Sourcing
Expanding Vaccine Capabilities

- If an appropriately matched vaccine is not available, a new vaccine may need to be developed and tested.
  - This could take many months.
- In 2018, the Secretary of Agriculture authorized the movement of a modified, non-infectious version of the FMD virus onto the U.S. mainland for continued vaccine development and study.
- Novel vaccine technologies on a variety of different platforms are currently being pursued both commercially and within Federal-government research institutions.

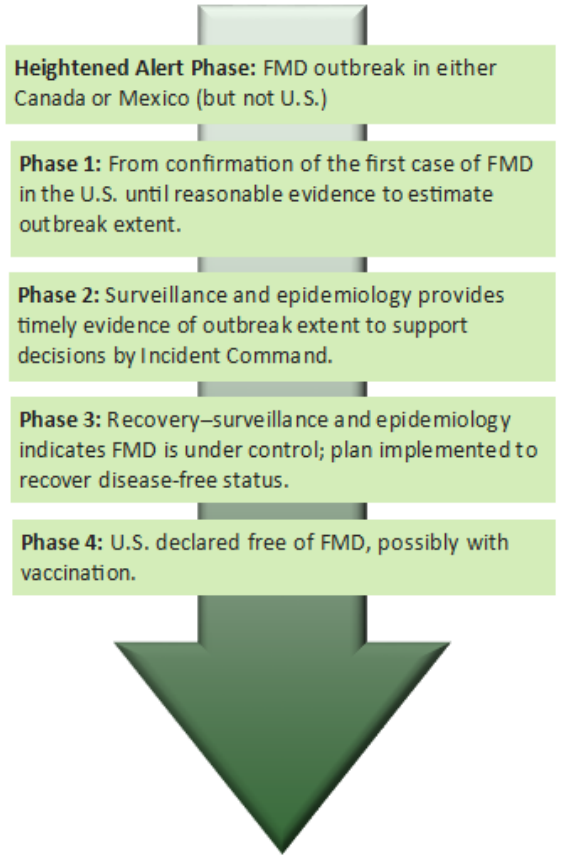
Phases and Types of FMD Outbreaks
Types of Outbreaks

- Having pre-defined phases and types may be useful as reference points to facilitate development and implementation of emergency response plans and processes.
- The phase (temporal) and type (extent) of the FMD outbreak will change over time.
- Type can loosely defined in a continuum as follows:

Phases and Types of FMD Outbreaks
Phases of Outbreaks

Phases are progressive.

1. Confirmed—confirmation to initial assessment of extent
2. Continued—surveillance and epidemiology underway to support incident management
3. Controlled—plan implemented to recover disease-free status
4. Freedom declared—possibly with vaccination



FMD Country Status Designations

The OIE has six official country recognitions for FMD:

- FMD-free **country** where vaccination **is not** practiced;
- FMD-free **country** where vaccination **is** practiced;
- FMD-free **zone** where vaccination **is not** practiced;
- FMD-free **zone** where vaccination **is** practiced
- FMD-free **compartment**; and
- FMD-infected country or zone.

OIE Minimum Time to FMD-Free Designations

- To recover *free* status, minimum time requirements apply in coordination with surveillance efforts and other documentation.
  - *3 months, if stamping-out*
    - *after the last animal killed*
  - *3 months, if stamping-out modified with emergency vaccination to slaughter*
    - *after the slaughter of all vaccinated animals*
  - *6 months, if a stamping-out modified with emergency vaccination to live*
    - *after the last case or last vaccination*

OIE Min Time to FMD-Free Designations (cont'd)

- *12 months, if stamping-out is not applied or is discontinued*
  - *but where a continued vaccination policy has been adopted, after the last vaccination*

Ø To apply for FMD freedom <u>with vaccination</u>

- 24 months after the last case, if stamping-out is not employed and vaccination is continuing

Surveillance for Recognition of Disease-Freedom

A country re-applying for country or zone freedom from FMD where vaccination is practiced or not practiced should show evidence of an active surveillance program for FMD as well as absence of FMDV infection/circulation.

These general surveillance conditions and methods for FMD are found in the OIE *Terrestrial Animal Health Code.*

Release of Control Area (CA) Restrictions

- Quarantine and movement controls will be maintained until at least 28 days have elapsed since the decontamination of all confirmed IP and negative results of surveillance activities.
  - If vaccination was used in the outbreak, vaccinates may still be subject to movement control and monitoring measures after CA release.
- Infected premises will remain vacant for a period of time before restocking susceptible animals.
  - The minimum recommendation is 21 days.

Country Freedom Declaration Caveat

- 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.

FMD RESPONSE PLAN

Critical Activities and Tools

Case Definitions
Suspect

An FMD-susceptible animal that has either

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

Case Definitions

Presumptive Positive

A suspect case that has both

- Ø epidemiological information indicative of FMD; AND
- Ø positive laboratory test results
  - – 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

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

Surveillance Goals

- Implement surveillance plans within 48 hours of the confirmation of an outbreak that
  - (1) define the present extent of FMD 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.
- 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 movement into and out of a control area.

Surveillance Plan Objectives

- Leverage available resources, satisfy jurisdictional requirements, and support implementation of COB measures.
- Consider the appropriate levels of surveillance in susceptible wildlife population in the area.
  - coordinated with representatives from APHIS Wildlife Services, DOI, State wildlife agencies and agriculture departments
- Provide guidance for complete surveillance data summaries and analysis at intervals specified by IC.

Surveillance Planning for FMD Outbreak

- A surveillance plan is 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, and
  - many other factors.

Surveillance Objectives by Time Period

- The initial 72 hours post-FMD outbreak declaration
  - Detect existing infected animals and premises as quickly as possible, and determine the size and extent of the FMD outbreak.
- The control and eradication period
  - From initial 72-hour period until last case is detected and depopulated.
  - Revise or prioritize ongoing control and surveillance activities to allow for permitted movement and, ultimately, provide evidence that the Free Area is free of disease.
- Post-eradication period
  - Prove disease freedom in control area (CA) and free area (FA) are free of disease.
- Additional surveillance, as needed, to restore international trade

Diagnostics

During an FMD outbreak, the key goals of response are to:

1. provide clear direction to responders on sample collection and processing procedures
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 *FAD Investigation Manual (FAD PReP Manual 4-0)* offers detailed information on diagnostic sample collection, diagnostic testing, and reporting.

Diagnostics After FMD Detection

- Ø Confirmation of FMD on any premises not currently in an FMD CA will be done by NVSL-FADDL.
  - – After NVSL confirmation of FMD on a premises (index case), subsequent swab samples for rRT-PCR may be sent to NAHLN network laboratories.
- Ø IC will provide specific instructions regarding the direction and collection of samples, which is likely to change as the outbreak evolves. In all cases,
  - – NVSL will confirm the index case,
  - – presumptive positive samples (on a rRT-PCR) from outside an established CA will be tested and confirmed by NVSL, and
  - – NVSL will receive samples routinely from *inside* the CA to monitor for changes in the FMDV.

Surge Capacity

- Additional capacity and resources for sample collection, such as personnel and materials, will be needed in an FMD outbreak.
- Adequate surge capacity can help facilitate a rapid response and continuity of business 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.

Reporting and Notification

- Cases of clinical illness that are confirmed positive by 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 OIE.
- Appropriate Federal-State-Tribal-industry response and containment measures will be initiated during FMD investigations.

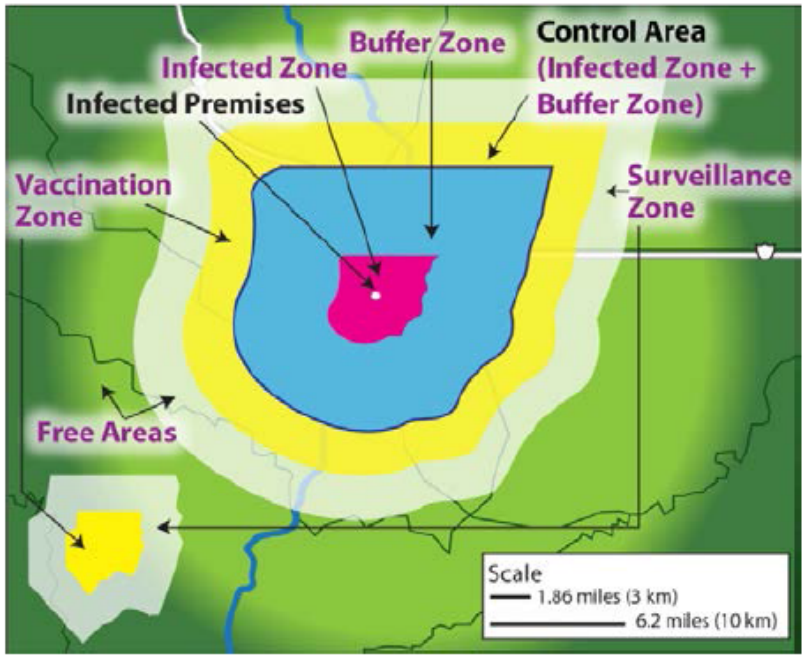
Zone, Area, and Premises Designations

Zone/Area	
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)	Either a Containment Vaccination Zone (inside a Control Area) or a Protection Vaccination Zone (outside a Control Area)

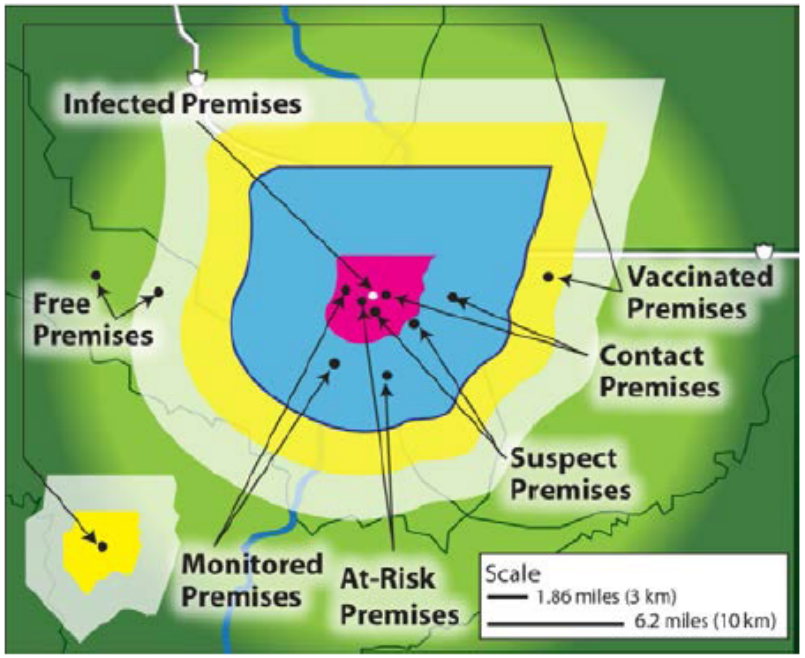
Premises	
Infected Premises (IP)	Premises with a presumptive or confirmed positive case
Contact Premises (CP)	Premises with susceptible animals that may have been exposed to FMD
Suspect Premises (SP)	Premises under investigation
At-Risk Premises (ARP)	Premises with susceptible animals, but none with clinical signs
Monitored Premises (MP)	Premises that is not an IP, CP, or SP—eligible for permitted movement
Free Premises (FP)	Premises outside of CA and not a CP or SP
Vaccinated Premises (VP)	Premises where vaccination has been performed

Example of Zones, Areas, and Premises in FMD Outbreak Response

Zones and Areas



Premises



Note: The Vaccination Zone can be either a Protection Vaccination Zone or Containment Vaccination Zone. Stamping-out is not pictured in these figures. The Surveillance Zone is part of the Free Area.

Infected Zone | Buffer Zone | Vaccination Zone | Surveillance Zone

Epidemiological Investigation

- Ø Epidemiological investigation and movement tracing during an outbreak are critical in controlling and eradicating FMD.
- Ø In an FMD outbreak, the goals are to
  - within 6 hours of identifying potential IP or CP through tracing activities, assign a premises classification and a priority of investigation; and
  - within 24 hours of identifying the IP or initial CP, identify all additional CP;
  - within 96 hours of identifying the index case, characterize the nature of the FMD outbreak, identify the risk factors for transmission, and develop mitigation strategies.

Tracing

- One of the most important activities during an FMD outbreak is to rapidly and diligently trace-back and trace-forward movements from an IP.
- Tracing aids in the control of the spread of FMD 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 also includes consideration of all potential modes of transmission and possible contact with wildlife.

Sizing a Control Area

- 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.

Information Management

- Accurate information management and reporting during an FMD incident ensures that leadership, responders and stakeholders have timely critical emergency response information for decision-making.
- EMRS2 is the official system of record for animal health incidents in the United States.
- Having accurate premises data in EMRS2 significantly facilitates response efforts, reporting, and resource tracking.

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.

Communication

- Establish a network of stakeholders and systems for communication prior to an incident or outbreak.
- Brief the media, public, industry, Congress, trading partners, and others on the FMD outbreak status and the actions being taken to control and eradicate the disease.
- Coordinate with Federal, State, and local agencies, Tribal entities, producer groups, and land grant university-based cooperative extensions.

Communication Objectives

Ø 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; address rumors, inaccuracies, and misperceptions as quickly as possible; and
- Take into account social media.

Key Communication Messages

- For consumers:
  - FMD does not cause disease in humans.
  - Meat and meat products are safe to eat.
  - Milk and dairy products are safe to eat.
  - We are responding quickly and decisively to eradicate the virus.
  - Meat and meat products from vaccinated animals are safe to eat.
  - Milk and dairy products from vaccinated animals are safe to eat.
- For producers:
  - Protect your herds with good biosecurity practices.
  - Be vigilant about reporting signs of illness.

Health and Safety and PPE

- During an FMD outbreak, responders are exposed to many hazards, particularly in working with heavy equipment and large animals.
- To ensure responders are safe and physically prepared for the rigors of their deployment assignment, they need to receive medical clearance.

- All workers involved in the handling, culling, transport, or disposal of items or animals infected with FMDV must be provided with appropriate PPE.

Mental Health Concerns

- FMD depopulation efforts can significantly affect the health of responders, livestock owners, and others impacted by the response efforts.
- Preserving the health and safety of those involved in a disease response effort includes addressing their mental states.
- HHS has developed resources specifically for emergency and disaster responders.

https://emergency.cdc.gov/coping/index.asp

Biosecurity

- Strict biosecurity measures need to be implemented to prevent or slow the spread of FMD.
- Biosecurity procedures should be
  1. Observed on all premises, even before an outbreak; and
  2. reviewed and enhanced within 24 hours of the identification of an index FMD case.
- Proper biosecurity measures have two functions:
  - containing the virus on IP (biocontainment); and
  - preventing the introduction of the virus via movement of personnel and material to naïve livestock and premises (bioexclusion).

FMD Biosecurity Hazards and Appropriate Biosecurity Measures

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

Biosecurity
Closed Herds

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

Quarantine and Movement Control

- Quarantine and movement control can be a powerful tool in controlling and eradicating an FMD outbreak
  - by restricting the movement of infected animals, animal products, and contaminated fomites.
- A 24- to 72-hour national standstill notice is likely to be implemented upon the initial finding of FMD.
- Subsequent movement control is accomplished through a permit system that allows movements without creating an unacceptable risk of disease spread.

Movement Standstill

- All movements of susceptible animals that are in progress when a national/regional movement standstill is announced should continue to move.
  - Destination premises should accept these movements.
- Exceptions may be made for critical movements.
- A national/regional movement standstill notice does not affect movement of milk.
  - Premises may continue moving milk to processing.
- A national movement standstill notice does not include any products produced from an FSIS-inspected establishment that are already at the establishment.

Permitted Movement

- Surveillance measures are required for movement of livestock and animal products for premises located in the CA.
- 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.

Moving Commodities, Animals, Conveyances

- Each State's animal health emergency response plan should describe the implementation of quarantine and movement controls.
- Because of the variation in the risk of the commodities, animals, and conveyances, it is possible that premises—particularly monitored and at-risk premises—are permitted to move one commodity, animal, or conveyance but not another.

Continuity of Business (COB)

- COB is the management of non-infected premises and non-contaminated animal products in the event of an FMD outbreak.
- Secure Food Supply Plan recommendations help animals and products keep moving during the outbreak.
  - These plans are at various stages in development.
- Successful COB efforts require collaboration between States (both sending and receiving product), the Unified Incident Command, and APHIS.

SPS SECURE PORK SUPPLY

SMS SECURE MILK SUPPLY

SBS SECURE BEEF SUPPLY

SSWS SECURE SHEEP AND WOOL SUPPLY

Regionalization for Trade

- 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.

Mass Depopulation and Euthanasia

The FAD PReP *Mass Depopulation and Euthanasia SOP* offers FMD-specific information on mass depopulation and euthanasia, including evaluation of various euthanasia methods, such as

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

Mass Depopulation and Euthanasia

- States should prepare in advance for the depopulation method(s) it will use and the resources it will need.
  - The National Veterinary Stockpile is unable to provide contracted labor for large animal handling or depopulation (at present).
- For planning purposes, reference the AVMA-published *Guidelines for the Depopulation of Animals*.

Disposal

- 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.
- 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.

Disposal Methods

- Disposal methods include
  - on-site burial
  - composting,
  - landfill
  - incineration, and
  - rendering.

APHIS' Carcass Management Dashboard is now available at www.aphis.usda.gov. It provides options and a time & cost calculator to aid in disposal planning.

- 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.

Cleaning and Disinfection

- Aggressive cleaning and disinfection practices are required for control and eradication due to FMD's high survival rate on both organic and inorganic materials.
- Because the aerosol transmission of FMD is a concern, care should be taken to reduce the generation and dispersal of potentially infective dust and aerosols.
- Cleaning and disinfection (or virus elimination activities) are to be conducted as quickly as is possible—ideally, within 48 hours of the disposal of depopulated animals.

Challenges of FMD Vaccination

In addition to having a sufficient quantity of vaccine that can be delivered quickly, effectively implementing a vaccination strategy and plan requires many additional resources.

- 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

Challenges of FMD Vaccination
Need for a Vaccine 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.

Challenges of FMD Vaccination
Developing a Vaccine Plan

Ø The State vaccine request should

- Include an estimate of the number of vaccine doses desired in the first shipment (first two weeks), and subsequent shipments; and
- Be based on all susceptible animals in the State, or of the population for which vaccine is planned, e.g., dairy cattle.

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			

Challenges of FMD Vaccination

Movement Restrictions for Vaccinates

- Animals receiving emergency vaccination may be subject to vaccinated animal identification, traceability, and DIVA testing.
- When vaccine is used, surveillance must continue to assess vaccination effectiveness and detect any antigenic change.
- Vaccinated premises will be subject to any national or international standards or conditions for such movement and may be subject to the movement restrictions of their primary premises designation.

Logistics—National Veterinary Stockpile

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.

Contact the NVS:

For routine questions, NVS@USDA.gov

For emergencies, 800-940-6524

Wildlife Management and Vector Control

- An assessment of the risk that wildlife poses for the transmission of FMDV to susceptible livestock will be conducted within 7 days of confirmation of the index case.
- If wildlife populations are determined to be infected with FMDV, appropriate wildlife management principles will be applied as needed to reduce exposure of wildlife to livestock.
- FMDV can be transmitted mechanically by mice, vultures, and other vectors.

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.
- 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.
  - Selective and/or welfare depopulation followed by controlled slaughter of recovered animals.

Appraisal and Compensation

- Indemnity payments are authorized to encourage disease reporting, reduce the spread of animal disease, and compensate owners on the basis of fair market value.
- 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.

Finance

- For responding to specific emergency situations, VS has access to a variety of sources for funding. The two most common sources are the APHIS Contingency Fund (CF) and the Commodity Credit Corporation (CCC).
- USDA APHIS will engage in supplemental or emergency cooperative agreements with States for conducting FAD control measures.

Incident Management

- The capability to rapidly scale up the size of an IC and integrate veterinary functions and countermeasures is critical for an effective FAD response. NRF and NIMS 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 the National Association of State Animal Health Officials, and the APHIS FAD PReP website.

www.aphis.usda.gov/fadprep

FAD PReP Supporting Documents and Materials

- Strategic Plans—Concept of Operations
- National Animal Health Emergency Management System (NAHEMS) Guidelines
- Industry Manuals
- Disease Response Plans
- Standard Operating Procedures (SOP) for Critical Activities
- Ready Reference Guides

www.aphis.usda.gov/fadprep