



FOOT-AND-MOUTH DISEASE RESPONSE PLAN

THE RED BOOK

https://web.archive.org/web/20170211080406/https://www.aphis.usda.gov/animal_health/acah/downloads/documents/FMD_Response_Plan_November_2010_FINAL.pdf (checked 4 April 2021)

FAD PReP

Foreign Animal Disease Preparedness & Response Plan



**National Center for Animal
Health Emergency Management**



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

Executive Summary

This *Foot-and-Mouth Disease Response Plan* (2010) has changed significantly from the *Foot-and-Mouth Disease Preparedness and Response Plan: Summary Response Plan to the Detection of FMD in the United States* (2008). The objectives of this plan are to (1) identify the capabilities needed to respond to an FMD outbreak, (2) identify the critical activities that will be involved in responding to that outbreak and time-frames for these activities. These critical activities will be the responsibility of Incident Command in an outbreak situation. This plan promotes agricultural security, protects the food supply, and guards animal health by providing strategic guidance on responding to an FMD outbreak. Developed by the National Center for Animal Health Emergency Management of the Animal and Plant Health Inspection Service (APHIS), the plan gives direction to emergency responders at the local, State, Tribal, and Federal levels to facilitate FMD control and eradication efforts in livestock in the United States. This plan is intended to complement, not replace, existing regional, State, Tribal, local, and industry plans.

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

The goals of an FMD response are to (1) detect, control, and contain FMD in animals as quickly as possible, (2) eradicate FMD using strategies that seek to stabilize animal agriculture, the food supply, 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. 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.

During an FMD outbreak response effort, many activities—such as tracing, surveillance, biosecurity, quarantine and movement control, and depopulation—must occur in a deliberate, coordinated fashion. In addition to providing strategic

direction on these various activities, this plan explains the underlying Incident Command System structure, applying *National Response Framework* (NRF) and *National Incident Management System* (NIMS) principles and systems to control and contain an outbreak of FMD in domestic livestock, and ultimately eradicate FMD.

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

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

This response plan is carefully integrated with other FAD PReP documents, including FMD standard operating procedures, FAD PReP checklists, and National Animal Health Emergency Management System guidelines. Together, these documents provide a comprehensive preparedness and response framework for an FMD outbreak.

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

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

Contents

Preface	xiii
Chapter 1 Introduction	1-1
1.1 PURPOSE OF DOCUMENT.....	1-2
1.2 AUDIENCE	1-2
1.3 RELATED DOCUMENTS	1-2
1.4 PRINCIPLES OF FAD PREP	1-4
Chapter 2 FMD Information	2-1
2.1 ETIOLOGY	2-1
2.2 HISTORY AND GLOBAL DISTRIBUTION.....	2-2
2.2.1 Prevalence of Serotypes.....	2-2
2.2.2 Threat of FMD in the United States	2-3
2.2.3 International Trade.....	2-3
2.3 IMPACT OF AN FMD OUTBREAK.....	2-3
2.3.1 Economic.....	2-3
2.3.2 Public Health Implications.....	2-4
2.4 ECOLOGY OF FMD.....	2-4
2.4.1 Carriers	2-5
2.4.2 Introduction and Transmission.....	2-5
2.4.3 Persistence in Environment and Animal Products	2-6
2.5 DIAGNOSIS	2-6
2.5.1 Clinical Signs	2-7
2.5.2 Gross Pathological Lesions	2-8
2.5.3 Differential Diagnoses.....	2-8
2.6 IMMUNITY	2-8
2.6.1 Natural Infection.....	2-8
2.6.2 Vaccination	2-9
Chapter 3 Framework for FMD Preparedness and Response.....	3-1
3.1 NRF, NIMS, AND NAHEMS INTEGRATION	3-1
3.1.1 NRF	3-1

3.1.2 NIMS.....	3-1
3.1.3 NAHEMS	3-2
3.1.4 Coordination and Collaboration	3-2
3.2 FEDERAL ROLES, RESPONSIBILITIES, AND PLANNING ASSUMPTIONS	3-3
3.2.1 Overview.....	3-3
3.2.2 USDA Roles and Responsibilities Overview.....	3-3
3.3 AUTHORITY.....	3-4
Chapter 4 USDA FMD Preparedness and Response.....	4-1
4.1 USDA	4-1
4.1.1 Preparedness Exercises	4-1
4.1.2 Domestic Activities.....	4-2
4.1.3 International Activities.....	4-3
4.1.4 International Trade.....	4-3
4.1.5 Compartmentalization	4-4
4.2 USDA ORGANIZATIONAL STRATEGY.....	4-4
4.3 APHIS INCIDENT MANAGEMENT STRUCTURE	4-5
4.3.1 Multi-Agency Coordination Group.....	4-7
4.3.2 National Incident Coordination Group.....	4-7
4.3.3 Organization for a Single Event	4-7
4.3.4 Organization for Multiple Events	4-8
4.3.5 Guidance on Incident Management and Organizational Strategy	4-9
4.4 APHIS INCIDENT MANAGEMENT LEVELS.....	4-9
4.5 NATIONAL ANIMAL HEALTH EMERGENCY RESPONSE CORPS	4-10
4.6 DIAGNOSTIC RESOURCES AND LABORATORY SUPPORT	4-10
4.6.1 National Veterinary Services Laboratories.....	4-10
4.6.2 National Animal Health Laboratory Network	4-11
4.6.3 Center for Veterinary Biologics	4-11
Chapter 5 General FMD Response.....	5-1
5.1 RESPONSE GOALS AND STRATEGY.....	5-1
5.1.1 Goals	5-1
5.1.2 Strategies for Control and Eradication of FMD in Domestic Livestock.....	5-1
5.1.3 Coordinated Public Awareness Campaign in Support of Response	5-3

5.1.4 Strategy A: Stamping-Out.....	5-3
5.1.5 Strategy B: Stamping-Out Modified with Emergency Vaccination to Slaughter	5-4
5.1.6 Strategy C: Stamping-Out Modified with Emergency Vaccination to Live	5-5
5.1.7 Strategy D: Emergency Vaccination to Live without Stamping-Out Policy	5-5
5.2 U.S. OUTBREAK RESPONSE POLICY.....	5-6
5.2.1 Desired FMD-Status Post-Outbreak	5-6
5.2.2 Factors Influencing Regulatory Intervention and Selection of Response Strategy	5-9
5.2.3 NAMFDVB Guidelines and FMD Vaccine Decision Tree	5-11
5.3 ZONES, AREAS, AND PREMISES IN RELATION TO FMD RESPONSE STRATEGIES	5-13
5.4 IMPLEMENTING VACCINATION STRATEGIES: AN EXAMPLE OF A LARGE-SCALE FMD OUTBREAK.....	5-18
5.5 SPECIFIC STRATEGIES FOR CONTAINMENT, CONTROL, AND ERADICATION	5-21
5.5.1 Authorization.....	5-21
5.5.2 Incident Management	5-22
5.5.3 Timeline in any FMD Response for First 72 Hours	5-22
5.5.4 Control and Eradication Strategy for Other Animals	5-23
5.6 INTERNATIONAL STANDARDS FOR FMD.....	5-23
5.6.1 Recognition of Disease-Free Status	5-23
5.6.2 Criteria Needed for FMD-Free Status	5-24
Chapter 6 Specific FMD Response Critical Activities and Tools.....	6-1
6.1 ETOLOGY AND ECOLOGY	6-1
6.2 LABORATORY DEFINITIONS AND CASE DEFINITIONS	6-1
6.2.1 Laboratory Definitions	6-1
6.2.2 Case Definitions.....	6-3
6.2.3 Case Definition Development Process.....	6-4
6.3 SURVEILLANCE	6-4
6.3.1 Surveillance Planning for FMD Outbreak.....	6-5
6.3.2 Surveillance Sampling	6-7

6.4	DIAGNOSTICS	6-10
6.4.1	Sample Collection and Diagnostic Testing.....	6-10
6.4.2	Surge Capacity	6-14
6.4.3	Reporting	6-14
6.5	EPIDEMIOLOGICAL INVESTIGATION AND TRACING	6-14
6.5.1	Summary of Zones, Areas, and Premises Designations.....	6-14
6.5.2	Epidemiological Investigation.....	6-16
6.5.3	Tracing.....	6-17
6.5.4	Considerations for Size of Control Area.....	6-17
6.5.5	Considerations for Size of Other Zones	6-19
6.6	INFORMATION MANAGEMENT	6-19
6.7	COMMUNICATION	6-20
6.7.1	Objectives	6-20
6.7.2	Key Messages	6-20
6.7.3	Further Communications Guidance	6-21
6.8	HEALTH AND SAFETY AND PERSONAL PROTECTIVE EQUIPMENT	6-21
6.8.1	Mental Health Concerns	6-22
6.8.2	Further Information on Health, Safety, and PPE	6-22
6.9	BIOSECURITY	6-23
6.9.1	Biosecurity Hazards and Mitigating Measures	6-23
6.9.2	Closed Herds	6-24
6.9.3	Waiting Period	6-24
6.10	QUARANTINE AND MOVEMENT CONTROL.....	6-24
6.10.1	Zones, Areas, and Premises Designations	6-25
6.10.2	Permit Guidance to Move within Control Area.....	6-25
6.10.3	Permit Guidance to Move Out of Control Area	6-26
6.10.4	Moving Commodities, Animals, and Conveyances in FMD Outbreak	6-28
6.10.5	Guidance for All Premises.....	6-28
6.10.6	Quarantine and Movement Controls for Products and Fomites.....	6-28
6.10.7	Surveillance Required for Livestock and Product Movement	6-30
6.10.8	OIE Treatment Guidelines for FMD	6-30
6.11	CONTINUITY OF BUSINESS	6-33

6.12 REGIONALIZATION AND COMPARTMENTALIZATION (INTERNATIONAL TRADE)	6-34
6.13 MASS DEPOPULATION AND EUTHANASIA	6-34
6.14 DISPOSAL.....	6-35
6.15 CLEANING AND DISINFECTION	6-36
6.16 VACCINATION.....	6-37
6.16.1 DIVA Testing	6-38
6.16.2 NAFMDVB Guidelines for Use of Vaccination in FMD Outbreak.....	6-39
6.16.3 Zone, Area, and Premises Designations.....	6-51
6.16.4 Movement Restrictions for Vaccinates	6-54
6.16.5 Cessation of Vaccination.....	6-55
6.17 NATIONAL VETERINARY STOCKPILE	6-55
6.18 WILDLIFE MANAGEMENT AND VECTOR CONTROL	6-55
6.18.1 Wildlife Management.....	6-56
6.18.2 Vector Control	6-56
6.19 ANIMAL WELFARE	6-56
6.20 MODELING AND ASSESSMENT TOOLS	6-57
6.21 APPRAISAL AND COMPENSATION	6-57
6.22 FINANCE.....	6-58
6.23 NATIONAL RESPONSE FRAMEWORK AND NATIONAL INCIDENT MANAGEMENT SYSTEM	6-59
Chapter 7 Recovery after FMD Outbreak.....	7-1
7.1 PROOF OF FREEDOM.....	7-1
7.1.1 Recognition of Disease-Free Status	7-1
7.1.2 Criteria Needed for FMD-Free Status	7-1
7.1.3 Surveillance for Recognition of Disease Freedom	7-9
7.1.4 Release of Control Area Restrictions.....	7-10
7.1.5 Disposition of Vaccinates.....	7-10
7.1.6 Country Freedom Declaration.....	7-10
7.2 REPOPULATION.....	7-11
7.2.1 Restocking Guidance.....	7-11
7.2.2 Testing Requirements for Restocking	7-11
7.2.3 Approved Sources of Livestock	7-11

-
- Appendix A FAD PReP Materials to Support FMD Response**
 - Appendix B Incident Management**
 - Appendix C Laboratory Network List for Foot-and-Mouth Disease**
 - Appendix D North American Foot-and-Mouth Vaccine Bank Guidelines for FMD Vaccine Use**
 - Appendix E Updated FMD Outbreak Surveillance Guidance and Rationale**
 - Appendix F Procedures for FMD Investigation and Specimen Submission**
 - Appendix G Epidemiological Investigation Questionnaire**
 - Appendix H Examples of Movement Control Notices**
 - Appendix I Secure Milk Supply Plan**
 - Appendix J Information on FMD Vaccines and Vaccination**
 - Appendix K Glossary**
 - Appendix L Abbreviations**
 - Appendix M References**

Figures

Figure 1-1. FAD PReP Suite of Documents and Materials	1-4
Figure 2-1. Distribution of FMD Serotypes Worldwide	2-2
Figure 4-1. APHIS Headquarters, MAC, Emergency Operations Center, and Incident Management Team Organizational Structure (Assuming Single Incident).....	4-6
Figure 4-2. APHIS Incident Management Structure (Assuming Multiple Incidents and Unified Area Commander).....	4-8
Figure 4-3. Incident Management Levels	4-9
Figure 5-1. North American Guidelines for FMD Vaccine Use	5-13
Figure 5-2. Examples of Zones and Areas in Relation to Stamping-Out Policy (All Infected Premises would be depopulated).....	5-15
Figure 5-3. Examples of Zones and Areas in Relation to Stamping-out Policy Modified with Emergency Vaccination to Slaughter (All Infected Premises would be depopulated)	5-16

Figure 5-4. Examples of Zones and Areas in Relation to Stamping-Out Policy Modified with Emergency Vaccination to Live (All Infected Premises would be depopulated).....	5-17
Figure 5-5. Examples of Zones and Areas in Relation to Vaccination to Live Policy without Stamping-Out.....	5-18
Figure 5-6. Notional Map #1	5-19
Figure 5-7. Notional Map #2	5-20
Figure 5-8. Notional Map #3	5-20
Figure 5-9. Critical Activities in First 72 Hours of U.S. FMD Outbreak.....	5-23
Figure 6-1. Developing an FMD Outbreak Surveillance Sampling Scheme	6-9
Figure 6-2. Diagnostic Flowchart for Initial Investigation of FMD	6-11
Figure 6-3. Outbreak Diagnostics after Positive Confirmation of FMD in United States	6-13
Figure 6-4. Example of Zones, Areas, and Premises in FMD Outbreak Response (Left: Circle; Right: Irregular)	6-16
Figure 6-5. Premises Designations in Relation to Permitting and Movement Control	6-27
Figure 6-6. Examples of Containment Vaccination Zones	6-52
Figure 6-7. Examples of Protection Vaccination Zones (Left: Circle, Right: Irregular).....	6-53
Figure 6-8. Vaccinated Premises (Left: Containment Vaccination Zone, Right: Protection Vaccination Zone)	6-54

Tables

Table 5-1. Factors Influencing a Response Strategy or Strategies for U.S. FMD Outbreak.....	5-10
Table 5-2. Summary of Premises.....	5-14
Table 5-3. Summary of Zones and Areas	5-15
Table 6-1. Summary of Premises.....	6-15
Table 6-2. Summary of Zones and Areas	6-15
Table 6-3. Factors Used to Determine Control Area Size for FMD	6-18
Table 6-4. Movement Control into, within, and out of Control Area for At-Risk Premises and Monitored Premises.....	6-29

Table 6-5. Movement Control into or out of Control Area for Infected Premises or Suspect Premises	6-30
Table 6-6. Scoring System for Vaccine Distribution Decision Based on Criteria Related to Outbreak (from Chapter 11 NAFMDVB Guidelines).....	6-50

Preface

This Foreign Animal Disease Preparedness and Response Plan (FAD PReP) provides operational guidance for dealing with an animal health emergency caused by foot-and-mouth disease (FMD) in the United States. This *Foot-and-Mouth Disease Response Plan* (2010) replaces the *Foot-and-Mouth Disease Preparedness and Response Plan: Summary Response Plan to the Detection of FMD in the United States* (2008). Many sections of this plan such as appraisal and compensation, vaccination, information management, and business continuity require further discussion and development with stakeholders.

This draft plan is under review. During the review process, which ends **February 15, 2011**, please send questions or comments to the following:

National Center for Animal Health Emergency Management
Veterinary Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
4700 River Road, Unit 41
Riverdale, MD 20732-1231
Telephone: (301) 734-8073
Fax: (301) 734-7817
E-mail: FAD.PReP.Comments@aphis.usda.gov.

Every effort is made to provide accurate and useful information. However, the U.S. Government, the U.S. Department of Agriculture (USDA), and the Animal and Plant Health Inspection Service (APHIS) and employees and contractors assume no legal liability for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed herein. Neither the U.S. Government, USDA, or APHIS, nor do their employees and contractors, makes any warranty (express or implied), including the WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE with respect to documents or information available in these guidelines. All indirect, consequential, implied, punitive, and special damages are deemed waived if you use the information in these guidelines in any manner. The sole remedy is the price paid or, at the seller's choice, replacement or repair of the defective information. Trade names are used solely for the purpose of providing specific information. Mention of a trade name does not constitute a guarantee or warranty of the product by USDA or an endorsement over other products not mentioned.

USDA prohibits discrimination in all its programs and activities on the basis of race, color, national origin, sex, religion, age, disability, political beliefs, sexual orientation, or marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and telecommunications device for the deaf [TDD]).

To file a complaint of discrimination, write USDA, Director, Office of Civil Rights, Room 326-W, Whitten Building, 1400 Independence Avenue SW, Washington, DC 20250-9410 or call (202) 720-5964 (voice and TDD). USDA is an equal opportunity provider and employer.

Chapter 1

Introduction

This *Foot-and-Mouth Disease Response Plan* (2010) has changed significantly from the 2008 version, *Foot-and-Mouth Disease Preparedness and Response Plan: Summary Response Plan to the Detection of FMD in the United States*. The objectives of this plan are to identify the (1) capabilities needed to respond to a foot-and-mouth disease (FMD) outbreak and (2) critical activities that will be involved in responding to that outbreak and their time frames. These critical activities will be the responsibility of Incident Command in an outbreak situation.

To achieve these objectives, this plan provides current information on FMD and its relevance to the United States, and it presents the organizational strategy for an effective FMD response. In addition, it offers guidance on (1) “stamping-out,” a key FMD outbreak response strategy, and (2) emergency vaccination strategies that may be employed. This plan also contains updated strategic guidance on 23 critical response activities and tools, ranging from disposal to appraisal and compensation, to quarantine and movement control. As indicated by links throughout the document, this plan is integrated and coordinated with other new and forthcoming Foreign Animal Disease Preparedness and Response Plans (FAD PReP) documents such as FMD standard operating procedures (SOPs), National Animal Health Emergency Management System (NAHEMS) guidelines, as well as existing Animal and Plant Health Inspection Service (APHIS) memoranda. (Appendix A lists documents related to FMD outbreak response.)

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

FMD is a highly contagious viral disease that may affect domestic cloven-hoofed animals (cattle, swine, sheep, and goats) and many wild animals (deer, bison, pronghorn antelope, and feral swine). The disease is characterized by fever, vesicular (blister-like) lesions, and subsequent erosions (ulcers) of the surfaces of the mouth, tongue, nostrils, muzzle, feet, and teats. FMD is not typically considered a public health risk. It is listed as number two on the National Veterinary Stockpile’s Most Dangerous Disease List and is the most contagious disease of livestock.

The United States has been FMD-free since 1929. However, the disease is still found in about two-thirds of the world. There are many susceptible animals in the United States, including approximately 94.5 million cattle, 67 million swine, and

8.5 million sheep and goats. Although FMD does not typically kill adult livestock, it does have very detrimental effects on productivity (meat and milk). In addition, high mortality rates may occur in young animals.

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

1.1 PURPOSE OF DOCUMENT

This plan is a guiding policy document for U.S. Department of Agriculture (USDA) APHIS and responders at all levels. It provides current policy information and a strategic framework for the control and eradication of FMD in the event of an outbreak in the United States.

1.2 AUDIENCE

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

1.3 RELATED DOCUMENTS

This disease-specific response plan is not a standalone document, but part of a comprehensive U.S. preparedness and response strategy for foreign animal disease (FAD) threats, such as FMD, in the United States. This preparedness and response framework consists of different types of integrated documents. In particular, this response plan is intended to provide specific information about capabilities and critical activities that would be required to respond to an FMD outbreak. This FMD specific plan is carefully integrated with the documents described below. Throughout this plan, there are links to these related FAD PReP documents.

- ◆ Strategic Plans—Concept of Operations
 - *APHIS Framework for Foreign Animal Disease Preparedness and Response:* This document provides an overall concept of operations for foreign animal disease preparedness and response for APHIS, explaining the framework of existing approaches, systems, and relationships.
 - *National Center for Animal Health Emergency Management (NCAHEM) Stakeholder Coordination and Collaboration Plan:* This plan describes NCAHEM strategy for enhancing stakeholder collaboration and identifies key stakeholders.

- *NCAHEM Incident Coordination Group Plan:* This document explains how APHIS headquarters will organize in the event of an animal health emergency.
- ◆ NAHEMS Guidelines and Industry Manuals
 - *NAHEMS Guidelines:* These guidelines cover many of the critical activities, and can be considered as a competent veterinary authority for important preparedness and response information to provide a foundation for APHIS personnel to use in an outbreak response.
 - *Industry Manuals:* These documents describe the complexity of industry to emergency planners and responders and provide industry a window into emergency response.
- ◆ FMD SOPs
 - For planners and responders, these SOPs provide details for conducting 23 critical activities such as disposal, depopulation, cleaning and disinfection, and biosecurity that are essential to effective preparedness and response for an FMD outbreak.
- ◆ FAD PReP Checklists
 - The checklists coordinate with the SOPs to provide planners and responders with functional guidance on critical activities.

In particular, the FMD SOPs and FAD PReP checklists—developed and maintained by the NCAHEM at APHIS—provide detailed guidelines for emergency responders and offer operational details that are not discussed in depth in this strategic disease response plan.

These related documents (Figure 1-1) can be found at the FAD PReP website (<https://fadprep.lmi.org>), where a username and password can be requested. Some documents referenced in this response plan are still under development and will be posted in coming months.

Figure 1-1. FAD PReP Suite of Documents and Materials



1.4 PRINCIPLES OF FAD PReP

The goal of FAD PReP is to integrate, synchronize, and de-conflict preparedness and response capabilities, as much as possible before an outbreak, by providing goals, guidelines, strategies, and procedures that are clear, comprehensive, easily readable, easily updated, and that comply with the National Incident Management System (NIMS).

In order to achieve successful outcomes, FMD preparedness and response should adhere to some general principles—or lessons-learned—of FAD planning.

- ◆ Unified State-Federal-Tribal-industry planning process must respect local knowledge and define stakeholder expectations for successful and timely outcomes.
- ◆ Science-based and risk-management approaches protect public health and animal health, and stabilize animal agriculture, the food supply and the economy.
- ◆ Identify resources and personnel needed for disease outbreaks.
- ◆ Identify and resolve issues that may become competing interests during an outbreak.
- ◆ Early detection and a coordinated, rapid response will mitigate outbreak severity.
- ◆ Unified State-Federal-Tribal-industry command sets clearly defined and obtainable goals; unified command acts with speed and certainty to achieve united goals.

- ◆ Guidelines, strategies, and procedures must be communicated and understood by responders and stakeholders.
- ◆ High expectations for timely and successful outcomes and high consequences for failure require:
 - the rapid scale-up of resources and trained personnel for veterinary activities and countermeasures, and
 - that issues that become competing interests before or during an outbreak are rapidly addressed.
- ◆ FAD tracing is essential for the efficient and timely control of highly contagious FAD outbreaks.

Competing priorities will exist in any FAD response. This response plan helps to resolve and mitigate some of these competing priorities prior to an outbreak by elevating awareness of priorities, identifying resources to accomplish disease control and eradication, and establishing commonly accepted and understood response objectives.

Chapter 2

FMD Information

This chapter provides an overview of FMD and covers the following:

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

Further information on FMD is contained in the FMD SOPs found on the FAD PReP website: <https://fadprep.lmi.org/Design/sops.aspx>.

2.1 ETIOLOGY

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

Chapter 6 includes the case definition for FMD. Additional etiology and ecology information is located in the Overview of Etiology and Ecology of FMD SOP (<https://fadprep.lmi.org/Design/sops.aspx>). This introductory document integrates the latest World Organization for Animal Health (OIE) guidance, information from the most recent version of *Foreign Animal Diseases* (published by the United States Animal Health Association), and the input of subject matter experts.

2.2 HISTORY AND GLOBAL DISTRIBUTION

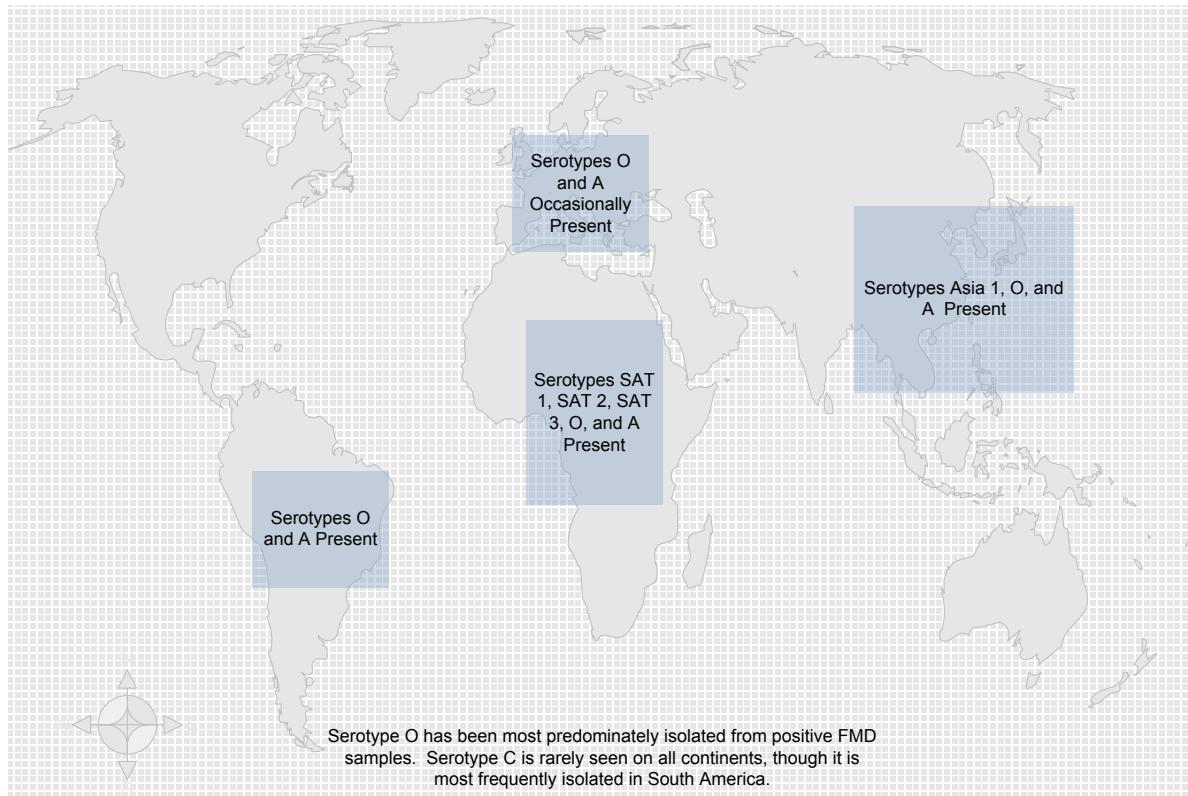
FMD is present in approximately two-thirds of the world and endemic in parts of Africa, Asia, Eastern Europe, the Middle East, and South America. North America (the United States, Canada, and Mexico) and Central America are free of FMD, as is Western Europe, Australia, and New Zealand. In 2010 alone, FMD outbreaks have occurred in Japan, China, Kazakhstan, Botswana, Nigeria, Zimbabwe, South Africa, Namibia, and other countries. Some of these outbreaks occurred outside endemic infection zones.

The United States has not experienced an FMD outbreak since 1929, Canada since 1952, and Mexico since 1954. The EU adopted a non-vaccination policy in 1991.

2.2.1 Prevalence of Serotypes

The seven FMDV serotypes show 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 2-1 maps the distribution of serotypes worldwide, as typically found.

Figure 2-1. Distribution of FMD Serotypes Worldwide



2.2.2 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. It is a critical threat to the United States because of the millions of susceptible cloven-hoofed livestock and wild animals, such as white-tailed deer and feral swine. FMD can be transmitted over long distances by animal products, fomites, people, and other mechanical vectors. FMD is also considered a potential agent for agricultural terrorism.

2.2.3 International Trade

Currently, the United States does not import livestock from countries that are not considered FMD-free. USDA maintains a list of countries and regions considered FMD-free:

http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_fmd.shtml. In addition, the United States takes additional precautions for FMD-free countries that employ import standards less restrictive than those of the United States and countries sharing a border with countries or regions not free of FMD.

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

http://www.fsis.usda.gov/Regulations_&_Policies/index_of_certified_countries/index.asp.

2.3 IMPACT OF AN FMD OUTBREAK

2.3.1 Economic

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

2.3.2 Public Health Implications

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

An FMD outbreak *may* have public health implications from the mental health effects on personnel and individuals associated with the response effort, particularly depopulation and disposal. The effects of an FMD outbreak on mental health may include post-traumatic stress disorder and depression. Support should be made available to those involved, particularly responders and owners of affected livestock.

2.4 ECOLOGY OF FMD

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

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

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

¹ A. R. Spickler, J. A. Roth, J. Galyon, and J. Lofstedt, eds., *Emerging and Exotic Diseases of Livestock*, 4th Ed (Ames, IA: Iowa State University, College of Veterinary Medicine, 2010); Department for Environment, Food, and Rural Affairs (DEFRA), *Foot and Mouth Disease: Commonly Asked Questions*, 2009. Available from <http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/fmd/qanda/index.htm#4> (September 20, 2010).

2.4.1 Carriers

There is no known reservoir for FMD—instead, there is a “carrier state.” FMDV carriers are defined as a “convalescent or sub-clinically infected animal in which FMDV persists in the pharyngeal region for more than 28 days (4 weeks) after infection.”² However, how an animal develops a carrier state and the role of FMD carriers in the infection of susceptible cattle are not well understood.³ Carriers of FMD can include cattle, sheep, goats, and African buffalo, though sheep and goats seem to become carriers less often and for shorter periods than cattle. Most cattle carry the virus for 6 months or less. Persistent infections have 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 whether they had clinical signs of the virus.

2.4.2 Introduction and Transmission

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

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

FMDV can also spread via aerosol transmission under favorable environmental conditions. Pigs, particularly, excrete large amounts of virus through their respiratory tract, which can lead to infectious aerosols that can be inhaled by other animals (typically cattle) in proximity. FMDV has also been known to spread in windborne transmission, where the virus infects animals some miles from known infected animals without any history of contact. The distance of windborne transmission over land surfaces depends on the atmospheric conditions and the amount of virus emitted into the air by the infected animals. Sources suggest FMDV may spread to distances of approximately 60 kilometers over land in favorable

² United States Animal Health Association, *Foreign Animal Diseases*, 7th ed. (Boca Raton, FL: Boca Publications Group, 2008).

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

conditions and potentially even greater distances over water. The conditions for long distance spread are likely to be highly specific, including high relative humidity, steady wind, minimal convection currents, and lack of topographical obstructions. These conditions tend to be met more often over water than over land.

2.4.3 Persistence in Environment and Animal Products

The FMD virus is susceptible to both acid and alkaline pH, and is quickly inactivated by pH < 6.0 and pH > 9.0.⁴ FMDV is preserved by refrigeration and freezing, but progressively inactivated by temperatures above 50 °C. FMDV can survive in frozen bone marrow or lymph nodes for long periods. Higher relative humidity increases the survival time of airborne FMDV. FMDV is resistant to many disinfectants such as hypochlorite and phenol, particularly when organic matter is present.

Meat must be subjected to heat treatment at 70 °C for 30 minutes to ensure FMDV deactivation. Typical industrial processes for salami inactivate the FMD 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 the FMD virus: (1) a sterilization process applying a 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.⁵

FMDV can also persist in wool, hair, and other products for substantial periods. Please refer to the SOP document, Overview of the Etiology and Ecology of FMD, as well as the OIE *Terrestrial Animal Health Code* (2010) for further information (<https://fadprep.lmi.org> and http://www.oie.int/eng/Normes/mcode/en_chapitre_1.8.5.htm).

2.5 DIAGNOSIS

Producers as well as veterinarians should be familiar with signs of vesicular disease, as they may be the initial detectors of an FMD outbreak. The incubation period is typically 2–14 days, depending on the dose of the virus and the route of infection. The OIE *Terrestrial Animal Health Code* (2010) defines the incubation period as 14 days. The incubation period varies between species.

⁴ OIE, *Foot-and Mouth Disease*, Technical Disease Card, 2010, http://www.oie.int/eng/maladies/en_technical_diseasecards.htm.

⁵ OIE, Article 8.5.38 “Procedures for the inactivation of the FMD virus in milk and cream for human consumption,” *Terrestrial Animal Health Code*, 2010, http://www.oie.int/eng/normes/mcode/en_chapitre_1.8.5.htm.

2.5.1 Clinical Signs

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

2.5.1.1 CATTLE

Common signs in cattle include the following:

- ◆ Pyrexia (fever), anorexia, shivering, reduction in milk production for 2–3 days, followed by
 - Smacking of the lips, grinding of the teeth, drooling
 - Excess nasal mucous secretions
 - Lameness, stamping, or kicking caused by vesicles on buccal and nasal mucous membranes or between the claws and coronary band
 - Ruptured vesicles
 - Vesicles on mammary gland
- ◆ 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.

2.5.1.2 PIGS

Typical signs of FMD in pigs include the following:

- ◆ Pyrexia (fever) and blanching of the coronary bands, followed by
 - Severe foot lesions
 - Severe lameness
 - Reluctance to move
 - No drooling
 - Lesions on snout, muzzle, gums, and interdigital spaces

-
- ◆ High mortality in piglets
 - ◆ Possible abortion.

2.5.1.3 SHEEP AND GOATS

Clinical signs of FMD in sheep and goats are typically less pronounced and less 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.

2.5.2 Gross Pathological Lesions

Lesions typically include vesicles or blisters on the tongue, dental pad, gums, cheek, hard and soft palate, lips, nostrils, muzzle, coronary bands, teats, udder, snout of pigs, corium of dewclaws, and interdigital spaces. Post-mortem lesions can be on rumen pillars, as well as in the myocardium. Necrosis may also occur.

Lesions will vary among cattle, swine, and sheep. For extensive pictures demonstrating the aging of FMD lesions, see

<http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/fmd/documents/aging-lesions.pdf>.

2.5.3 Differential Diagnoses

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

2.6 IMMUNITY

2.6.1 Natural Infection

Infection with FMDV causes animals to develop a humoral antibody that is transient and also specific for the subtype of the infecting FMD virus. Approximately 7 to 14 days post-infection, protective antibodies are developed against FMDV

structural proteins. Evidence has not suggested any maternal antibodies are produced.

2.6.2 Vaccination

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

- ◆ Vaccines provide only serotype-specific protection. Vaccination against one serotype may fail to protect fully or at all against other strains within the serotype. This protection depends on
 - the similarity between the field strain and the vaccine, and
 - the potency of the vaccine (more potent vaccines are likely to be protective against even less well-matched strains).
- ◆ Onset of immunity is not immediate. Inactivated FMD vaccines may decrease viral shedding and clinical signs in cattle and sheep in challenge studies as early as 4 days after vaccination with protection improving for the next 2–3 weeks.
 - Swine appear to be more difficult to protect shortly after challenge, limited studies have reported some protection as soon as 3–4 days after vaccination; however, with more severe challenges, pigs may not be completely protected against disease until 21–28 days after vaccination.⁶
- ◆ No currently available vaccine provides “sterilizing immunity” which will prevent subsequent infection.
- ◆ It is possible that individual vaccinated cattle infected with FMDV could become asymptomatic virus carriers.^{7,8}

Differentiating infected from vaccinated animals, known as a “DIVA” strategy, is critical to emergency vaccination in an FMD outbreak. DIVA diagnostic tech-

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

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

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

niques typically use tests for antibodies against viral NSPs to differentiate animals that are infected with FMDV in the field (natural infection) from those that have been vaccinated with an FMD vaccine. This diagnostic DIVA capability is critical for an effective vaccination campaign, business continuity processes, and FMDV surveillance.

Vaccination and DIVA are further discussed later in this document, in the FMD Vaccination SOP, and in the NAHEMS Guidelines: Vaccination (2010). Both the SOP and the guidelines documents are available at <https://fadprep.lmi.org>.

Chapter 3

Framework for FMD Preparedness and Response

3.1 NRF, NIMS, AND NAHEMS INTEGRATION

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

3.1.1 NRF

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

3.1.2 NIMS

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

NIMS consists of five key components:

1. A set of preparedness concepts and principles for all hazards
2. Essential principles for a common operating picture and interoperability of communications and information management
3. Standardized resource management procedures that enable coordination among different jurisdictions or organizations

-
4. Scalability, for use in all incidents (ranging from day to day to large scale)
 5. A dynamic system that promotes ongoing management and maintenance.

3.1.3 NAHEMS

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

Topics addressed in NAHEMS guidelines (and in other FAD PReP documents) include

- ◆ field investigations of animal health emergencies,
- ◆ disease control and eradication strategies and policies,
- ◆ operational procedures for disease control and eradication,
- ◆ site-specific management strategies for various types of facilities,
- ◆ administrative and resource management,
- ◆ health and safety issues, and
- ◆ educational resources.

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

These NAHEMS documents can be found at the FAD PReP website (<https://fadprep.lmi.org>), where a username and password can be requested.

3.1.4 Coordination and Collaboration

This FMD response plan is coordinated with the other FAD PReP documents, which follow NRF and NIMS. This document provides strategic guidance for responding to an FMD outbreak. Other FAD PReP documents provide information on general veterinary activities and include industry or facility manuals for industry stakeholders as well as SOPs and checklists for planners and responders.

Together, these documents provide strategic and tactical details for Federal, State, Tribal, and local officials that are useful for FMD preparedness and response.

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

3.2 FEDERAL ROLES, RESPONSIBILITIES, AND PLANNING ASSUMPTIONS

3.2.1 Overview

Understanding the roles and responsibilities of Federal departments or agencies involved in responding to a domestic incident of foreign animal disease promotes an effective, coordinated emergency response. The subsections that follow describe the roles and responsibilities of the Federal departments and agencies that may be part of an FMD response. The functions described are consistent with the roles and responsibilities outlined in the NRF.

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

3.2.2 USDA Roles and Responsibilities Overview

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

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

- ◆ ESF #3—Public Works and Engineering

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

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

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 Framework for Foreign Animal Disease Preparedness and Response*. (Appendix B of this plan contains an organizational chart showing the coordination between DHS/Federal Emergency Management Agency (FEMA) and USDA in the event of a major FMD outbreak.)

3.3 AUTHORITY

The Animal Health Protection Act (AHPA), 7 U.S. Code 8301 et seq., authorizes the Secretary of Agriculture to restrict the importation, entry, or further movement in the United States or order the destruction or removal of animals and related conveyances and facilities to prevent the introduction or dissemination of livestock pests or diseases. It authorizes related activities with respect to exportation, interstate movement, cooperative agreements, enforcement and penalties, seizure, quarantine, and disease and pest eradication. The act also authorizes the Secretary to establish a veterinary accreditation program and enter into reimbursable fee agreements for pre-clearance abroad of animals or articles for movement into the United States.

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

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

For further information on USDA APHIS authorities, see the *APHIS Framework for Foreign Animal Disease Preparedness and Response*:
<https://fadprep.lmi.org/Design/strategicdocs.aspx>.

Chapter 4

USDA FMD Preparedness and Response

4.1 USDA

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

USDA is the primary Federal liaison to the U.S. animal industry. In addition, it operates the National Veterinary Services Laboratories (NVSL), OIE reference laboratories for identifying and confirming FMD.

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

4.1.1 Preparedness Exercises

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

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

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

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

4.1.2 Domestic Activities

USDA has a variety of preparedness and response activities ongoing both internationally and domestically with respect to FMD. Domestically, USDA works to prevent the introduction of FMD into the country and also conducts FAD investigations as needed for suspected or reported vesicular conditions:

- ◆ *Smuggling Interdiction and Trade Compliance (SITC).* SITC conducts risk management and anti-smuggling activities to prevent unlawful entry and distribution of prohibited agricultural commodities. It looks at domestic markets likely to have illegal imported animal products to establish baseline estimates on how much product is bypassing ports of entry.
- ◆ *National Center for Import Export (NCIE).* NCIE facilitates international trade, monitoring the health of animals presented at the border as well as regulating the import and export of animals and animal products. All cattle must go through a 60-day quarantine before export to the United States. In addition, all cattle (except those from Canada and Mexico) must be quarantine for 30 days at a USDA Animal Import Center. Cattle from countries affected with FMD are not permitted to be imported into the United States.
- ◆ *Vesicular disease surveillance.* USDA rapidly responds to reported or suspected cases of vesicular conditions in the United States with FAD investigations. These investigations are intended to rapidly detect and diagnose any vesicular disease in the United States. APHIS is planning for additional, collaborative surveillance for vesicular diseases.
- ◆ *Other preparedness and training models.* USDA uses various models to develop computer-generated scenarios for FMD. This allows it to evaluate the potential consequences of FMD in the United States, as well as the countermeasures, materials, and supplies needed for control and eradication.
- ◆ *Emergency veterinary assistance.* USDA will work to assist States in training and maintaining State incident management teams and veterinary reserve corps, such as the National Animal Health Emergency Response Corps, NAHERC (Subsection 4.5). State groups will serve as early response teams for an FMD event and can educate groups on the signs, symptoms, and reporting procedures.

4.1.3 International Activities

USDA also conducts international activities in support of FMD eradication:

- ◆ *Hemispheric collaboration.* APHIS works with South American countries in support of FMD eradication and coordinates planning with international organizations, reducing duplication of effort and increasing sociopolitical support for FMD eradication. APHIS offers support for vesicular disease outbreaks and provides resources for diagnostic testing. USDA has contributed significant funds to eradication in South America. In addition, USDA support programs create a buffer zone between North and Central America, which are FMD-free, and South America, which is not.
- ◆ *Global Foot-and-Mouth Disease Research Alliance (GFRA).* USDA's Agricultural Research Service (ARS) also participates in GFRA, a worldwide association of animal research organizations involved in combating FMD. This global alliance creates collaborative partners and results in sharing of progressive FMD control and eradication measures.
- ◆ *Emergency veterinary assistance.* USDA also has sent veterinarians to assist in FMD response efforts at the request of foreign governments. In providing this assistance, USDA not only gains a bank of valuable expertise in FMD response and control efforts, but also helps to ensure the rapid eradication of FMD.

4.1.4 International Trade

USDA, in collaboration with the Department of State and the United States Trade Representative (USTR), will promptly address foreign governments that unjustifiably restrict livestock and livestock product trade in the event of an FMD outbreak.

USDA overseas embassy offices also have guidance on how to rapidly report trade disruptions to Washington, DC, headquarters and how to help foreign officials respond to such events. Multiple USDA agencies, led by the Foreign Agricultural Service (FAS), also respond to trade disruptions, extending communication to U.S. industry. USDA would also respond to any foreign official request for additional scientific assistance, such as case surveillance, movement control measures, and laboratory diagnostics.

These efforts focus on cases where bans are inconsistent with OIE standards. OIE member countries, like the United States, are required to “immediately” notify the OIE in any confirmed FMD case. International standards for FMD *do* allow countries to impose bans on imports from FMD-infected countries and FMD-free countries where vaccination is practiced.

4.1.5 Compartmentalization

In addition to other preparedness tools for an FMD outbreak, compartmentalization may be considered proactively to help ensure continuity of business in the event of an FMD outbreak. Compartmentalization defines subpopulations of distinct health status by management and husbandry practices, as related to biosecurity. Compartmentalization is best implemented, as suggested by the OIE in Article 4.3.1 of the *Terrestrial Animal Health Code* (2010), by trading partners through the establishment of parameters and agreement on necessary measures *before a disease outbreak*.

For compartmentalization to succeed in fostering animal and product movement, the importing country must be satisfied that its animal health status is appropriately protected by the biosecurity measures undertaken by the exporting country. The livestock industry has important responsibilities (including documentation of bio-security measures, movement tracing, surveillance, and quality assurance) if a compartment is to be established.

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

Chapters 4.3 and 4.4 of the OIE *Terrestrial Animal Health Code* (2010) explain the concept and the application of compartmentalization. More information on compartmentalization can be found in the Regionalization and Compartmentalization SOP and Continuity of Business SOP.

4.2 USDA ORGANIZATIONAL STRATEGY

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

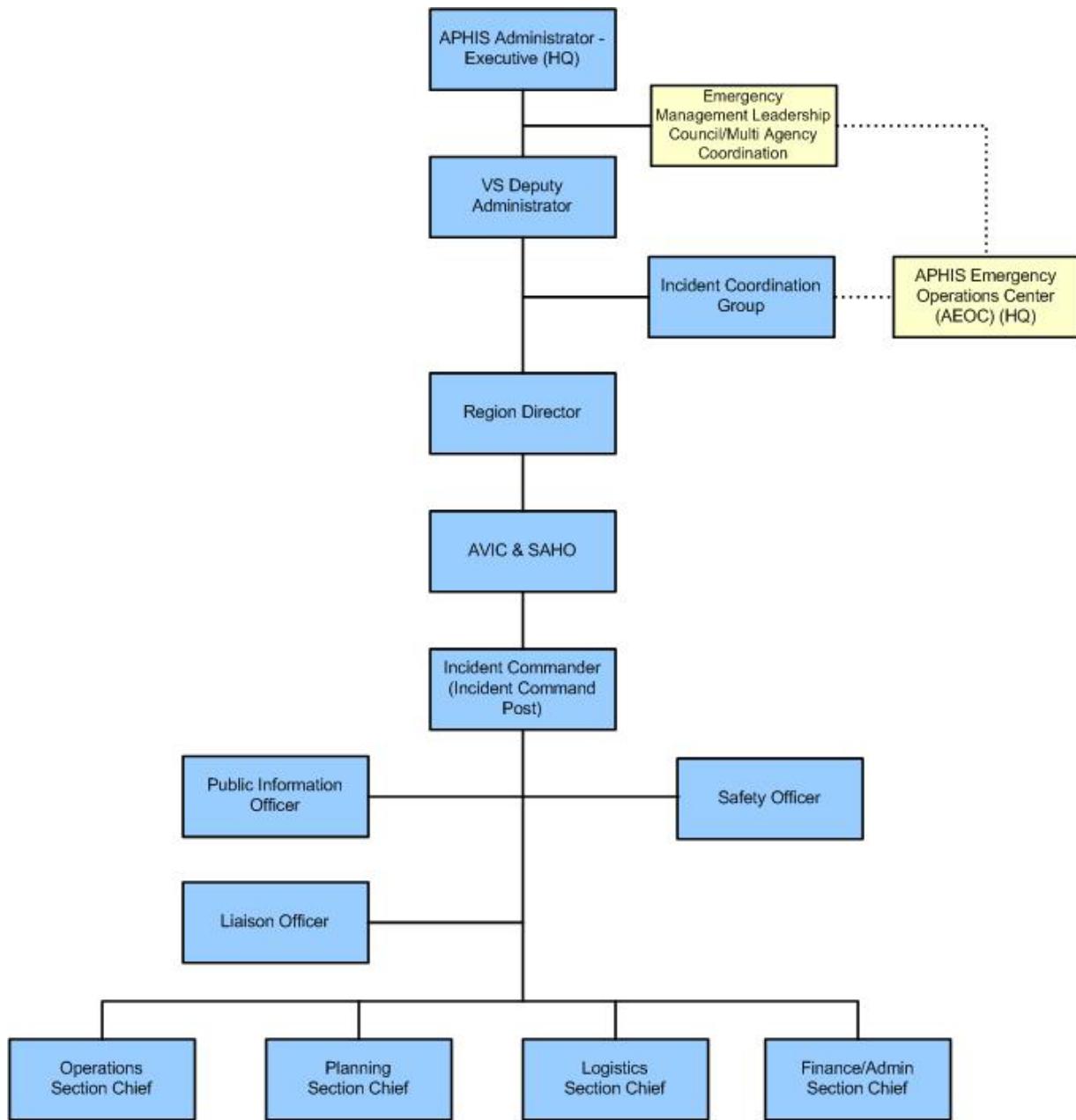
4.3 APHIS INCIDENT MANAGEMENT STRUCTURE

The APHIS Administrator is the Federal executive responsible for managing an FMD outbreak. The APHIS Administrator will delegate much of the actual management of the incident to the Veterinary Services (VS) Deputy Administrator, who is the Chief Veterinary Officer (CVO) of the United States, and the APHIS Emergency Management Leadership Council (EMLC).

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

Figure 4-1 displays the APHIS foreign animal disease incident management organizational structure, starting with the APHIS Administrator.

Figure 4-1. APHIS Headquarters, MAC, Emergency Operations Center, and Incident Management Team Organizational Structure (Assuming Single Incident)



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

The following subsections describe the MAC and National Incident Coordination Group, as well as the APHIS organization for single and multiple events. (Appendix B contains further information and organizational diagrams describing APHIS's Incident Management Structure.) Also, see the *APHIS Framework for Foreign Animal Disease Preparedness and Response* and *NCAHEM Incident Coordination Group Plan* (<https://fadprep.lmi.org/Design/strategicdocs.aspx>).

4.3.1 Multi-Agency Coordination Group

The APHIS *Emergency Mobilization Guide* defines coordination for FMD responses. In the event of an FMD outbreak, the EMLC serves as the APHIS MAC group, unless it decides to transfer responsibility for a specific incident. The MAC group—formed if the FMD response needs more support—establishes supportive relationships among the agencies responding to an FMD outbreak.

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

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

4.3.2 National Incident Coordination Group

The VS or APHIS National Incident Coordination Group is responsible for supporting the ICP and Area Command in acquiring resources, formulating policy, and developing and implementing a response and recovery strategy for an FMD outbreak. For additional information, see the *NCAHEM Incident Coordination Group Plan*. National Incident Coordination Group responsibilities in an FMD outbreak include

- ◆ supporting ICPs and Area Commands,
- ◆ assisting in coordinating resources, and
- ◆ providing information to the Joint Information Center (JIC) for use in media and stakeholder briefings.

4.3.3 Organization for a Single Event

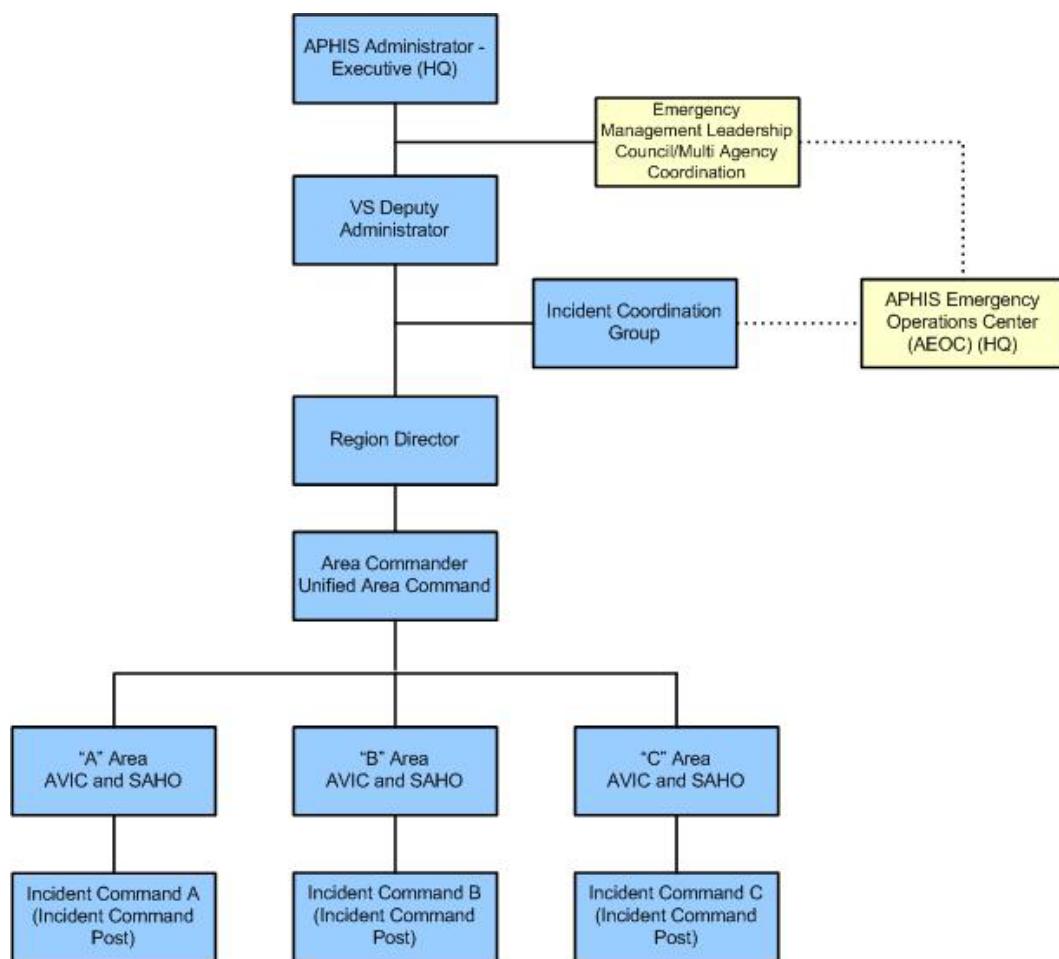
In the event of a single FMD incident, the VS Deputy Administrator and EMLC will initially delegate responsibility for managing the regional incident response to the VS Region Director, who will initially delegate responsibilities for managing the Federal incident response to the Area Veterinarian in Charge (AVIC).

The AVIC and affected State Animal Health Official (SAHO) will initially serve as the co-incident commanders for the unified ICP. The AVIC may be relieved by a VS Incident Management Team Incident Commander if authority is delegated to the VS Incident Management Team.

4.3.4 Organization for Multiple Events

When more than one FMD incident happens simultaneously, more than one ICP may be established. The VS Region Director will establish a Unified Area Command, and the Area Commander will be responsible for managing all the incidents. The AVIC and SAHO for each incident (or the Incident Management Team) will report to the Area Command. Figure 4-2 shows the organization for multiple incidents.

*Figure 4-2. APHIS Incident Management Structure
(Assuming Multiple Incidents and Unified Area Commander)*



If the emergency response becomes too complex for a single National Incident Coordination Group to handle efficiently—for example, a multistate FMD incident with numerous response activities—cooperation with other agencies or committees can be negotiated. As stated previously, this is referred to as multi-agency coordination. USDA's Agricultural MAC (AgMAC) represents USDA. MAC groups make decisions regarding the prioritizing of incidents and the sharing and use of critical resources, but are not a part of the on-scene ICS and are not involved in developing incident strategy or tactics.

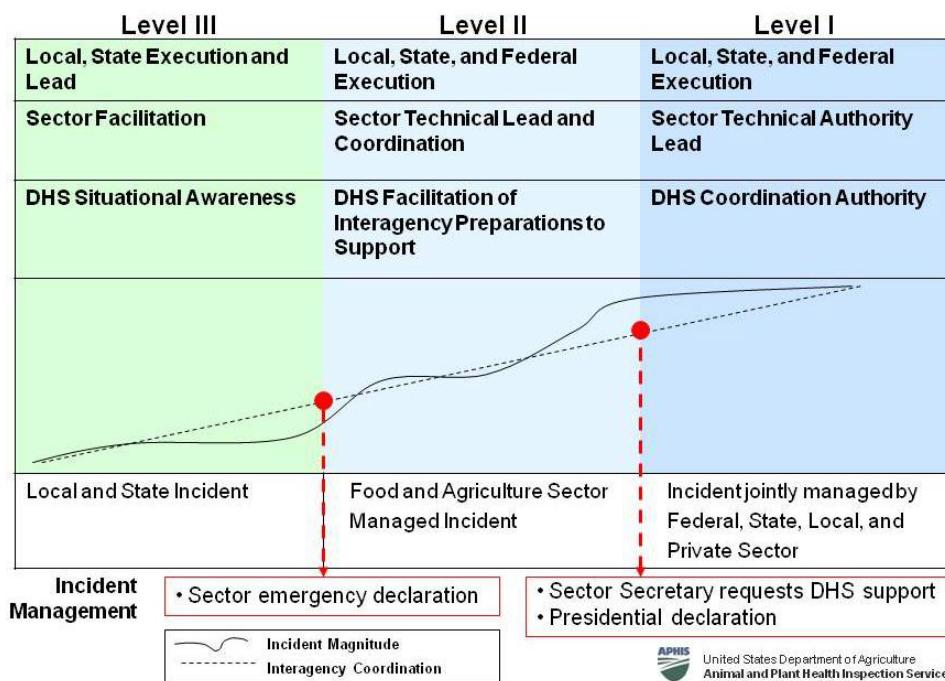
4.3.5 Guidance on Incident Management and Organizational Strategy

For further information on incident management and organizational structure, please see Appendix B, which contains Chapter 5 of the *APHIS Framework for Foreign Animal Disease Preparedness and Response*.

4.4 APHIS INCIDENT MANAGEMENT LEVELS

APHIS uses a three-level system of emergency response types. The levels range from Level III, which has the lowest significance, to Level I, which is an event of national significance. The levels are used within APHIS and externally to communicate the resource requirements for an event or incident. Figure 4-3 illustrates these three incident management levels. Additional information can be found in the *APHIS Emergency Mobilization Guide* and in the *APHIS Framework for Foreign Animal Disease Preparedness and Response*.

Figure 4-3. Incident Management Levels



These levels are as follows:

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

response effort. An equine piroplasmosis outbreak would be a Level III incident.

- ◆ *Level II.* A response to an event or incident that requires resources beyond an area or State's resource capacity but which is within the lead program unit's ability to provide resources to support the response. Requests for additional resources outside the lead program unit are not necessary for a Level II response. However, volunteers will be considered for assignment from outside the unit if they wish to be considered for the assignment, have supervisory approval, and are qualified for the position requested. Typically, a highly pathogenic avian influenza outbreak in domestic poultry would be a Level II event.
- ◆ *Level I.* A response that requires resources or expertise beyond the lead program unit's capacity to respond. In many cases, these emergencies will be of national significance. If the lead program unit lacks qualified resources to meet the response needs, it will make a request through the EMLC to the APHIS Administrator to declare a total mobilization. If qualified volunteers are insufficient, direct assignments will be made. A multistate FMD outbreak would be a Level I event.

4.5 NATIONAL ANIMAL HEALTH EMERGENCY RESPONSE CORPS

In addition to the activities just discussed, NAHERC assists and augments Federal and State response to domestic and international animal disease outbreaks, threats, or natural disasters. NAHERC is composed of veterinarians and veterinary technicians who volunteer to become temporary Federal employees in the event of a national animal health emergency. For further information on NAHERC and NAHERC deployment, see the NAHEMS Guidelines: NAHERC Deployment Guide (2010) (<https://fadprep.lmi.org>).

4.6 DIAGNOSTIC RESOURCES AND LABORATORY SUPPORT

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

4.6.1 National Veterinary Services Laboratories

The NVSL is the official reference laboratory for FAD diagnostic testing and study in the United States. The NVSL performs animal disease testing in support of USDA-APHIS programs designed to protect the health of the Nation's livestock. The NVSL provides 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 are isolated and the serotype and strain identified to determine the vaccine to stock or use for the outbreak. FADDL also assists in testing currently available vaccines.

4.6.2 National Animal Health Laboratory Network

The NAHLN consists of more than 60 laboratories and coordinates the veterinary diagnostic laboratory capacity of State animal health laboratories and their extensive infrastructure, including facilities, equipment, and professional expertise. Of these laboratories, 41 are approved to conduct FMD disease testing diagnostics (Appendix C), including the two NVSL laboratories.

The NAHLN will provide the means for early detection of FMD, rapid response through surge capacity to test outbreak samples, and appropriate recovery by its capability to test large a large number of samples to provide FMD freedom information. Laboratories in the NAHLN can conduct diagnostic testing for outbreak response, though all new cases of FMD outside the established Infected Zone must be confirmed by the NVSL.

4.6.3 Center for Veterinary Biologics

APHIS's Center for Veterinary Biologics (CVB) 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 5

General FMD Response

5.1 RESPONSE GOALS AND STRATEGY

5.1.1 Goals

The goals of an FMD response are to (1) detect, control, and contain FMD in animals as quickly as possible, (2) eradicate FMD using strategies that seek to stabilize animal agriculture, the food supply, 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. 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.

5.1.2 Strategies for Control and Eradication of FMD in Domestic Livestock

There are four possible strategies for the control and eradication of FMD in domestic livestock. Each of these four strategies is supported by critical activities, such as surveillance, biosecurity, cleaning and disinfection, epidemiological tracking, quarantine and movement control, and communication. These strategies are officially recognized by the OIE in Article 8.5.47 of the *Terrestrial Animal Health Code* (2010).

- A. *Stamping-out policy.* Slaughter of all clinically affected and in-contact susceptible animals.
- B. *Stamping-out policy modified with emergency vaccination to slaughter.* Slaughter of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, with subsequent slaughter of vaccinated animals. In the event that animals are not USDA Food Safety and Inspection Service (FSIS) approved for slaughter or vaccinate to slaughter is not feasible because of other conditions, vaccination to kill may be considered after other relevant options.
- C. *Stamping-out policy modified with emergency vaccination to live.* Slaughter of all clinically affected and in-contact susceptible animals and

vaccination of at-risk animals, without subsequent slaughter of vaccinated animals.

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

At this time, any FMD control and eradication strategy in the United States that employs emergency vaccination will involve the North American Foot-and-Mouth Disease Vaccine Bank (NAFMDVB). The SAHO or Tribal official and the APHIS VS Deputy Administrator (the CVO of the United States) must agree on the decision to vaccinate before activating the NAFMDVB. FMD vaccine use in Mexico, Canada, and the United States will follow the guidance of the NAFMDVB, which is jointly administered by the CVOs of Mexico, Canada, and the United States. Chapter 6 of this FMD Response Plan discusses the NAFMDVB and its role in any vaccination strategy, and provides key sections of the NAFMDVB Guidelines (2007).

5.1.2.1 SUPPORTING EPIDEMIOLOGICAL PRINCIPLES

Three supporting epidemiological principles underlie the four response strategies discussed in this chapter:

1. *Prevent contact between FMD virus and susceptible animals.*
 - a. This is accomplished through quarantine of infected animals, movement controls in the Infected Zones and Buffer Zones (Control Areas), and biosecurity procedures to protect non-infected animals.
 - b. Certain circumstances may warrant accelerating the slaughter of animals at risk for exposure to FMD to decrease the population density of susceptible animals.
2. *Stop the production of FMD virus in infected or exposed animals.* This is accomplished by timely slaughter or mass depopulation (and disposal) of infected and potentially infected animals.
3. *Increase the disease resistance of susceptible animals to the FMD virus or reduce the shedding of FMD virus 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.

5.1.3 Coordinated Public Awareness Campaign in Support of Response

A coordinated public awareness campaign must occur in conjunction with any of the four response strategies. This public awareness campaign will support the response strategy by

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

5.1.4 Strategy A: Stamping-Out

Stamping-out has been a common approach in past FMD outbreaks in previously FMD-free countries. This strategy is appropriate if the outbreak is contained to a jurisdictional area or a region in which FMD can be readily contained and further dissemination of the virus is unlikely. Stamping-out is currently defined in the *OIE Terrestrial Animal Health Code* (2010), as

carrying out under the authority of the Veterinary Authority, on confirmation of a disease, the killing of the animals which are affected and those suspected of being affected in the herd and, where appropriate, those in other herds which have been exposed to infection by direct animal to animal contact, or by indirect contact of a kind likely to cause the transmission of the causal pathogen. All susceptible animals, vaccinated or unvaccinated, on an infected premises should be killed and their carcasses destroyed by burning or burial, or by any other method which will eliminate the spread of infection through the carcasses or products of the animals killed.

This policy should be accompanied by the cleansing and disinfection procedures defined in the Terrestrial Code.

The term modified stamping-out policy should be used in communications to the OIE whenever the above animal health measures are not implemented in full and details of the modifications should be given.

Box 5-1 lists the critical elements of stamping-out. The OIE recognizes that if outbreaks cannot be confined to a Containment Zone (equivalent to a Control Area), response strategies other than just stamping-out may be necessary.

Box 5-1. Strategy of Stamping-Out FMD

Stamping-Out: Critical Goals

- Within 24 hours, or as soon as possible, after classification of premises as Infected Premises, the infected and susceptible livestock will be euthanized or depopulated. In many cases, susceptible livestock on Contact Premises must 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. For example, infected swine may be stamped out before cattle.
- Based on an epidemiological assessment, those with clinical signs may be prioritized for depopulation to reduce virus excretion.
- Public concerns about stamping-out will require a well planned and proactive public relations and liaison campaign. Stakeholders, the public, and the international community must be involved.
- Care should be taken to consider mental health implications for owners and responders in the event of stamping-out of livestock.

5.1.5 Strategy B: Stamping-Out Modified with Emergency Vaccination to Slaughter

This strategy involves the slaughter of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, *with* subsequent slaughter of all vaccinated animals.¹ This approach involves the following:

- ◆ A suppressive emergency vaccination strategy.
- ◆ The goal is to suppress virus replication in high-risk susceptible animals by using emergency vaccination and then slaughtering vaccines at a later date as determined by Incident Command and the VS Deputy Administrator (U.S. CVO).
- ◆ The targeted vaccination of high-risk susceptible animals in an Infected Zone, Control Area, or Vaccination Zone.² Ring or regional vaccination around an Infected Premises or Infected Zone is a frequently cited example for this strategy.

¹ Animals FSIS approved for slaughter may be slaughtered. In the event that animals are not FSIS approved for slaughter or vaccinate to slaughter is not feasible because of other conditions, vaccination to kill may be considered after other relevant options.

² See Chapters 2, 6, and Appendix J for more on DIVA.

- ◆ DIVA capability is necessary for movement between zones, interstate commerce, and international trade.
- ◆ Requires vaccinated animal identification, traceability, and an effective, scalable permitting system.

5.1.6 Strategy C: Stamping-Out Modified with Emergency Vaccination to Live

This strategy involves the slaughter of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, *without* subsequent slaughter of vaccinated animals because of their vaccination status. This approach involves the following:

- ◆ A protective emergency vaccination strategy.
- ◆ The goal is to protect susceptible animals from infection using emergency vaccination with the deliberate intent to maintain vaccines 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 Vaccination Zones free of FMD, the establishment of one or more Control Areas for infected animals, and movement controls to keep infected animals out of Vaccination Zones free of FMD.
- ◆ DIVA capability is necessary for movement between zones, interstate commerce, and international trade.
- ◆ Requires vaccinated animal identification, traceability, and an effective, scalable permitting system.

5.1.7 Strategy D: Emergency Vaccination to Live without Stamping-Out Policy

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

outbreak that the decision might be made to switch to this strategy if the disease becomes widespread.

This approach involves the following:

- ◆ A protective emergency vaccination strategy.
- ◆ The goal is to protect susceptible animals from infection with emergency vaccination, with the intention of not slaughtering vaccines at a later date because of vaccination status.
- ◆ Requires the establishment of one or more Vaccination Zones free of FMD, the establishment of one or more Control Areas for infected animals, and movement controls to keep infected animals out of Vaccination Zones free of FMD.
- ◆ DIVA capability is necessary for movement between zones, interstate commerce, and international trade.
- ◆ Requires vaccinated animal identification, traceability, and an effective, scalable permitting system.

5.2 U.S. OUTBREAK RESPONSE POLICY

Choosing one strategy or multiple response strategies in an FMD outbreak, or modifying strategies as an outbreak unfolds, is an important and complex decision process. In the event of FMD detection, USDA and the affected States and Tribal nations will work together in a unified command, per NIMS, to detect, control, and contain FMD as expeditiously as possible. Detection of FMD in the United States will result in emergency intervention by State, Tribal, and Federal authorities. If it becomes apparent at any point in the response that stamping-out will not achieve control, containment, and ultimately eradication of FMD, alternative strategies will immediately be considered. Currently, it is not possible to delineate *a priori* the specific factors that might signal the need to modify the response to an FMD outbreak. However, Subsections 5.2.1 and 5.2.2 list factors that influence a response strategy or strategies and the nature and extent of regulatory intervention in an FMD outbreak. Any response strategy or strategies with emergency vaccination need to be approved by the CVO of the United States prior to implementation.

5.2.1 Desired FMD-Status Post-Outbreak

To select an appropriate response strategy, the U.S. preferred FMD-status post-outbreak and the desired timeline to achieve that status must be considered. The OIE recognizes FMD-free status with and without vaccination in both countries

and zones.³ ([Subsection 5.6](#) details the OIE requirements for FMD-free status for a country or zone.)

5.2.1.1 FMD-FREE DESIGNATIONS

- ◆ *FMD-free country where vaccination is not practiced*
 - The OIE recognizes 65 countries (as of June 2010) as having this OIE status.
 - The United States does not recognize all of these countries as FMD-free for import purposes.⁴
 - This is the most desired outcome after an FMD outbreak, particularly when the country has previously been classified as having this status.
 - Stamping-out is the most efficient strategy for achieving this status though vaccination to slaughter and vaccination to live strategies could achieve this status over a longer period.
- ◆ *FMD-free country where vaccination is practiced*
 - The OIE recognizes one country (as of June 2010) 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.⁵
 - Vaccination to slaughter and vaccination to live strategies could be used to achieve this status over time.
 - This status could be achieved in the interim before an FMD-free country where vaccination is *not* practiced is achieved.
- ◆ *FMD-free zone where vaccination is not practiced*
 - The OIE recognizes 10 zones (as of June 2010) as having this status.

³ OIE, “List of Foot and Mouth Disease Free Members,” 2010,
http://www.oie.int/eng>Status/FMD/en_fmd_free.htm.

⁴ APHIS, USDA, Foot-and-Mouth and Rinderpest: Countries/Regions Free of Foot-and-Mouth Disease (FMD) and Rinderpest, 2010,
http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_fmd.shtml.

⁵ APHIS, USDA, Foot-and-Mouth and Rinderpest: Countries/Regions Free of Foot-and-Mouth Disease (FMD) and Rinderpest, 2010,
http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_fmd.shtml.

-
- The United States recognizes one of these zones as FMD free for import purposes.⁶
 - This is a possible outcome if FMD-free country status is not obtainable.
 - This status could be achieved in the interim before an FMD-free country status where vaccination is *not* practiced is achieved.
 - Stamping-out, vaccination to slaughter, and vaccination to live strategies all could be used to achieve this status over time.
 - ◆ *FMD-free zone where vaccination is practiced*
 - The OIE recognizes six zones (as of June 2010) as 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.⁷
 - Vaccination to slaughter and vaccination to live strategies could be used to achieve this status over time.
 - This status could be achieved in the interim before an FMD-free country where vaccination is *not* practiced is achieved.
 - ◆ *Countries not recognized as FMD free*
 - The remaining OIE member countries, those not recognized as FMD free, are generally considered to be FMD-infected countries.
 - A country will not be recognized as FMD free until the requirements are met for one of the FMD-free classifications, per OIE standards, as described in Subsection 5.6.

5.2.1.2 OIE MINIMUM TIME TO FMD-FREE DESIGNATIONS

If the United States is recovering its free status after an outbreak, the following minimum time requirements apply in coordination with surveillance efforts and other documentation. Subsection 5.6 lists complete requirements from the OIE

⁶ APHIS, USDA, Foot-and-Mouth and Rinderpest: Countries/Regions Free of Foot-and-Mouth Disease (FMD) and Rinderpest, 2010,
http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_fmd.shtml.

⁷ APHIS, USDA, Foot-and-Mouth and Rinderpest: Countries/Regions Free of Foot-and-Mouth Disease (FMD) and Rinderpest, 2010,
http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_fmd.shtml.

Terrestrial Animal Health Code (2010) Article 8.5.9. These time requirements apply to both free countries and free zones where vaccination is not practiced:

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

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

5.2.2 Factors Influencing Regulatory Intervention and Selection of Response Strategy

The scope of regulatory intervention and the selection of a response strategy or strategies in an FMD outbreak will 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 national security, food security, animal health, environment, economy, 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 infected, and susceptible animal population density for infected areas or areas at high-risk of becoming infected with FMDV.
- ◆ *Rate of outbreak spread.* The rate of spread of infection in terms of number of premises, types of premises, number of animals, types of animals; rate at which each Infected Premises leads to infection of one or more additional Infected Premises.
- ◆ *Veterinary countermeasures available.* The availability and efficacy of veterinary countermeasures such as FMD vaccines.
- ◆ *Domestic animal disease management capabilities.* The capability, feasibility, and resources available to eradicate FMD in domestic animals as an

emergency response operation, or control as an animal disease program, or monitor as an endemic animal disease.

- ◆ *Wildlife management capabilities.* The capability, feasibility, and resources available to assess, eradicate, control, or monitor FMD in potential wildlife reservoirs.

Table 5-1 highlights key factors to be considered when determining whether a particular response strategy would be appropriate and advantageous for responding to an FMD outbreak.

Table 5-1. Factors Influencing a Response Strategy or Strategies for U.S. FMD Outbreak

Factor or criterion	Strategy			
	For Stamping Out	For Stamping-Out Modified with Emergency Vaccination to Slaughter	For Stamping-Out Modified with Emergency Vaccination to Live	For Emergency Vaccination to Live without Stamping-Out
Suitable vaccine for FMD outbreak strain	Not available	Available	Available	Available
Resources for stamping-out (such as disposal)	Adequate	Available	Limited	Limited
Resources for vaccination (such as diagnostic testing, tracing efforts, and permitting activities)	Limited	Adequate	Adequate	Adequate
Population density of susceptible animals at high risk of becoming infected	Low	High	High	High
Population density of virus amplifying animals	Low	Moderate	High	High
Movement of infected animals, products, or fomites out of Control Area	No evidence of extensive movement	Evidence of extensive movement	Evidence of extensive movement	Evidence of extensive movement
Origin of outbreak	Known	Unknown	Unknown	Unknown
Location of initial outbreak	Isolated premises	Livestock producing area	Livestock producing area	Livestock producing area
Spread of outbreak	Slow	Rapid	Rapid	Rapid
Distribution of outbreak	Limited or restricted	Widespread	Widespread	Widespread
Risk of infection in valuable, rare, endangered, or high value genetic livestock	High	High	Moderate	Low
Likelihood that FMD could become prevalent in feral swine, deer, or other wildlife	High	High	Moderate	Low
Public reaction to stamping-out policy (may vary by animal species, scale of stamping-out policy, and disease agent)	Neutral reaction or weak opposition	Weak opposition	Strong opposition	Strong opposition

Table 5-1. Factors Influencing a Response Strategy or Strategies for U.S. FMD Outbreak

Factor or criterion	Strategy			
	For Stamping Out	For Stamping-Out Modified with Emergency Vaccination to Slaughter	For Stamping-Out Modified with Emergency Vaccination to Live	For Emergency Vaccination to Live without Stamping-Out
Surveillance, diagnostic, and laboratory resources for serosurveillance after vaccination	Limited	Limited	Available	Available
Domestic stakeholders' acceptance of regionalization with vaccination to live or vaccination to slaughter	No	Yes	Yes	Yes
Third country acceptance of regionalization with vaccination to slaughter	N/A	Accepted	N/A	N/A
Third country acceptance of regionalization with vaccination to live	N/A	Not Accepted	Accepted	Accepted
Assessments and economic analysis of competing control strategies (particularly for producers)	It is likely that a control strategy with emergency vaccination will lead to significantly higher economic losses, or longer duration of the outbreak.	It is likely that a control strategy without stamping-out modified with emergency vaccination to slaughter will lead to significantly higher economic losses or longer duration of the outbreak.	It is likely that a control strategy without stamping-out modified with emergency vaccination to live will lead to significantly higher economic losses or longer duration of the outbreak.	It is likely that a control strategy without emergency vaccination to live will lead to significantly higher economic losses or longer duration of the outbreak.
Impact of vaccination on food supply	Significant negative impact	Neutral impact	Neutral impact	Neutral impact

5.2.3 NAMFDVB Guidelines and FMD Vaccine Decision Tree

Any emergency vaccination strategy employed in the United States, using vaccine from the NAFMDVB, will follow the NAFMDVB Guidelines (2007). (Chapter 6 has more information on vaccination, and Appendix D has further information on the NAFMDVB decision tree.)

5.2.3.1 NAFMDVB EMERGENCY VACCINATION POLICY

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

1. Mexico, Canada, and the United States shall ensure that the use of FMD vaccines is prohibited in their countries except as provided in this Program.

-
- a. Member countries shall ensure that the production, manipulation, storage, supply, distribution and marketing of FMD vaccines are authorized by competent authority and under official control in accordance with their country's legislation.
 - b. Member countries shall ensure that the use of vaccines against foot-and-mouth disease in laboratory investigations is authorized by competent authority and carried out under appropriate biosecurity conditions.
- 2. Notwithstanding the above, it may be decided to use targeted emergency vaccination in specific geographic areas with particular animal husbandry and management characteristics when FMD has been confirmed and threatens to become extensive.
 - 3. Each member country will establish an expert group to evaluate the epidemiological and clinical situation in the event of an outbreak of FMD to determine the:
 - a. Origin of the infection;
 - b. Estimated date of introduction of the FMD virus;
 - c. Possible spread of the disease.
 - 4. The expert group will weigh the factors as described in the North American Decision Tree for FMD Vaccine Use (Appendix 3, p.46) to recommend emergency vaccination to the Chief Veterinary Officer (CVO).
 - 5. In the event that emergency FMD vaccination is considered necessary, affected stakeholders, such as federal, state or provincial and local governments shall be consulted.
 - 6. The CVO(s) of the infected country (ies) will make a recommendation for decision to the Minister or Secretary of Agriculture.
 - 7. The decision to activate the NAFMDVB shall be taken according to the Chapter on Activation, Chapter 17.

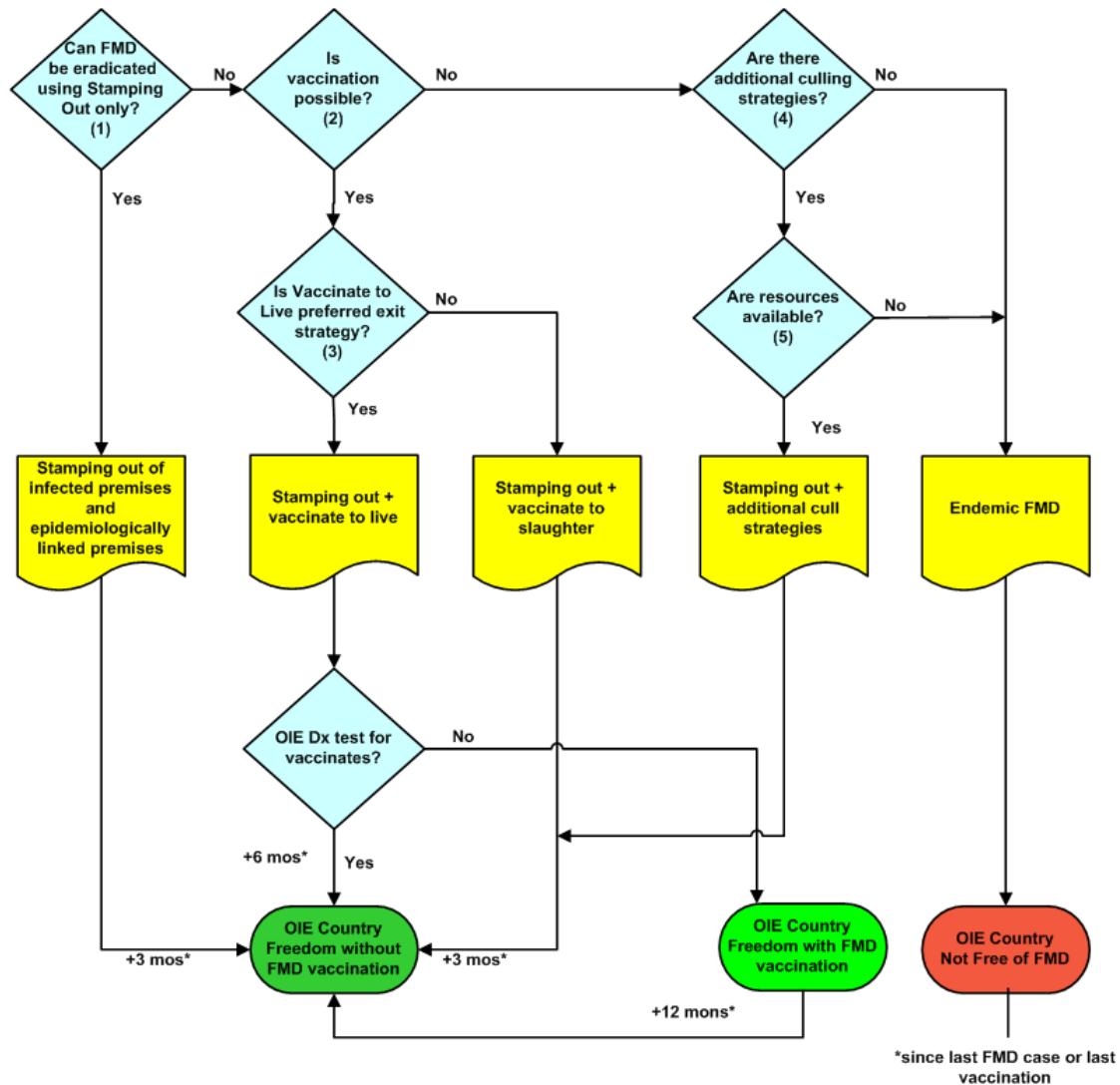
The complete Guidelines are available at
<https://fadprep.lmi.org/Design/diseaseresplans.aspx> and to APHIS employees at
<http://inside.aphis.usda.gov/vs/em/fadprep.shtml>.

5.2.3.2 DECISION TREE

Figure 5-1 shows the NAFMDVB decision tree. Each of the decision boxes in this tree is supported by a decision matrix that weighs factors that will impact the decision node. Appendix D of this FMD Response Plan contains Appendix 3 of the NAFMDVB Guidelines, which details the criteria upon which this tree is based.

This information should be reviewed in coordination with Figure 5-1. (Chapter 6 and Appendix J contain additional scientific information on vaccination.)

Figure 5-1. North American Guidelines for FMD Vaccine Use



5.3 ZONES, AREAS, AND PREMISES IN RELATION TO FMD RESPONSE STRATEGIES

Quarantine and movement control of infected animals, contaminated premises, and contaminated fomites are critical activities in stopping the spread of FMD. Movement control of susceptible animals and animal products within, into, and out of a Control Area is accomplished by risk assessments, surveillance requirements, biosecurity procedures, and permitting.

State or Tribal Nation animal health emergency response plans should describe implementation of quarantine, movement controls, and a permit system.

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

Table 5-2 summarizes the premises designations that would be employed in an FMD outbreak response. Table 5-3 is a compilation of the zones and areas used in an FMD response.

The *APHIS Framework for Foreign Animal Disease Preparedness and Response* (<https://fadprep.lmi.org/Design/strategicdocs.aspx>) provides a complete description of the zones, areas, and premises.

Table 5-2. Summary of Premises

Premises	Definition	Zone
Infected Premises (IP)	Premises where presumptive positive case or confirmed positive case exists based on FMD case definition.	Infected Zone
Contact Premises (CP)	Premises with susceptible animals that have been exposed directly or indirectly to animals, contaminated animal products, fomites, or people from Infected Premises.	Infected Zone, Buffer Zone
Suspect Premises (SP)	Premises with susceptible animals under investigation for a report of compatible clinical signs for FMD.	Infected Zone, Buffer Zone
At-Risk Premises (ARP)	Premises that have susceptible animals, but none of those susceptible animals have clinical signs compatible with FMD. Premises objectively demonstrate that they are not Infected Premises, Contact Premises, or Suspect Premises. At-Risk Premises seek to move susceptible animals or products within the Control Area by permit.	Infected Zone, Buffer Zone
Monitored Premises (MP)	Premises that objectively demonstrate that they are not Infected Premises, Contact Premises, Suspect Premises, or At-Risk Premises. Monitored Premises seek to move susceptible animals or products out of the Control Area by permit.	Infected Zone, Buffer Zone
Vaccinated Premises (VP)	Premises where emergency vaccination has been performed. This is a secondary premises designation.	Containment Vaccination Zone, Protection Vaccination Zone
Free Premises (FP)	Premises outside of the Control Area and not Infected, Contact, Suspect, At-Risk, or Monitored Premises.	Surveillance Zone, Free Area

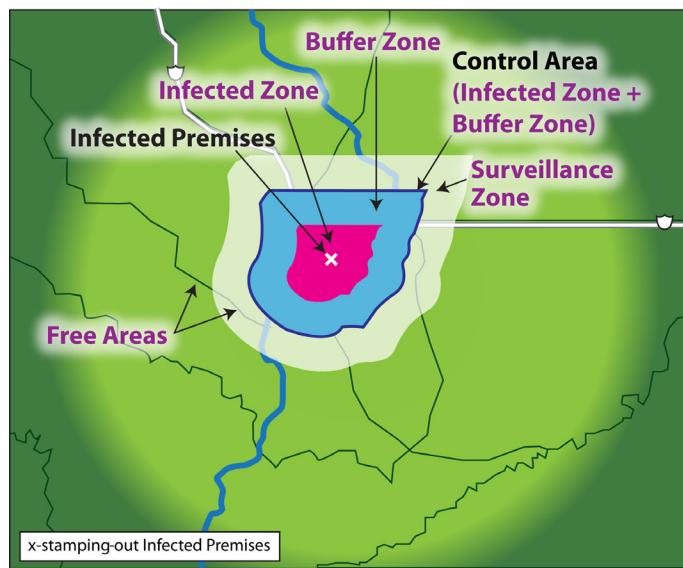
Table 5-3. Summary of Zones and Areas

Zone/Area	Definition
Infected Zone (IZ)	Zone that immediately surrounds the Infected Premises.
Buffer Zone (BZ)	Zone that immediately surrounds the Infected Zone.
Control Area (CA)	Consists of an Infected Zone and a Buffer Zone.
Surveillance Zone (SZ)	Zone established within and along the border of the Free Area, separating the remainder of the Free Area from the Control Area.
Free Area (FA)	Area that includes a Surveillance Zone, but extends beyond the Surveillance Zone.
Containment Vaccination Zone (CVZ)	Emergency Vaccination Zone within the Control Area.
Protection Vaccination Zone (PVZ)	Emergency Vaccination Zone outside the Control Area.

5.3.1.1 ZONES AND AREAS IN RELATION TO STAMPING-OUT POLICY

Figure 5-2 shows an example of a stamping-out policy, where IP are depopulated.

*Figure 5-2. Examples of Zones and Areas in Relation to Stamping-Out Policy
(All Infected Premises would be depopulated)*



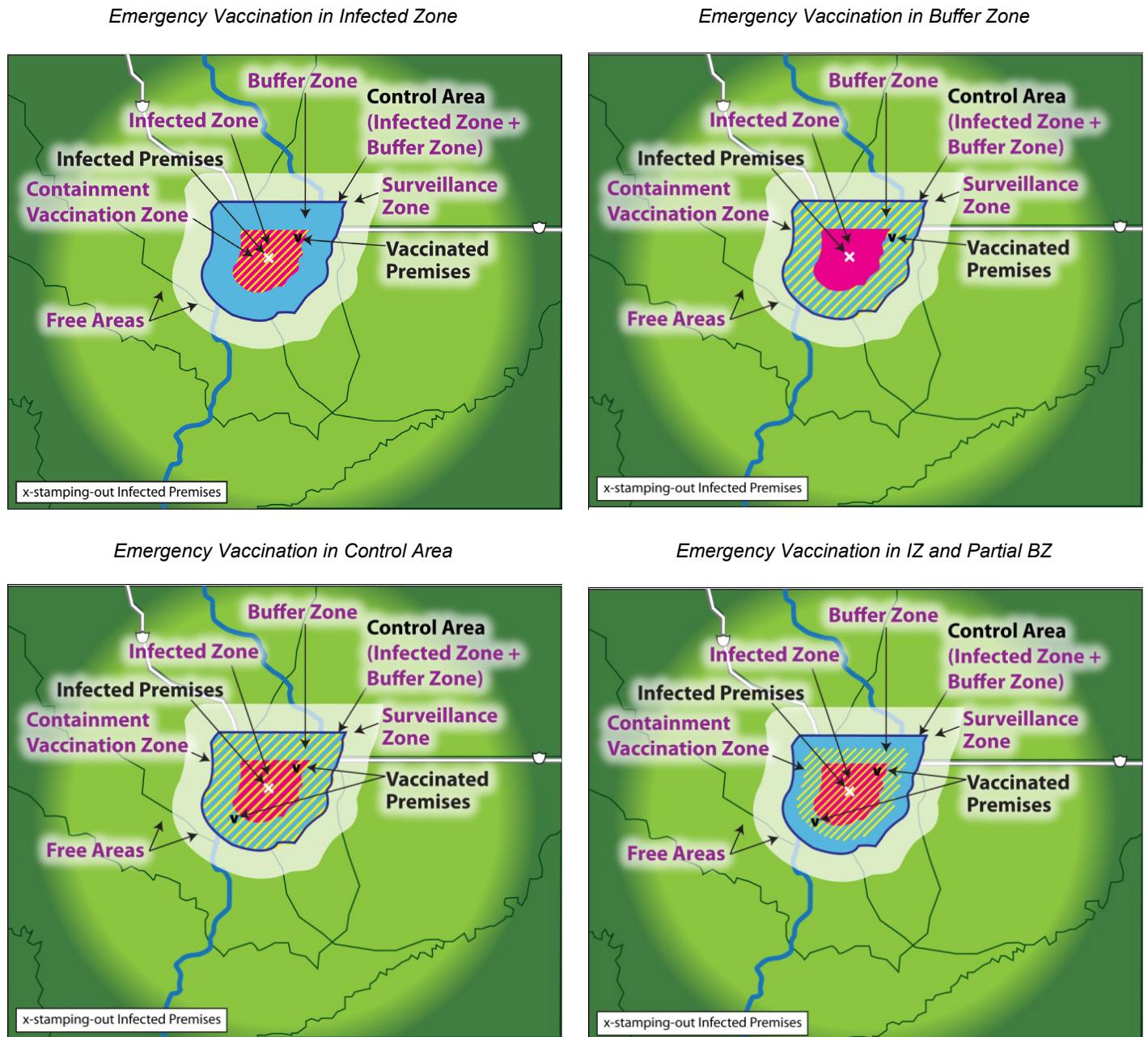
Note: Figure is not to scale.

5.3.1.2 ZONES AND AREAS IN RELATION TO STAMPING-OUT POLICY MODIFIED WITH EMERGENCY VACCINATION TO SLAUGHTER

Figure 5-3 shows four examples of how a stamping-out policy modified with emergency vaccination to slaughter might be implemented. Animals on IP would be depopulated, while other animals in CVZ may be vaccinated. Any animals vaccinated would subsequently be slaughtered. In the event that animals are not FSIS approved for slaughter or vaccinate to slaughter is not feasible because of

other conditions, vaccination to kill may be considered after other relevant options.

**Figure 5-3. Examples of Zones and Areas in Relation to Stamping-out Policy Modified with Emergency Vaccination to Slaughter
(All Infected Premises would be depopulated)**

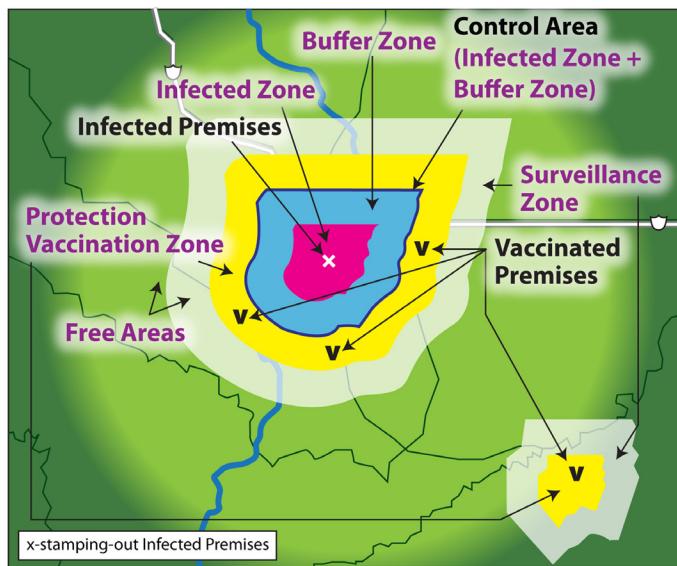


Note: Figures are not to scale.

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

Figure 5–4 shows how a stamping-out policy modified with vaccine to live could be implemented. Animals on IP would be depopulated, while other animals in PVZ would be vaccinated. Any animals vaccinated would not be subsequently slaughtered on the basis of vaccination status.

*Figure 5-4. Examples of Zones and Areas in Relation to Stamping-Out Policy Modified with Emergency Vaccination to Live
(All Infected Premises would be depopulated)*



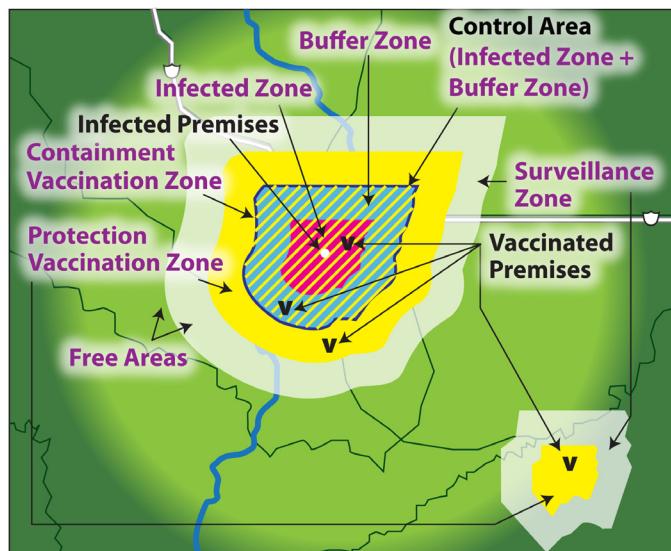
Note: Figure is not to scale.

5.3.1.4 ZONES AND AREAS IN RELATION TO VACCINATION TO LIVE POLICY WITHOUT STAMPING-OUT

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

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

Containment Vaccination Zone and Protection Vaccination Zone



Note: Figure is not to scale. Containment Vaccination Zone is the Control Area; Protection Vaccination Zones are the yellow areas that are not the Control Area. Protection Vaccination Zones are intended to be zone(s) without infected animals.

5.4 IMPLEMENTING VACCINATION STRATEGIES: AN EXAMPLE OF A LARGE-SCALE FMD OUTBREAK

In order to achieve the goals of an FMD response—to 1) detect, control, and contain FMD in animals as quickly as possible, (2) eradicate FMD using strategies that seek to stabilize animal agriculture, the food supply, 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—different strategies may need to be applied in different areas of the country. In each case, the decision and application of a specific response strategy or strategies will be based on weighing many criteria, such as those listed in Table 5-1.

Figure 5-6 illustrates how response strategies could be implemented in a large-scale, multifocal FMD outbreak to facilitate the control and containment of FMD, while seeking continuity of business and agricultural stability. Any response strategy or strategies with emergency vaccination need to be approved by the CVO of the United States prior to implementation.

Figure 5-6. Notional Map #1

Response to Multifocal FMD Outbreak: Implementing (1) Stamping-Out Policy Modified with Vaccinate to Slaughter and (2) Stamping-Out Policy Modified with Vaccinate to Live

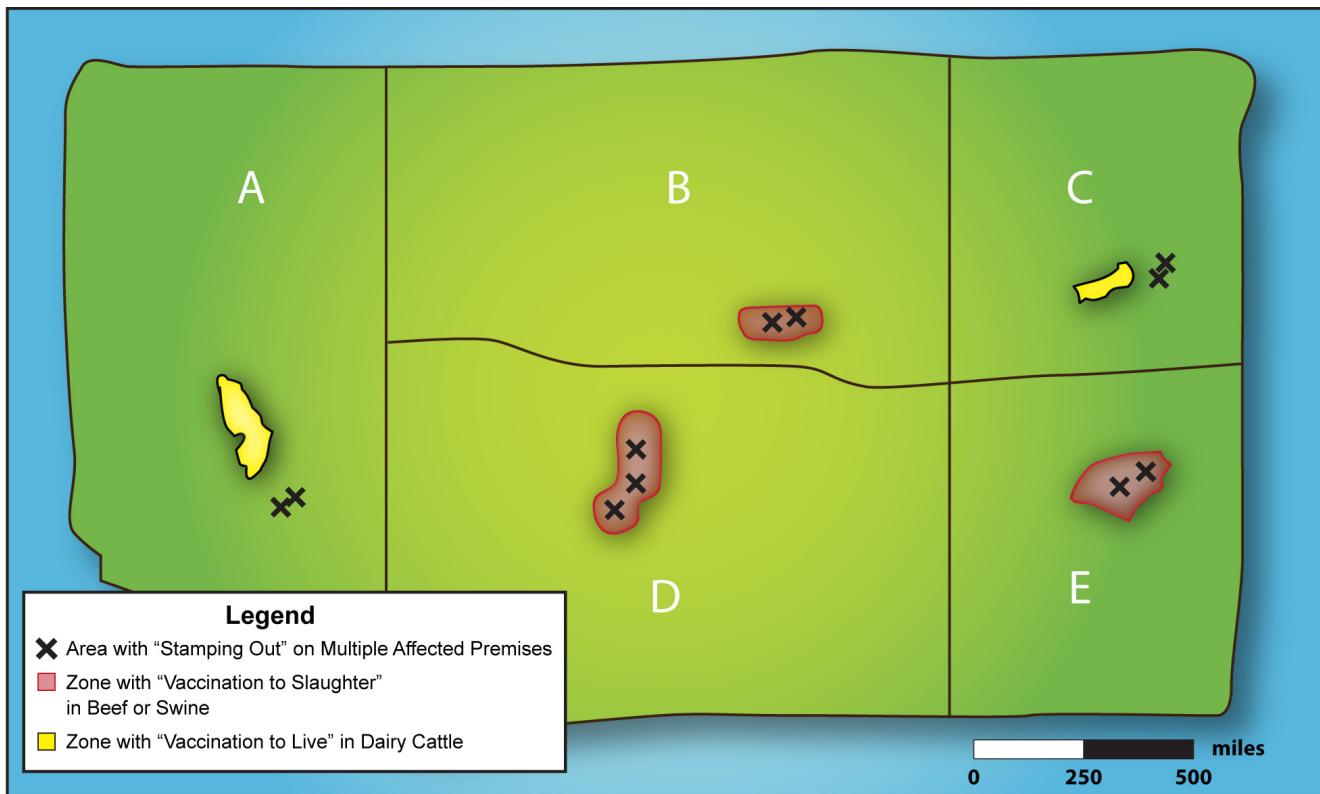


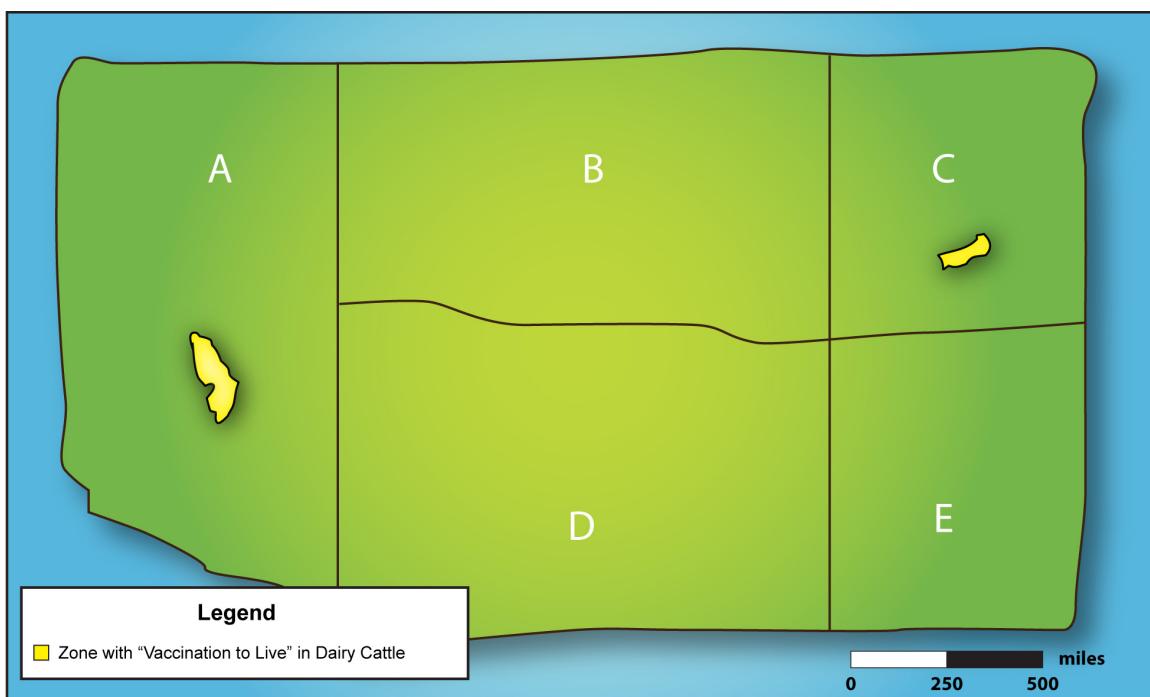
Figure 5-6 shows a **hypothetical or notional example** of emergency vaccination strategies for a large-scale, multifocal FMD outbreak. In this notional example, Area B, Area D, and Area E implement a stamping-out policy modified with emergency vaccination to slaughter (red zones) in beef cattle or swine. Area A and Area C implement a stamping-out policy modified with emergency vaccination to live (yellow zones) in dairy cattle.

Figures 5-7 and 5-8 show the progression of the hypothetical country as it reestablishes freedom from FMD. As seen in Figure 5-7, the vaccination to slaughter zones have been removed, indicating that vaccines that were in those zones were slaughtered, and only vaccination to live zones remain in Area A and Area C, where animals vaccinated for FMD continue to live. Serological surveillance has demonstrated the absence of FMDV circulation. Other requirements, per the OIE, apply for the country to successfully be declared an FMD-free country where vaccination is practiced (see Subsection 5.6.2).

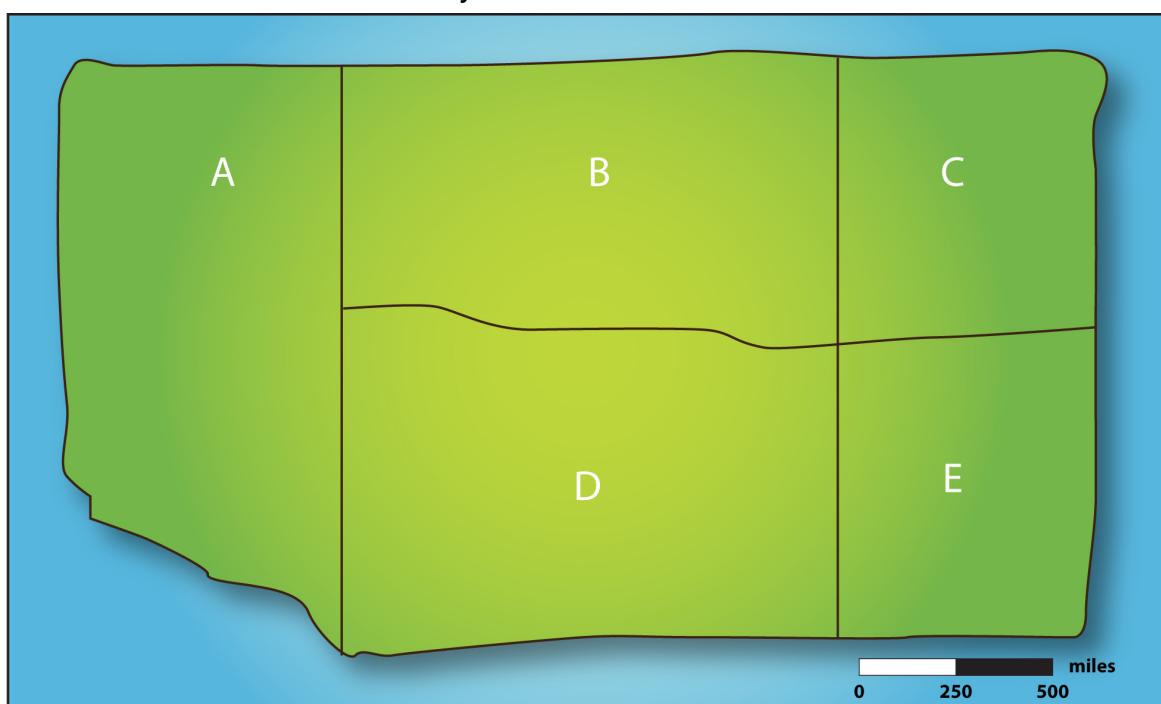
Subsequently, Figure 5-8 demonstrates the country's return to FMD-free country without vaccination status after a length of time. There are no longer vaccination to live zones, and vaccination is no longer practiced, and has not been practiced for at least six months. Serological surveillance has demonstrated the absence of

FMDV circulation. Other requirements, per the OIE, apply for the country to successfully be declared an FMD-free country where vaccination is not practiced (see Subsection 5.6.2).

*Figure 5-7. Notional Map #2
FMD-Free Country Where Vaccination is Practiced*



*Figure 5-8. Notional Map #3
FMD-Free Country Where Vaccination is Not Practiced*



At the start of any FMD outbreak, the desired outcome is to reestablish FMD-free status. Trading partners have discretion when to recognize FMD freedom for a country or zone or whether to recognize FMD freedom with vaccination for a given country or zone. Subsection 5.6.2 contains more information on a U.S. (or zone therein) return to FMD-free status, listing the requirements of the OIE *Terrestrial Animal Health Code* (2010) Articles 8.5.2 to 8.5.9.

5.5 SPECIFIC STRATEGIES FOR CONTAINMENT, CONTROL, AND ERADICATION

A science and risk-based approach that protects public and animal health and stabilizes animal agriculture, the food supply, and the economy will be employed at all times. To rapidly contain, control, and eradicate FMD in the United States, and to minimize the impact on U.S. livestock industries, the following specific strategies will be employed (see Chapter 6):

- ◆ Epidemiological investigation and tracing
- ◆ Biosecurity
- ◆ Surveillance
- ◆ Zoning
- ◆ Quarantine and movement control
- ◆ Cleaning and disinfection
- ◆ Disposal
- ◆ Public awareness campaign
- ◆ Continuity of business measures for non-infected premises.

If determined necessary by authorities, given input from other stakeholders, and weighing the numerous factors listed in Table 5-1, the following activities may also be implemented given particular circumstances:

- ◆ Preemptive culling.

5.5.1 Authorization

When the criteria for a presumptive FMD case have been met (see Chapter 6), the APHIS Administrator or VS Deputy Administrator (CVO of the United States) can authorize APHIS personnel—in conjunction with State, Tribal, and Incident Command personnel—to initiate depopulation, cleaning, and disinfection procedures of the index case and investigation of CP. APHIS and SAHOs will

assess the need to initiate depopulation of herds and cleaning and disinfection procedures on other livestock herds around the index case.

5.5.2 Incident Management

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

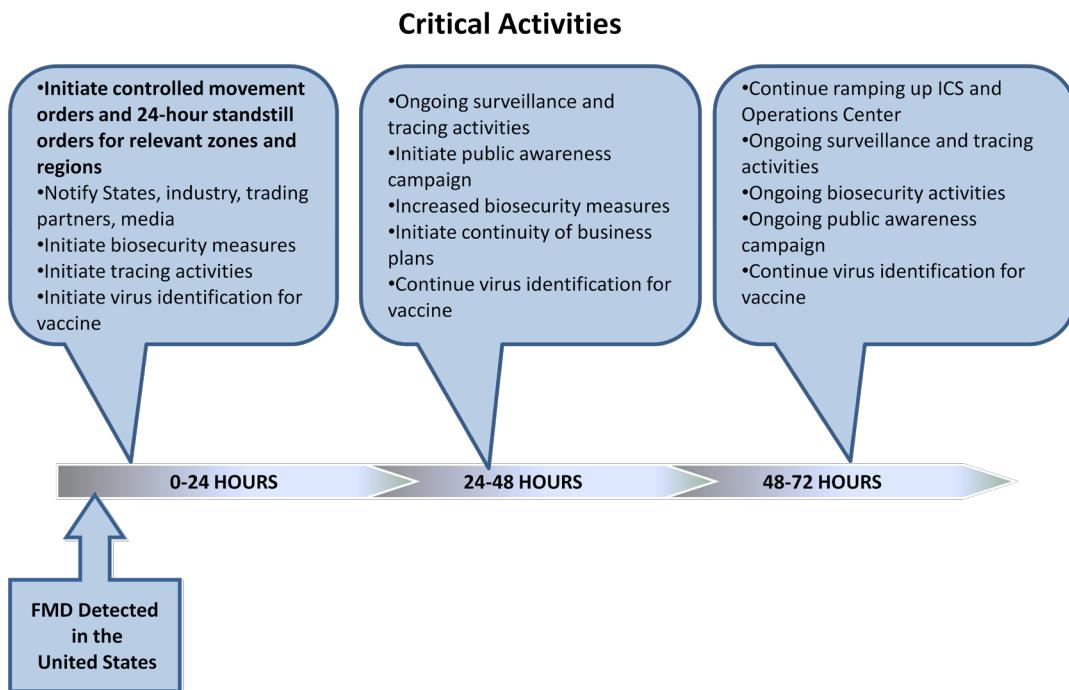
An Incident Commander should be identified and an ICP established. In-State resources (whether State, Federal, Tribal, or privately owned) should be used to manage a local response. Out-of-State resources will be used to support the State impacted by the outbreak.

Incident management will include quarantine and movement control, tracing, and activation of response plans to communicate these actions to all stakeholders, the public, and the international community. Cooperative Federal, State, Tribal, local, and industry response measures will be carried out with extreme urgency using the broadest geographic scope possible. (Appendix B contains organizational charts and further information on organizational structure in an incident. Additional information can be found in the NCAHEM Incident Coordination Plan at <https://fadprep.lmi.org/Design/strategicdocs.aspx>.)

5.5.3 Timeline in any FMD Response for First 72 Hours

In the first 72 hours after the detection of FMD in the United States, specific actions will occur, regardless of specific outbreak characteristics. These critical tasks are fundamental to the rapid control and containment of FMD. Figure 5-9 highlights these tasks.

Figure 5-9. Critical Activities in First 72 Hours of U.S. FMD Outbreak



5.5.4 Control and Eradication Strategy for Other Animals

Animals not susceptible to FMD can carry FMDV as mechanical vectors. Appropriate and effective biosecurity, quarantine, and movement control measures should control this transmission pathway.

Wildlife could be considered a risk factor in the dissemination or persistence of FMD. Appropriate measures will be applied to wildlife populations as needed to assess the risk. Any attempt to control FMD in wildlife must be balanced against the risk of disease dispersal. (See Subsection 6.18 for information on wildlife management.)

5.6 INTERNATIONAL STANDARDS FOR FMD

As a member of the OIE, the United States has agreed to abide by standards drafted and approved by member countries. This section describes the OIE standards for FMD-free status.

5.6.1 Recognition of Disease-Free Status

In May 1994, the World Assembly of Delegates of the OIE requested the Foot-and-Mouth Disease and Other Epizootics Commission (now called the Scientific Commission for Animal Diseases) to develop a procedure for OIE to officially recognize the FMD-free status of members. In 1998, the official agreement

between the World Trade Organization and the OIE further confirmed the OIE's mandate to recognize disease-free areas (Agreement on the Application of Sanitary and Phytosanitary Measures) for trade purposes.

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

5.6.2 Criteria Needed for FMD-Free Status

The OIE has six official country recognitions for FMD: (1) FMD-free country where vaccination is not practiced, (2) FMD-free country where vaccination is practiced, (3) FMD-free zone where vaccination is not practiced, (4) FMD-free zone where vaccination is practiced (in an FMD-free country where vaccination is not practiced or in a country of which parts are infected), (5) FMD-free compartment, and (6) FMD-infected country or zone. (The OIE [*Terrestrial Animal Health Code \(2010\)*](#) Articles 8.5.2 to 8.5.7 list the criteria for these recognitions.)

5.6.2.1 RECOVERY OF FREE STATUS

However, there are separate requirements for the recovery of free status in previously FMD-free countries. These requirements are listed in the OIE *Terrestrial Animal Health Code (2010)* Article 8.5.9.

1. When an FMD outbreak or FMDV infection occurs in an FMD free country or zone where vaccination is not practiced, one of the following waiting periods is required to regain the status of FMD free country or zone where vaccination is not practiced:
 - a. 3 months after the last case where a stamping-out policy and serological surveillance are applied in accordance with Articles 8.5.42 to 8.5.48; or
 - b. 3 months after the slaughter of all vaccinated animals where a stamping-out policy, emergency vaccination and serological surveillance are applied in accordance with Articles 8.5.42 to 8.5.48; or
 - c. 6 months after the last case or the last vaccination (according to the event that occurs the latest), where a stamping-out policy, emergency vaccination not followed by slaughtering of all vaccinated animals, and serological surveillance are applied in accordance with Articles 8.5.42 to 8.5.48, provided that a serological survey based on the detection of antibodies to non-structural proteins of FMDV demonstrates the absence of infection in the remaining vaccinated population.

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

2. When an FMD outbreak or FMDV infection occurs in an FMD free country or zone where vaccination is practiced, one of the following waiting periods is required to regain the status of FMD free country or zone where vaccination is practiced:
 - a. 6 months after the last case where a stamping-out policy, emergency vaccination and serological surveillance in accordance with Articles 8.5.42 to 8.5.48 are applied, provided that the serological surveillance based on the detection of antibodies to non-structural proteins of FMDV demonstrates the absence of virus circulation; or
 - b. 18 months after the last case where a stamping-out policy is not applied, but emergency vaccination and serological surveillance in accordance with Articles 8.5.42 to 8.5.48 are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation.
3. When an FMD outbreak or FMDV infection occurs in an FMD free compartment, Article 8.5.6 applies.

5.6.2.2 FMD-FREE COUNTRY WHERE VACCINATION IS NOT PRACTICED

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

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

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

-
3. supply documented evidence that:
 - a. surveillance for both FMD and FMDV infection in accordance with Articles 8.5.42 and 8.5.48 is in operation;
 - b. regulatory measures for the early detection, prevention, and control of FMD have been implemented.
 4. describe in detail the boundaries and measures of a protection zone, if applicable.

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

5.6.2.3 FMD-FREE COUNTRY WHERE VACCINATION IS PRACTICED

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

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

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that:
 - a. there has been no outbreak of FMD during the past 2 years;
 - b. no evidence of FMDV circulation for the past 12 months;
3. supply documented evidence that:
 - a. surveillance for FMD and FMDV circulation in accordance with Articles 8.5.42 and 8.5.48 is in operation;
 - b. regulatory measures for the early detection, prevention, and control of FMD have been implemented;
 - c. routine vaccination is carried out for the purpose of the prevention of FMD;
 - d. the vaccine used complies with the standards described in the Terrestrial Manual and is appropriate for the strains of virus currently circulating;

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

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

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

5.6.2.4 FMD-FREE ZONE WHERE VACCINATION IS NOT PRACTICED

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

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

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that within the proposed FMD free zone:
 - a. there has been no outbreak of FMD during the past 12 months,
 - b. No evidence of FMDV infection has been found during the past 12 months;
 - c. no vaccination against FMD has been carried out during the past 12 months;
 - d. no vaccinated animal has been introduced into the zone since the cessation of vaccination, except in accordance with Article 8.5.10;

-
3. supply documented evidence that:
 - a. surveillance for FMD and FMDV infection in accordance with Articles 8.5.42 and 8.5.28 is in operation;
 - b. regulatory measures for the early detection, prevention and control of FMD have been implemented;
 4. describe in detail and supply documented evidence that these are properly implemented and supervised:
 - a. the boundaries of the proposed FMD free zone,
 - b. the boundaries and measures of a protection zone, if applicable,
 - c. the system for preventing the entry of the virus (including the control of the movement of susceptible animals) into the proposed FMDV free zone (in particular if the procedure described in Article 8.5.10 is implemented).

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

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

5.6.2.5 FMD-FREE ZONE WHERE VACCINATION IS PRACTICED

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

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

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE that within the proposed FMD free zone;
 - a. there has been no outbreak of FMD for the past 2 years;

- b. no evidence of FMDV circulation for the past 12 months;
3. supply documented evidence that:
 - a. surveillance for FMD and FMDV infection in accordance with Articles 8.5.42 and 8.5.48 is in operation;
 - b. regulatory measures for the early detection, prevention, and control of FMD have been implemented;
 - c. routine vaccination is carried out for the purpose of the prevention of FMD;
 - d. the vaccine used complies with the standards described in the Terrestrial Manual and is appropriate for the strains of virus currently circulating;
4. describe in detail and supply documented evidence that these are properly implemented and supervised:
 - a. the boundaries of the proposed FMD free zone,
 - b. the boundaries and measures of a protection zone, if applicable,
 - c. the system for preventing the entry of the virus (including the control of the movement of susceptible animals) into the proposed FMD free zone (in particular if the procedure described in Article 8.5.10 is implemented).

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

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

5.6.2.6 FMD-FREE COMPARTMENT

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

A Member wishing to establish an FMD free compartment should:

1. have a record of regular and prompt animal disease reporting and if not FMD free, have an official control program and a surveillance system for FMD in place according to Articles 8.5.42 and 8.5.44 that allows an accurate knowledge of the prevalence of FMD in the country or zone;
2. declare for the FMD free compartment that:
 - a. there has been no outbreak of FMD during the past 12 months;
 - b. no evidence of FMDV infection has been found during the past 12 months;
 - c. vaccination against FMD is prohibited;
 - d. no animal vaccinated against FMD within the past 12 months is in the compartment;
 - e. animals, semen, and embryos should only enter the compartment in accordance with relevant Articles in this chapter;
 - f. documented evidence should show that surveillance in accordance with Articles 8.5.42 and 8.5.48 is in operation for FMD and FMDV infection;
 - g. an animal identification and traceability system in accordance with Chapters 4.1 and 4.2 is in place;
3. describe in detail the animal subpopulation in the compartment and the biosecurity plan for FMD and FMDV infection.

The compartment should be approved by the Veterinary Authority. The first approval should only be granted when no outbreak of FMD has occurred within the zone in which the compartment is situated, during the last 3 months.

5.6.2.6.1 FMD-Free Compartments

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

5.6.2.7 FMD-INFECTED COUNTRY OR ZONE

An FMD-infected country is one that does not fulfill the requirements to qualify as either an FMD-free country where vaccination is not practiced or an FMD-free country where vaccination is practiced.

An FMD-infected zone is one that does not fulfill the requirements to qualify as either an FMD-free zone where vaccination is not practiced or an FMD-free zone where vaccination is practiced.

Chapter 6

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 business continuity in an outbreak. This chapter describes key parts of these tools and strategies and provides links to the 23 accompanying SOPs that further detail them.

6.1 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 2). The SOP entitled Overview of Etiology and Ecology of FMD contains further information, such as the factors influencing transmission and the persistence of the FMD virus in the environment (<https://fadprep.lmi.org/Design/sops.aspx>).

6.2 LABORATORY DEFINITIONS AND CASE DEFINITIONS

Laboratory and case definitions provide a common point of reference for all responders.

6.2.1 Laboratory Definitions

The following subsections are the APHIS-VS Centers for Epidemiology and Animal Health (CEAH) National Surveillance Unit (NSU) draft definitions for FMD from September 2010, which are undergoing review. For further information on the diagnostic tests conducted by NVSL-FADDL in the event of an FMD outbreak, please see Subsection 6.4.

6.2.1.1 LABORATORY CRITERIA

1. *Agent identification:* Virus isolation (VI), antigen enzyme-linked immunosorbent assays (ELISAs), and real-time reverse transcriptase polymerase chain reaction (rRT-PCR) assays are used to detect FMDV-infected animals. Samples to collect for testing include vesicular epithelium, vesicular fluid, epithelial tissues, oesophageal-pharyngeal fluid, blood, serum, and oral and nasal swabs.
 - a. VI in cell cultures: VI is highly sensitive and specific when used with antigen ELISAs to confirm the presence of FMDV after cytopathic effect is observed.
 - b. Antigen ELISA (AgELISA): 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. Real-time reverse transcriptase polymerase chain reaction (rRT-PCR): Detects FMDV nucleic acids (RNA). It only takes 2-3 hours to obtain test results. Most rRT-PCRs detect all known FMDV serotypes, often with equal or greater sensitivity than VI; rRT-PCR does not identify virus serotype or subtype.
 - d. Strain characterization by nucleotide sequencing: RT-PCR amplification of the P1 region of FMDV genome or a portion of the P1 region that contains VP1 of the genome, followed by nucleotide sequencing is the preferred method for generating sequence data for strain characterization. If necessary, the whole genome of FMDV can be sequenced. Antigen ELISA is used to determine the serotype of the FMD present in the outbreak samples.
2. *Serological tests:* The following serological assays detect FMDV-exposed animals and some help to discriminate vaccinated from infected animals.
 - a. Structural protein-based assays: Virus neutralization test (VNT), solid phase competitive ELISA (SPCE), and liquid phase blocking ELISA (LPBE) are OIE-prescribed tests for trade purposes. These are highly sensitive, serotype-specific tests that detect FMDV antibodies. These assays may be utilized for confirmation of infection (previous or ongoing) and to monitor immunity following vaccination. Low titer ELISA-positive sera must be confirmed by VNT to exclude false positive results. The VNT confirms the FMDV serotype and a version of this test is used to determine the serotype subtype during vaccine matching.

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

6.2.2 Case Definitions

The following subsections are the APHIS-VS CEAH NSU draft definitions for FMD from September 2010, which are undergoing review. Case definitions are developed according to the Case Definition Development Process SOP (2010) (see Subsection 6.2.3).

6.2.2.1 SUSPECT CASE

An FMD-susceptible animal that has either:

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

6.2.2.2 PRESUMPTIVE POSITIVE CASE

A suspect case that has both:

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

6.2.2.3 CONFIRMED POSITIVE CASE

An animal from which FMDV has been *isolated* and *identified* at the National Veterinary Services Laboratory-Foreign Animal Disease Diagnostic Laboratory (NVSL-FADDL) or other laboratory designated by the Secretary of the United States Department of Agriculture.

6.2.2.4 EVOLVING DEFINITIONS

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

6.2.3 Case Definition Development Process

The Case Definition Development Process SOP (2010) (<https://fadprep.lmi.org/Designs/sops.aspx>) 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 the NSU, in cooperation with NCAHEM. NSU coordinates review with SAHOs, subject matter experts, stakeholders, and VS units. Case definitions are approved by the VS Deputy Administrator (the U.S. CVO) and VS management team. Case definitions enhance the usefulness of animal disease data by providing uniform criteria for reporting purposes.

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

6.3 SURVEILLANCE

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

- ◆ To implement surveillance plans within 48 hours of the confirmation of an outbreak.
- ◆ To develop effective surveillance plans that can achieve desired outcomes by leveraging available resources, satisfying jurisdictional requirements, and implementing continuity of business measures.
- ◆ To implement a surveillance plan that will (1) define the present extent of FMD and (2) detect unknown Infected Premises quickly.
- ◆ To have the surveillance plan consider the susceptible wildlife population in the area, and to coordinate with Wildlife Services (WS), the Department

of the Interior (DOI), State wildlife agencies, and State agriculture departments to perform appropriate FMD surveillance in wildlife populations.

At the APHIS level, NSU is responsible for surveillance activities. Box 6-1 lists the key objectives of surveillance activities during and immediately after an FMD outbreak.

Box 6-1. Surveillance Objectives in an FMD Outbreak

Objectives of Surveillance

- Detect FMD Infected Premises during an outbreak.
- Determine the size and extent of an FMD outbreak.
- Supply information to evaluate outbreak control activities.
- Provide information for animal and product movement within the Control Area.
- Provide information for animal and product movement out of the Control Area.
- Prove disease freedom and regain disease-free status after eradication of the outbreak.

6.3.1 Surveillance Planning for FMD Outbreak

6.3.1.1 GENERAL CONSIDERATIONS

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

1. *Design (threshold) prevalence.* The goal is to determine the lowest feasible prevalence that can be used to detect infected herds on premises. The chosen proportion of animals or premises infected that if exceeded will indicate the disease has been detected for a given confidence level and population size (1 percent vs. 5 percent vs. 15 percent).
2. *Confidence level.* The selected level (90 percent confident vs. 95 percent confident) that the disease can be detected for the chosen design threshold, given the population size.
3. *Types of tests.* Test choices—clinical inspection, polymerase chain reaction testing, serology testing, etc.—and the test cutoff values can influence the design prevalence choice. Each test has a sensitivity and specificity that varies with the cutoff values.

-
4. *Sampling frequency.* Previous negative test results can augment information gained from negative test results if the time period between sampling is short—ideally daily, but definitely less than the incubation period. The value of the previous negative test results decreases as the interval between sampling increases (daily vs. every other day).
 5. *Risk-based sampling.* Selecting populations with a higher proportion of infected animals (1 percent vs. 10 percent) reduces the number of samples needed for a given confidence and population size.
 6. *Sampling scheme.* Within the selected population (risk-based or total population), a random, convenience, or other scheme may be used, and the choice will influence the number of animals/premises sampled.

6.3.1.2 SURVEILLANCE OBJECTIVES BY TIME PERIOD

There are three key segments of surveillance activity in an outbreak. These segments have distinct goals to aid in the control, containment, and eradication of FMD from domestic livestock. For more information on the zone, area, and premises designations referred to in this section, please refer to Subsection 6.5.

1. *The initial 72 hours post FMD outbreak declaration.* The objective is to detect existing infected animals and premises as quickly as possible to determine the extent of the outbreak. In this period, there are four goals of Incident Command:
 - a. Determine the size and extent of the outbreak by detecting all Infected Premises, new and existing.
 - b. Create the initial Buffer Zone designation and the boundary of the Control Area.
 - c. Create a list of premises with susceptible herds in the Control Area.
 - d. Determine the boundary of the Surveillance Zone and start developing a surveillance plan to be used in the Surveillance Zone.
2. *The control and eradication period (from initial 72-hour period until last case is detected and eradicated).* Four key surveillance objectives need to be accomplished simultaneously in this period.
 - a. Detect Infected Premises, new and existing, so that control measures can be put in place.
 - b. Prove premises are free of FMD, thereby permitting animal and animal product movements in the Control Area.

- c. Evaluate the outbreak management control activities.
 - d. Prove that the Free Area is free of disease, thereby enabling unrestricted animal and animal product movement.
3. *Post eradication.* The objective is to prove that the Control Area and Free Area are free of disease.

6.3.2 Surveillance Sampling

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

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

1. Are resources limited to intensively survey premises (e.g., collect tissue samples from the needed number of animals)?
2. Is it unlikely that the outbreak can be contained locally (e.g., on a farm or within a small geographic area)?
3. Does evidence suggest that the introduction of virus (i.e., start of the outbreak) on the premises or in the zone began at least 7 days ago?
4. Is there evidence that the FMD serotype is highly pathogenic (i.e., a high proportion of infected animals will show clinical signs and/or severe clinical signs)?
5. Are there limited movements of animals, vehicles, products, or personnel on and off premises (i.e., it is unlikely that virus will be introduced to, or spread from, this premises or zone)?
6. Are sheep present in the zone or on the premises?
7. Are there noncommercial or feral swine in the zone?
8. Are there noncommercial or small premises in the zone?
9. Are there premises with more than one susceptible species?

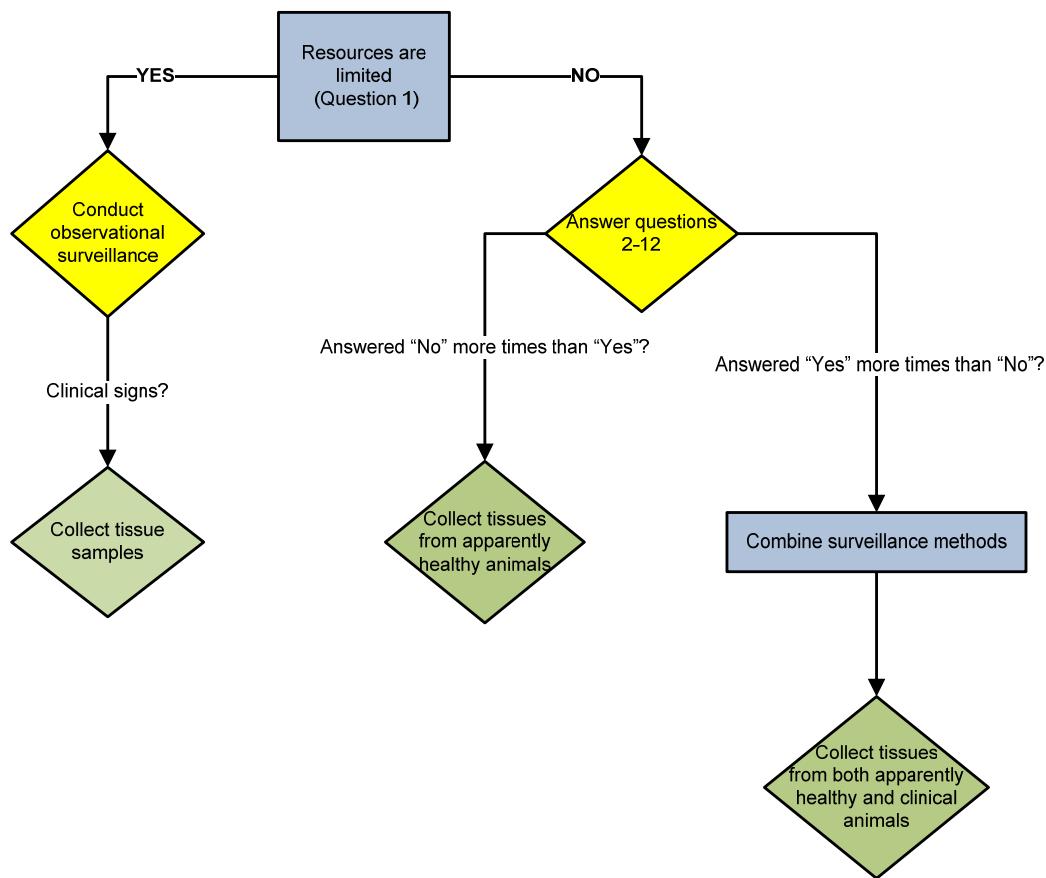
-
10. Are there large feedlots or swine operations in the zone?
 11. Are dairy cattle, feedlots, or swine operations in the zone managed to present low-risks of exposure (e.g., biosecurity practices, little opportunity for fomite transmission)?
 12. Are there beef cattle (cow-calf or small operations) in the zone?

Figure 6-1 demonstrates how these questions should be used to inform a surveillance sampling scheme.

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

If the answer to Question 1 is “no,” and

- ◆ There are more “no” than “yes” answers for Questions 2-12, then surveillance may include the collection of tissue samples from herds and animals which appear to be healthy.
- ◆ There are more “yes” than “no” answers for Questions 2-12, then surveillance may include a combination that leads to collection of tissue samples from both animals that appear to be healthy and animals with clinical signs of FMDV.

Figure 6-1. Developing an FMD Outbreak Surveillance Sampling Scheme

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

6.3.2.1 ADDITIONAL INFORMATION

Appendix E of this FMD Response Plan contains additional guidance on creating a surveillance scheme based on the sensitivity and specificity of available diagnostics, FMD prevalence in a population, herd size, and other factors for commercial and noncommercial premises. The FMD Surveillance SOP provides additional information on the protocol for a surveillance team responding to FMD Infected Premises, the distinction between commercial and noncommercial premises surveillance, equipment checklists, and surveillance for disease proof-of-freedom (<https://fadprep.lmi.org/Design/sops.aspx>). The Outbreak Surveillance Toolbox (<https://fadprep.lmi.org/Design/outbreakresptools.aspx>) provides additional surveillance resources.

6.4 DIAGNOSTICS

Effective and appropriate sample collection, diagnostic testing, surge capacity, and reporting are critical in an effective FMD response. Diagnostic activities will require additional resources in the event of an FMD outbreak. 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 testing, sample collection, surge capacity, and reporting capabilities.

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

The FMD Diagnostics SOP offers detailed information on sample collection, diagnostic testing, surge capacity, and reporting (<https://fadprep.lmi.org/Design/sops.aspx>). In particular, this SOP provides additional guidance on who is responsible for diagnostic testing, sample collection and processing, and analyzing diagnostic test results. (Appendix F contains more information on submitting diagnostic samples. For packaging and labeling submissions, see http://www.aphis.usda.gov/animal_health/lab_info_services/packaging_labeling.shtml.)

6.4.1 Sample Collection and Diagnostic Testing

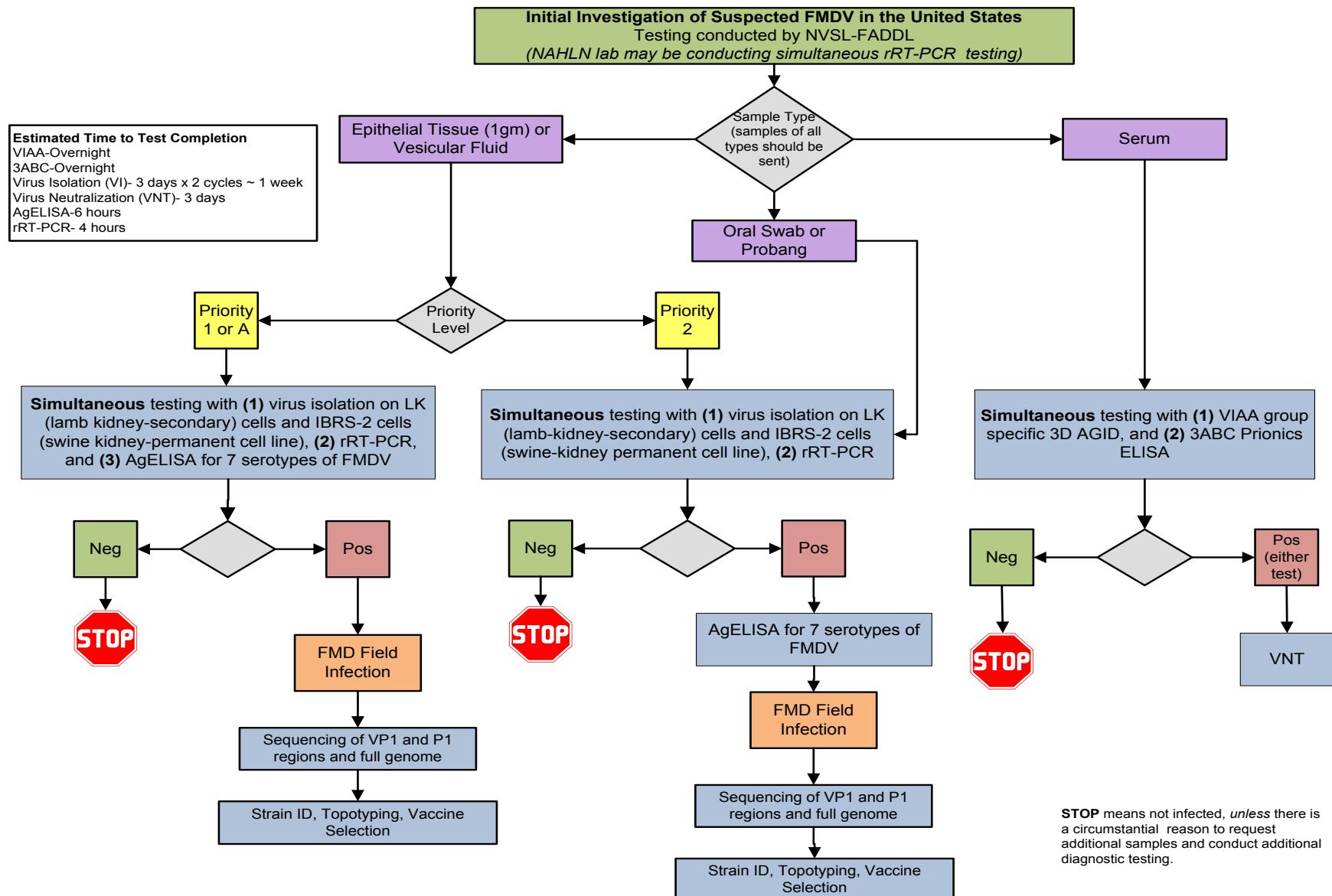
Trained personnel and field collection kits are required to effectively collect samples from large animals.

Specific diagnostic tests are used for antigen detection, virus identification, and antibody detection. For antigen detection, rRT-PCRs are used simultaneously with other tests selected on the basis of the type and priority of the sample. Virus isolation is used to confirm a FMD diagnosis, but this can take up to 7 days. The following subsections describe the diagnostic tests performed when FMDV is suspected (Figure 6-2) and when it has been confirmed in the United States (Figure 6-3).

6.4.1.1 DIAGNOSTICS FOR NEW FMD INVESTIGATION

Figure 6-2 displays the diagnostics for a suspected case of FMD. In the figure, Priority 1 or A and Priority 2 refer to categorizations explained in VS Memo 580.4. (Appendix F contains the ready reference guide for this memorandum.)

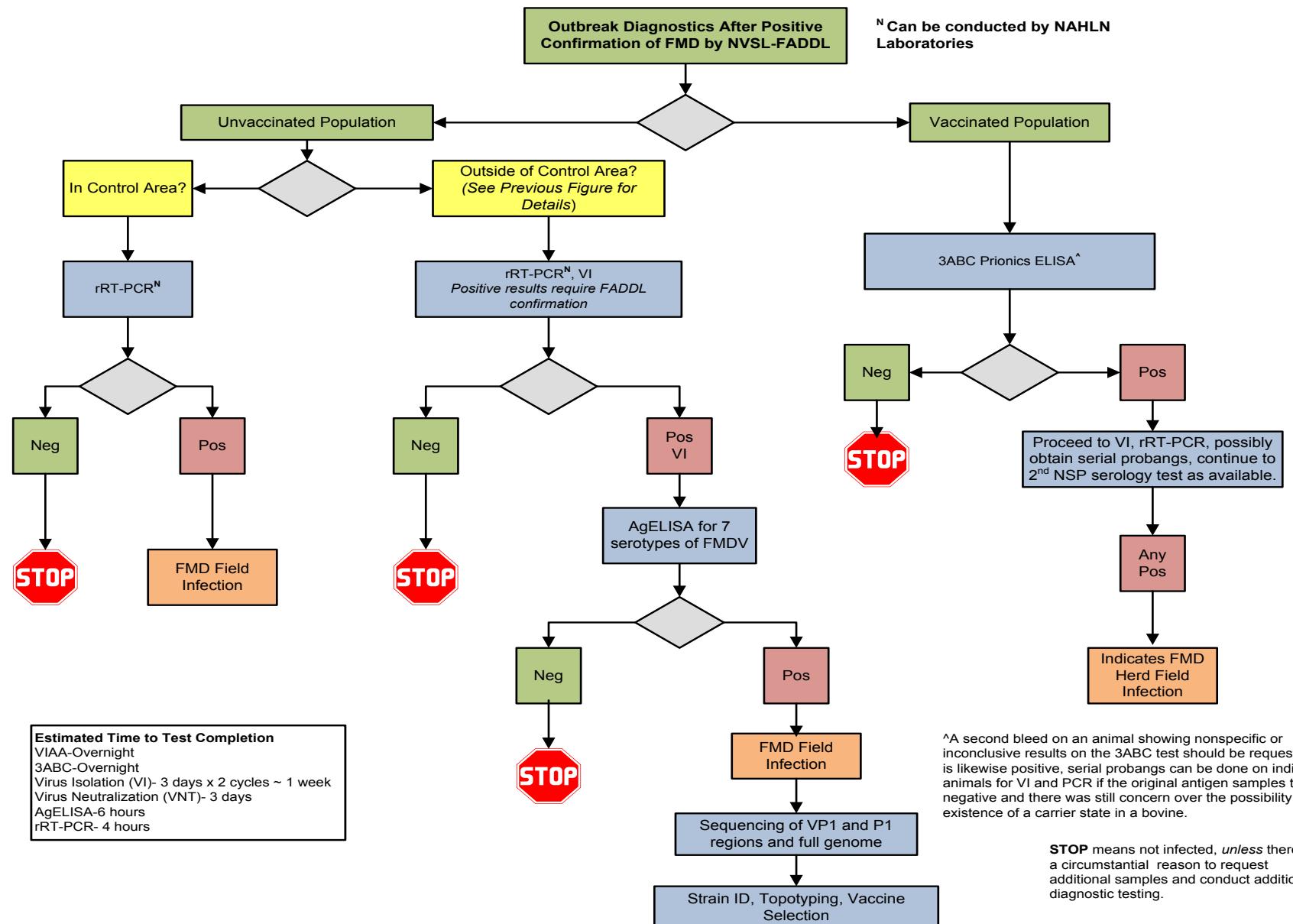
Figure 6-2. Diagnostic Flowchart for Initial Investigation of FMD



6.4.1.2 DIAGNOSTICS AFTER FMD DETECTION

After NVSL confirmation of FMD on premises (index case), subsequent swab samples for RRT-PCR can be sent to USDA-approved laboratories which are part of the NAHLN network. (Appendix C lists NAHLN laboratories approved for FMD testing.) If a presumptive positive RRT-PCR result is found on a subsequent sample at a NAHLN laboratory, the samples are forwarded to NVSL for confirmatory testing. Figure 6–3 illustrates the diagnostic flow after FMD has been detected.

Figure 6-3. Outbreak Diagnostics after Positive Confirmation of FMD in United States



6.4.2 Surge Capacity

Surge capacity may be needed in an FMD outbreak. Additional resources, such as personnel and materials, will be needed for sample collection. Additional capacity may also be required for laboratory sample testing. Surge capacity can help facilitate a rapid response and continuity of business for uninfected premises. NAHLN will provide surge capacity in the event of an FMD outbreak; this network has the capacity to test larger numbers of samples than NVSL-FADDL alone.

NAHLN labs currently have the capability to conduct rRT-PCR tests, as shown in Figure 6-3. Ideally, NAHLN labs will also have the capability to conduct 3ABC ELISA tests to detect FMDV in herds. It is a priority to ensure that NAHLN labs have this diagnostic capacity to test samples in the event of an FMD outbreak, particularly for recovering and proving disease freedom.

6.4.3 Reporting

Box 6–2 clarifies reporting and notification of presumptive FMD cases. See VS Memorandum 580.4 (regarding FAD investigations) for further information on FMD investigation and reporting. This memorandum is available on the FAD PReP website: <https://fadprep.lmi.org/Design/emergmgmt.aspx>.

Box 6–2. Reporting and Notification

Reporting and Notification

- Cases considered presumptive FMD will be immediately 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.

6.5 EPIDEMIOLOGICAL INVESTIGATION AND TRACING

6.5.1 Summary of Zones, Areas, and Premises Designations

A critical component of epidemiological investigation and tracing is the designation of zones, areas, and premises. The Incident Commander will work with the Operations Section and Situation Unit within the Planning Section to determine appropriate premises designations in the event of an FMD outbreak (see Appendix B for organizational charts). Epidemiological investigation and tracing will be used to classify premises. Table 6–1 summarizes the premises employed. Table 6–2

summarizes the associated zones and areas used in quarantine and movement control efforts. The *APHIS Framework for Foreign Animal Disease Preparedness and Response* (<https://fadprep.lmi.org/Design/strategicdocs.aspx>) contains additional information on the zones, areas, and premises designations.

Table 6-1. Summary of Premises

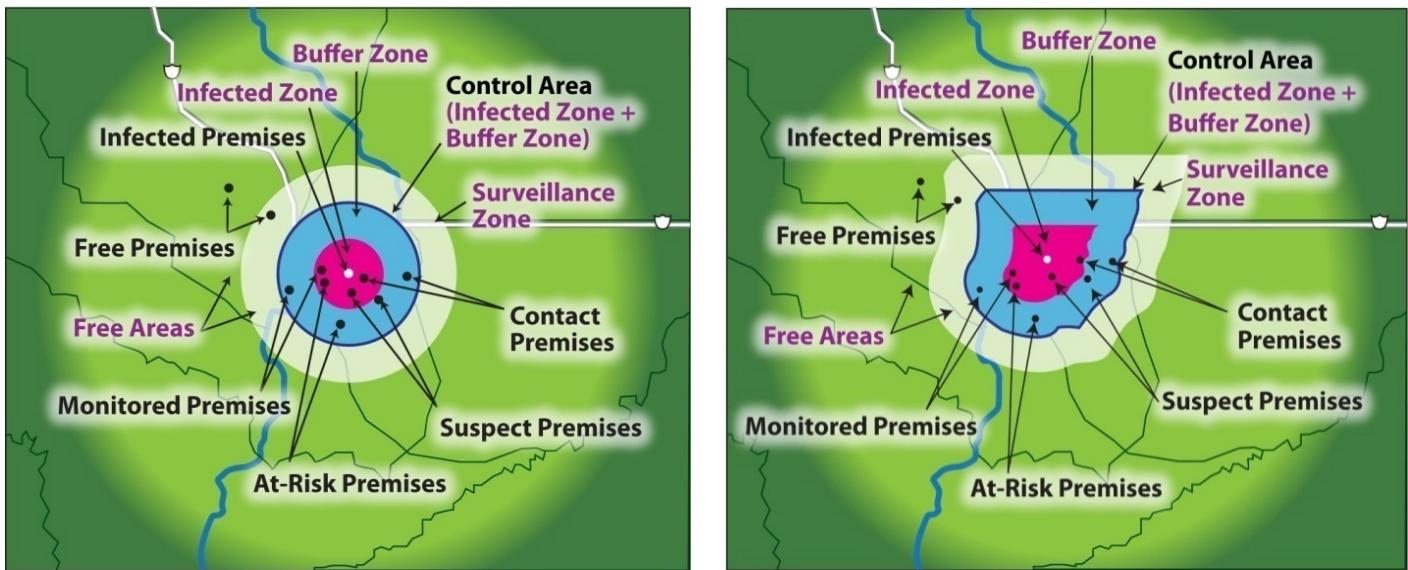
Premises	Definition	Zone
Infected Premises (IP)	Premises where presumptive positive case or confirmed positive case exists based on FMD case definition.	Infected Zone
Contact Premises (CP)	Premises with susceptible animals that have been exposed directly or indirectly to animals, contaminated animal products, fomites, or people from Infected Premises.	Infected Zone, Buffer Zone
Suspect Premises (SP)	Premises with susceptible animals under investigation for a report of compatible clinical signs for FMD.	Infected Zone, Buffer Zone
At-Risk Premises (ARP)	Premises that have susceptible animals, but none of those susceptible animals have clinical signs compatible with FMD. Premises objectively demonstrate that they are not Infected Premises, Contact Premises, or Suspect Premises. At-Risk Premises seek to move susceptible animals or products within the Control Area by permit.	Infected Zone, Buffer Zone
Monitored Premises (MP)	Premises that objectively demonstrate that they are not Infected Premises, Contact Premises, Suspect Premises, or At-Risk Premises. Monitored Premises seek to move susceptible animals or products out of the Control Area by permit.	Infected Zone, Buffer Zone
Vaccinated Premises (VP)	Premises where emergency vaccination has been performed. This is a secondary premises designation.	Containment Vaccination Zone, Protection Vaccination Zone
Free Premises (FP)	Premises outside of the Control Area and not Infected, Contact, Suspect, At-Risk, or Monitored Premises.	Surveillance Zone, Free Area

Table 6-2. Summary of Zones and Areas

Zone/Area	Definition
Infected Zone (IZ)	Zone immediately surrounds the Infected Premises.
Buffer Zone (BZ)	Zone immediately surrounds the Infected Zone.
Control Area (CA)	Consists of an Infected Zone and a Buffer Zone.
Surveillance Zone (SZ)	Zone established within and along the border of the Free Area, separating the remainder of the Free Area from the Control Area.
Free Area (FA)	Includes a Surveillance Zone, but extends beyond the Surveillance Zone.
Containment Vaccination Zone (CVZ)	Emergency Vaccination Zone within the Control Area.
Protection Vaccination Zone (PVZ)	Emergency Vaccination Zone outside the Control Area.

Figure 6-4 illustrates zones, areas, and premises designations.

*Figure 6-4. Example of Zones, Areas, and Premises in FMD Outbreak Response
(Left: Circle; Right: Irregular)*



Note: Excludes Containment Vaccination Zone, Protection Vaccination Zone, and Vaccinated Premises. Figures are not to scale. See Subsection 6.16.3 for examples of the Containment Vaccination Zone, Protection Vaccination Zone, and Vaccinated Premises.

6.5.2 Epidemiological Investigation

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

- ◆ 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;
- ◆ assign a premises classification and priority of investigation within 6 hours of identifying a potential IP or CP through tracing activities; and
- ◆ identify all CP within 24 hours of identifying the IP or the initial CP.

These measures will aid in the control of FMD and lessen the impact of the outbreak during the response effort. (Appendix G contains a sample epidemiological questionnaire.) The FMD Epidemiological Investigation and Tracing SOP as well as the NAHEMS Guidelines: Epidemiology, Surveillance, and FAD Tracing (2011) both provide more information: <https://fadprep.lmi.org>.

6.5.3 Tracing

Box 6–3 explains the fundamental importance of movement tracing in an FMD response effort.

Box 6–3. Importance of Movement Tracing in FMD Outbreak

Tracing

One of the single most important and urgent veterinary activities during an FMD outbreak is to rapidly and diligently trace-back and trace-forward movements from an IP. This tracing will aid in the control of the spread of 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 be collected for at least 28 days prior to the appearance of clinical signs in an animal infected with FMD. Additional tracing information will be collected for movements up to the time quarantine was imposed.

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

6.5.4 Considerations for Size of Control Area

The radius of the CA may be as small as 6.2 miles (10 kilometers) 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. In an FMD outbreak, it is likely that the CA will be larger than the minimum size. The boundaries of the CA can be modified or redefined when tracing and other epidemiological information becomes available. Table 6-3 reviews the factors used to determine the size of the CA.

Table 6-3. Factors Used to Determine 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 or contiguous 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 ◆ 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 spread diseases)	<ul style="list-style-type: none"> ◆ Prevailing winds ◆ Humidity
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 backyard or transitional premises	<ul style="list-style-type: none"> ◆ Types of premises and network of animal and fomite movements
Business continuity requirements	<ul style="list-style-type: none"> ◆ Business continuity, movement and marketability, or compartmentalization plans and practices in place at time of outbreak

6.5.5 Considerations for Size of Other Zones

The radius of the IZ may be as small as 1.86 miles (3 kilometers) beyond the perimeters of the presumptive or confirmed IP. The boundaries of the IZ can be modified or redefined as needed by the circumstances of the outbreak.

The BZ is a scalable area that will at least match the width of the IZ, but it can be much larger than the IZ. The radius may be as small as 4.35 miles (7 kilometers) beyond the perimeters of the presumptive or confirmed IP.

The minimum width of the SZ should be greater than 6.2 miles (10 kilometers). The maximum size of the SZ may be much greater.

These are minimum zone sizes. In an FMD outbreak, the IZ, BZ, and SZ are likely to be larger than these minimum sizes.

6.6 INFORMATION MANAGEMENT

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

The Overview of Information Management SOP (2010) (<https://fadprep.lmi.org/Design/sops.aspx>) provides information on the following VS systems:

- ◆ Animal Health and Surveillance Management (AHSM)
- ◆ Veterinary Services Process Streamlining (VSPS)
- ◆ Traceability
- ◆ NAHLN
- ◆ EMRS
- ◆ National Veterinary Logistics System (NVLS)
- ◆ Licensing, Serial Release, and Testing Information System (LSRTIS)
- ◆ LabWare Laboratory Information Management System (LIMS).

It also covers the following APHIS information technology systems:

- ◆ Resource Ordering and Status System (ROSS)

-
- ◆ APHIS Emergency Qualifications System (EQS).

6.7 COMMUNICATION

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

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

- ◆ establishing a network of stakeholders and systems for communication prior to an incident or outbreak;
- ◆ briefing the media, public, industry, Congress, trading partners, and others on the FMD outbreak status and the actions being taken to control and eradicate the disease;
- ◆ coordinating with local, State, and Tribal entities to ensure a consistent message; 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.

6.7.1 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.

6.7.2 Key Messages

Five key messages will be conveyed in an FMD outbreak (Box 6-4).

Box 6-4. FMD Communication Messages

Key Communication Messages

For consumers:

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

For producers:

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

6.7.3 Further Communications Guidance

In addition to the FMD Communications SOP (<https://fadprep.lmi.org/Design/sops.aspx>), the following resources provide guidance on communication and information about various stakeholder groups:

- ◆ APHIS Animal Health website (http://aphis.usda.gov/animal_health)
- ◆ FAD PReP Stakeholder Coordination and Collaboration Strategy (2010) (<https://fadprep.lmi.org/Design/strategicdocs.aspx>).

6.8 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. 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 from FMD. 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 will be required after leaving.

For further information on health and safety and personal protective equipment, see the FMD Health and Safety and Personal Protective Equipment SOP (<https://fadprep.lmi.org/Design/sops.aspx>). This SOP 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 (OSHA) respirator fit testing and a PPE selection matrix
- ◆ Pre-deployment information and guidance
- ◆ A protocol for staff field safety in an FMD response.

6.8.1 Mental Health Concerns

The health and safety of all personnel is affected by the mental state of those involved in the FMD response effort. Considering the toll an FMD outbreak may take on mental and physical health is critical in protecting the health and safety of all personnel.

FMD depopulation efforts can significantly affect the health of responders, livestock owners, and others impacted by the outbreak and response efforts. The Department of Health and Human Services (HHS) has developed resources specifically for emergency and disaster responders, States and planners, health professionals, and the general public (www.bt.cdc.gov/mentalhealth/). The FMD Euthanasia and Depopulation SOP (<https://fadprep.lmi.org/Design/sops.aspx>) provides further information on how personnel can effectively deal with euthanasia-related stress.

6.8.2 Further Information on Health, Safety, and PPE

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

- ◆ *APHIS Health and Safety Manual*. Available to APHIS employees at http://inside.aphis.usda.gov/mrbps/publications/safety_health_wellness_manual/index.shtml.
- ◆ NAHEMS Guidelines: Health and Safety (2010) (<https://fadprep.lmi.org>).
- ◆ NAHEMS Guidelines: Personal Protective Equipment (2010) (<https://fadprep.lmi.org>).

6.9 BIOSECURITY

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

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

The FMD Biosecurity SOP and the NAHEMS Guidelines: Biosecurity (2010) (<https://fadprep.lmi.org>) contain additional information and guidance on appropriate biosecurity measures in an FMD outbreak.

6.9.1 Biosecurity Hazards and Mitigating Measures

Box 6–5 shows biosecurity hazards and biosecurity measures to mitigate these risks during an FMD outbreak.

Box 6–5. 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).

6.9.2 Closed Herds

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

Box 6–6. Biosecurity Measure—Closed Herds

Biosecurity: Closed Herds

- To the fullest extent possible, it is critical to maintain a herd that is closed to the introduction of new livestock (with population increases occurring only from offspring).
- If a closed herd is not possible, purchase livestock only from the healthiest possible sources and isolate newly purchased and returning livestock from existing herds for a suitable period (typically 30 days or more).
- Do not introduce vaccinated animals to naïve herds.

6.9.3 Waiting Period

Another important biosecurity measure is to ensure personnel are not travelling between IP and unknown or uninfected premises. During an FMD outbreak, it is important that personnel wait the allotted time between premises visits—72 hours—in addition to following appropriate biosecurity and cleaning and disinfection protocols (see Subsection 6.15). This period is based on the 72-hour rule followed by the United Kingdom during the 2001 FMD outbreak.¹ Actual waiting periods can be dictated by Incident Command on the basis of the outbreak circumstances. Team members should not travel from IP or SP to unknown or uninfected premises. However, they may travel *between* IP, if proper mitigating procedures are followed.

Some studies suggest that extended avoidance periods 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 Incident Command.

6.10 QUARANTINE AND MOVEMENT CONTROL

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

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

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

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

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

The following subsections provide further information on movement control guidelines. The FMD Quarantine and Movement Control SOP (<https://fadprep.lmi.org/Design/sops.aspx>) provides specific, detailed guidance on measures considered necessary to prevent the spread of FMD through movement, including (1) keeping FMD out of livestock populations in areas free of FMD and (2) preventing the spread of FMD to uninfected livestock in areas where FMD exists. NAHEMS Guidelines: Quarantine and Movement Control (2011) also contains more details (<https://fadprep.lmi.org>).

6.10.1 Zones, Areas, and Premises Designations

The Incident Commander will work with the Disease Surveillance Branch (Operations Section) and the Situation Unit (Planning Section) to determine appropriate premises designations in the event of an FMD outbreak (see Appendix B for an organizational chart) as explained in Subsection 6.5, “Epidemiological Investigation and Tracing.” These zone, area, and premises designations will be used for quarantine and movement control efforts. Again, refer to Tables 6–1 and 6–2 and Figure 6–4 for the designations used here.

6.10.2 Permit Guidance to Move within Control Area

During an FMD outbreak, the following guidance will be used to issue permits in movement control efforts (for permit guidance for milk and milk products, see the *Secure Milk Supply Plan*, <https://fadprep.lmi.org/Design/SecureMilk.aspx>):

- ◆ ARP in the CA (IZ or BZ) that are not IP, CP, or SP are eligible to move susceptible animals or animal products within a CA (IZ or BZ).

-
- ◆ Movement control of susceptible animal species or animal products from ARPs is limited to other premises within the CA (IZ or BZ) and is accomplished by risk assessment, surveillance requirements, biosecurity procedures, and permits.
 - ◆ ARPs that seek to move susceptible animals or animal products out of the CA need to become MP.
 - ◆ Non-susceptible species on IP, CP, or SP are subject to movement control and may seek to move within the CA (IZ or BZ) by permit.
 - ◆ Susceptible animals outside a BZ should not move into or through a CA, except for those going to slaughter when the only option is movement by permit to a slaughter facility inside the CA. Other susceptible animal conveyances should be rerouted around the CA.
 - ◆ FP (premises not located in the CA) that seek to move susceptible animals into the CA may only do so by permit.

6.10.3 Permit Guidance to Move Out of Control Area

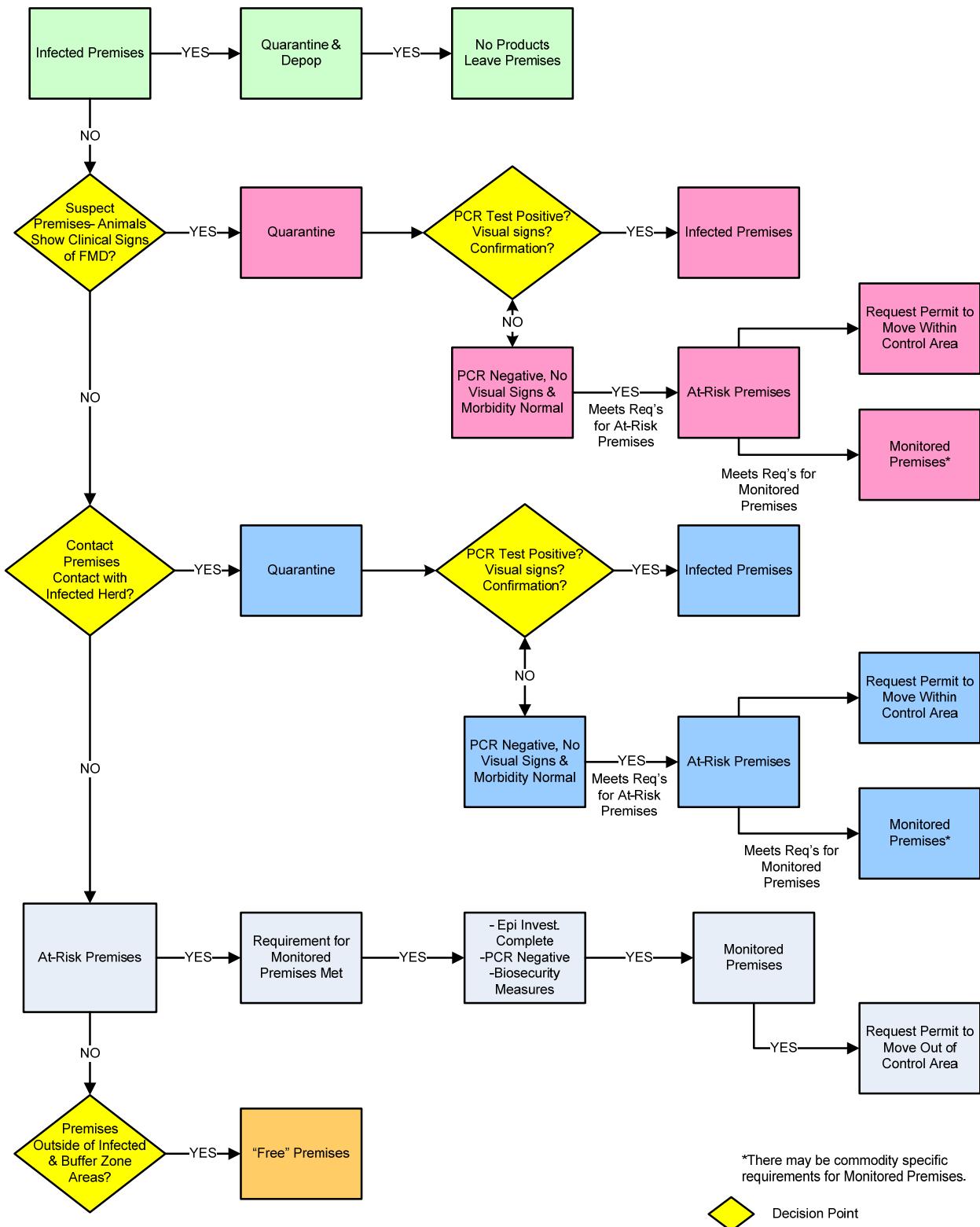
During an FMD outbreak, the following guidance will be used to issue permits to move out of a CA (for permit guidance for milk and milk products, see the *Secure Milk Supply Plan*, <https://fadprep.lmi.org/Design/SecureMilk.aspx>):

- ◆ MP can apply for a permit to move susceptible animals and susceptible animal products out of the CA (IZ and BZ).
 - MP, located in the CA (IZ or BZ), have susceptible animals that do not have clinical signs (or other epidemiological evidence) compatible with FMD.
 - MP objectively demonstrate they are not IP, CP, SP, or ARP.
 - MP are subject to epidemiological investigation, risk assessment, surveillance requirements, and biosecurity procedures.

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

Figure 6-5 illustrates movement control and permitting in relation to premises designation.

Figure 6-5. Premises Designations in Relation to Permitting and Movement Control



6.10.4 Moving Commodities, Animals, and Conveyances in FMD Outbreak

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

6.10.5 Guidance for All Premises

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

6.10.6 Quarantine and Movement Controls for Products and Fomites

Tables 6–4 and 6–5 provide movement guidance for livestock, equipment, vehicles, other animals, and other fomites. Table 6–4 provides guidelines for moving into, within, and out of the CA. Table 6–5 provides guidelines for moving in or out of an IP or SP.

Table 6-4. Movement Control into, within, and out of Control Area for At-Risk Premises and Monitored Premises

Item Moving	Movement into Control Area	Movement within Control Area ^a	Movement out of Control Area
Susceptible animals	Prohibited unless there are exceptional circumstances. Permit for movement must be approved by ICP with appropriate biosecurity measures.	At-Risk Premises <i>only</i> allowed to move by permit approved by ICP; surveillance requirements, negative diagnostic tests, premises biosecurity, and risk assessment may be required for permit.	Monitored Premises <i>only</i> allowed to move by permit approved by ICP; surveillance requirements, negative diagnostic tests, premises biosecurity, and risk assessment may be required for permit.
Semen, embryos from susceptible animals	Prohibited unless there are exceptional circumstances. Permit for movement must be approved by ICP with appropriate biosecurity measures.	Allowed by permit approved by ICP and appropriate bio-security measures.	Monitored Premises <i>only</i> allowed by permit approved by ICP and appropriate bio-security measures.
Other animals (non-susceptible animals)	Prohibited unless there are exceptional circumstances. Permit for movement must be approved by ICP with appropriate biosecurity measures.	At-Risk Premises <i>only</i> allowed to move by permit approved by ICP; surveillance requirements and negative diagnostic tests for susceptible animals on premises, premises biosecurity, and risk-assessment may be required for permit.	Monitored Premises <i>only</i> allowed to move by permit approved by ICP; surveillance requirements and negative diagnostic tests for susceptible animals on premises, premises biosecurity, and risk-assessment may be required for permit.
Milk and milk products	See <i>Secure Milk Supply Plan</i> (under development)	See <i>Secure Milk Supply Plan</i> (under development)	See <i>Secure Milk Supply Plan</i> (under development)
Skin and hides	Allowed by permit approved by ICP and appropriate bio-security measures.	Allowed by permit approved by ICP and appropriate bio-security measures.	Monitored Premises <i>only</i> allowed by permit approved by ICP, appropriate bio-security measures, and OIE treatment guidelines.
Wool	Allowed by permit approved by ICP and appropriate bio-security measures.	Allowed by permit approved by ICP and appropriate bio-security measures.	Monitored Premises <i>only</i> allowed by permit approved by ICP, appropriate bio-security measures, and OIE treatment guidelines.
Carcasses, meat, offal, wastes from susceptible animals	Prohibited unless permit approved by ICP and appropriate biosecurity measures.	Prohibited unless permit approved by ICP and appropriate biosecurity measures.	Monitored Premises <i>only</i> allowed by permit approved by ICP and appropriate bio-security measures.
Crops and grain (premises with susceptible species)	Allowed with appropriate biosecurity measures.	Allowed by permit approved by ICP and appropriate bio-security measures.	Monitored Premises <i>only</i> allowed by permit approved by ICP and appropriate bio-security measures.
Equipment, vehicles, and other fomites (premises with susceptible species)	Allowed with appropriate biosecurity measures.	Allowed by permit approved by ICP and appropriate bio-security measures.	Monitored Premises <i>only</i> allowed by permit approved by ICP and appropriate bio-security measures.

^a Not including movement on a single, contiguous premises.

Table 6-5. Movement Control into or out of Control Area for Infected Premises or Suspect Premises

Item Moving	Movement into Infected Premises or Suspect Premises	Movement Out of Infected Premises or Suspect Premises
Susceptible animals	Prohibited, except slaughter, under certain circumstances.	Prohibited, except slaughter, under certain circumstances.
Semen, embryos from susceptible animals	Prohibited.	Prohibited.
Other animals	Prohibited unless permit approved by ICP and appropriate biosecurity measures.	Prohibited unless permit approved by ICP and appropriate biosecurity measures.
Milk and milk products	Prohibited. See <i>Secure Milk Supply</i> for any derogations or biosecurity mitigations.	Prohibited. See <i>Secure Milk Supply</i> for any derogations or biosecurity mitigations.
Skin and hides	Prohibited unless permit approved by ICP and appropriate biosecurity measures.	Prohibited unless permit approved by ICP and appropriate biosecurity measures.
Wool	Prohibited unless permit approved by ICP and appropriate biosecurity measures.	Prohibited unless permit approved by ICP and appropriate biosecurity measures.
Carcasses, meat, offal, wastes from susceptible animals	Prohibited unless permit approved by ICP and appropriate biosecurity measures.	Prohibited unless permit approved by ICP and appropriate biosecurity measures.
Crops and grain	Allowed with appropriate biosecurity measures.	Prohibited unless permit approved by ICP and appropriate biosecurity measures.
Equipment, vehicles, and other fomites	Allowed with appropriate biosecurity measures.	Prohibited unless permit approved by ICP and appropriate biosecurity measures.

See Subsection 6.16 for additional guidance for movement control of vaccines.

6.10.7 Surveillance Required for Livestock and Product Movement

Surveillance measures are required for movement of livestock and animal products for premises located in the CA (IZ and BZ). These steps include visual surveillance along with diagnostic testing prior to movement. (Appendix E contains more information on surveillance for the movement of livestock and animal products.) See the *Secure Milk Supply Plan* for surveillance measures for movement of milk and milk products (<https://fadprep.lmi.org/Design/SecureMilk.aspx>).

6.10.8 OIE Treatment Guidelines for FMD

The OIE *Terrestrial Animal Health Code* (2010) provides guidance for the importation of animals, products, and commodities from FMD infected countries or zones, as well as processes for inactivating FMD in meat. The guidance for the

inactivation of FMD in meat, wool and hair, bristles, raw hides/skins, and milk/cream is provided below (Article 8.5.34 to 8.5.39). [Chapter 8.5 of the Terrestrial Animal Health Code](#) (2010) also contains guidance for other items, such as skins, trophies, and casings, as well as importation.

6.10.8.1 PROCEDURES FOR THE INACTIVATION OF FMD VIRUS IN MEAT

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

1. Canning

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

2. Thorough cooking

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

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

3. Drying after salting

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

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

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

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

1. industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide (soda) or potassium hydroxide (potash);
2. chemical depilation by means of slaked lime or sodium sulphide;

-
3. fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours. The most practical method is to place potassium permanganate in containers (which must NOT be made of plastic or polyethylene) and add commercial formalin; the amounts of formalin and potassium permanganate are respectively 53 ml and 35 g per cubic metre of the chamber;
 4. industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60-70°C
 5. storage of wool at 18°C for 4 weeks, or 4°C for 4 months, or 37°C for 8 days.

6.10.8.3 PROCEDURES FOR THE INACTIVATION OF FMD VIRUS IN BRISTLES

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

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

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

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

6.10.8.5 PROCEDURES FOR THE INACTIVATION OF FMD VIRUS IN MILK AND CREAM FOR HUMAN CONSUMPTION

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

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

6.10.8.6 PROCEDURES FOR THE INACTIVATION OF FMD VIRUS IN MILK FOR ANIMAL CONSUMPTION

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

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

6.11 CONTINUITY OF BUSINESS

Business continuity in the event of an FMD outbreak will allow critical agriculture and food industries to maintain typical business, or quickly return to business during a disease response, after the risk of disease spread or threat to public health has been effectively managed. Continuity of business planning can help to minimize unintended consequences on producers and consumers impacted by FMD. During an FMD outbreak, permitting, movement control, and prioritized disruptions—all based on science and risk-based approaches—are critical measures to ensure continuity of business. The Continuity of Business SOP (<https://fadprep.lmi.org/Design/sops.aspx>) covers

- ◆ key roles and responsibilities in business continuity planning,
- ◆ benefits of continuity of business planning,
- ◆ potential competing interests, and
- ◆ preparedness and response goals.

The *Secure Milk Supply Plan* (<https://fadprep.lmi.org/Design/SecureMilk.aspx>) offers additional continuity of business information, particularly applicable to interstate trade. (Appendix I contains information on the *Secure Milk Supply Plan*.)

6.12 REGIONALIZATION AND COMPARTMENTALIZATION (INTERNATIONAL TRADE)

Regionalization and compartmentalization are important, related concepts that can help to facilitate and reestablish international trade of livestock, milk, and associated products. The goal of regionalization or compartmentalization is to develop science-based international trade policy and procedures to reduce the adverse economic effects of an FMD outbreak.

As defined by the OIE, regionalization (also called zoning) applies to an animal subpopulation defined primarily on a geographical basis (using natural, artificial, or legal boundaries). Regionalization recognizes that risk may be tied to factors that are not reflected by national political boundaries and provides information to the OIE and member countries that can be used in deciding whether to receive or reject our exports.

On the other hand, compartmentalization refers to an animal subpopulation defined by management and husbandry practices related to biosecurity. Compartmentalization will allow veterinary authorities to demonstrate and maintain disease freedom in certain commercial establishments, enabling trade movement of animal products.

Compartmentalization has not been fully implemented in a disease outbreak to date, and it depends on the recognition of compartments by international trading partners. State compartmentalization will depend on producers, industry, and State and Federal animal health authorities developing and strengthening relationships and agreeing to procedures preceding an FMD outbreak. Efforts to compartmentalize should be made prior to any FMD outbreak.

The OIE *Terrestrial Animal Health Code* (2010) also offers guidance on regionalization and compartmentalization in [Chapter 4.3](#). Article 8.5.6 provides specific requirements for an FMD-free compartment (Chapter 5 contains the article in full). There are no OIE-recognized FMD-free compartments in the world, and an FMD-free compartment is unlikely to be established in the event of an FMD outbreak in the United States.

The Regionalization and Compartmentalization SOP (<https://fadprep.lmi.org/Design/sops.aspx>) contains further information on both regionalization and compartmentalization.

6.13 MASS DEPOPULATION AND EUTHANASIA

IP will be depopulated within 24 hours after declaration of an FMD outbreak, and in many cases, susceptible animals on CP will also be depopulated within 24 hours of the premises being classified as CP. The FMD Mass Depopulation and Euthanasia SOP (<https://fadprep.lmi.org/Design/sops.aspx>) provides instructions

for personnel following the declaration of an FMD outbreak and the classification of IP and CP. This SOP offers FMD-specific information on mass depopulation and euthanasia, including evaluation of various euthanasia methods, such as

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

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

Mass depopulation and euthanasia are not synonymous. Mass depopulation is employed in an FMD response to prevent or mitigate the spread of FMD through elimination of infected or potentially infected animals. Best practice guidance issued in 2007 from the American Veterinary Medical Association (AVMA) states “Under unusual conditions, such as disease eradication and natural disasters, euthanasia options may be limited. In these situations, the most appropriate technique that minimizes human and animal health concerns must be used.” Qualified personnel should perform mass depopulation in the event of an FMD outbreak using the safest, quickest, and most humane procedure in accordance with AVMA guidance.

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

NAHEMS Guidelines: Mass Depopulation and Euthanasia (2010) (<https://fadprep.lmi.org>) contains additional information on euthanasia and mass depopulation.

6.14 DISPOSAL

Effective disposal of animal carcasses and materials is a critical component of a successful FMD response. FMD can survive for long periods on both organic and inorganic materials. The FMD Disposal SOP (<https://fadprep.lmi.org/Design/sops.aspx>) discusses how to dispose of carcasses, animal products, other materials, and items that cannot be properly cleaned and disinfected (such as manure, litter, and bedding), products of the response effort (such as PPE), and products of vaccination response. Disposal will occur within 24 hours of the destruction of FMD-susceptible animals on premises.

Disposal must be done in a manner that does not allow FMD virus to spread, minimizes negative environmental effects, and conserves meat or animal protein if logically supportable from a biosecurity standpoint. In some cases, moving clinically normal animals to a slaughter facility within the CA may be possible, though they may have been exposed to the FMD virus on IP or CP.

On-site burial is an inexpensive and biosecure method of disposal that minimizes the transportation of infected materials. However, on-site methods may be limited by several factors such as topography, soil type, soil depth to bedrock, seasonal high-water table, and environmental regulations.

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

Disposal must always occur in a biosecure way that minimizes environmental impact. In addition, local and State regulations must be observed or memorandums of understanding must be obtained to ensure disposal capability. If movement is required for disposal, Incident Command must permit such movement. In the event that available personnel are insufficient for disposal requirements in an FMD outbreak, the Incident Commander can request emergency 3D contractor support from the NVS. NAHEMS Guidelines: Disposal (2011) (<https://fadprep.lmi.org>) contains further guidance.

6.15 CLEANING AND DISINFECTION

Because of FMD's high survival rate on both organic and inorganic materials, aggressive cleaning and disinfection (C&D) practices are required for control and eradication. C&D are to be conducted within 48 hours of the disposal of FMD infected and susceptible animals. The FMD Cleaning and Disinfection SOP (<https://fadprep.lmi.org>) provides information on

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

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.

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

NAHEMS Guidelines: Cleaning and Disinfection (2010) (<https://fadprep.lmi.org>) contains additional information.

6.16 VACCINATION

The use of emergency vaccination in the event of FMD has been extensively discussed in Chapter 5. This subsection explains important details in the event emergency vaccination is employed in an FMD outbreak. Box 6–7 summarizes key concerns of using emergency vaccination strategies in an FMD outbreak.² (Appendix J contains additional scientific information on FMD vaccines and vaccination.) The NVS Countermeasures Working Group Report on Foot-and-Mouth Disease (2007) and the NAHEMS Guidelines: Vaccination for Contagious Diseases (2010) contain additional information (<https://fadprep.lmi.org>).

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

Box 6–7. Challenges of Emergency Vaccination for FMD

Challenges of FMD Vaccination: Vaccine Production

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

Challenges of FMD Vaccination: Vaccine Use

- Vaccines provide only serotype-specific protection. Vaccination against one serotype may fail to protect fully or at all against other strains within the serotype, depending on how closely the vaccine and field strain are related, and the potency of the vaccine.
- Onset of immunity is not immediate. Inactivated FMD vaccines may decrease viral shedding and clinical signs in cattle and sheep in challenge studies as early as 4 days after vaccination with protection improving for the next 2-3 weeks; swine appear to be more difficult to protect shortly after challenge, limited studies have reported some protection as soon as 3-4 days after vaccination; however, with more severe challenges, pigs may not be completely protected against disease until 21-28 days after vaccination.
- Duration of immunity depends on the type of vaccine used and varies by species of animal. No currently available vaccine provides “sterilizing immunity” which will prevent subsequent infection.
- It is possible that individual vaccinated cattle infected with FMDV could become asymptomatic virus carriers.
- Diagnostic testing capabilities to differentiate infected and vaccinated animals are necessary if a vaccination strategy is utilized (see Subsection 6.16.1).

6.16.1 DIVA Testing

One of the most significant challenges to any emergency vaccination strategy is differentiating infected and vaccinated animals for effective surveillance of FMDV. As illustrated in Figure 6–3, a 3ABC Prionics ELISA conducted by NVSL-FADDL would typically be used to differentiate infected herds from vac-

cinated herds. Individual animal tests remain a diagnostic challenge. Other non-structural protein (NSP) tests that may assist in DIVA testing are currently being validated for use in the United States.

6.16.2 NAFMDVB Guidelines for Use of Vaccination in FMD Outbreak

The following subsections come directly from NAFMDVB Guidelines (2007). They provide guidance for the usage of FMD vaccine in the United States in the event that an emergency vaccination strategy is employed in an outbreak. Other documents that will also guide FMD vaccination are forthcoming, including NAHEMS Guidelines: Vaccination for Contagious Diseases (2010) with an FMD Appendix and the FMD Vaccination SOP.

6.16.2.1 ACCESS TO NAMFDVB BY MEMBERS AND OTHER COUNTRIES

This subsection is Chapter 6 in the NAFMDVB Guidelines (2007):

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

6.16.2.2 EMERGENCY VACCINE FIELD USAGE GUIDE

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

1. Each member country should establish a usage plan, including a clear policy, administrative and implementation procedures, and requirements for recording usage sufficient to meet OIE guidelines.

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

6.16.2.3 FMD VACCINATE IDENTIFICATION

This is Chapter 8 of the NAFMDVB Guidelines (2007):

1. All FMD vaccines shall have no fewer than two (2) visible external means of identification.

- a. If the animal has no official identification before vaccination, an FAD Vaccination Ear tag shall be applied in the proximal portion of each ear; OR
 - b. If the animal has an existing official identification ear tag, e.g., Health of Animals, CCIA, or USA tag, TB Official Campaign ear tag, a single FMD Vaccination ear tag should be applied to the proximal portion of the left ear.³
 - c. Should the vaccinated premises have a unique individual animal identification system in place, e.g., an electronic identification system or readily readable tattoos, only a single FMD tag may be applied to the left ear of each vaccinated animal. Use of such systems shall be at the discretion of the animal health official on site in order to allow system flexibility and greater efficiency of the vaccination crews.
 - d. Identification methods such as plastic tags that are numbered manually with indelible ink, brands, or ear notches are not considered acceptable unique animal identification for this circumstance.
 - e. In swine operations which employ all-in/all-out animal management systems, it may be acceptable to vaccinate all animals in a specific swine building without identifying the individual animals providing the competent authority controls movement.
 - f. Since piglet identification will be infrequent, each country will order its own piglet tags as needed.
2. FMD Vaccination tags shall be pink metal ear tags beginning with “V” followed by alphanumeric identifications. Ear tags are inserted in the proximal third of the anterior border of the animal’s ear with the alpha-numeric sequence “out” i.e. the number is on the dorsal surface of the ear.⁴
 3. The ear tags are
 - a. To be used only for FMD vaccination identification;
 - b. Are not considered official for interstate/international movement; and
 - c. Do not replace or satisfy the requirements of other program identification that may be required by the country.

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

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

-
4. Each FMD vaccination ear tag or other official means of identification
 - a. May NOT be removed from the animal until final disposition;
 - b. May NOT be reused or reissued to another animal;
 - c. Will be recorded at final disposition of the animal whether it be following natural death, on-farm euthanasia, rendering, or slaughter;
 - d. In the case of swine with building identification, no individual identification shall be required if an exact count of the animal is available, and the animals in the barn are under control by the competent authority with the only option for disposal being destruction.
 5. Each country should have a means of enforcement such as a system of fines and penalties to ensure identification provisions.
 6. Six million [5 million large (cattle) & 1 million small (sheep, swine)] fluorescent pink metal ear tags beginning with "V" followed by alphanumeric identifications; 96 large pliers and 134 small pliers are stockpiled for the NAFMDVB at the APHIS warehouse 1510 E. Bannister Road, Kansas City, Missouri, USA 64131. Telephone (816) 926-1629, and fax (816) 823-4360.
 - a. In the event of an FMD outbreak, the country(ies) infected shall be allocated tags from the stockpile in quantities estimated to coincide with the initial units of vaccine being made available.
 - b. A record of vaccination ear tags issued to each country shall be kept at the warehouse.
 - c. Replacement ear tags shall be ordered following the outbreak at the expense of the requesting country.
 7. Additional ear tags can be manufactured at a minimum rate of 300,000 tags per week. The USDA contract requires the manufacturer to have the capacity to deliver a maximum of 1,500,00 tags a week.

6.16.2.4 FMD VACCINATE RECORDS AND DISPOSITION

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

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

- c. Animal species
 - d. FMD vaccine ear tag(s)
 - e. Officially legislated identification or tattoo
 - f. Breed
 - g. Sex
 - h. Age
 - i. Color or markings
 - j. Commercial or purebred
 - k. Registration numbers (if purebreds). In the case of purebred animals, the information on the registration/pedigree certificates must be verified for each animal.
2. Vaccination records should take advantage of existing databases. Collaboration with livestock industry associations is critical but competent authorities in each member country must retain the official secure records for tracing vaccines. The following fields are required in the official database:
- a. Owner;
 - b. Address;
 - c. Location (legal land description, +/- GIS coordinates);
 - d. Telephone(s);
 - e. Email if available;
 - f. Vaccination date;
 - g. Vaccination team;
 - h. Vaccine serial number & expiry date;
 - i. All on-farm records animal characteristics-species, sex, age, color, registration (if purebred; FMD Vaccine Ear Tag; official ear tag (H or A tag, CCIP tag or tattoo); any other unofficial ear tag, brands or electronic implants;
 - j. Any licensed movements (origin and destination);
 - k. Disposition of animal.
3. Where possible, records should be kept electronically.

-
4. Vaccinated animals may be:
 - a. Euthanized on the infected premises or at other approved location;
 - b. Shipped to slaughter for human consumption following required vaccine withdrawal period; or
 - c. Entered into the general animal population after an acceptable level of risk is determined. A proper NSP test will be recommended by the Technical Committee for use to determine the level of risk.

The decision will be taken by the 3 CVOs.

6.16.2.5 CONTROL MEASURES IN THE VACCINATION ZONE

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

1. Movement within zone during vaccination campaign: The Mexican Secretariat of Agriculture and Rural Development (SAGARPA), the Canadian Food Inspection (CFIA) Agency and the United States Department of Agriculture (USDA) shall ensure that the following control measures are applied in the vaccination-buffer zone(s) during the period of vaccination until 30 days after last herd is vaccinated as this allows time to remove circulating virus:
 - a. No movement of animals is permitted onto or from vaccinated premises without appropriate licenses. Upon vaccination, premises are quarantined (under appropriate authority for each country). Movement permit conditions will require that:
 - i) No animal in herd of origin has shown clinical signs of FMD within 30 days.
 - ii) No additions to herd of origin for 30 days.
 - iii) No clinical FMD within 10 km for 30 days.
 - iv) A vaccinated animal may only move to another vaccinated premises.
 - v) Transport conveyances meet C&D requirements of zone.
 - b. Vaccinated animals may be moved under license within the vaccination-buffer zone(s) but may not leave the zone except to slaughter.

- c. In the absence of an abattoir in the vaccination-buffer or surveillance-buffer zone, vaccinated animals can exceptionally be transported to the nearest abattoir for immediate slaughter at the end of the day provided suitable cleaning & disinfection procedures were followed.
- d. Since the carrier state cannot be ruled out, animal products and by-products from vaccinated animals shall be considered potentially infected and their distribution restricted to the infected zone unless treated to OIE standards for FMD destruction.
- e. People and service vehicles present the greatest risk for fomite transmission of FMD to hitherto undiagnosed premises. All premises shall implement enhanced biosecurity approved by the competent authority.
- f. Trucks used to transport animals or animal products or used to service a farm within the vaccination-buffer zone shall
 - i) Have an external cleaning and disinfection at origin prior to departure; and
 - ii) A thorough cleaning and disinfection at destination.
- g. Trucks used to transport animals or animal products or used to service a farm shall not leave the vaccination-buffer zone without a thorough cleaning and disinfection under official inspection at cleaning and disinfection facility approved by the competent authority.
- h. Periodic monitoring of transport carriers should be conducted to determine compliance.
- i. Animal service industries personnel including veterinary practitioners, inseminators, feed delivery, transporters working on vaccinated premises in the vaccination-buffer zone shall
 - i) Restrict service to that zone since a vaccinated premises can more readily mask the presence of FMD virus than non-vaccinated premises;
 - ii) Strictly follow an approved cleaning and disinfection protocol.
- j. Semen and embryo collection within vaccination zone shall be suspended unless it is frozen and stored separately for at least 30 days then dispatched only if the vaccinated donors meet conditions stipulated in the Code, Annex 2.1.1.14, Annex 2.1.1.16, and Annex 2.1.1.19 as appropriate.
- k. Straw and forage meet conditions stipulated in the Code 2002 Annex 2.1.1.130 and move under permit.

-
- l. All stockyards, auction markets, sales, fairs, zoos, assembly points, and other livestock concentration points shall operate under inspection by the competent authority. Only vaccinated animals under permit may enter such premises in the vaccination-buffer zone under permit.
 - m. Animals in zoos within the vaccination-buffer zone may be vaccinated pending risk assessment and in line with the Code, Article 2.1.1.5.
 - n. Any concentration points must be cleaned and disinfected after assembly of animals.
 - o. Transportation through the vaccination-buffer zone of susceptible (non-vaccinated) animals will be permitted if by shortest direct route and vehicles are sealed by the competent authority.
 - p. Susceptible wildlife in the vaccination-buffer zone will undergo a risk assessment considering information on
 - i) Population density and distribution;
 - ii) Social structure; habitat; contact with domestic species;
 - iii) FMD virus strain and length of time of potential exposure.

These will be factored into three non-exclusive options

- i) Containment
- ii) Surveillance and sampling; or
- iii) Population reduction.

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

2. Surveillance within vaccination zone post-vaccination: The Mexican Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA), the Canadian Food Inspection Agency (CFIA) and the United States Department of Agriculture (USDA) shall ensure that the following control measures are applied in the vaccination zone(s) during the period between at least 30 days from the time of completion of vaccination until the completion of a clinical and serological survey.
 - a. A clinical and serological survey shall be carried out with the aim to identify herds of animals of susceptible species that have had contact with FMD virus without clinical signs including:
 - i) Clinical inspection of all animals of susceptible animals in the vaccination-buffer zone.

- ii) Serological testing for non-structural protein antibodies or other OIE approved test suitable to detect circulating virus in all vaccinated animals and their non-vaccinated offspring.
 - b. Any herd found infected through the confirmed presence of FMD virus or previous contact with FMD virus shall be subject to
 - i) Destruction of animals positive to the approved test (above);
 - ii) Slaughter of the remaining animals under controlled conditions authorized by the competent authorities;
 - iii) Decontamination (=cleaning and disinfection) of the premises;
 - iv) Restocking according to country's contingency plan;
 - v) Tracing and treatment for FMD virus destruction of any products from the estimated time of introduction of FMD virus.
 - c. Movement of animals, animal products and by-products shall be as for 8.1 with the additions as described below.
 - d. Movement of non-vaccinated susceptible animals may be authorized at least 6 months after completion of vaccination where vaccines are not slaughtered or not earlier than three months if vaccines are slaughtered.
 - e. Movement of non-vaccinated susceptible animals, offspring of vaccines shall be restricted to move to:
 - i) A slaughterhouse outside the vaccination-buffer zone for immediate slaughter;
 - ii) A feedlot from which they are sent directly to slaughter;
 - iii) Any premises after a negative serological test for the detection of FMD virus antibody.
3. Movement post-surveillance: Following completion of the serological survey in paragraph 2, The Mexican Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA), the Canadian Food Inspection Agency (CFIA) and the United States Department of Agriculture (USDA) shall ensure that the following control measures are applied in the vaccination-buffer zone(s):
- a. North American trade in vaccinated animals is prohibited except under authorized conditions as outlined below;

-
- b. Movement of animals of susceptible species out of the vaccination-buffer zone may be authorized following Annex 2.1.1.6 bis of the Code where originating and receiving zones are of equivalent Animal Health status and transportation through zones of higher status is in trucks sealed by the competent authority and travelling the shortest distance on a direct route.
 - 4. The above conditions will apply only if all vaccines are ear tagged, movements of vaccines remain under veterinary service control until death, and an active program of slaughter of vaccines is followed.

6.16.2.6 FMD VACCINE DISTRIBUTION

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

- 1. The purpose of this Chapter is to propose the criteria for sharing and distribution if more than one Tripartite country wants to use FMD vaccine. This chapter is to be used in conjunction with the North American Guidelines for FMD Vaccine Use Consideration on page.
- 2. It is assumed that this decision planning would not be necessary unless there were cases of FMD in more than one country or that an outbreak in one country was very near or on the border of a neighboring country.
- 3. It has been suggested that it may not be in the best interests of a situation to base the availability of vaccine entirely on the 70/20/10 (US/Mexico/Canada) funding ratio.
- 4. It appears that most of the criteria used in the decision tree for FMD vaccination would also apply to the decision on how to distribute vaccine to more than one country. They are:
 - a. Number of susceptible animals in the vaccination zone: to be defined based on the national statistical sources identified by each country. The size of the vaccination zone may vary according to local epidemiological conditions.
 - b. Number of affected herds: based on the number of affected herds at the time the decision to vaccinate is taken.
 - c. Rate of spread: measure of the number of new cases per week, based on the week the decision to vaccinate is taken.
 - d. Geographic spread: the distance separating affected herds or clusters of affected herds provides an indication of the distribution of disease in the vaccination zone.
 - e. Number of affected swine herds: swine play an important role in the spread of FMD as they are great amplifiers of the FMD virus.

- f. Kind of farms—a description of the predominant species and production systems in the vaccination zone is required.
 - g. Ability/capacity to depopulate.
 - h. Density of the susceptible livestock population (herds & animals) in the vaccination zone.
 - i. Contact rate. Contact rates the susceptible livestock in the infected zone may have to be based on quite a bit of subjectivity. Some factors that affect contact rates would be the time of year, weather, farm crop harvesting, density of livestock, and presence of livestock markets in the area.
 - j. Natural barriers—well defined and easily controlled access; few or many points of entry and exit.
 - k. Free-ranging wildlife involvement.
 - l. Climate—warm and dry versus cold, a relatively high humidity, and slow/steady winds.
5. There would have to be agreement on what livestock population data are to be used and how it will be obtained. Once FMD has been diagnosed and a decision made to vaccinate, there may not be time to organize and send out survey crews to establish a current livestock population estimate.
- a. Canada would use the Statistics Canada Census of Agriculture completed every five years. The last census was carried out in 2001.
 - b. The United States would base their estimates on the Department of Agriculture (USDA) National Agricultural Statistics Service (NASS) published yearly and the Census of Agriculture published every 5 years.
 - c. Mexico would use data gathered by SAGARPA Delegations in each state as the most likely source of population data.
6. If the NAFMDVB will provide immediate support based on the official estimates of the susceptible livestock population in each vaccination zone, no other criterion may need to be considered. If there is not enough vaccine immediately available, then the other criteria would be used.
7. The decision criteria for vaccine distribution should be applied when
- a. Two or more concurrent outbreaks occur in more than one country;

- b. The number of susceptible species in the vaccination zone exceeds the number of doses present in the bank and commercially produced vaccine of the appropriate subtype is not available.
8. Table 6-6 shows the proposed rating system for distribution of vaccine:

Table 6-6. Scoring System for Vaccine Distribution Decision Based on Criteria Related to Outbreak (from Chapter 11 NAFMDVB Guidelines)

Criteria in order of impact priority	High	Medium	Low
Number of susceptible animals in vaccination zone. High = >500,000 Medium = 250,00 - 500,000 Low = <250,000	25	20	15
Number of affected herds in the infected zone. High = 5 or more Medium = 3 or 4 Low = 1 or 2	25	20	15
Rate of spread in the infected zone. High = > 7 cases per wk. Medium = 3 to 7 cases per wk. Low = < 3	25	20	15
Geographic spread of affected herds. High = 2 or more outbreaks separated by > or = 10 km Medium = 2 or more affected herds less than 10 km apart Low = 1 affected herd	25	20	15
Number of affected swine herds in the infected zone. High = 2 or more infected swine herds Med. = 1 swine herd Low = 0 swine	25	20	0
Kinds of farms in the vaccination zone. High = swine predominant in the zone Medium = Bovine herds predominant in the zone Low = sheep/goats predominant in the zone	25	20	15
Ability/capacity to depopulate. High = on-farm disposal not possible; capacity of 1 small herd per day Medium = on-farm disposal possible but limited capacity of 2 small herds per day Low = on-farm disposal possible; capacity of 2 large herds per day	20	15	10
Density of livestock in the vaccination zone. High = >1 per acre (>2.5/Ha) Medium = 1/2 to 1 per acre (1.2-2.5/Ha) Low = < 1/2 per acre (<1.2/Ha)	15	10	5
Density of herds in the vaccination zone. High = 5 or more herds per 3 sq. km. (about 1 sq. mile) Medium = 1 - 4 herds per 3 sq. km. Low = < 1 herd per 3 sq. km.	15	10	5
Contact rate. High = > 10 per wk. Medium = 5 to 10 per wk. Low = less than 5	15	10	5
Natural barriers. High = affected area is in a flat mainland area with many roads and traffic Medium = some presence of barriers such as major river or major mountain range Low = very isolated area such as a desert, island, or isthmus	15	10	5
Wildlife involvement. High = wild swine in the zone Medium = wild ruminants in the zone but no swine Low = no wildlife involvement	10	5	0
Climate. High = cold, relative humidity at 60 % or above, slow/steady winds Medium = cold, relative humidity 40 to 59%, moderate/variable winds Low = warm , dry, strong/straight winds	5	3	1
Totals of Ratings	230	173	101

a. Example:

- i) Country A and Country B both have outbreaks and both want to vaccinate at the same time.
- ii) Each country is rated (scored) on each of the criterion by the same small committee of experts. Country A receives a total score of 215. Country B received a total score of 195.
 $215+195=410$.
- iii) Country A would receive 52% (215/410) of the doses and country B would receive 48% (195/410).
- iv) It is suggested that the committee be made up of three epidemiologists, one from each of the three tripartite countries.
- v) The objective for the committee is to present objective information as an aid to the decision makers.

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

- i) Country A and Country B both have outbreaks and both want to vaccinate at the same time.
- ii) Country B has two distinct infected zones and two distinct vaccination zones.
- iii) Each country is rated (scored) on each of the criterion by the same small committee of experts. Country A receives a total score of 215. Country B received a total score of 300 (120 for Vaccination zone 1 and 180 for Vaccination zone 2).
 $215+300=515$.
- iv) Country A would receive 42% (215/515) of the doses and Country B would receive 58% (300/515). Within Country B, Vaccination zone 1 would receive 40% (120/300) and vaccination zone 2 would receive 60% (180/300) of the vaccine.

6.16.3 Zone, Area, and Premises Designations

Also provided in Chapter 5 of this document, this subsection provides figures to illustrate the use of emergency vaccination in an FMD outbreak. For figures that show the different strategies that could be employed in an outbreak in relation to zones, areas, and premises, see Chapter 5. The subsequent subsections explain a CVZ and PVZ more generally. Chapter 3 of the *APHIS Framework for Foreign Animal Disease Preparedness and Response* (<https://fadprep.lmi.org>) contains additional information and figures about zone, area, and premises designations.

6.16.3.1 CONTAINMENT VACCINATION ZONE

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

Figure 6-6. Examples of Containment Vaccination Zones

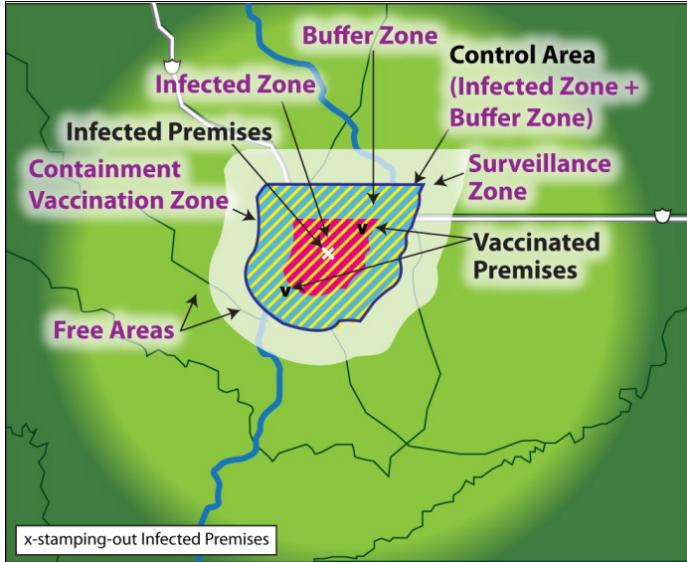
Emergency Vaccination in Infected Zone



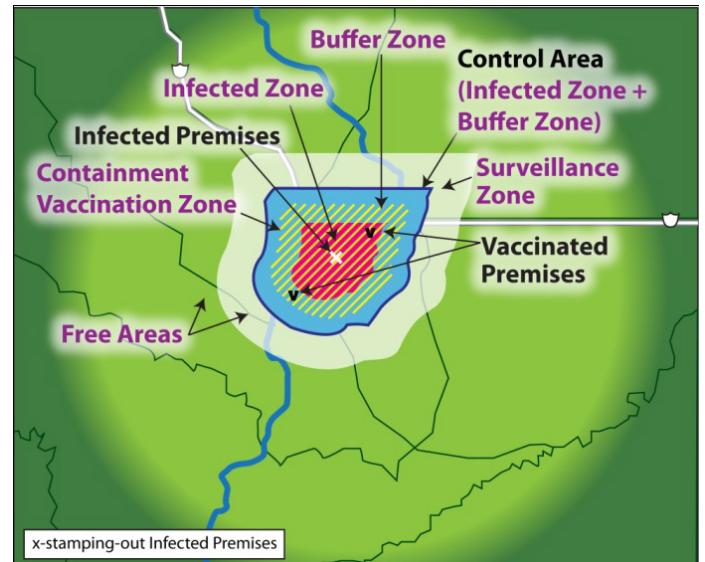
Emergency Vaccination in Buffer Zone



Emergency Vaccination in Control Area



Emergency Vaccination in IZ and Partial BZ



Note: Figures are not to scale.

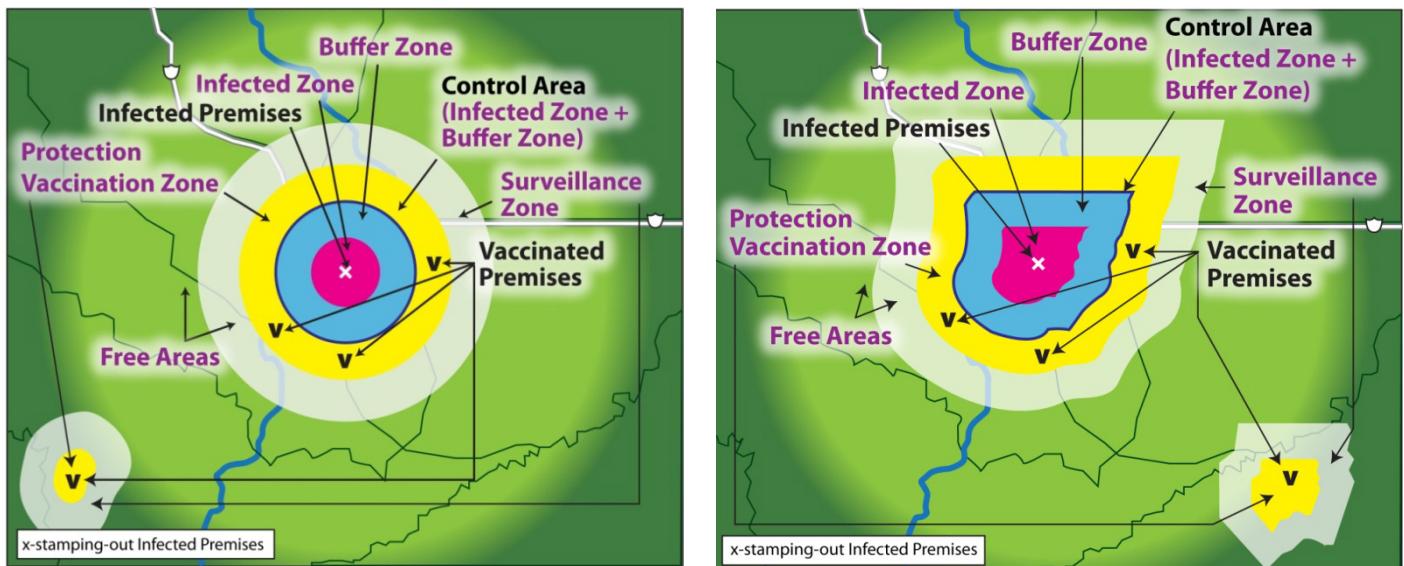
6.16.3.2 PROTECTION VACCINATION ZONE

The PVZ is an emergency vaccination zone in the FA. It is consistent with the OIE *Terrestrial Animal Health Code* (2010) definition for a Protection Zone:

A zone established to protect the health status of animals in a free country or free zone, from those in a country or zone of a different animal health status, using measures based on the epidemiology of the disease under consideration to prevent spread of the causative pathogenic agent into a free country or free zone. These measures may include, but are not limited to, vaccination, movement control and an intensified degree of surveillance.

Typically, a PVZ would be observed with a stamping-out policy modified with vaccination to live. Figure 6–7 shows examples of PVZ.

Figure 6-7. Examples of Protection Vaccination Zones (Left: Circle, Right: Irregular)

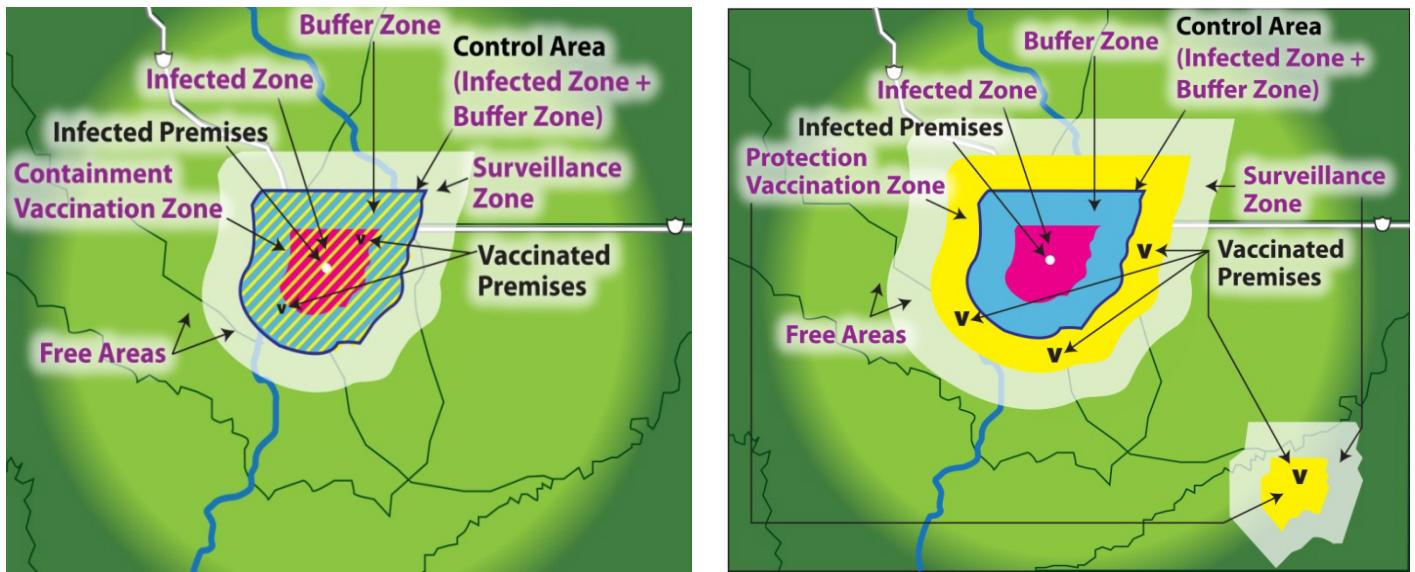


Note: Figures are not to scale.

6.16.3.3 VACCINATED PREMISES

VP is a secondary designation to another premises designation and is only used if vaccination is employed in an outbreak. A VP may be located in the CVZ within the CA (IZ or BZ) or in the PVZ in the FA. Figure 6–8 shows VP in a CVZ (left) and in a PVZ (right).

*Figure 6-8. Vaccinated Premises
(Left: Containment Vaccination Zone, Right: Protection Vaccination Zone)*



Note: Figures are not to scale. Infected Premises are not stamped-out in these figures.

6.16.4 Movement Restrictions for Vaccinates

If vaccination is used, a vaccination plan will define procedures to prevent the spread of FMD by vaccination teams. Vaccination occurs within a CVZ or a PVZ. All vaccinated animals must 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:

- ◆ VP may be located in the CVZ within the CA (IZ and BZ) or in the PVZ within the FA.
- ◆ VP will be subject to the risk assessments, surveillance requirements, and biosecurity procedures established for the primary premises or zone designation (can be an IP, CP, SP, ARP, MP, or FP).
- ◆ Animals receiving emergency vaccination on the VP will be subject to vaccinated animal identification, vaccinated animal traceability, and DIVA testing.
- ◆ For movement of emergency vaccinated animals out of the CVZ or PVZ to a FA, the permit process must take into account any OIE international standards or conditions for such movement.

6.16.5 Cessation of Vaccination

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

The NAFMDVB Guidelines, NAHEMS Guidelines: Vaccination for Contagious Diseases (2010), and FMD Vaccination SOP contain further guidance.

6.17 NATIONAL VETERINARY STOCKPILE

The Overview of the National Veterinary Stockpile SOP (2010) (<https://fadprep.lmi.org/Design/sops.aspx>) provides information on NVS capabilities and lays out the required steps to request countermeasures from the NVS. It also provides a direct link to the NVS website, where State preparedness officials and responders can download important publications to help them understand the NVS. This website provides

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

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

6.18 WILDLIFE MANAGEMENT AND VECTOR CONTROL

APHIS VS will work in close collaboration, communication, and coordination with State, Tribal, and local wildlife agencies that have primary jurisdictional authority and subject matter expertise for wildlife. This collaboration, communication, and coordination will occur in both the Unified Command as well as in MAC groups.

The FMD Wildlife Management and Vector Control SOP (<https://fadprep.lmi.org/Design/sops.aspx>) also discusses personnel and equipment required for wildlife management, quarantine and movement control for wildlife, wildlife risk assessment, wildlife surveillance, and related activities. Further information can also be found in the NAHEMS Guidelines: Wildlife Management and Vector Control (2011) on the FAD PReP website: <https://fadprep.lmi.org>.

6.18.1 Wildlife Management

A wildlife management plan that addresses both captive and free-ranging wildlife will be developed as soon as possible after identification of the index case in livestock. An assessment of the risk that wildlife poses for the transmission of FMD virus to susceptible livestock will be conducted within 7 days of confirmation of the index case. Assessment of the risks posed by wildlife will require information on

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

If wildlife populations are determined to be infected with FMD virus 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 FMD virus to livestock, wildlife management tools will be implemented to keep wildlife populations from acting as mechanical vectors.

6.18.2 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 FMD virus 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.

The FMD Wildlife Management and Vector Control SOP (<https://fadprep.lmi.org/Design/sops.aspx>) also discusses personnel and equipment required for wildlife management, quarantine and movement control for wildlife, wildlife risk assessment, wildlife surveillance, and related activities.

6.19 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 Animal Welfare SOP (<https://fadprep.lmi.org/Design/sops.aspx>) contains additional information.

6.20 MODELING AND ASSESSMENT TOOLS

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

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

The Overview of Modeling and Assessment Tools SOP (2010) (<https://fadprep.lmi.org/Design/sops.aspx>) provides information on modeling and risk assessment, covering the following:

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

6.21 APPRAISAL AND COMPENSATION

Indemnity payments are to encourage disease reporting, reduce the spread of animal disease, and compensate owners on the basis of fair market value. Fair market value appraisals should be provided to owners of destroyed animals and materials within 12–72 hours after the destruction of said animals and materials. The FMD Appraisal and Compensation SOP focuses on specifying personnel responsibilities, appraisal procedures, assessment of compensation eligibility, payment of indemnity, and required forms and reports during an FMD outbreak.

The Animal Health Protection Act (AHPA) gives APHIS authority to establish and implement an indemnification program to prevent or eradicate an FMD outbreak. Indemnity is a key component of APHIS's disease control programs in that the promise of fair compensation for losses helps to ensure cooperation from

the owners of affected livestock. Such cooperation is important for rapid disease control and eradication.

The best practices for containment and eradication of FMD will in many instances require depopulation, disposal, and decontamination that are faster than can be achieved with slow or deliberate appraisal processes. 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 FMD virus during a response to a confirmed or presumptive FMD incident. All data required to determine fair market value will be collected prior to depopulation, including a complete inventory of livestock being destroyed.

The following resources offer additional guidance on appraisal and compensation:

- ◆ NAHEMS Guidelines: Appraisal and Compensation (2010) (<https://fadprep.lmi.org>)
- ◆ FMD Appraisal and Compensation SOP (<https://fadprep.lmi.org>)
- ◆ APHIS's Livestock Appraisal, Indemnity, and Compensation Website (http://www.aphis.usda.gov/animal_health/emergingissues/compensation/comp.shtml).

6.22 FINANCE

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

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

APHIS contingency funds take care of unforeseen, unpredictable programs. The following four conditions must exist to qualify for the release of agency contingency funds:

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

4. The proposed program must have industry support.

The Finance SOP (2010) (<https://fadprep.lmi.org/Design/sops.aspx>) 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.

6.23 NATIONAL RESPONSE FRAMEWORK AND NATIONAL INCIDENT MANAGEMENT SYSTEM

In any FMD outbreak, the capability to rapidly scale up the size of an Incident Command and integrate veterinary functions and countermeasures is critical for an effective response. NRF and NIMS, already discussed in this plan, allow such scalability. The Overview of NRF and NIMS SOP (2010) (<https://fadprep.lmi.org/Design/sops.aspx>) provides additional information on the relation of NRF and NIMS to APHIS and lists the responsibilities of Federal, State, Tribal, and local governments in an FMD outbreak.

Chapter 7

Recovery after FMD Outbreak

7.1 PROOF OF FREEDOM

7.1.1 Recognition of Disease-Free Status

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

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

7.1.2 Criteria Needed for FMD-Free Status

There are six OIE official country recognitions for FMD: (1) FMD-free country where vaccination is not practiced, (2) FMD-free country where vaccination is practiced, (3) FMD-free zone where vaccination is not practiced, (4) FMD-free zone where vaccination is practiced (this zone can be established in either an FMD-free country where vaccination is not practiced or in a country of which parts are infected), (5) FMD-free compartment, and (6) FMD-infected country or zone. The criteria for these recognitions are listed in the [2010 OIE Terrestrial Animal Health Code, Articles 8.5.2 to 8.5.7.](#)

7.1.2.1 RECOVERY OF FREE STATUS

However, there are separate requirements for the recovery of free status in previously FMD-free countries. These requirements, listed below, are taken from Article 8.5.9 of the 2010 *Terrestrial Animal Health Code*:

-
1. When an FMD outbreak or FMDV infection occurs in an FMD free country or zone where vaccination is not practiced, one of the following waiting periods is required to regain the status of FMD free country or zone where vaccination is not practiced:
 - a. 3 months after the last case where a stamping-out policy and serological surveillance are applied in accordance with Articles 8.5.42 to 8.5.48; or
 - b. 3 months after the slaughter of all vaccinated animals where a stamping-out policy, emergency vaccination and serological surveillance are applied in accordance with Articles 8.5.42 to 8.5.48; or
 - c. 6 months after the last case or the last vaccination (according to the event that occurs the latest), where a stamping-out policy, emergency vaccination not followed by slaughtering of all vaccinated animals, and serological surveillance are applied in accordance with Articles 8.5.42 to 8.5.48, provided that a serological survey based on the detection of antibodies to non-structural proteins of FMDV demonstrates the absence of infection in the remaining vaccinated population.

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

2. When an FMD outbreak or FMDV infection occurs in an FMD free country or zone where vaccination is practiced, one of the following waiting periods is required to regain the status of FMD free country or zone where vaccination is practiced:
 - a. 6 months after the last case where a stamping-out policy, emergency vaccination and serological surveillance in accordance with Articles 8.5.42 to 8.5.48 are applied, provided that the serological surveillance based on the detection of antibodies to non-structural proteins of FMDV demonstrates the absence of virus circulation; or
 - b. 18 months after the last case where a stamping-out policy is not applied, but emergency vaccination and serological surveillance in accordance with Articles 8.5.42 to 8.5.48 are applied, provided that the serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation.
3. When a FMD outbreak or FMDV infection occurs in a FMD free compartment, Article 8.5.6 applies.

7.1.2.2 FMD-FREE COUNTRY WHERE VACCINATION IS NOT PRACTICED

The following text is taken from Article 8.5.2 of the 2010 *Terrestrial Animal Health Code*:

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

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

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that:
 - a. there has been no outbreak of FMD during the past 12 months;
 - b. no evidence of FMDV infection has been found during the past 12 months;
 - c. no vaccination against FMD has been carried out during the past 12 months;
 - d. no vaccinated animal has been introduced since the cessation of vaccination;
3. supply documented evidence that:
 - a. surveillance for both FMD and FMDV infection in accordance with Articles 8.5.42 and 8.5.48 is in operation;
 - b. regulatory measures for the early detection, prevention, and control of FMD have been implemented.
4. describe in detail the boundaries and measures of a protection zone, if applicable.

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

7.1.2.3 FMD-FREE COUNTRY WHERE VACCINATION IS PRACTICED

The following text is taken from Article 8.5.3 of the 2010 *Terrestrial Animal Health Code*:

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

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

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that:
 - a. there has been no outbreak of FMD during the past 2 years;
 - b. no evidence of FMDV circulation for the past 12 months;
3. supply documented evidence that:
 - a. surveillance for FMD and FMDV circulation in accordance with Articles 8.5.42 and 8.5.48 is in operation;
 - b. regulatory measures for the early detection, prevention, and control of FMD have been implemented;
 - c. routine vaccination is carried out for the purpose of the prevention of FMD;
 - d. the vaccine used complies with the standards described in the Terrestrial Manual and is appropriate for the strains of virus currently circulating;
4. describe in detail the boundaries and measures of a protection zone, if applicable.

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

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

7.1.2.4 FMD-FREE ZONE WHERE VACCINATION IS NOT PRACTICED

The following text is taken from Article 8.5.4 of the 2010 *Terrestrial Animal Health Code*:

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

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

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that within the proposed FMD free zone:
 - a. there has been no outbreak of FMD during the past 12 months,
 - b. no evidence of FMDV infection has been found during the past 12 months;
 - c. no vaccination against FMD has been carried out during the past 12 months;
 - d. no vaccinated animal has been introduced into the zone since the cessation of vaccination, except in accordance with Article 8.5.10;
3. supply documented evidence that:
 - a. surveillance for FMD and FMDV infection in accordance with Articles 8.5.42 and 8.5.28 is in operation;
 - b. regulatory measures for the early detection, prevention and control of FMD have been implemented;

-
4. describe in detail and supply documented evidence that these are properly implemented and supervised:
 - a. the boundaries of the proposed FMD free zone,
 - b. the boundaries and measures of a protection zone, if applicable,
 - c. the system for preventing the entry of the virus (including the control of the movement of susceptible animals) into the proposed FMDV free zone (in particular if the procedure described in Article 8.5.10 is implemented)

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

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

7.1.2.5 FMD-FREE ZONE WHERE VACCINATION IS PRACTICED

The following text is taken from Article 8.5.5 of the 2010 *Terrestrial Animal Health Code*:

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

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

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE that within the proposed FMD free zone:
 - a. there has been no outbreak of FMD for the past 2 years;
 - b. no evidence of FMDV circulation for the past 12 months;

3. supply documented evidence that:
 - a. surveillance for FMD and FMDV infection in accordance with Articles 8.5.42 and 8.5.48 is in operation;
 - b. regulatory measures for the early detection, prevention, and control of FMD have been implemented;
 - c. routine vaccination is carried out for the purpose of the prevention of FMD;
 - d. the vaccine used complies with the standards described in the Terrestrial Manual and is appropriate for the strains of virus currently circulating;
4. describe in detail and supply documented evidence that these are properly implemented and supervised:
 - a. the boundaries of the proposed FMD free zone,
 - b. the boundaries and measures of a protection zone, if applicable,
 - c. the system for preventing the entry of the virus (including the control of the movement of susceptible animals) into the proposed FMD free zone (in particular if the procedure described in Article 8.5.10 is implemented).

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

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

7.1.2.6 FMD-FREE COMPARTMENT

The following text is taken from Article 8.5.6 of the 2010 *Terrestrial Animal Health Code*:

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

A Member wishing to establish a FMD free compartment should:

1. have a record of regular and prompt animal disease reporting and if not FMD free, have an official control program and a surveillance system for FMD in place according to Articles 8.5.42 and 8.5.44 that allows an accurate knowledge of the prevalence of FMD in the country or zone;
2. declare for the FMD free compartment that:
 - a. there has been no outbreak of FMD during the past 12 months;
 - b. no evidence of FMDV infection has been found during the past 12 months;
 - c. vaccination against FMD is prohibited;
 - d. no animal vaccinated against FMD within the past 12 months is in the compartment;
 - e. animals, semen, and embryos should only enter the compartment in accordance with relevant Articles in this chapter;
 - f. documented evidence should show that surveillance in accordance with Articles 8.5.42 and 8.5.48 is in operation for FMD and FMDV infection;
 - g. an animal identification and traceability system in accordance with Chapters 4.1 and 4.2 is in place;
3. describe in detail the animal subpopulation in the compartment and the biosecurity plan for FMD and FMDV infection.

The compartment should be approved by the Veterinary Authority. The first approval should only be granted when no outbreak of FMD has occurred within the zone in which the compartment is situated, during the last 3 months.

7.1.2.6.1 FMD-Free Compartments

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

7.1.2.7 FMD INFECTED COUNTRY OR ZONE

The following text is taken from Article 8.5.7 of the 2010 *Terrestrial Animal Health Code*:

An FMD infected country is a country that does not fulfill the requirements to qualify as either an FMD free country where vaccination is not practiced or an FMD free country where vaccination is practiced.

An FMD infected zone is a zone that does not fulfill the requirements to qualify as either an FMD free zone where vaccination is not practiced or an FMD free zone where vaccination is practiced.

7.1.3 Surveillance for Recognition of Disease Freedom

Surveillance is fundamental in proving disease freedom to regain disease-free status after an FMD outbreak. The 2010 *OIE Terrestrial Animal Health Code* specifies surveillance procedures for members re-applying for recognition of freedom from FMD for the whole country or zone where vaccination is either practiced or not practiced, following an outbreak. General OIE surveillance guidelines are provided in [Article 8.5.43](#).

The following text is taken from Article 8.5.47 of the 2010 *Terrestrial Animal Health Code*:

In addition to the general conditions described in the above-mentioned articles, a country re-applying for country or zone freedom from FMD where vaccination is practiced or not practiced should show evidence of an active surveillance program for FMD as well as absence of FMDV infection/circulation. This will require serological surveillance incorporating, in the case of a country or a zone practicing vaccination, tests able to detect antibodies to NSPs as described in the Terrestrial Manual.

Four strategies are recognized by the OIE in a program to eradicate FMDV infection following an outbreak:

1. slaughter of all clinically affected and in-contact susceptible animals;
2. slaughter of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, with subsequent slaughter of vaccinated animals;

-
3. slaughter of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, without subsequent slaughter of vaccinated animals;
 4. vaccination used without slaughter of affected animals or subsequent slaughter of vaccinated animals.

The time periods before which an application can be made for re-instatement of freedom from FMD depend on which of these alternatives is followed. The time periods are prescribed in Article 8.5.9.

In all circumstances, a Member re-applying for country or zone freedom from FMD with vaccination or without vaccination should report the results of an active surveillance program implemented according to general conditions and methods in this Chapter.

The use and interpretation of serological tests is covered in Article 8.5.48 of the *OIE Terrestrial Animal Health Code* (2010) and in the *OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (2010). These sections discuss serological tests for both structural proteins (SP) and nonstructural proteins (NSP). Tests for SP are serotype specific and include SP-ELISAs and the virus neutralization test (VNT). Tests for NSP antibodies include the 3ABC Prionics ELISA, which is conducted by NVSL-FADDL. Additional information on diagnostic testing is provided in Chapter 6, and in the aforementioned OIE documents.

7.1.4 Release of Control Area Restrictions

Quarantine and movement control restrictions will be maintained until at least 28 days have elapsed since the decontamination of all confirmed Infected Premises and negative results of surveillance activities. 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).

7.1.5 Disposition of Vaccinates

If vaccination was used in the outbreak, FMD vaccines will still be subject to movement control and monitoring measures.

7.1.6 Country Freedom Declaration

The United States will apply to the OIE after meeting OIE requirements. FMD-free status will require a formal submission detailing FMD policy, eradication procedures, surveillance, monitoring and tracing of vaccinees, 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.

7.2 REPOPULATION

7.2.1 Restocking Guidance

The convention is to leave Infected Premises vacant for a period before restocking animals onto premises. Following appropriate cleaning and disinfection procedures, Infected Premises will remain vacant for a minimum of 28 days. 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 Incident Command.

The producer should provide a restocking plan, including details of the species, number of animals, and locations of sentinel animals. Once introduced to the previously Infected Premises, no animals may leave until all locations on that premises have been restocked and serological diagnostics are negative. Replacing the slaughtered 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 28 days after full cleaning and disinfection procedures, as non-susceptible species can act as mechanical vectors for FMDV.

7.2.2 Testing Requirements for Restocking

During restocking, animals will be subject to clinical inspection every 3 days for the first 14 days, and once per week thereafter up to 28 days. 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.

7.2.3 Approved Sources of Livestock

Introduced livestock must be derived from areas not subject to quarantine and movement control measures. All livestock must test negative before introduction. A 24-hour pre-movement clinical inspection is also required. Animals must originate on and come from premises on which there has not been a confirmed case of FMD within 6.2 miles (10 kilometers) for at least 30 days.

Appendix A

FAD PReP Materials to Support FMD Response

Appendix A lists the FAD PReP documents that directly support this FMD Response Plan (2010). These new and revised documents will be useful in FMD preparedness and response. Many have been released in 2010, and others will be forthcoming in the near future. These resources are found on line at <https://fadprep.lmi.org> and on Inside APHIS for APHIS employees at <http://inside.aphis.usda.gov/vs/em/fadprep.shtml>.

FMD CONTINUITY OF BUSINESS PLANNING

Secure Milk Supply Plan (Coming 2011),
<https://fadprep.lmi.org/Design/SecureMilk.aspx>

FMD STANDARD OPERATING PROCEDURES— CRITICAL ACTIVITIES

These SOPs provide a common picture or set of procedures for the following tools and strategies used in FMD response. Unless a date is specified, these SOPs are currently under development.

1. Overview of Etiology and Ecology
2. Case Definition Development Process (June 2010)
3. Surveillance
4. Diagnostics (Sample Collection, Surge Capacity and Reporting)
5. Epidemiological Investigation and Tracing
6. Overview of Information Management (September 2010)
7. Communications
8. Health and Safety and PPE
9. Biosecurity
10. Quarantine and Movement Control

-
- 11. Continuity of Business
 - 12. Regionalization and Compartmentalization
 - 13. Mass Depopulation and Euthanasia
 - 14. Disposal
 - 15. Cleaning and Disinfection
 - 16. Vaccination
 - 17. Overview of the National Veterinary Stockpile (March 2010)
 - 18. Wildlife Management and Vector Control
 - 19. Animal Welfare
 - 20. Overview of Modeling and Assessment Tools (September 2010)
 - 21. Appraisal and Compensation
 - 22. Finance (September 2010)
 - 23. Overview of the National Response Framework and National Incident Management System (March 2010)

INDUSTRY MANUAL

- Swine (July 2010)
- Dairy (July 2010)
- Beef Feedlot (Coming 2010)

NAHEMS GUIDELINES

- ◆ Health and Safety (March 2010)
- ◆ Personal Protective Equipment (February 2010)
- ◆ Biosecurity (March 2010)
- ◆ Quarantine and Movement Control (Coming 2011)
- ◆ Mass Depopulation and Euthanasia (November 2010)
- ◆ Disposal (Coming 2011)

- ◆ Cleaning and Disinfection (March 2010)
- ◆ Vaccination (Coming 2010)
- ◆ Wildlife Management and Vector Control (Coming 2011)
- ◆ Appraisal and Compensation (Coming 2010)
- ◆ National Animal Health Emergency Response Corp (NAHERC) Deployment Guide (March 2010)
- ◆ Epidemiology, Surveillance, and FAD Tracing (Coming 2011)

STRATEGIC PLANS—CONCEPT OF OPERATIONS

- ◆ APHIS Framework for Foreign Animal Disease Preparedness and Response (July 2010)
- ◆ NCAHEM Stakeholder Coordination and Collaboration Plan (March 2010)
- ◆ NCAHEM Incident Coordination Group Plan (February 2010)

Appendix B

Incident Management

Appendix B contains Chapter 5 from the *APHIS Framework for Foreign Animal Disease Preparedness and Response* (2010) document. This chapter explains incident management in the event of an FMD outbreak. Please refer to the *APHIS Framework for Foreign Animal Disease Preparedness and Response* and the *NCAHEM Incident Coordination Group Plan* for more information (available at <https://fadprep.lmi.org>).

Chapter 5

Incident Management

In the event of an outbreak of foreign animal disease, incident management and communication among multiple agencies and stakeholders involved in the event are critical activities.

HSPD-5, Management of Domestic Incidents, directed the development and administration of the NIMS. NIMS provides a systematic, proactive approach to guide departments and agencies at all levels of government, non-governmental organizations, and the private sector to prevent, protect against, respond to, recover from, and mitigate the effects of incidents, regardless of cause, size, location, or complexity, in order to reduce the loss of life and property and harm to the environment.

NIMS works hand in hand with the NRF. NIMS provides the template for managing incidents, while the NRF provides the structure and mechanisms for national-level policy for incident management.

The ICS is a management system designed to enable effective and efficient domestic incident management by integrating a combination of facilities, equipment, personnel, procedures, and communication operating within a common organizational structure, designed to enable effective and efficient domestic incident management.

APHIS has adopted NIMS and ICS organizational structures and processes to manage emergency responses and other events.

Additional information on NIMS can be found at:
<http://www.fema.gov/emergency/nims/>.

Additional information on ICS can be found at:
<http://training.fema.gov/EMIWeb/IS/ICSResource/index.htm>.

5.1 APHIS INCIDENT MANAGEMENT STRUCTURE

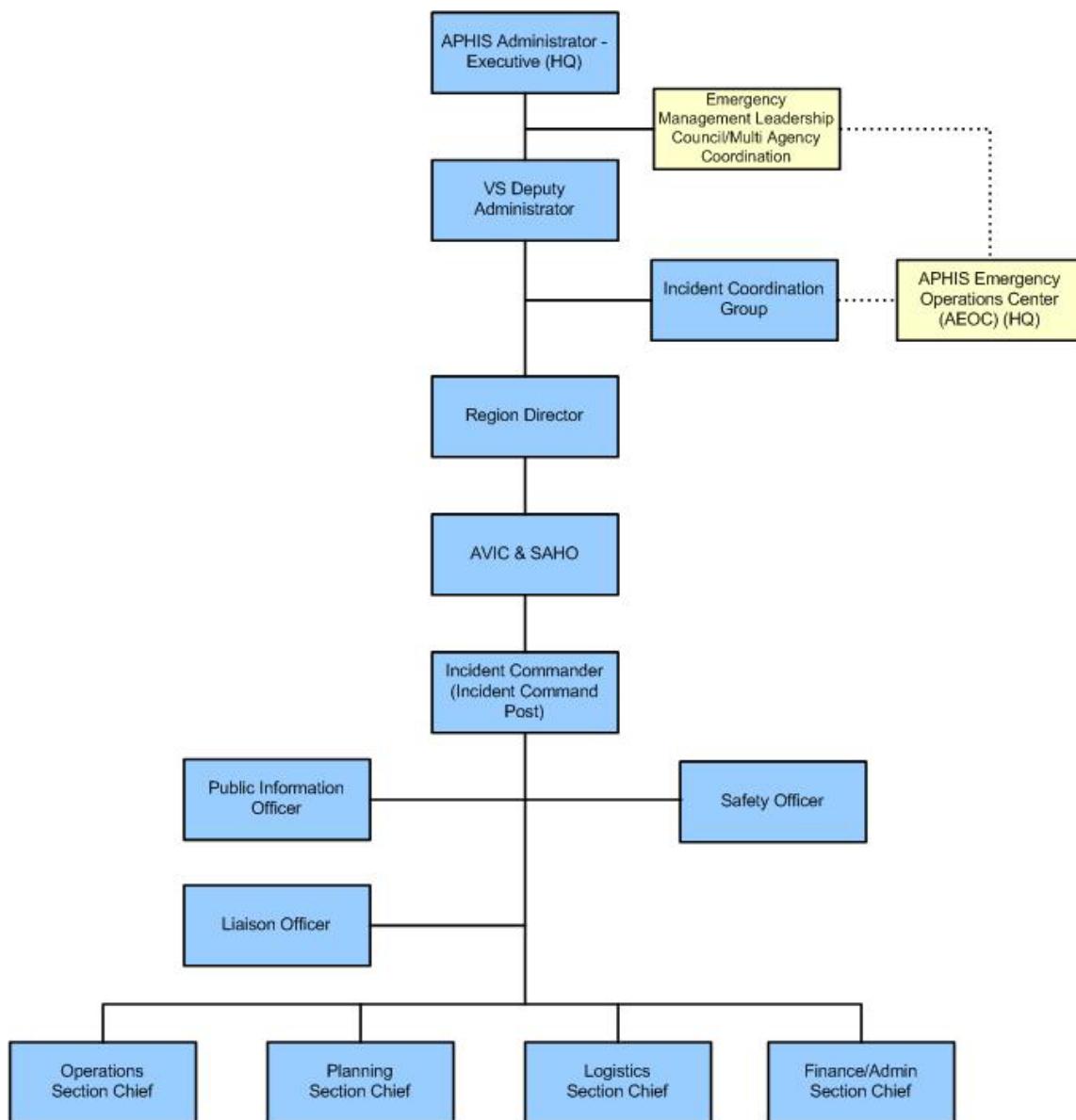
Figure 5-1 displays the APHIS FAD incident management organizational structure, starting with the APHIS Administrator.

The APHIS Administrator is the Federal executive responsible for managing an FAD outbreak. The APHIS Administrator will delegate much of the actual management of the incident to the VS Deputy Administrator (Chief Veterinary Officer

of the United States) and the APHIS Emergency Management Leadership Council (EMLC).

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

*Figure 5-1. APHIS Headquarters, MAC, Emergency Operations Center, and Incident Management Team Organizational Structure
(Assuming a Single Incident)*

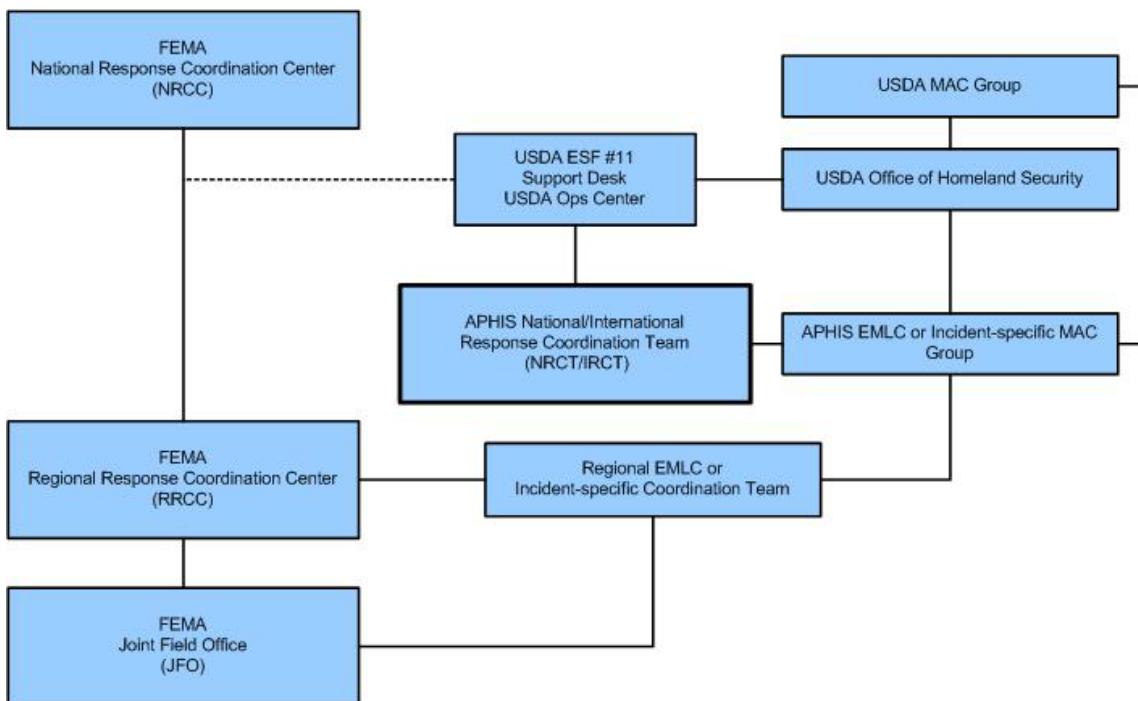


5.2 APHIS MULTI-AGENCY COORDINATION GROUP

The APHIS Emergency Mobilization Guide defines coordination for major agricultural disasters and agro-terrorism responses (see Figure 5-2). In the event of an animal emergency, the EMLC serves as the APHIS MAC group, unless it decides to transfer responsibility for a specific incident. The MAC group—established if the incident response needs more support—establishes supportive relationships among the agencies preparing for and responding to animal health events.

The complexity of the incident and its multi-agency geographic impact will determine whether a Geographical Multi-Agency Coordination (GMAC) Group or Agricultural Multi-Agency Coordination (AgMAC) Group is established. The GMAC and AgMAC structure is flexible and scalable. The GMAC and AgMAC organization provides overall strategic coordination for incidents and is not intended to direct Incident Management Teams. Direction and responsibility for incidents lie with the Incident Commanders, who report to Agency Administrators.

Figure 5-2. Coordination Structures: USDA and DHS/FEMA



5.2.1 Purpose

The APHIS MAC Group provides a forum to discuss actions that need to be taken to ensure that an adequate number of resources are available to meet anticipated needs. The MAC Group strategically coordinates the incident response, but does not typically direct the Incident Coordination Group.

5.2.2 Activation

In the event of a significant FAD emergency, the EMLC serves as the APHIS MAC Group, unless it transfers responsibility for a specific incident. During some incidents, activating a MAC Group may be beneficial even if USDA is not the lead agency. The NIC has the authority to activate the MAC Group. One or more of the following conditions may require activation:

- ◆ Complex incidents that overwhelm local and regional assets
- ◆ Overlapping USDA agency jurisdictions
- ◆ An incident that crosses international borders
- ◆ The existence of or potential for a high level of national political and media interest.

5.2.3 Responsibilities

The APHIS MAC Group offers guidance on the most efficient way to allocate resources during an animal health event. Specific responsibilities vary from disease to disease, but the general functions of the APHIS MAC group include

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

In the event of a significant threat to or impact on the public health and welfare, natural environment, or economy, the APHIS MAC Group may include representatives from USDA departments and agencies, as well as other Federal agencies. The APHIS MAC Group structure is flexible and easily expands and contracts to provide flexibility.

The USDA Department level may also stand up a USDA MAC group. Representatives to the USDA MAC Group or APHIS MAC Group may potentially come from the agencies listed in Chapter 1 along with the following USDA agencies and APHIS programs:

- ◆ USDA
 - Office of Homeland Security and Emergency Coordination
 - Food Safety and Inspection Service
 - Agricultural Research Service

- Agricultural Marketing Service
- National Institute of Food and Agriculture (formerly Cooperative State Research, Education, and Extension Service)
- Foreign Agricultural Service
- Food and Nutrition Service
- National Resources Conservation Service
- ◆ APHIS
 - Animal Care
 - Biotechnology Regulatory Services
 - International Services
 - Legislative and Public Affairs
 - Marketing and Regulatory Programs Business Services
 - Planning and Finance Staff
 - Plant Protection and Quarantine
 - Policy and Program Development
 - Emergency Management and Safety and Security Division
 - Veterinary Services
 - Field Operations
 - Emergency Management and Diagnostics
 - National Animal Health Policy and Programs
 - Chief Operating Officer and Staffs
 - Wildlife Services.

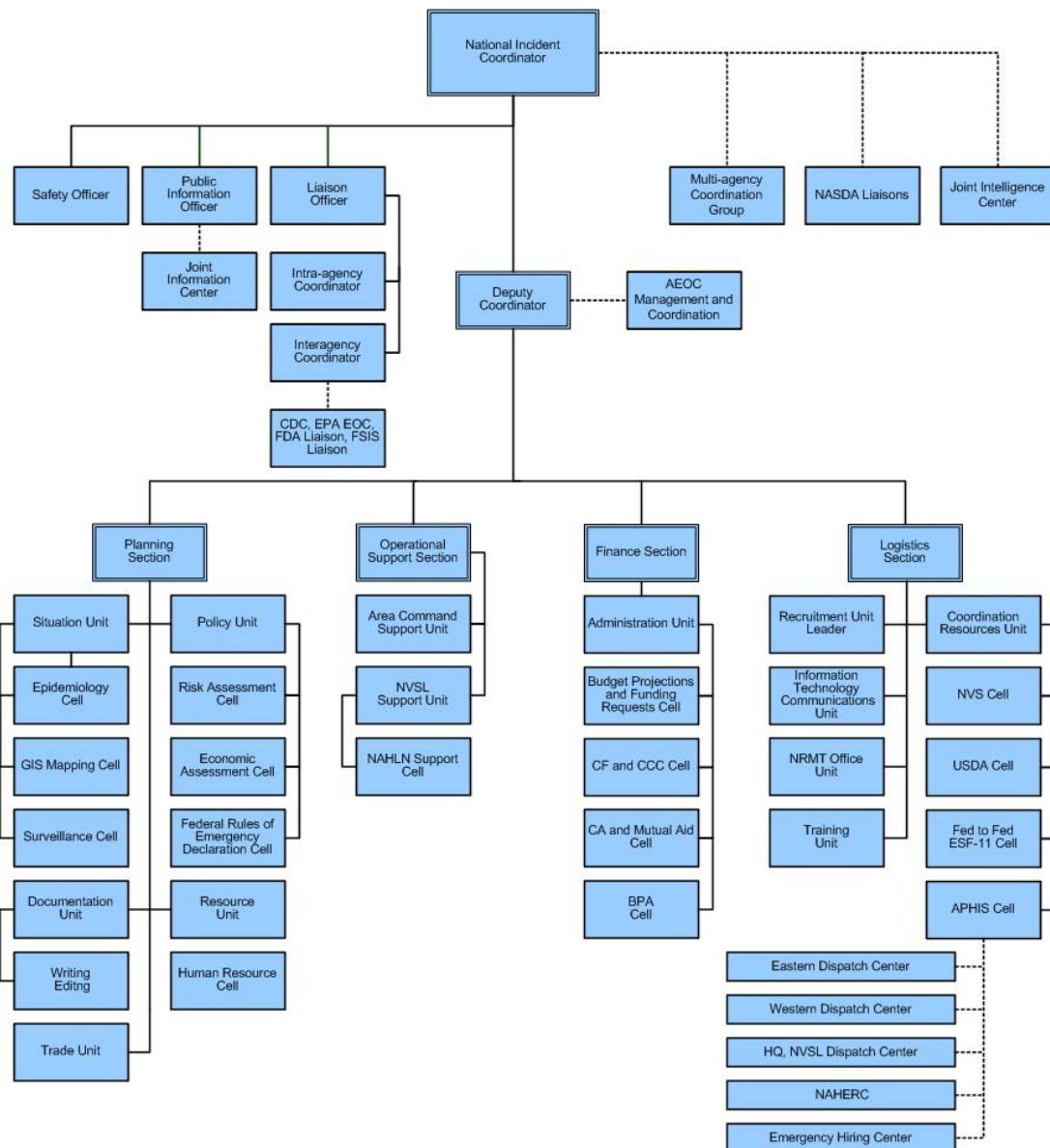
5.3 NATIONAL INCIDENT COORDINATION GROUP

The VS or APHIS Incident Coordination Group is responsible for supporting the ICP and AC in acquiring resources, formulating policy, and developing and im-

plementing a response and recovery strategy for FAD outbreaks. For additional information and details, see the NCAHEM Incident Coordination Group Plan. Figure 5-3 illustrates an example organization chart for an Incident Coordination Group. The group has the following responsibilities:

- ◆ Supporting ICPs and ACs
- ◆ Assisting in developing response policy as needed
- ◆ Coordinating effective communication
- ◆ Coordinating resources
- ◆ Assisting in establishing epidemiological priorities
- ◆ Assisting in developing incident objectives and approving response strategies for emergency vaccination as needed
- ◆ Assisting in integration of response organizations into the ICS
- ◆ Assisting in developing protocols as needed
- ◆ Ensuring worker and public health and safety
- ◆ Informing the media and stakeholders
- ◆ Providing budget requests and projections as needed
- ◆ Assessing response progress, response strategies, and provide economic analyses as needed.

Figure 5-3. Notional Incident Coordination Group Organizational Structure



5.4 APHIS ORGANIZATION FOR A SINGLE EVENT

In the event of a single incident, the VS Deputy Administrator and EMLC will initially delegate the responsibility for managing the regional incident response to the VS Region Director. The VS Region Director, in turn, will initially delegate responsibilities for managing the Federal incident response to the Area Veterinarian in Charge (AVIC). The AVIC and the affected State Animal Health Official will initially serve as the Co-Incident Commanders for the unified ICP. The AVIC may be relieved by a VS Incident Management Team Incident Commander if

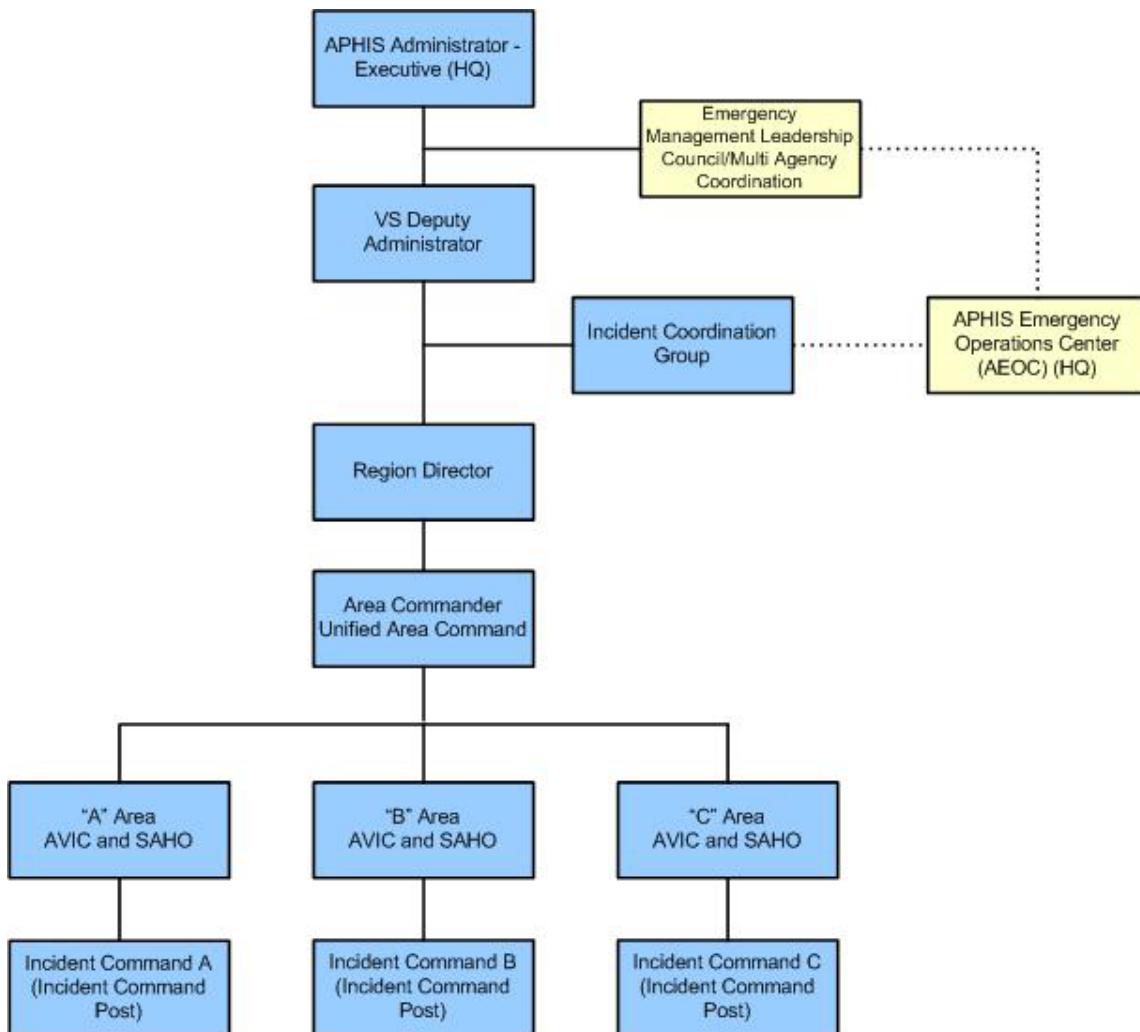
there is a delegation of authority to the VS Incident Management Team. Figure 5-1 is an example of an organization chart for single incident.

5.5 APHIS ORGANIZATION FOR MULTIPLE EVENTS

When more than one incident is occurring at the same time, more than one Incident Command may be established. In this case, the VS Region Director will establish a Unified Area Command. The Area Commander will be responsible for managing all the incidents, and the AVIC and State Veterinarian for each incident (or the Incident Management Team) will report to the Area Command. The organization for multiple incidents is shown in Figure 5-4.

If the emergency response becomes too large for a single NIC to handle efficiently—for example, a large multistate incident with numerous response activities—cooperation with other agencies or committees can be negotiated. This is referred to as MAC. The USDA’s AgMAC represents the USDA. MAC groups make decisions regarding the prioritizing of incidents and the sharing and use of critical resources, but are not a part of the on-scene Incident Command System and are not involved in developing incident strategy or tactics.

*Figure 5-4. APHIS Headquarters, MAC, APHIS Emergency Operations Center, and Incident Management Team Organizational Structure
(Assuming Multiple Incidents and a Unified Area Commander)*



5.6 APHIS INCIDENT MANAGEMENT TEAMS

Upon detection and confirmation of an emergency outbreak, the AVIC/State Veterinarian establishes an Incident Command Post with an Incident Management Team (IMT), headed by an Incident Commander. Figure 5-5 depicts the organization of the IMT for management of the incident.

The IMT comprises an Incident Commander who has staff for all types of communication, safety, and liaison purposes. This staff and the heads of the Incident Commander's line organization sections are considered the Incident Commander's general staff. The IMT also includes four line organizations to perform all of the effort required to identify, contain, eradicate, recover, and return the situation

to normal business practices. These line organizations include sections for operations, planning, logistics, and finance and administration. Within each of these sections is the capability to accomplish all of the tasks necessary to ensure a successful outcome to an emergency outbreak.

Figure 5-5. Current VS IMT—Short Team Configuration

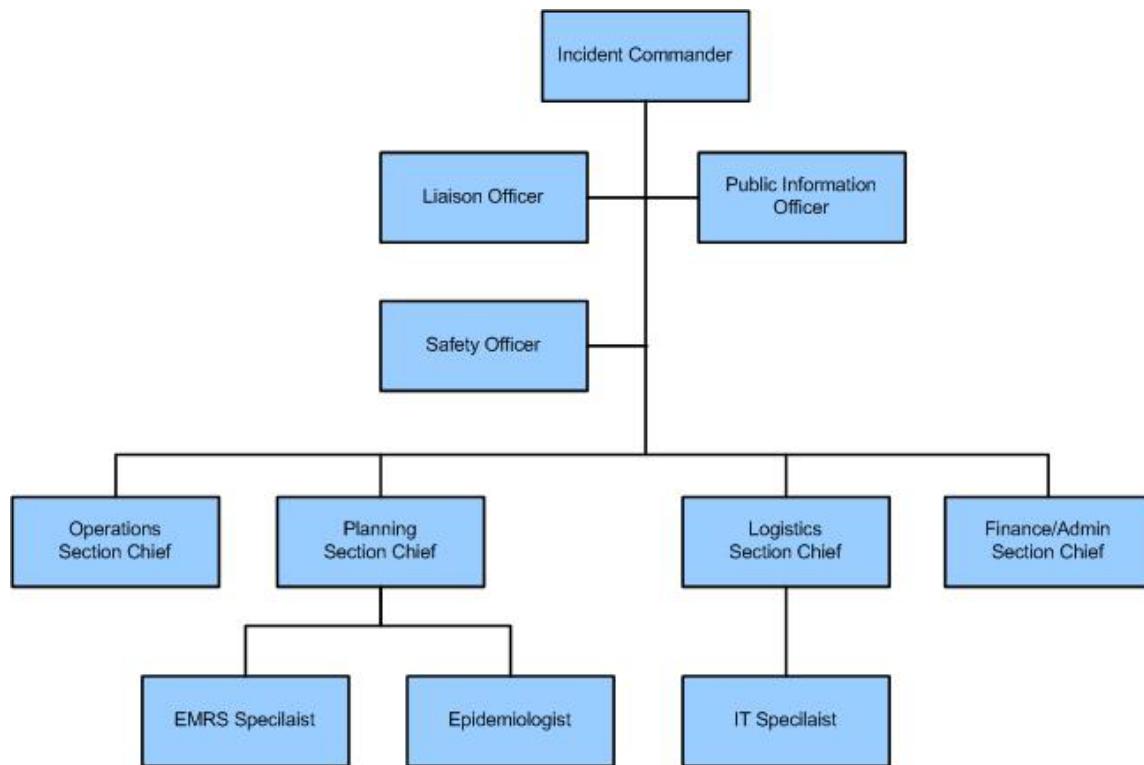


Table 5-1. List of Short Team Configuration Positions

APHIS IMT short team	APHIS emergency qualifications catalog
Incident Commander	A049 Command Staff
Deputy Incident Commander	A018 Command Staff
Operations Section Chief	A067 Operations Section
Deputy Operations Section	A020 Operations Section
Planning Section Chief	A072 Planning Section
Deputy Planning Section	A021 Planning Section
Logistics Section Chief	A061 Logistics Section
Deputy Logistics Section	A019 Logistics Section
Finance Section Chief	A094 Finance Section
Deputy Finance Section	A017 Finance Section
Safety Officer	A082 Command Staff

Table 5-1. List of Short Team Configuration Positions

APHIS IMT short team	APHIS emergency qualifications catalog
Deputy Safety Officer	A082 Command Staff
Public Information Officer	A076 Command Staff
Liaison Officer	A060 Command Staff
Deputy Liaison Officer	A060 Command Staff
Information Technology	A057/A422 Logistics Section
Deputy Information Technology	A057/A422 Logistics Section
EMRS Specialist	A038 Planning Section
Deputy EMRS Specialist	A038 Planning Section
Epidemiologist	A003 Planning Section
Deputy Epidemiologist	A003 Planning Section

For single-incident outbreaks where the potential for spread is low, a short team configuration as depicted in Figure 5-5 and Table 5-1 will suffice. When an outbreak occurs at more than one incident location, a long team configuration, as depicted in Figure 5-6 and Table 5-2, will be established. The long team consists of additional team members beyond those in the initial short team configuration. Figure 5-6 shows a notional long team configuration; however, the exact makeup of the long teams will depend on the type of disease and magnitude of spread.

Figure 5-6. Example IMT Organizational Structure

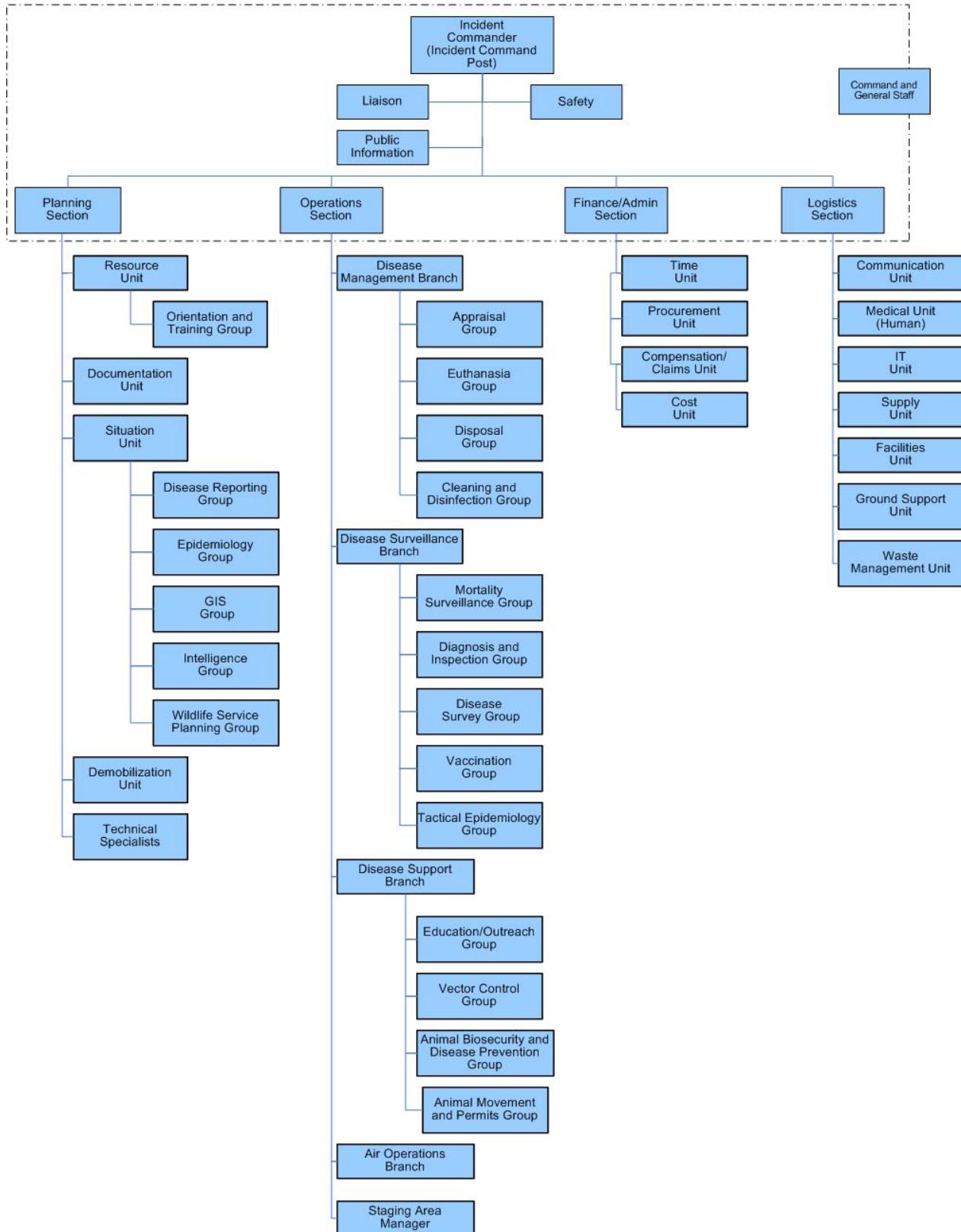


Table 5-2. Typical Positions—Long Team Configuration

APHIS long IMT configuration	APHIS emergency qualifications system catalog
Deputy Operations Section Chief	A020 Operations Section
Deputy Planning Section Chief	A021 Planning Section
Deputy Logistics Section Chief	A019 Logistics Section
Deputy Finance Section Chief	A017 Finance Section
Disease Management Branch Director	A024 Operations Section
◆ Appraisal Group Supervisor	A007
◆ Euthanasia Group Supervisor	A042
◆ Disposal Group Supervisor	A122
◆ Cleaning & Disinfection Group Supervisor	A012
Disease Surveillance Branch Director	A028 Operations Section
◆ Mortality Surveillance Group Supervisor	A103
◆ Diagnosis and Inspection Group Supervisor	A022
◆ Disease Survey Group Supervisor	A028
◆ Vaccination Group Supervisor	A089
◆ Tactical Epidemiology Group Supervisor	A004
Disease Support Branch Director	A120 Operations Section
◆ Education/Outreach Group Supervisor	A129
◆ Vector Control Group Supervisor	A137
◆ Biosecurity and Disease Prevention Group Supervisor	A075
◆ Movement and Permits Group Supervisor	A065
Air Operations Branch	Operations Section
Staging Area Manager (Operations)	Operations Section
Resources Unit Leader	A080 Planning Section
◆ Orientation and Training Group Supervisor	A070
Documentation Unit Leader	A034 Planning Section
Situation Unit Leader	A083 Planning Section
◆ Disease Reporting Group Leader	A026
◆ Epidemiology Group Leader	A003
◆ Geographic Information System (GIS) Group Supervisor	A108
◆ Intelligence Group Leader	A054
◆ Wildlife Specialist	A288
Demobilization Unit Leader	A015 Planning Section
◆ Technical Specialist—Animal Welfare Specialist	A005
Communications Unit Leader	A051 Logistics Section
◆ Medical Unit Leader	A047
◆ IT Manager	A057
◆ Supply Unit Leader	A085
◆ Facilities Unit Leader	A043
◆ Ground Support Unit Leader	A046
◆ Waste Management Unit Leader	A090

Table 5-2. Typical Positions—Long Team Configuration

APHIS long IMT configuration	APHIS emergency qualifications system catalog
Time Unit Leader ◆ Procurement Unit Leader ◆ Compensation/Claims Unit Leader ◆ Cost Unit Leader	A086 Finance Section A110 A013 A043

5.7 RESPONSE RESOURCES

The IMT, Incident Coordination Group, and APHIS MAC Group can use a number of systems to aid in staffing and resourcing during an event. Two systems used are the Emergency Qualification System (EQS) and the Resource Ordering and Status System (ROSS), which are discussed below. Two response planning documents are the APHIS Emergency Mobilization Guide and the NCAHEM Incident Coordination Group Plan.

5.7.1 APHIS Emergency Mobilization Guide

The APHIS Emergency Mobilization Guide provides information and policy for the mobilization of APHIS personnel for emergency events.

5.7.2 NCAHEM Incident Coordination Group Plan

The NCAHEM Incident Coordination Group Plan provides details on how the VS program unit will provide incident coordination support during FAD outbreaks.

5.7.3 APHIS Emergency Qualification System

The APHIS EQS is used to store the skills and qualifications of emergency response personnel and other data imported from National Finance Center and AgLearn, and to feed certification data to ROSS. It is customizable to APHIS program needs.

EQS can also house training documents. For APHIS employees, training documents flow into EQS from AgLearn. If NAHERC volunteers do not have access to AgLearn, their training documents can be manually entered or imported through an Excel spreadsheet.

5.7.4 APHIS Resource Ordering and Status System

The APHIS ROSS allows APHIS to identify, track, and mobilize the resources needed to support emergency response. It provides a database of qualified emergency response personnel. The database can be searched according to personnel

training levels and subject of expertise, such as procurement, epidemiology, or public information. Being able to quickly identify and dispatch appropriate personnel and supplies is a key component of emergency response, and ROSS facilitates that process. ROSS initiatives include the following:

- ◆ Developing the APHIS Agricultural Health Position Catalog
- ◆ Integrating ROSS into APHIS emergency management practices
- ◆ Training and sustaining an APHIS dispatch community.

Figure 5-7 illustrates the relationships among the VS Incident Coordination Group, Dispatch Coordination Centers, AC, and ICP.

Figure 5-8 illustrates the emergency dispatch process for APHIS personnel.

Figure 5-7. Resource Ordering Coordination

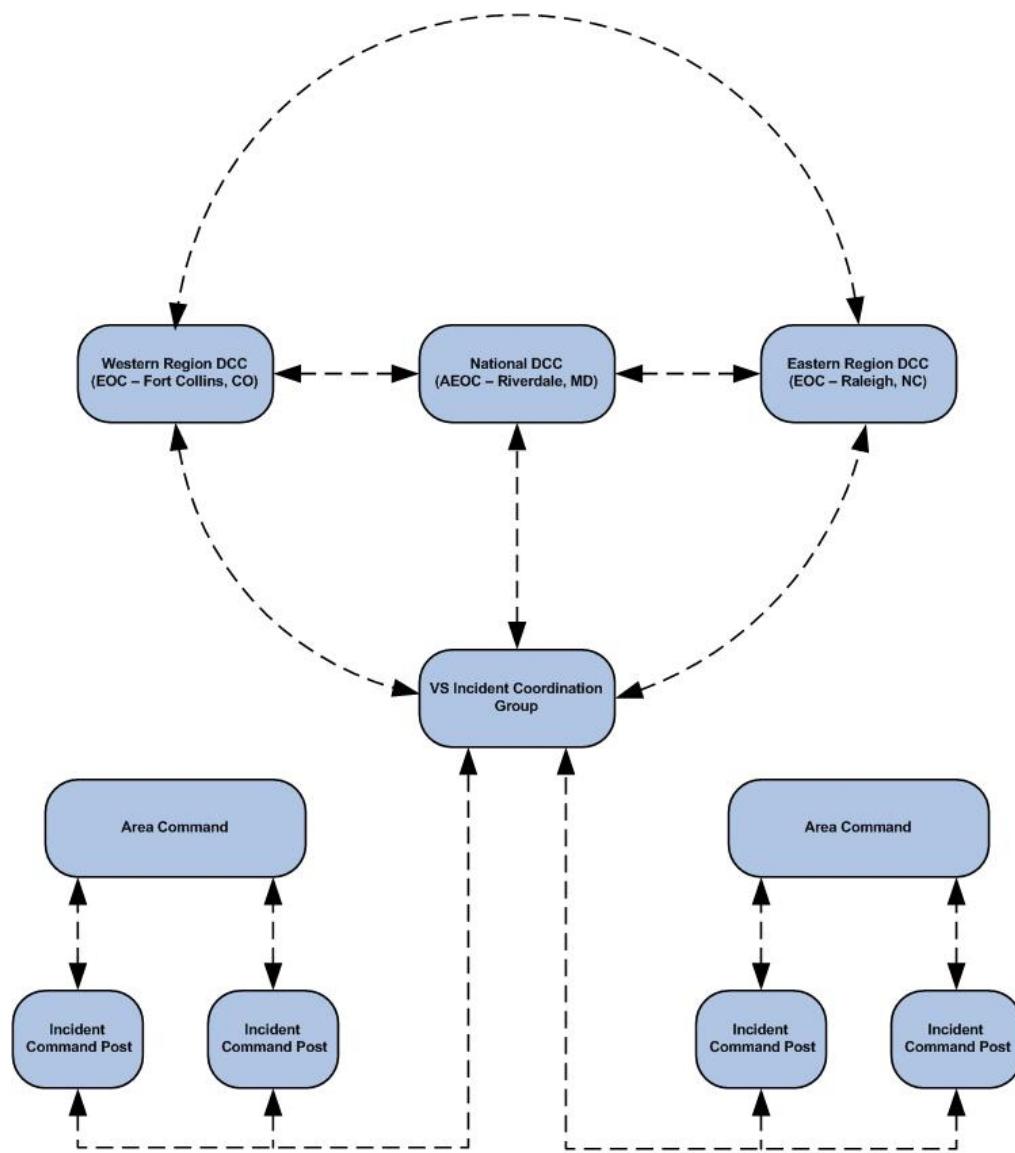
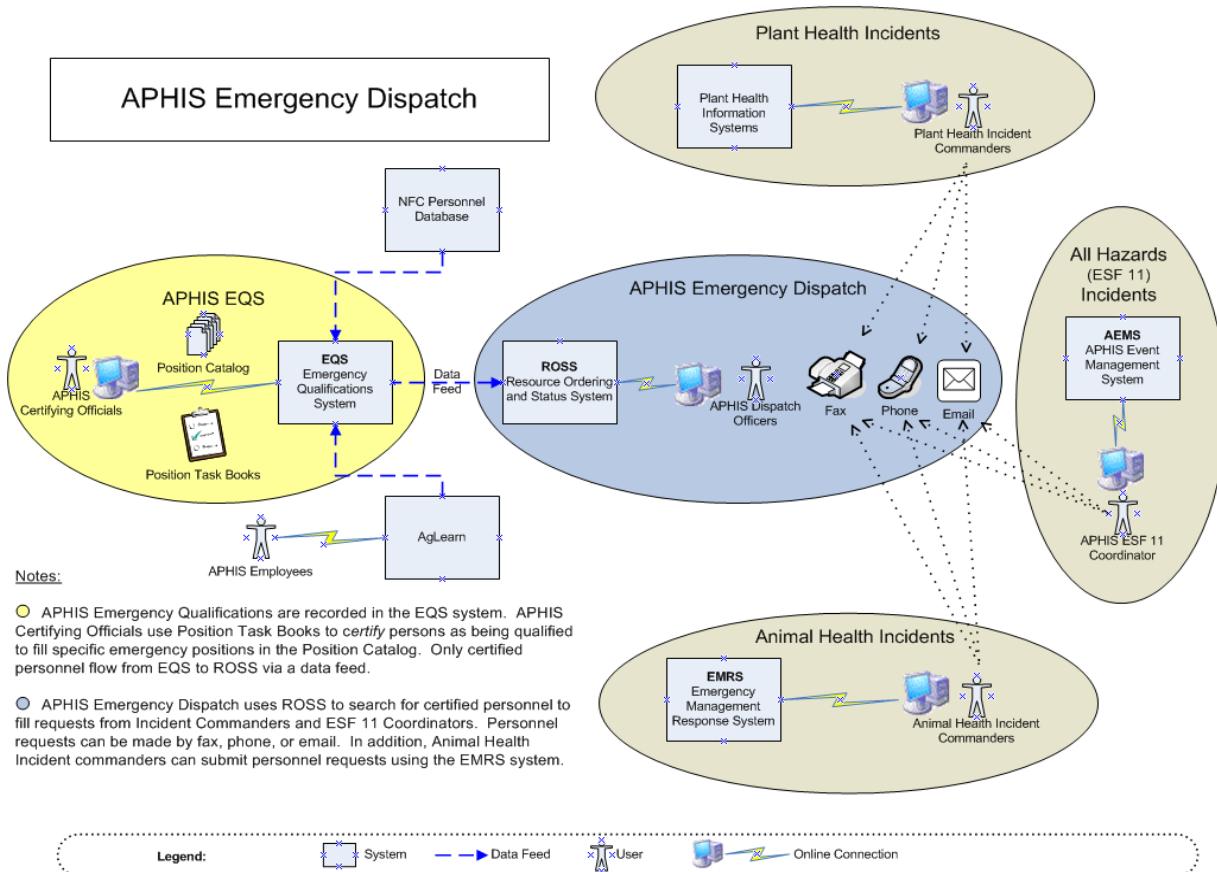


Figure 5-8. APHIS Emergency Dispatch Process



Appendix C

Laboratory Network List for Foot-and-Mouth Disease

The list of laboratories in the National Animal Health Laboratory Network (NAHLN) is found here:

http://www.aphis.usda.gov/animal_health/nahln/labs.shtml. The following laboratories can currently perform testing for FMDV after NVSL confirmation of FMD. This list is current as of August 24, 2010.

Table C-1. FMD NAHLN Laboratories

#	State	Laboratory	Phone numbers
1	Arizona	Arizona Veterinary Diagnostic Laboratory 2831 N. Freeway Tucson, AZ 85705	520-621-2356 Fax 520-626-8696
2	Arkansas	Arkansas Livestock & Poultry Commission Lab One Natural Resources Dr. Little Rock, AR 72205	501-907-2430 Fax 501-907-2410
3	California	California Animal Health & Food Safety Lab University of California, School of Vet Med W. Health Science Drive Davis, CA 95616	530-752-8709 (Backup 951-751-0025) Fax 530-752-5680
4	Colorado	Colorado State University Veterinary Diag. Lab 300 West Drake Rd, Bldg C Fort Collins, CO 80523-1644	970-297-1281 Fax 970-297-0320
5	Colorado	Colorado State University Veterinary Diagnostic Lab-Rocky Ford 27847 County Road 21 Rocky Ford, CO 81067	719-254-6382
6	Connecticut	Connecticut Veterinary Medical Diagnostic Laboratory University of Connecticut Unit 3089, 61 N. Eagleville Rd. Storrs, CT 06269-3089	860-486-3738 Fax 860-486-2737
7	Florida	Bronson Animal Disease Diagnostic Laboratory 2700 N. John Young Parkway Kissimmee, FL 34741	321-697-1400 Fax 321-697-1467
8	Georgia	University of Georgia Tifton Veterinary Diag. Laboratory 43 Brighton Road, PO Box 1389 Tifton, GA 31793-3000	229-386-3340 Fax 229-386-3399

Table C-1. FMD NAHLN Laboratories

#	State	Laboratory	Phone numbers
9	Georgia	Athens Veterinary Diagnostic Laboratory University of Georgia College of Vet Med, Building 1079 Athens, GA 30602	706-542-5568 Fax 706-542-5977
10	Illinois	University of Illinois Veterinary Diagnostic Laboratory 2001 S. Lincoln Urbana, IL 61802-6199	217-333-1620 Fax 217-244-7421
11	Indiana	Indiana Animal Disease Diagnostic Laboratory at Purdue University 406 South University St. West Lafayette, IN 47907	765-494-7440 Fax 765-494-9181
12	Iowa	Iowa State University Veterinary Diagnostic Laboratory 1600 S. 16th St. Ames, IA 50011	515-294-1950 Fax 515-294-3564
13	Iowa	USDA, APHIS, VS, NVSL, Diagnostic Virology Laboratory 1920 Dayton Ave Ames, IA 50010	515-337-7200 Fax 515-337-7418
14	Kansas	Kansas State Veterinary Diagnostic Laboratory Kansas State University, CVM L232 Mosier Hall, 1800 Dennison Ave Manhattan, KS 66506	785-532-5650 Fax 785-532-4039
15	Kentucky	Breathitt Veterinary Center Murray State University 715 North Drive Hopkinsville, KY 42240	270-886-3959 Fax 270-886-4295
16	Louisiana	Louisiana Animal Disease Diagnostic Laboratory Veterinary Med Diag. Laboratory, LSU Baton Rouge, LA 70803	225-578-9777 Fax 225-578-9784
17	Michigan	Diagnostic Center for Population and Animal Health Michigan State University 4125 Beaumont Rd, Ste 201H Lansing, MI 48910	517-353-1683 Fax 517-432-5836
18	Minnesota	University of Minnesota Veterinary Diagnostic Lab 1333 Gortner Ave, 244 Vet D L St. Paul, MN 55108	612-625-8787 Fax 612-624-8707
19	Mississippi	Mississippi Veterinary Research & Diagnostic Laboratory 3137 Hwy 468 West Pearl, MS 39208	601-420-4700 Fax 601-420-4719
20	Missouri	Veterinary Medical Diagnostic Laboratory University of Missouri 1600 East Rollins Columbia, MO 65211	573-882-6811

Table C-1. FMD NAHLN Laboratories

#	State	Laboratory	Phone numbers
21	Montana	Montana Veterinary Diagnostic Laboratory PO Box 997 Marsh Laboratory, 19th and Lincoln Bozeman, MT 59771	406-994-4885 Fax 406-994-6344
22	Nebraska	Veterinary Diagnostic Center University of Nebraska 137 VDC UNL Lincoln, NE 68583-0907	402-472-1434 Fax 402-472-3094
23	New Jersey	New Jersey Dept of Agriculture, Division of Animal Health State Diagnostic Lab, H & A Bldg Rm 201 John Fitch Plaza, P.O. Box 330 Trenton, NJ 08625	609-984-2293 Fax 609-777-8395
24	New Mexico	New Mexico Department of Agriculture Veterinary Diagnostic Services 700 Camino de Salud, NE Albuquerque, NM 87106	505-301-6194 Fax 505-841-2518
25	New York	Animal Health Diagnostic Center Upper Tower Road College of Vet Med, Cornell University Ithaca, NY 14853	607-253-3900
26	New York	USDA, APHIS, VS, NVSL, Foreign Animal Disease Diagnostic Laboratory PO Box 848 40550 Route 25 Greenport, NY 11857	631-323-3256 Fax 631-323-3366
27	North Carolina	Rollins Diagnostic Laboratory North Carolina Department of Agriculture 2101 Blue Ridge Rd. Raleigh, NC 27607	919-733-3986 Fax 919-733-0454
28	North Dakota	Veterinary Diagnostic Laboratory North Dakota State University Dept. 7691, PO Box 7691 Fargo, ND 58108-6050	701-231-8307 Fax 701-231-7514
29	Ohio	Ohio Department of Agriculture Animal Disease Diagnostic Lab 8995 E. Main Street, Building 6 Reynoldsburg, OH 43068	614-728-6220 Fax 614-728-6310
30	Oklahoma	Oklahoma Animal Disease Diagnostic Laboratory Oklahoma State Univ., College of Vet. Med. Farm & Ridge Road Stillwater, OK 74078	405-744-6623 Fax 405-744-8612
31	Oregon	Oregon State University Veterinary Diagnostic Lab Magruder Hall, 30th & Washington Way Corvallis, OR 97331	541-737-3261 Fax 541-737-6817

Table C-1. FMD NAHLN Laboratories

#	State	Laboratory	Phone numbers
32	Pennsylvania	Pennsylvania Veterinary Laboratory Pennsylvania Department of Agriculture 2305 N. Cameron Street Harrisburg, PA 17110	717-772-2852 Fax 717-772-3895
33	South Carolina	Clemson Veterinary Diagnostic Center 500 Clemson Road, PO Box 102406 Columbia, SC 29229	803-788-2260 Fax 803-699-8910
34	South Dakota	Animal Disease Research & Diagnostic Lab South Dakota State University Box 2175, N. Campus Dr. Brookings, SD 57007	605-688-5171 Fax 605-688-6003
35	Tennessee	CE Kord Animal Disease Diagnostic Lab Ellington Agricultural Center 440 Hogan Rd. Nashville, TN 37220	615-837-5125 Fax 615-837-5250
36	Texas	Texas Veterinary Medical Diagnostic Laboratory 1 Sippel Road, Drawer 3040 College Station, TX 77843	979-845-3414 Fax 979-845-1794
37	Texas	Texas Veterinary Medical Diagnostic Laboratory - Amarillo 6610 Amarillo Blvd West Amarillo, TX 79106	806-353-7478 Fax 806-359-0636
38	Utah	Utah Veterinary Diagnostic Laboratory 950 E. 1400 North Logan, UT 84322-5700	435-797-1895 Fax 435-797-2805
39	Washington	Washington Animal Disease Diagnostic Laboratory Bustad Hall, Room 155-N Pullman, WA 99164-7034	Phone 509-335-9696/ 509-335-6190 Fax 509-335-7424
40	Wisconsin	Wisconsin Veterinary Diagnostic Laboratory University of Wisconsin-Madison 445 Easterday Road Madison, WI 53706	608-262-5432 Fax 847-574-8085
41	Wyoming	Wyoming State Veterinary Laboratory 1174 Snowy Range Road Laramie, WY 82070	307-742-6638 Fax 307-721-2051

Appendix D

North American Foot-and-Mouth Vaccine Bank Guidelines for FMD Vaccine Use

Appendix D contains an excerpt from the North American Foot-and-Mouth Vaccine Bank Guidelines for FMD vaccine use, explaining the vaccination decision tree found in Chapter 5 of this FMD Response Plan (2010).

Appendix 3 – North American Guidelines for FMD Vaccine Use

The decision tree has been updated to include changes to the Code of 2004. The change permits return to “FMD freedom without vaccination” in 6 months without slaughtering all vaccines. This is provided serological surveillance is sufficient to detect antibodies to non-structural proteins (NSP) of FMDV indicating the absence of infection in the remaining vaccinated population for countries previously FMD free (Article 2.1.1.7). The option for slaughtering all vaccines or if there is no accepted NSP test are also illustrated. It has also been updated with modifications made in the UK to reflect that consideration for vaccination would be made much sooner (decision box 2) than in the past, prior to other, more drastic culling strategies.

It has also been updated with modifications made in the UK to reflect that consideration for vaccination would be made much sooner (decision box 2) than in the past, prior to other, more drastic culling strategies.

The development of this decision tree and matrix resulted from a request at the Tripartite Exercise 2000 Program. It was determined to use a decision tree flowchart combined with decision matrices. The rationale for this choice was that a *decision tree* has linear reasoning and can only evaluate single factors sequentially. Thus, simple linear logic:

i.e. A → B → C → D → F → G → H = decision ie VACCINATE cannot be devised

For non-linear or multi factorial decisions, a *decision table* or *matrix* is required with the following logic,
i.e. If A + C + F then VACCINATE; or If A + C + F + H then PRE-EMPTIVE SLAUGHTER

A *decision matrix* conceptually evaluates factors in parallel, not in sequence and thus has the capacity to consider multiple factors at the same time. Connector words such as *and*, *even*, *if*, and *but* can be used to weight the factors.

However, a *decision matrix* also does not reflect decision making in reality because human reasoning cannot consider all factors simultaneously. Logical reasoning seeks to group related factors. Thus, a *decision tree* flowchart was developed with five decision boxes. The decision flow chart is illustrated on page 44. The decision process starts from the top left (decision box 1) and proceeds to decision box 5 in the bottom right of the figure.

Future Work

This decision matrix will be updated as results are obtained from modelling work (epidemiological and economical)³². These results will be used to identify the trigger points for the various control measures in the North American context.

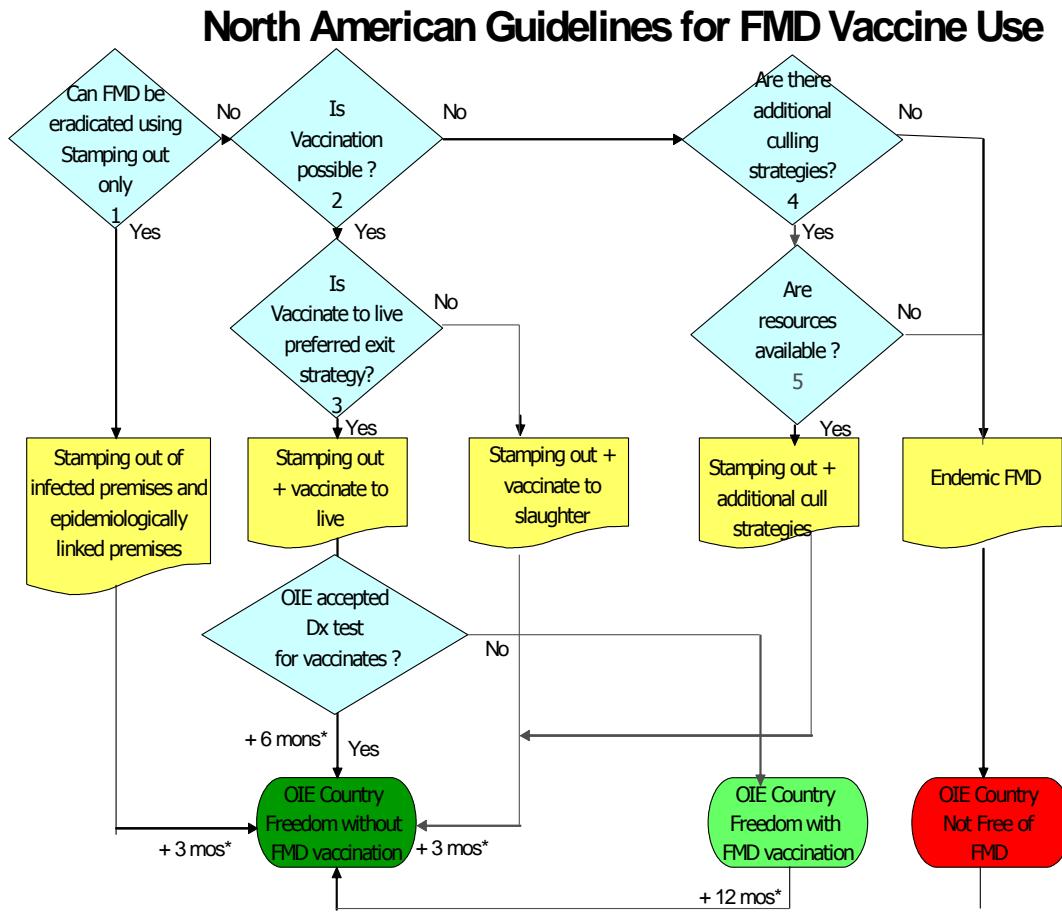


Figure 4. North American guidelines for FMD Vaccine use.

Each decision box is supported by a *decision matrix* where appropriate factors are listed for consideration. The factors have been grouped into four pivotal factors that characterize the nature of the epidemic (OUTBREAK FACTORS) and four pivotal factors which describe mitigation measures for the outbreak (MITIGATION FACTORS). Each pivotal factor has numerous sub-factors described below.

OUTBREAK FACTORS are:

- Contact Rate
- Host or Species affected/species at risk
- Status of Outbreak
- Environmental

MITIGATION FACTORS include:

- Physical Resources
- Human Resources
- Socio-political factors
- Economic considerations

Note that only factors appropriate to the specific decision box are provided. For example, *decision matrix 1* is the only matrix that contains all the outbreak factors. *Decision matrices 2-5* contain only mitigation factors in addition to stamping out of infected herds. In order to leave the decision box, one must determine the direction by deciding YES or NO considering all the factors and sub-factors in that box. Tables are available to facilitate record keeping of decisions.

1st Decision Box – Can disease be eradicated with stamping out alone (of infected premises and epidemiologically linked premises)?

In this decision box, *all* outbreak factors and mitigation factors must be considered. This is the point of departure from the preferred, traditional policy of stamping out of infected premises and epidemiology linked premises. In most instances, such factors will not be known at the start of an outbreak. Decisions may need to be revisited as more information becomes available. Modelling work done *a priori* based on normal movements patterns may help early in the outbreak.

1. Time to Detection

Detecting infected premises early after exposure reduces the probability of transmitting FMD to other premises. Age of oldest lesions at detection can provide an estimate of this delay between exposure and detection.

2. Contact Rate

In simulated outbreaks using the North American model for FMD, contact rate (direct, indirect) was identified as one of the most sensitive parameters. This suggests that for the same resource capacity, variations in the contact rate will influence how quickly the outbreak will be controlled. The contact rate will be influenced by the following factors:

2.1 Kind of Farms – Contact rates may vary by type and size of farms. A higher level of transmission may be expected if an outbreak is declared in premises known to have high contact rates.

2.2 Type of contact – Movement of animals (direct), people or equipment (indirect) or possible vectors such as wildlife can spread FMD. Direct movements have a higher probability of transmission of infection compared to indirect movements. Indirect movements include but are not limited to fomites such as equipment, contamination of supply delivery vehicles, veterinarians, artificial insemination technicians, and farm workers. It also includes marketing of animal products and by-products. Indirect movements that include close contacts with livestock or their products and by-products should be considered at higher risk of spreading FMD.

2.3 Movement distances – An important factor in the spread of the outbreak. Knowledge of routine movement distances will help in the implementation of the size of the control zones.

2.4 Efficacy of movement controls – this factor is critical in preventing the spread of FMDV and should include an estimate of illegal movements in the outbreak area as well as past movements.

3. Host

The species affected and species at risk must be considered. Intractability of zoo or exotic livestock must also be considered.

3.1 Domestic livestock only - Of the domestic livestock under consideration, swine are crucial because of their ability to amplify the amount of virus that can be spread by airborne means. Sheep and goats tend to be sub clinical and tend to be less likely to spread virus by aerosol but are spreading the disease following movements. Cattle are more at risk of infection by aerosol whereas swine are more susceptible through ingestion of contaminated material.

Modelling in Australia²³ suggests:

Swine:

- 100 sows put livestock at risk 10 km downwind
- 1000 swine create a virus plume in 12 hr, infecting livestock over a 200 km² area

Feedlot:

- 1000 cattle over 24 hr infected an area of 0.5 km², 3.4 km downwind
- 5000 cattle over 24 hr infected an area of 6.2 km², 15.2 km downwind
- 5000 cattle over 24 hr infected an area of 26 km², 37.2 km downwind

2.2 Game farms; zoos - Are there genetics or endangered species that will not be able to be slaughtered? How effective would quarantine or isolation methods be?

2.3 Wildlife - Are there genetics or endangered species that will not be able to be slaughtered? How effective would quarantine or isolation methods be?

2.4 Virus tropism - Tropism of the virus will not likely be immediately known. By the time it will be known, mitigation measures can be modified but they will not reduce the trade disruption. Additional surveillance testing of non-target species will be required.

4. Status of Outbreak

Estimation of FMD extent and duration of the epidemic. Sub-factors to be considered include:

4.1 # affected herds - A greater number would indicate more undiscovered or incubating herds. This observation would be of concern in that it could indicate biological terrorism.

4.2 # foci - One focus of infection would be less likely to spread before stamping out could contain the outbreak. Two or more foci separated by 10 or more km would indicate that the outbreak has already spread.

4.3 Rate of spread - Rapid spread would be reflected in increasing number of cases per day or increasing number of cases per week. Rate of spread estimates whether the outbreak is in the arithmetic (initial) or logarithmic (expansion) portion of the epidemiological curve.

5. Environment

Includes cultural and physical geography as well as climate.

5.1 Livestock density and distribution - How many herds/animals are there per square unit of area? Obviously, the more herds and the more widely distributed they are, the greater the likelihood of spread. Density of livestock and farms are key issues.

5.2 Livestock management - Whether the majority of affected producers are large corporations/owners on private land; communes; as opposed to small producers or backyard subsistence producers may have an impact on outbreak due to socio-political status and influence.

5.3 Casual access - Network of transportation corridors in outbreak area with casual human and vehicle traffic may promote spread although it is noted that the UK determined that footpaths would not be closed in future epidemics after the outbreak in 2001.

5.4 Physical barriers - Is the outbreak in a naturally isolated area, i.e. desert, island/isthmus, or protected by rivers, mountains or any other physical geographic feature that would limit spread?

5.5 Climate - Do prevailing winds, temperature and humidity conditions favour airborne spread?

6. Physical Resources

6.1 Slaughter capacity - FMD infected animals are slaughtered on-farm by policy. Thus farm technology and mustering facilities, intractability of livestock are factors. If wildlife is affected, capability to slaughter all infected animals is very difficult unless confined.

6.2 Transportation capacity - If conditions prohibit on-farm disposal, bio-secure transportation of carcasses and all animal products or any other such thing used in respect of animals is essential.

6.3 Disposal capacity - If on-farm disposal is available, heavy equipment would be required for burial or incinerator facilities for burn. If off farm disposal, rendering facilities, burn or burial sites are needed. If these are easily available, then slaughter of animals and disposal of all animal products or any other such thing used in respect of animals is facilitated.

7. Human Resources

7.1 Emergency response system /movement control - Is there sufficient trained staff for stamping out and to enforce movement control restrictions to limit FMD spread. Is the level and quality of surveillance sufficient to evaluate the effect movement controls? Is the administration able to meet the needs of the emergency response system?

7.2 Epidemic projections - potential outcomes for region, species, costs to aid in decision-making.

8. Social-Political

8.1 Legislation available - Is there legislation in place for stamping out activities?

8.2 Public opinion / legislative will / appearance of government - What is the current welfare/animal rights climate? Public perception of affected animal destruction. Public perception that the government is acting responsibly. Legislative and public attitude to vaccination, pre-emptive slaughter and compensation.

8.3 Industry acceptance - Will the producer organizations concur with the decision? Is information on which tracebacks are based credible? Will industry disclose all traceback information? What is the opinion of non-FMD affected livestock industry sectors? Is the agricultural economy in general affected by international FMD restrictions? What is their opinion?

8.4 Socio- economic status of producers and / or of a region - What is the level of sophistication of the producers in the affected region? What is their socio-political influence? Are there genetic preservation considerations against stamping out?

9. Economic

9.1 Compensation - Is there sufficient funding for the potential number of animals to be eliminated by stamping out (commercial versus purebred)? Could numbers necessary to be depopulated significantly be reduced by vaccination? Is there compensation for lost production, animal products, by-products etc.

9.2 Value of exports - Cost-benefit of country-free status versus stamping out eradication effort. Are there enough funds available for other emergency response activities and supplies?

9.3 Regionalization – Is there the ability to zone or regionalize the affected area with international acceptance without eradication of FMD? If not international, can a Tripartite agreement be reached to permit North American trade in spite of OIE restrictions without eradication of FMD in affected area?

2nd Decision Box – Is vaccination possible?

One arrives at this decision box when stamping-out of infected premises and epidemiologically linked premises is not sufficient to eradicate the disease or resources are insufficient to keep up to the volume of animals requiring slaughter and disposal. In either case, in this vaccination decision box, factors surrounding the decision to vaccinate are outlined.

1. Physical Resources

1.1 Vaccine strain available - Does the NAFMDVB have the correct strain? Does the NAFMDVB have a cross-protection strain available in the Bank? (Little or no cross-protection between 7 serological types) In cases of bio-terrorist action, more than one serotype of virus may be involved.

1.2 Vaccine doses available – Vaccine is not immediately available. The NAFMDVB has negotiated an initial standby supply to be delivered within a time period specified in the manufacturers' contract. Animals may require to be vaccinated twice (2-4 wks apart) to maximize the immunity and decrease the probability of having "carrier animals."

1.3 Vaccine logistics - Are all logistics for vaccination in place, i.e. equipment, supplies such as ear tags from NAFMDVB, taggers, record keeping system, portable corrals, head gates. Are there cold chain provisions for the vaccine to the field outbreak centre?

1.4 Vaccine distribution - Vaccine required for ring vaccination/high risk situations (feedlot or intensive swine) Australian models shows: ring vaccination decreases length of outbreak 0.1- 0.6 weeks; whereas high risk situation vaccination decreases length of outbreak 1.2 - 2.9 weeks.

1.5 Laboratory capacity- Does laboratory have diagnostic capability to distinguish vaccines from infected animals? Does laboratory have diagnostic capability to analyse suspect and surveillance samples needed to assure trading partners that all animals at risk have been vaccinated

1.6 Time - Are there sufficient physical resources to permit vaccination of herds in the affected area prior to spread of infection from the outbreak (incubation period = 7+- 4 d ;OIE =14d for cattle and swine)?

2. Human Resources

2.1 Emergency response system /movement control - Is there sufficient trained staff for vaccinating the numbers required, including intractable species? Are there enough resources to conduct pre-emptive slaughter if both options are being employed? And to enforce movement control restrictions to limit FMD spread? Is the administration able to meet the needs of the emergency response system? Are training staff & material available to train vaccination teams? Is competent contract staff available?

2.1 Risk of FMD introduction - Risk of vaccinating teams spreading FMD while vaccinating. Is there sufficient time and protocols in place to train vaccinating teams to minimize risk?

2.2 Epidemic projections- Potential outcomes including risk of outbreak due to early field challenge or less than 85% coverage in vaccination region. Identification of high risk herds that would seroconvert prior to field virus challenge, cattle (1-2 weeks); swine (3 weeks). Early field FMD challenge increases FMD carrier state in vaccine cattle (3 yr), sheep (9 mos), goats (4 mos).

3. Social-Political

3.1 Legislation available - Is there legislation required for mandatory vaccination?

3.2 Public opinion /appearance of government - What is the current welfare/animal rights climate? Are there public perceptions of FMD vaccination that could lead to trade restrictions? Public perception that the government is acting responsibly.

3.3 Industry acceptance- Will the producer organizations concur with the vaccination decision? Will industry present all susceptible animals for vaccination? Will industry rather be FMD infected and be compensated at market value or vaccinate and have livestock market value reduced.

3.4 Social- economic status of producers/region -What is the sophistication of the producers in the affected area? What is their social-political influence?

4. Economic

4.1 Cost of vaccination - Cost of vaccination requires requesting country to pay \$US 400,000 to the vaccine bank for vaccine finishing plus replacement cost of antigen within 60 days of request. Is this cost prohibitive for a single country?

4.2 Value of exports - Does vaccination reduce exportation from the country in general? Cost-benefit of additional time to attain country-free status after vaccination. Other vaccines restrictions (OIE code)?

4.3 Regionalization - within country/ Tripartite? - Ability to regionalize the affected area with international acceptance with vaccination for FMD? Can a Tripartite agreement be reached to permit North American trade in spite of OIE restrictions on FMD vaccination?

4.4 Compensation for decrease value of vaccinated animals?

3^d Decision Box – Is the exit strategy “Vaccinate to live”?

The disposition of vaccines is a separate consideration from decision to vaccinate but necessary to regain “FMD free without vaccination” status. The third decision box has been split into two because the decision to slaughter vaccines is dependent on two main criteria. The first is the economic and ethical question of slaughtering apparently healthy vaccines that could be co-infected with a field strain of FMD. The second consideration is whether trading partners will accept the validity of a non-structural protein (NSP) test to identify vaccines from non-clinical expressions of field FMD. At the time of writing, there is no OIE sanctioned discriminatory test.

The economic criteria here is based in the gain of 3 months trade at OIE standards since “FMD free without vaccination” status is achieved 3 months after the slaughter of the last vaccine where as “FMD free without vaccination” status is achieved 6 months after the slaughter of the case or the last vaccination provided that a serological survey based on the detection of antibodies to nonstructural proteins

of FMD virus demonstrates the absence of infection in the remaining vaccinated population. If no such test is available OR acceptable, “FMD free without vaccination” can be achieved 12 months after the last FMD case or last vaccination. During the interim period, a country would be FMD free with vaccination.

International markets discriminate between countries that are FMD free without vaccination from those that are FMD free with vaccination. Europe, North America, Australia and New Zealand enjoy a superior status without FMD vaccination. Thus, this decision is primarily an economic consideration but other MITIGATION factors also play a role.

1. Physical Resources

1.1 Slaughter capacity - Slaughter of FMD vaccines would likely be done off farm as it would be more efficient. On-farm slaughter may be considered under set circumstances. Thus farm technology and mustering facilities, intractability of livestock are factors.

1.2 Disposal capacity - If vaccines are not salvaged for meat or other animal products, on-farm disposal may be considered in some circumstances. Requirements for heavy equipment for burial or incinerator facilities for burning, rendering facilities or burial sites must be located.

1.3 Time - Are there sufficient physical resources to permit slaughter and disposal of vaccines within 6 weeks of vaccination (no 2nd dose required)?

2. Human Resources

2.1 Emergency response system /movement control - Is there sufficient trained staff for slaughter of vaccines in addition to surveillance activities required for OIE country freedom recognition? Can movement control of vaccines be tracked to ensure that all vaccines are slaughtered? Is the administration able to meet the needs of the emergency response system?

2.2 Epidemic projections - Potential outcomes including risk of another outbreak once vaccines eliminated from the region.

3. Social-Political

3.1 Legislation available - Is there legislation for mandatory slaughter of vaccines?

3.2 Public opinion /appearance of government - What is the current welfare/animal rights climate? Public perception of slaughter of healthy FMD vaccines. Public perception that government is acting responsibly

3.3 Industry acceptance - Besides record keeping, what are the movement restrictions of vaccines? Will FMD vaccines be allowed to move (under permit) to other affected tripartite countries? Will the producer organizations concur with the slaughter of vaccines? Will industry assist in tracking all vaccines and respect movement controls? (Influenced by 4.2 if the government compensates for loss of market share of vaccinated animals). Will industry agree to slaughter the offspring of vaccines (maternal antibodies)? What is the opinion of non-FMD affected livestock industry sectors? Is the agricultural economy in general affected by international FMD restrictions? What is their opinion?

3.4 Social- economic status of producers/region - What is the sophistication of the producers in the affected area? What is their social -political influence?

4. Economic

4.1 Cost of vaccine slaughter - Cost of vaccine slaughter including tracking of all vaccines to ensure that all are slaughtered.

4.2 Compensation- Compensation costs for vaccinated animals as well as animal products and by-products, decreased market value of vaccines, cost of maintenance of vaccines between vaccination and slaughter? Are compensation funds available in short term to allow rapid slaughter?

4.3 Value of Exports - Cost-benefit of country-free status versus cost of compensating for vaccines until discrimination test of vaccine versus infected animal is internationally accepted (OIE code)?

4.4 Regionalization - within country / Tripartite? Ability to regionalize the affected area with international acceptance with vaccination for FMD? Can a Tripartite agreement be reached to permit North American trade in spite of OIE restrictions on FMD vaccination?

4th Decision Box – Are there additional cull strategies to consider?

This fourth box deals with culling strategies other than stamping-out of infected premises and dangerous contacts (i.e. ring or contiguous cull, culling of premises in order to stop the spread outside an area, etc.). Only social-political and economic factors must be considered. Of particular importance is the existence of legislation to support these culling strategies. The issue of adequate resources to perform these measures at the rate required is dealt with in decision box 5.

1. Social-Political

1.1 Legislation available - Is there legislation in place for pre-emptive slaughter on traceback and peripheral herds?

1.2 Public opinion /appearance of government - What is the current welfare/animal rights climate? Public perception of healthy animal destruction based on risk. Public perception that the government is acting responsibly.

1.3 Industry Acceptance - Will the producer organizations agree to slaughter tracebacks and peripheral herds? Is the information on which tracebacks are based credible? Will industry disclose all traceback information? What is the opinion of non-FMD affected livestock industry sectors? Is the agricultural economy in general affected by international FMD restrictions? What is their opinion?

1.4 Social - economic status of producers/region - What is the sophistication of the producers in the affected region? What is their social-political influence? Are there genetic preservation considerations against pre-emptive slaughter?

2. Economic

2.1 Compensation - Is there sufficient funding for potential number of animals to be eliminated by stamping out and pre-emptive slaughter on tracebacks and peripheral herds (commercial / purebred)? Is there compensation for lost production time, animal products, by-products etc? Are animal products (including meat) salvageable for human consumption from pre-emptively slaughtered animals (unknown FMD infection status)?

2.2 Value of Exports - Cost-benefit of country-free status versus cost of eradication effort including pre-emptive slaughter costs.

2.3 Regionalization/zoning - Ability to zone or regionalize the affected area with international acceptance without eradication of FMD? Can a Tripartite agreement be reached to permit North American trade in spite of OIE restrictions without eradication of FMD in affected area?

5th Decision Box – Are resources available to perform additional culling strategies?

In this fifth decision box, *only* resource factors are considered. The social-political and economic considerations are such that other culling strategies are an option. The prime concern is whether adequate physical and human resources exist to accommodate the anticipated number of livestock to be pre-emptively slaughtered *in addition* to those slaughtered under stamping out.

1. Physical Resources

1.1 *Slaughter capacity* FMD infected/ high-risk animals should be slaughtered on-farm. Thus farm technology and mustering facilities, intractability of livestock are factors. However, the majority of pre-emptive slaughter would likely be done off farm as it would be more efficient. The presence of slaughter facilities within the infected zone is important.

1.2 *Transportation capacity* - Unless tested immediately prior to movement, peripheral / traceback herds could be incubating and thus contagious for FMD. If pre-emptive slaughter is done off farm, biosecure transportation of animals is necessary to prevent spread.

1.3 *Disposal capacity* - If on-farm disposal available, heavy equipment would be required for burial or incinerator facilities for burn. For off farm disposal, rendering facilities, burn or burial sites are needed. If these are easily available, then pre-emptive slaughter and stamping out are good options.

1.4 *Time* - Are there sufficient physical resources to permit pre-emptive slaughter of peripheral herds in addition to tracebacks and infected herds *before* peripheral and traceback herds develop FMD? (Incubation period = 7+- 4days; OIE= 14 days).

2. Human Resources

2.1 *Emergency response system /movement control* - Is there sufficient trained staff for stamping out and pre-emptive slaughter without impacting on enforcement of movement control restrictions to limit FMD spread within the required time frame (see 1.4)? Is the administration able to meet the needs of the emergency response system?

2.2 *Epidemic projections* Potential outcomes including risk of another outbreak with pre-emptive slaughter for region, species, costs to aid in decision making. Identification of high-risk herds that would have priority for pre-emptive slaughter.

Appendix E

Updated FMD Outbreak Surveillance Guidance and Rationale

FMD OUTBREAK SURVEILLANCE GUIDELINES

These are updated recommendations for FMD outbreak surveillance, prepared by the National Surveillance Unit (NSU) of the Centers for Epidemiology and Animal Health (CEAH), VS, APHIS. These guidelines are under development, and will be updated periodically.

Purpose

The purpose of these guidelines is to provide recommendations for this FMD Response Plan (2010). Surveillance will be conducted at intervals as specified by the Incident Command using the most current scientific information and best practice guidance available.

Objectives

The objectives of FMD outbreak surveillance are to:

- ◆ Detect FMD Infected Premises during an outbreak.
- ◆ Determine the size and extent of an FMD outbreak.
- ◆ Supply information to evaluate outbreak control activities.
- ◆ Provide information for animal and product movement within the Control Area.
- ◆ Provide information for animal and product movement out of the Control Area.
- ◆ Prove disease freedom and regain disease-free status after eradication of the outbreak.

Definitions

There are two key definitions that are important in outbreak surveillance.

- ◆ *Clinically ill animals.* Animals with clinical signs compatible with FMD in an epidemiological unit (milk string, feedlot pen, pasture) on premises.
- ◆ *Detection probability.* Likelihood that the sampling scheme will detect at least one infected animal in each epidemiological unit (EU) with 95 percent confidence at the selected design threshold, population size, and sensitivity of the chosen validated test.

Rationale for Selecting a Design Threshold

It is difficult to recommend a single surveillance sampling scheme for an FMD outbreak because many factors impact the nature and characteristics of the outbreak. Each outbreak is different; surveillance plans will need to be tailored to individual outbreaks.

GENERAL CONSIDERATIONS FOR SELECTING A DESIGN THRESHOLD

There are a number of general factors that impact an FMD surveillance plan. Some of these factors are related to the nature of the FMD outbreak itself, while others to the surveillance plan.

- ◆ Outbreak or disease related factors:
 - *Prevalence.* (1) proportion of infected animals on the premises, or (2) proportion of infected premises in the area at a specific time period.
 - *Incubation Period.* Length of the period that elapses between the introduction of the pathogen into the animal and the occurrence of the first clinical signs.
 - *Transmission and Generation.* Length of time between when one animal is infected, becomes infectious, and infects another animal.
 - *Ease of Recognition.* The ease of recognition of clinical signs of FMD in affected species.
 - *Time.* The length of time which has passed since the disease was introduced to the premises or area.
 - *Herd Size.* Number of animals on a given premises.
 - *Density of Premises.* Number of Infected Premises in a given area.

- ◆ Surveillance plan factors:
 - *Resources.* Resources that are available for sample collection or visual observation, including personnel.
 - *Diagnostics.* Tests that are available, including how many animals must be tested, and what type of test (tissue, vesicular fluid, serum).
 - *Detection Time.* How long it takes before a test can detect the presence of FMDV in an animal. For example, does the test require the animal to be clinically ill or can it detect prior to visual signs.
 - *Test Sensitivity.* The estimated proportion of true positive (diseased or infected) animals that will test positive.
 - *Test Specificity.* The estimated proportion of true negative (non-diseased or non-infected) animals that will test negative.
 - *Frequency.* How often samples must be collected and diagnostic tests must be conducted for effective surveillance.
 - *Goal of Surveillance.* A surveillance scheme will depend on whether the goal is to prove disease freedom or detect disease in a vaccinated or unvaccinated population.
 - *Confidence Level.* The probability of accepting the null hypothesis when it is true.

All of the factors listed above are interrelated. Table E-1 lists the factors and general surveillance design in an outbreak response effort. It is important to consider all factors together, rather than independently, when developing a surveillance plan.

Table E-1. Interaction of Disease/Outbreak and Surveillance Factors, with Suggested Adaptations in Surveillance Scheme

Disease/Outbreak Factor	Surveillance Factors							
	Design prevalence	Sampling frequency	Visual exam (lower sensitivity test)	Animal handling	Test sensitivity	Early detection	Tissue testing (higher sensitivity test)	
Shorter incubation period	Increase	Increase	Use, depending on strength of clinical signs	Decrease	Less important	Increased likelihood	Less important	
Strong clinical signs	Increase	Depends	Use	Decrease	Less important	Increased likelihood	Less important	
Size of epidemiological unit	Decrease	Frequent	Depends	Depends	More important	?	More important	
Increased prevalence	Decrease	Less frequent	Depends	Depends	Less important	Depends	Less important	

REASONS TO SELECT A LOW DESIGN THRESHOLD

It is impossible to select one disease factor and one surveillance factor from Table E-1 and to understand how the surveillance factor should change based on that one disease factor independently of the other factors. However, if possible, it is always desired to (1) select the test that detects FMDV as early as possible, and (2) use the lowest design threshold. A low design threshold is consistent with surveillance schemes used for disease detection, business continuity, and proof of disease freedom.

The reasons for selecting the low design threshold are as follows.

- ◆ FMD virus is highly contagious. In a naïve population, the virus multiplies rapidly in multiple animals and spreads quickly throughout the population via direct contact, indirect contact (fomites), and possible aerosol transmission.
- ◆ Animals infected with FMDV may become infectious and transmit the virus early in the infectious process (1 to 7 days after exposure, depending on serotype and species); this is before clinical signs are apparent.
 - Clinical infection varies from very mild to severe; animals with mild clinical signs may not be detected.
- ◆ Low design prevalence will be exceeded rapidly, as FMD spreads quickly through an EU, which fosters early disease detection in comparison to a high design prevalence.
- ◆ Early detection reduces the time that premises are infectious.

- ◆ The FMD virus is detectable in epithelial tissue (for example, pharyngeal epithelium, teats, muzzles, and coronary bands), vesicular fluid, and tissues before animals display clinical signs.
- ◆ Samples required for approved and validated diagnostic tests—such as epithelium, vesicular fluid, serum, oral swabs—require direct contact with the animal.
- ◆ There are no approved and validated mass population or pooled sampling procedures.
- ◆ Monitoring feed intake and/or milk production in large herds may require more than a few infected animals before signs trigger additional diagnostics.
- ◆ It is not likely that the index premises is the first Infected Premises; FMD virus may be widely dispersed.
 - All Infected Premises may be a source for transmission of FMDV.
 - More undetected Infected Premises (without movement controls) increases the probability that the FMD outbreak will be widespread.
 - Personnel may unknowingly transmit FMD from clinically normal but infected animals to uninfected animals.
- ◆ Following appropriate biosecurity and cleaning and disinfection requirements, surveillance teams can sample approximately 2 premises per day if taking individual samples.

Surveillance Scheme Sampling Considerations

Surveillance on susceptible premises should detect the presence of FMDV at the earliest possible moment after viral introduction. This occurs when the virus is detectable, using the lowest possible design prevalence, in tissues, serum, or vesicular fluid.

The choice of the design prevalence depends on (1) the surveillance methodology, (2) the diagnostic test sensitivity, and (3) the chosen confidence level.

At present, there are no validated mass population sampling techniques, as explained in Chapter 6 of this FMD Response Plan. It is a priority to validate mass population or pooled sample testing.

Currently, as explained in Chapter 6, the following diagnostic tests will be used in an FMD outbreak to detect and characterize FMDV. Please refer to Figure 6-2 and Figure 6-3 for the diagnostic testing scheme used by the NVSL-FADDL.

- ◆ Virus Isolation (VI)
- ◆ 3ABC enzyme-linked immunosorbent assay (3 ABC ELISA)
- ◆ Virus infection association antigen (VIAA) group specific 3D agarose immunodiffusion (AGID)
- ◆ Antigen ELISA (AgELISA)
- ◆ Virus Neutralization (VNT)
- ◆ Real-time reverse transcriptase polymerase chain reaction (rRT-PCR).

The rRT-PCR test will be used in an outbreak to detect infected, unvaccinated animals because of its rapid turnaround time (approximately 4 hours).

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

1. Are resources limited to intensively survey premises (for example, collect tissue samples from the needed number of animals)?
2. Is it unlikely that the outbreak can be contained locally (such as on a farm or within a small geographic area)?
3. Does evidence suggest that the introduction of virus (for example, start of the outbreak) on the premises or in the zone began at least 7 days ago?
4. Is there evidence that the FMD serotype is highly pathogenic (for example, a high proportion of infected animals will show clinical signs and/or severe clinical signs)?
5. Are there limited movements of animals, vehicles, products, or personnel on and off premises (for example, it is unlikely that virus will be introduced to, or spread from, this premises or zone)?
6. Are sheep present in the zone or on the premises?
7. Are there noncommercial or feral swine in the zone?
8. Are there noncommercial or small premises in the zone?
9. Are there premises with more than one susceptible species?

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

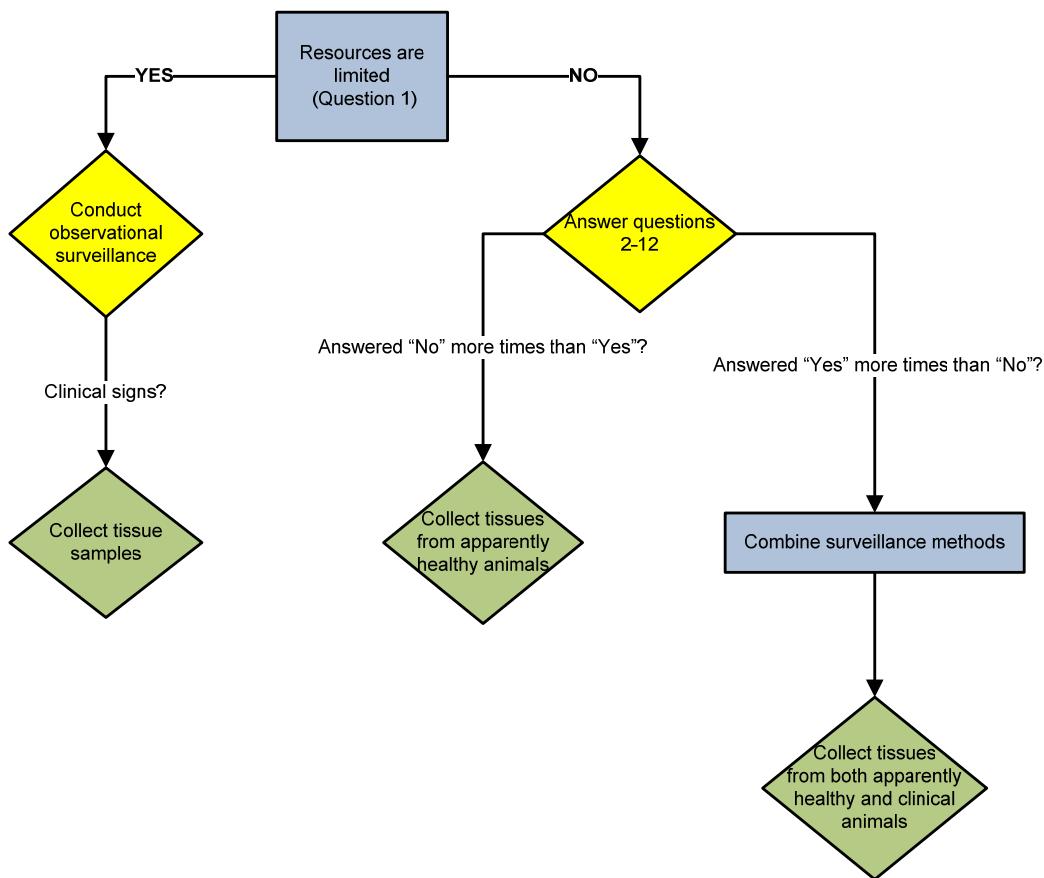
Figure E-1 demonstrates how these questions should be used to inform a surveillance sampling scheme.

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

If the answer to Question 1 is “no,” and

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

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



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

Surveillance Test Choices

The predictive positive value (PPV) of a diagnostic test depends, foremost, on the disease prevalence in the population. The PPV also depends on test specificity and sensitivity. The PPV of any test is poor if the prevalence in the population is less than 5 percent. Early in the disease outbreak, it can be difficult to estimate the prevalence of Infected Premises in a given area, or the prevalence of infected animals on a given premises. The goal is always to detect viral presence with the *least* number of infectious animals. Subsequently, it is important to use the lowest design prevalence possible.

The negative predictive value of a test (NPV) is best used when the disease is not prevalent (less than 1 percent), the specificity of the test is high, and there is little disease clustering. These conditions, coupled with low design prevalence and

negative diagnostic test results, facilitate proving disease freedom in a given population.

As FMD viral prevalence increases, the PPV increases and the specificity of the test plays a minor role in disease detection. With FMD, the rRT-PCR has the ability to detect viral presence earlier than visual examination.

FACTORS THAT INFLUENCE DIAGNOSTIC TEST CHOICE

The choice of a diagnostic test or tests is influenced by a number of choices.

- ◆ Resources available.
- ◆ *FMD prevalence in the population.* The following factors increase prevalence:
 - Highly contagious animals.
 - Short incubation period (2 days vs. 2 weeks).
 - Number of contacts between infectious and susceptible animals.
 - Animals infected with FMDV may become infectious and transmit the virus early in the infectious process (1 to 7 days after exposure, depending on serotype and species); this is before clinical signs are apparent.
 - Pathogenicity of the virus.
- ◆ Test characteristics.
 - Prevalence at which the test can detect disease.
 - For example, visual inspection requires approximately 50–75 percent of the herd to be infected before morbidity is likely to appear abnormally high.
 - Speed of test results.
 - Sensitivity.
 - Sampling frequency.
 - Level of animal contact required.

SAMPLING ALTERNATIVES

If resources are not significantly limited, (1) use the lowest intra-premises and inter-premises design threshold, and (2) sample at least three times per incubation period.

If mass population sampling tests become available, substitute these tests for individual animal sampling, and sample frequently.

The following are sampling scheme alternatives to individual sampling, using a 1 percent design prevalence.

- ◆ Increase the design intra-premises prevalence from 1 to 2 percent, or 5 to 10 percent. With each percent increase, fewer animals will be sampled.
- ◆ With a highly contagious FMD viral strain, there will be less time lost between infection and detection when using higher design prevalence. This is because the number of ill animals increase exponentially ($R_0=1, 1, 2, 4, 8, \text{ etc.}; R_0= 1, 1, 5, 25, 125, \text{ etc.}$).¹
 - Visual detection of FMD infected animals will become easier.
- ◆ If the FMDV strain has a short incubation period, there will be less time lost between infection and detection using a higher design prevalence because the animals become infectious and display clinical signs rapidly.
 - The reverse is true with an FMD virus that has a longer incubation period.

SAMPLING EXAMPLES

1. *rRT-PCR*. The rRT-PCR test would sample animals which are selected from the population of animals without clinical signs, where the prevalence of infected animals (in the population without clinical signs) is expected to be *less than* in the sub-population of animals with clinical signs. All clinically ill animals should be included in animals sampled, but the remainder of the calculated number of samples will be from non-clinically sick animals.

For example, on a premises there are 10 sick animals, all with FMD compatible signs: 5 pyretic cows that may be expected each day in a group of 250 milking cows (mastitis, pneumonia, etc.) plus 5 FMD infected cows. The rRT-PCR test can detect 4 non-clinically ill, but virus shedding animals, and one clinical virus shedding animal. This is 5 detectable, infected animals, suggesting the prevalence in the population of 250 milk cows is 2 percent.

¹ R_0 is the basic reproduction number, or the expected number of cases produced by a single case in a susceptible population.

2. *Visual examination.* Visual examination will occur in the sub-population of animals with clinical signs.

For example, 5 pyretic cows may be expected each day in a group of 250 milking cows (mastitis, pneumonia, etc.). Visual observation would detect the additional 5 clinically ill cows (the prevalence of FMD infected animals in the 250 cows may vary 10 to 80 percent). The prevalence of FMD infected cows would be 50 percent in the sub-group of clinically sick animals.

MINIMUM SAMPLE SIZES

Tissue collection from apparently healthy animals/herds is performed to detect subclinical animals as quickly as possible, reducing the risk of virus spread. The selection of an appropriate prevalence level in an FMD outbreak should be based on known or estimated epidemiological findings. Table E-2 presents sample sizes based on prevalence level. Five percent and 10 percent prevalence rates are also provided.

Table E-2. Minimum Sample Sizes with Various Prevalence Levels Needed to Detect FMD in Apparently Healthy Herds/Animals

Herd Size or Number of Premises	Prevalence			
	1%	2%	5%	10%
<=50	ALL	ALL	37	23
51–100	ALL	82	47	27
101–200	164	111	54	28
201–300	199	124	56	29
301–400	222	131	58	29
401–500	237	136	59	30
501–600	248	139	62	30
601–700	256	141	62	30
701–800	262	143	62	30
801–900	268	144	62	30
901–1000	272	146	62	30
1001–2000	292	157	62	30
>2000	314	157	62	30

Note: These sample sizes are based on an rRT-PCR sensitivity of 95 percent for detecting FMD virus in appropriately collected samples from infected cattle. The sizes provide 95 percent confidence that the premises or area has an FMD prevalence less than the design prevalence given that the virus is there and all animals test negative. Prevalence in this table indicates:

1. If determining the number of animals in a herd, then the within herd prevalence is the level chosen.
2. If determining the number of herds in a zone to test, then the herd level prevalence is the level chosen.

The selection of an appropriate prevalence level in an FMD outbreak should be based on known or estimated epidemiological findings. Table E-3 presents sample

sizes, based on prevalence level expected in the group of clinically infected animals on a premises. The provided sample sizes in the table are based on within-herd prevalence of FMD by the time cattle develop visible lesions.

Table E-3. Minimum Sample Sizes with Various Prevalence Levels Needed to Detect an Infected Animal Using Visual Observation

Herd Size or Number of Premises	Prevalence		
	40%	60%	80%
<=15	6	4	3
16–75	7	4	3
>75	8	4	3

Note: These sample sizes are based on an rRT-PCR sensitivity of 85 percent for detecting FMD virus in appropriately collected samples from infected cattle with clinical signs of infection. The sizes provide 95 percent confidence of detecting infection in a herd or zone, given that it is there at the given prevalence. Prevalence in this table indicates:

1. If determining the number of animals in a herd, then the within herd prevalence is the level chosen. Thus using rRT-PCR for detection, we have 95 percent confidence of detecting an infected animal in the herd if the prevalence in the herd is 40 percent, 60 percent, 80 percent (in Table E-3).
2. If determining the number of herds in a zone to test, then the herd level prevalence is the level chosen. Thus using rRT-PCR for detection, we have 95 percent confidence of detecting an infected herd in the zone if the prevalence in the herd is 40 percent, 60 percent, 80 percent (in Table E-3).

Sampling Schemes for Commercial and Noncommercial Premises

The following definitions apply to both commercial and noncommercial premises.

1. *Sampling Unit.* Premises or epidemiological unit(s) on premises (for example, feedlot pens, air management units in swine operations, milk cow groups, etc.).
2. *Sample.* (1) Visual examination of sick or dead animals followed by rRT-PCR confirmation if suspicion of FMD, (2) Collection of individual animal tissue, vesicular fluid, or oral/nasal swabs from calculated number of animals or premises and then test with rRT-PCR.

Frequency recommendations are based on the following:

- ◆ Short incubation period of FMD (2 – 14 days).
- ◆ Sufficient personnel available for surveillance activities.
- ◆ High probability of spreading FMD with frequent inspection/sampling.

- ◆ Recommendations for changing frequency of premises inspection and sampling are listed in Table E-4.

COMMERCIAL PREMISES

Infected Zone

1. Census of premises within zone; sample premises as prioritized by results of epidemiological investigation and continuity of business requirements.
2. Sampling frequency:
 - ◆ Contact Premises, Suspect Premises, and Monitored Premises:
 - a. Collect samples from the calculated number of animals (Tables E-2 and E-3), or calculated using the Outbreak Toolbox,² on each premises every 5th day for two observed incubation periods, or 28 days, whichever is longest.
 - b. Treat Contact Premises, Suspect Premises, and Monitored Premises that test negative as At-Risk Premises, and sample as such.
 - c. Monitored Premises may be sampled more frequently depending on the need to move products, but must be sampled at the minimum listed above. For example, a dairy farm needing to ship milk daily will be evaluated daily. See the *Secure Milk Supply Plan* for further information. On a feedlot, premises will be evaluated on each of the 3 days prior to shipping the animals.
 - ◆ At-Risk Premises
 - a. Collect samples on each premises once every 5 days for duration of the area quarantine.

Buffer Zone

1. Census of premises within zone; sample premises as prioritized by results of epidemiological investigation and continuity of business requirements.
2. Sampling frequency:
 - ◆ Contact Premises, Suspect Premises, and Monitored Premises:
 - a. Collect samples from the calculated number of animals (Tables E-2 and E-3), or calculated using the Outbreak Toolbox,³ on each premises

² <http://inside.aphis.usda.gov/nsu>, or e-mail National.Surveillance.Unit@aphis.usda.gov.

³ <http://inside.aphis.usda.gov/nsu>, or e-mail National.Surveillance.Unit@aphis.usda.gov.

every 5th day for two observed incubation periods, or 28 days, whichever is longest.

- b. Treat Contact Premises, Suspect Premises, and Monitored Premises that test negative as At-Risk Premises, and sample as such.
- c. Monitored Premises may be sampled more frequently depending on the need to move products, but must be sampled at the minimum listed above. For example, a dairy farm needing to ship milk daily will be evaluated daily. See *Secure Milk Supply Plan for further information*. On a feedlot, premises will be evaluated on each of the 3 days prior to shipping the animals.
 - ◆ At-Risk Premises
 - a. Collect samples on each premises once every 7 days for duration of the area quarantine.

Surveillance Zone

1. Number of premises to be sampled:
 - ◆ Calculate using the Outbreak Toolbox⁴ or Cannon and Roe formulae.
 - ◆ Premises to be sampled is based on detecting at least one Infected Premises with 95 percent confidence, where:
 - Infected Premises prevalence equals or exceeds 1 percent of all premises with susceptible animals, or
 - A census, if the number of premises in the zone is small, and
 - In order as prioritized by results of epidemiological investigation and continuity of business requirements.
2. Sampling frequency:
 - a. Randomly select the calculated number of premises to be sampled (as determined above, such as 60), and collect the appropriate samples on each of the selected premises once during the first 3-week period of the area quarantine. Then,
 - b. Randomly select in the sampling list frame the premises sampled (in the first 3-week period) and sample an equal number of premises (as calculated above) once during each additional 3-week period of the area quarantine.

⁴ <http://inside.aphis.usda.gov/nsu>, or e-mail National.Surveillance.Unit@aphis.usda.gov.

- i. For example, select and sample 60 premises once during the first 3-week period, then reselect (with replacement) another 60 premises to be sampled in the second 3-week period.

NONCOMMERCIAL PREMISES

The same sampling unit and sample is used.

Infected Zone

1. Census of premises within zone; sample premises as prioritized by results of epidemiological investigation and continuity of business requirements.
2. Observe the herd for FMD compatible signs.
3. If FMD compatible signs are observed, or in species that show few signs, collect appropriate samples on the premises using 1 percent design prevalence. Most noncommercial premises will have few animals, requiring a census.
4. Sampling frequency:
 - ◆ Contact Premises, Suspect Premises, and Monitored Premises:
 - a. Observe/sample entire herd/flock for FMD signs (swab any with FMD signs) every 5 days for two observed incubation periods or 28 days (whichever is longest).
 - Frequency of sampling depends on available personnel, number of premises to be sampled, owner resistance, and other factors.
 - Incident Command must balance premises' transmission risks and detection costs in deciding sampling frequency.
 - MPs may be sampled more frequently depending on the need to ship product, but at the minimum listed above.
 - b. Treat Contact Premises, Suspect Premises, and Monitored Premises that test negative in the above sampling regime as At-Risk Premises, and sample as described for At-Risk Premises.
 - ◆ At-Risk Premises:
 - a. Observe/sample entire herd/flock on each premises once every 5 days for the duration of the area quarantine.

Buffer Zone

1. Census of premises within zone; sample premises as prioritized by results of epidemiological investigation and continuity of business requirements.

-
2. If FMD compatible signs are observed or in species that show few signs: collect appropriate samples on the premises using 1 percent design prevalence (most noncommercial premises will have few animals, thereby requiring a census).
 3. Sampling frequency:
 - ◆ Contact Premises, Suspect Premises, and Monitored Premises:
 - a. Observe/sample entire herd/flock for FMD signs (swab any with FMD signs) every 5 days for two observed incubation periods or 28 days (whichever is longest).
 - Frequency of sampling depends on available personnel, number of premises to be sampled, owner resistance, and other factors.
 - Incident Command must balance premises' transmission risks and detection costs in deciding sampling frequency.
 - MPs may be sampled more frequently depending on the need to ship product, but at the minimum listed above.
 - b. Treat Contact Premises, Suspect Premises, and Monitored Premises that test negative in the above sampling regime as At-Risk Premises, and sample as described for At-Risk Premises.
 - ◆ At-Risk Premises:
 - a. Observe/sample entire herd/flock on each premises once every 7 days for the duration of the area quarantine.

Surveillance Zone

1. Observe/sample the herd/flock for FMD compatible signs (swab any with FMD signs).
2. If FMD compatible signs are observed or in species that show few signs: collect appropriate samples on the premises using 1 percent design prevalence (most noncommercial premises will have few animals, thereby requiring a census).
3. Number of premises to be sampled:
 - ◆ Calculate using the Outbreak Toolbox⁵ or Cannon and Roe formulae.
 - ◆ Premises to be sampled is based on detecting at least one Infected Premises with 95 percent confidence, where:

⁵ <http://inside.aphis.usda.gov/nsu>, or e-mail National.Surveillance.Unit@aphis.usda.gov.

- Infected Premises prevalence equals or exceeds 1 percent of all premises with susceptible animals, or
- A census, if the number of premises in the zone is small, and
- In order as prioritized by results of epidemiological investigation and continuity of business requirements.

4. Sampling frequency:

- a. Randomly select the calculated number of premises to be sampled (as determined above, such as 60), and collect the appropriate samples on each of the selected premises once during the first 3-week period of the area quarantine. Then,
- b. Randomly reselect (include the premises observed/sampled in the first 3-week period in the sampling list frame) and sample an equal number of premises (as calculated above) once during each additional 3-week period of the area quarantine. For example, randomly select and observe/sample 60 premises during the first 3-week period, then reselect (with replacement) another 60 premises to be observed/sampled in the second 3-week period.

Proof of Disease Freedom Surveillance

1. Surveillance samples will be tested using the 3ABC ELISA that demonstrates exposure to the virus, thus, adds a time element into the surveillance scheme. Additionally, there will be enhanced passive clinical surveillance with accepted testing protocols of suspect cases, surveillance in slaughter plants, and enhanced surveillance in markets and shows. Surveillance for proof of disease freedom starts 21 days (OIE requirement) after depopulation of the last Infected Premises.
2. The goal is to demonstrate that all premises are disease free at the design prevalence level because diagnostic tests are negative. OIE recommends intensifying surveillance schemes in conjunction with (1) active investigation of herds/flocks with suspicious clinical signs, and (2) increased slaughter sero-surveillance.

COMMERCIAL PREMISES (DISEASE FREEDOM)

Infected Zone, Buffer Zone, and Surveillance Zone

1. Number of samples per herd:
 - ◆ Calculate using the Outbreak Toolbox⁶ or Cannon and Roe formulae.
 - ◆ Premises to be sampled is based on detecting at least one Infected Premises with 95 percent confidence, where:
 - Infected Premises prevalence equals or exceeds 5 percent where the maximum animals sampled doesn't exceed 60 animals per herd/flock.
2. Number of premises to be sampled:
 - ◆ Calculate using the Outbreak Toolbox⁷ or Cannon and Roe formulae.
 - ◆ Premises to be sampled is based on detecting at least one Infected Premises with 95 percent confidence, where:
 - The Infected Premises prevalence equals or exceeds 1 percent of all premises with susceptible animals in the Infected Zone.
3. Sampling frequency:
 - ◆ Sample the number of premises calculated above (for example, 60 premises one time each) during a 3-month period after the outbreak has been eradicated.

NONCOMMERCIAL PREMISES (DISEASE FREEDOM)

Infected Zone, Buffer Zone, and Surveillance Zone

1. Number of samples per herd:
 - ◆ Calculate using the Outbreak Toolbox⁸ or Cannon and Roe formulae.
 - Infected Premises prevalence equals or exceeds 1 percent where the maximum animals sampled doesn't exceed 60 animals per herd/flock.

⁶ <http://inside.aphis.usda.gov/nsu>, or e-mail National.Surveillance.Unit@aphis.usda.gov.

⁷ <http://inside.aphis.usda.gov/nsu>, or e-mail National.Surveillance.Unit@aphis.usda.gov.

⁸ <http://inside.aphis.usda.gov/nsu>, or e-mail National.Surveillance.Unit@aphis.usda.gov.

2. Number of premises to be sampled:
 - ◆ Calculate using the Outbreak Toolbox⁹ or Cannon and Roe formulae.
 - ◆ Premises to be sampled is based on detecting at least one Infected Premises with 95 percent confidence, where:
 - The Infected Premises prevalence equals or exceeds 1 percent of all premises with susceptible animals in the Infected Zone.
3. Sampling frequency:
 - ◆ Sample the number of premises calculated above (for example, 60 premises one time each) during a 3-month period after the outbreak has been eradicated.

FURTHER SURVEILLANCE INFORMATION

Table E-4 shows the incubation periods and sampling frequency.

Table E-4. Incubation Periods and Sampling Frequency

Estimated Incubation Period Based on Field Information		
Incubation Period	Frequency of Sampling (days between sampling)	
	Minimum (Days)	Maximum (Days)
1 to 2 Days	1	1
3 to 4 Days	2	3
5 to 7 Days	4	6
8 to 14 Days	7	10
> 14 Days	10	

⁹ <http://inside.aphis.usda.gov/nsu>, or e-mail National.Surveillance.Unit@aphis.usda.gov.

Table E-5 summarizes the outbreak surveillance scheme for disease detection.

Table E-5. Outbreak Surveillance for Disease Detection

Disease Detection						
Post Outbreak Response Authorization						
	Commercial			Noncommercial		
Sampling	Infected Zone	Buffer Zone	Surveillance Zone	Infected Zone	Buffer Zone	Surveillance Zone
Number of Premises	Census	Census	1% Prevalence Threshold°	Census	Census	1% Prevalence Threshold°
Unit	Individual Animal Sample	Individual Animal Sample	Individual Animal Sample	Observation or Individual Animal Sample ^	Observation or Individual Animal Sample ^	Observation or Individual Animal Sample ^
Frequency						
At-Risk Premises	5 Days	7 Days	21 Days	5 Days	7 Days	21 Days
Contact, Suspect and Monitored Premises	Every 5th day for 2 incubation periods or 28 days (whichever is longest)			Every 5th day for 2 incubation periods or 28 days (whichever is longest)		
Product Movement	Daily evaluation for daily product movement; evaluation each day, 3 days prior for non-daily movement.			Daily evaluation for daily product movement; evaluation each day, 3 days prior for non-daily movement.		

° Prevalence threshold is a predetermined proportion of Infected Premises (for example, 5 percent) used to calculate the number of premises to be sampled at a specific confidence level (for example, 95 percent) in a population of a given size (for example, 1,000 premises) based on detecting at least one Infected Premises.

^ Types of sample depend on available tests. Visual sampling followed 3ABC ELISA.

Table E-6 shows surveillance requirements to prove FMD freedom.

Table E-6. Surveillance for Proof of Disease Freedom

Proof of Disease Freedom [#]												
Post Outbreak Response Authorization												
	Commercial			Noncommercial								
Sampling*	Infected Zone ^{\$}	Buffer Zone ^{\$}	Surveillance Zone ^{\$}	Infected Zone ^{\$}	Buffer Zone ^{\$}	Surveillance Zone ^{\$}						
Number of Samples per Premises	5% Prevalence Threshold ^{&}	5% Prevalence Threshold ^{&}	5% Prevalence Threshold ^{&}	1% Prevalence Threshold ^{&}	1% Prevalence Threshold ^{&}	1% Prevalence Threshold ^{&}						
Number of Premises	1% Prevalence Threshold [°]	1% Prevalence Threshold [°]	1% Prevalence Threshold [°]	1% Prevalence Threshold [°]	1% Prevalence Threshold [°]	1% Prevalence Threshold [°]						
Frequency	Sample each premises of the Calculated Number of Premises once during a 3-month Period											
# Sero-surveillance conducted in the area to be proved disease free in addition to any other animal sampling.												
\$ Infected, Buffer, and Surveillance zones combine as one unit for proof of disease freedom.												
& Number of animals sero-sampled based on 5 percent prevalence in herd/flock at the 95 percent confidence level where the maximum number of animals sampled per epidemiological unit does not exceed 60 animals.												
° Prevalence threshold is a predetermined proportion of Infected Premises (for example, 5 percent) used to calculate the number of premises to be sampled at a specific confidence level (for example, 95 percent) in a population of a given size (for example, 1,000 premises) based on detecting at least one Infected Premises. A census of the premises in a zone will be sampled if there are few premises. Sample premises in order as by epidemiological investigation and continuity of business requirements.												
* Sampling Unit used in all Surveillance Schemes: Individual animals observation, appropriate individual animal sample or, if available, mass population sampling techniques (for example, bulk tank).												

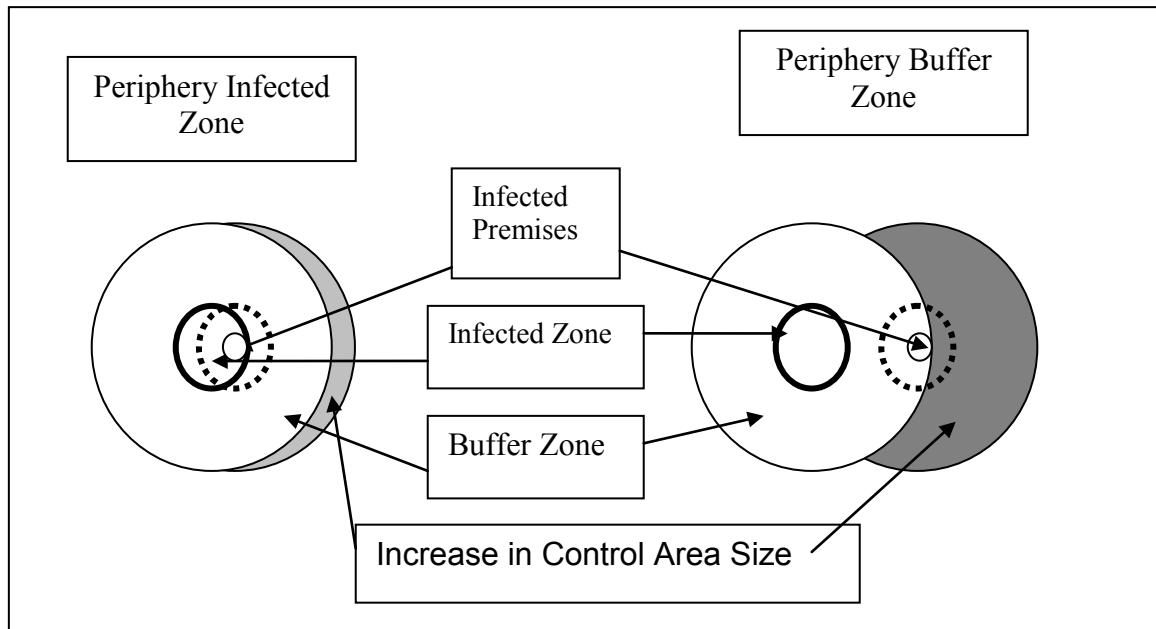
Assumptions for Surveillance Schemes

1. Production parameters will be monitored for indications of FMD intrusion.
2. The consequences of an infected but undetected premises is greater if it is located at the periphery of the Buffer Zone vs. the periphery of the Infected Zone:
 - ◆ Increased opportunity of disease spread due to less stringent movement requirements in the Buffer Zone,
 - ◆ Increased difficulty of surveillance:
 - A larger number of At-Risk Premises that require sampling

- A larger geographic area over which to sample At-Risk Premises.
3. *Increased Size of the Control Area:* An Infected Premises will increase the size of the Control Area by the radius of the Infected Zone. However, if the newly detected Infected Premises is located on the periphery of the Buffer Zone, the size of the Control Area will increase by the radius of the Infected Zone and the Buffer Zone.

Figure E-2 shows that the size of the Control Area depends on where the new Infected Premises is located.

Figure E-2. Infected Premises' Effect on Size of Control Area



References

- Blackwell, J.H., J.L. Hyde. "Effect of heat on foot-and-mouth disease virus (FMDV) in components of milk from FMDV-infected cows." *J Hyg Camb*, 1976, 77(77).
- Blackwell, J. H., P.D. McKercher, F.V. Kosikowski, L.E. Carmichael, and R.C. Gorewit. "Concentration of foot-and-mouth disease virus in milk of cows infected under simulated field conditions." *Journal Dairy Science*, 1982, 65, pp. 1624 – 1631.
- Burrows, R. "Excretion of Foot-and-Mouth Disease Virus Prior to the development of Lesions." *Vet Record*, 1968, pp. 387 – 388.

- Burrows, R., J.A. Mann, A. Greig, W.G. Chapman, and D. Goodridge. "The growth and persistence of foot-and-mouth disease virus in the bovine mammary gland." *J Hyg Camb*, 1971, 69, pp. 307 – 321.
- Davies, G. "Foot and mouth disease." *Res Vet Sci*, 2002, 73, pp.195 – 199.
- Dawson, P.S. "The involvement of milk in the spread of foot-and-mouth disease: an epidemiological study." *Vet Rec*, 1970, 87, pp. 543 – 548.
- DeLeeuw, P.W., J.G. Van Bekkum, J.W.Tiessink. "Excretion of foot-and-mouth disease virus in oesophageal-pharyngeal fluid and milk of cattle after intranasal infection." *J Hyg Camb*, 1978, pp. 415 – 425.
- De Leeuw, P.W., J.W. Tiessink, J.G. Van Bekkum. "Aspects of heat inactivation of foot-and-mouth disease virus in milk from intramammarily infected susceptible cows." *J Hyg Camb*, 1980, 84, pp. 159 – 172.
- Gibbens, J.C., C.E. Sharpe, J.W. Wilesmith, L.M. Mansley, E. Michalopoulou, J.B.M. Ryan, M. Hudson. "Descriptive epidemiology of the 2001 foot-and-mouth disease epidemic in Great Britain: the first five months." *Vet Record* 2001, 149, pp. 729 – 743.
- Hedger, R.S. "Foot-and-mouth disease virus in milk: an epidemiological study." *Vet Rec*, 1970, 87, pp. 186 – 188, 213.
- Hugh-Jones, M.E. "Epidemiological studies on the 1967–1968 foot-and-mouth disease epidemic; the reporting of suspected disease." *J Hygiene Camb*, 1976, 77, pp. 299 – 306.
- Hyde, J.L., J.H. Blackwell, J.J. Callis. "Effect of pasteurization and evaporation on foot-and-mouth disease virus in whole milk from infected cows." *Can J Comp Med*, 1975, 39, pp. 305 – 309.
- Reid, S.M., S. Parida, D.P. King, G.H. Hutchings, A.E. Shaw, N.P. Ferris, Z. Zhang, J.E. Hillerton, D.J. Paton. "Utility of automated real-time RT-PCR for the detection of foot-and-mouth disease virus excreted in milk." *Vet Res*, 2006, 37, pp. 121 – 132.
- Production: Considerations for Potential Growers, Oklahoma Cooperative Extension service, <http://www.osuextra.com>.

Appendix F

Procedures for FMD Investigation and Specimen Submission

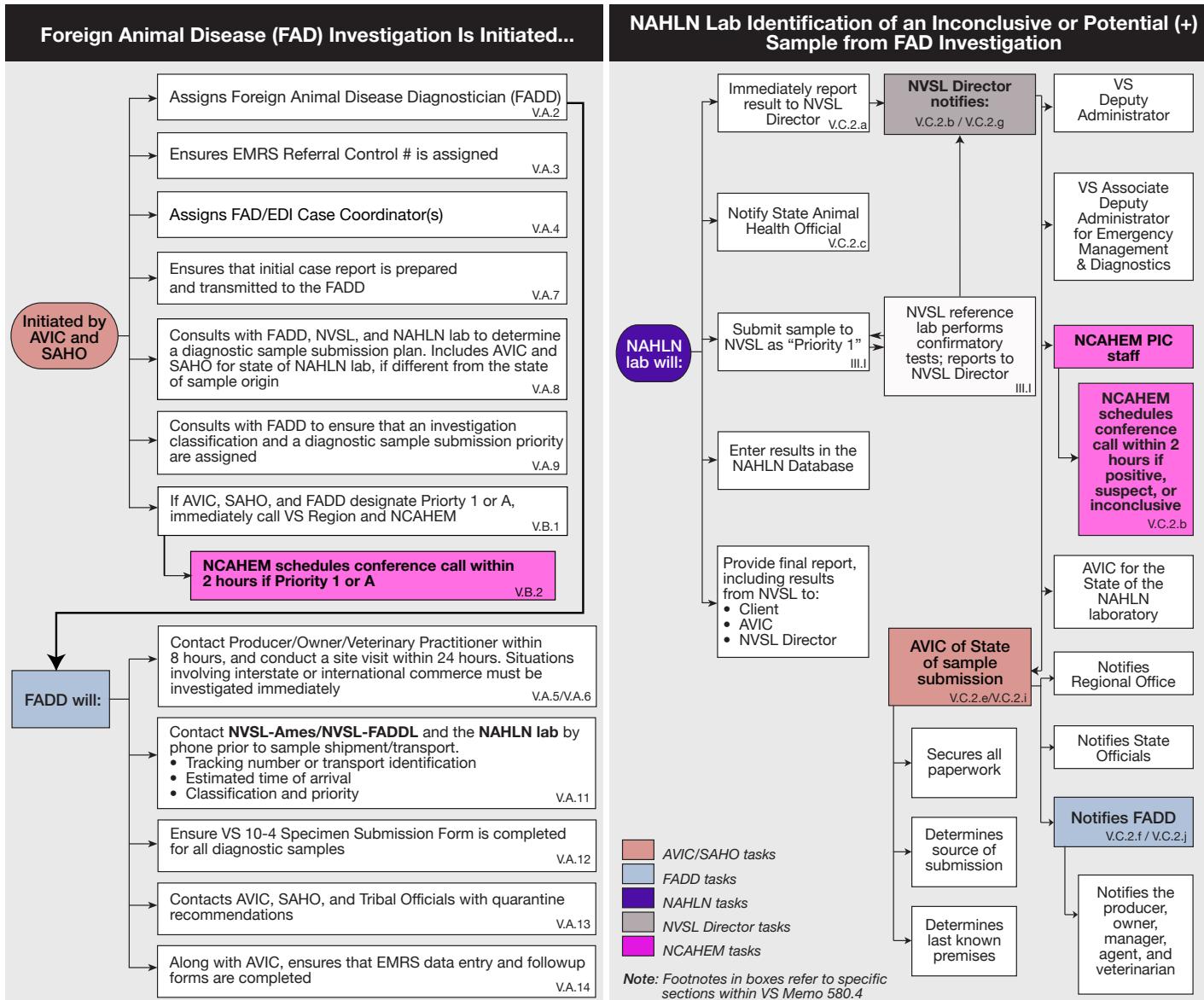
Veterinary Services (VS) Memorandum 580.4 provides guidance for the investigation of potential foreign animal disease/emerging disease incidents. VS Memo 580.4 is available at <https://fadprep.lmi.org/Design/emergmgmt.aspx> and <http://inside.aphis.usda.gov/vs/em/fadprep.shtml>.

Appendix F provides the Ready Reference Guide for VS Memo 580.4.



Ready Reference Guide

VS Memorandum 580.4: Procedures for the Investigation of Potential Foreign Animal Disease/Emerging Disease Incidents (FAD/EDI)



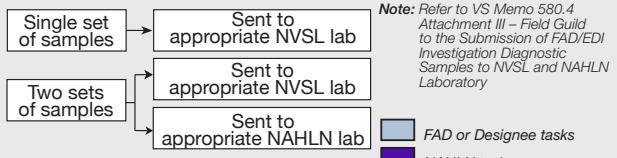
FAD Investigation Classification and Diagnostic Sample Prioritization

Priority 1	Priority 2	Priority 3	Priority A	Definitions/Notes
<ul style="list-style-type: none"> High Suspicion (Formerly Highly Likely) NCAHEM schedules conference call within 2 hours if Priority 1 or A Rapid or Extraordinary methods for sample collection and transport Testing conducted immediately upon arrival (Overtime services as needed) 	<ul style="list-style-type: none"> Intermediate Suspicion (Formerly Possible) Rapid methods for sample collection and transport Testing conducted as necessary (Overtime services as needed). If samples arrives: <ul style="list-style-type: none"> > Before close of business – tested immediately > After close of business – tested the following day > Saturday – tested on weekends only with prior notification and approval 	<ul style="list-style-type: none"> Low Suspicion (Formerly Unlikely) Routine methods for sample collection and transport Testing conducted in accession order (No overtime services) 	<ul style="list-style-type: none"> Intermediate or Low Suspicion (Formerly Possible or Unlikely) Potential circumstances of investigation indicate need for Rapid or Extraordinary methods for sample collection and transport Testing conducted immediately upon arrival (overtime services as needed) NCAHEM schedules conference call within 2 hours if Priority 1 or A 	<ul style="list-style-type: none"> Extraordinary methods – hand carried samples, couriers, counter-to-counter services, and complete commercial services (e.g., Air Net, FedEx, Custom Critical, UPS Express Critical) Note: Priority 1 and A may use extraordinary methods (more info on reverse side) Rapid methods – express shipping services (e.g., FedEx priority overnight)

FAD Collection and Transportation of Diagnostic Samples

- All packaging and labeling of biological substances for shipment requires familiarity and training with current rules and compliance with the IATA (www.iata.org) regulations for dangerous goods
- Proper completion of FedEx Airbill, EMRS FAD/EDI Investigation Summary Form, and VS Form 10-4 Specimen Submission Form and Continuation Sheet (if needed)
- For more information, refer to: www.aphis.usda.gov/animal_health/lab_info_services/packaging_labeling.shtml

- Testing laboratory completes the appropriate chain-of-custody procedures as described in Article #12 of NAHLN Qualification Checklist for Membership of a Veterinary Diagnostic Laboratory
- Laboratory Director(s) confirms receipt of samples and testing schedule with:
 - NVSL Director
 - AVIC
 - SAHO



NVSL-AMES Contact Information and FedEx Airbill Information

NVSL-AMES must be contacted by phone prior to shipment or transport of diagnostic samples regardless of Priority 1, 2, 3, or A diagnostic sample designation.

NVSL-Ames Phone Contact Information During Business Hours:
Monday – Friday 8:00 AM – 4:30 PM Central Time

Department Laboratory	Phone Number
Diagnostic Virology	515-337-7551
Diagnostic Pathobiology	515-337-7521
Diagnostic Bacteriology	515-337-7568

After Hours/Weekends: If Unable to Reach Someone Listed Above

National Centers for Animal Health Dispatch	515-337-7266
---	--------------

If you have a Priority 1 or Priority A Diagnostic Sample

If transported by courier, counter-to-counter service, or complete commercial carrier such as FedEx Custom Critical, AirNet or UPS Express Critical

- Call NCAHEM PIC & VS Region Director or designee immediately to arrange transportation details
- Call NVSL-Ames immediately to arrange diagnostic sample and transportation details

Phone contact or notification must be made with NVSL-Ames prior to shipment.

FedEx Airbill Address:
USDA, NVSL
1920 Dayton Road
Ames, IA 50010

FedEx Priority Overnight Airbill Instructions

- Billing/Payment: Use the billing number or account number obtained from the AVIC
- Internal Billing Reference (Section 2), use the accounting code obtained from the AVIC
- Check the FedEx Priority Overnight box (Section 4a)
- Saturday delivery should be marked for Priority 1, 2, 3, and A samples sent on Friday.
- Retain the sender's copy of the airbill for your records

NVSL-FADDL Contact Information and FedEx Airbill Information

NVSL-FADDL must be contacted by phone prior to shipment or transport of diagnostic samples regardless of Priority 1, 2, 3, or A diagnostic sample designation.

Arrangements must always be made to pick up the diagnostic samples from the FedEx office, or meet a courier, counter-to-counter service at an airport or other location. Unless FADDL is notified by phone prior to the shipment or transport, the diagnostic samples will be delayed in delivery to FADDL.

NVSL-FADDL Phone Contact Information During Business Hours:
Monday – Friday 8:30 AM – 4:15 PM Eastern Time
Main Office Number: 631-323-3256 or 631-323-3206

After Hours/Weekends	Phone Number
Samia Metwally	631-375-5314
Acting Diagnostic Services Section Head	631-332-6814
Barry Latney	631-377-9877

After Hours/Weekends: If Unable to Reach Someone Listed Above

National Centers for Animal Health Dispatch	515-337-7266
---	--------------

If you have a Priority 1 or Priority A Diagnostic Sample

If transported by courier, counter-to-counter service, or complete commercial carrier such as FedEx Custom Critical, AirNet or UPS Express Critical

- Call NCAHEM PIC & VS Region Director or designee immediately to arrange transportation details
- Call NVSL-FADDL immediately to arrange diagnostic sample and transportation details

FedEx Priority Overnight Airbill Instructions

Phone contact or notification must be made with NVSL-FADDL prior to shipment by FedEx Priority Overnight.

“Company” (Section 3):	USDA/APHIS/FADDL
“Recipient’s Address” (Section 3):	Orient Point Warehouse, 40550 Rte 25
“Address” (Section 3):*	579 Edwards Ave., Calverton, NY 11933
“City” (Section 3):	Orient Point
“State” (Section 3):	NY
“Zip” (Section 3):	11957

* Shipper must include the FedEx Calverton Office address: 579 Edwards Ave., Calverton, NY 11933. The additional FedEx Calverton Office address (and zip code) enables NVSL-FADDL personnel to pick up the package in the morning or as soon as possible.

USDA APHIS VS Emergency Management and Diagnostics (EM&D) National Center for Animal Health Emergency Management (NCAHEM)

Normal Business Hours
Monday – Friday 8:00AM – 4:30PM Eastern Time

NCAHEM Main Office Number 301-734-8073
NCAHEM 24/7 Emergency Answering Service 800-940-6524

NCAHEM PIC Staff Person	Mobile
Jon Zack.....	240-252-8074
Randy Crom	240-508-9753
Steve Finch.....	240-508-8619
Diego Fridmann.....	240-252-8089
Darrel Styles	240-581-3958

VS APHIS Regional Offices

VS Eastern Region Office:
Phone: 919-855-7250
Fax: 919-855-7295

VS Western Region Office:
Phone: 970-494-7400
Fax: 970-494-7355

Appendix G

Epidemiological Investigation Questionnaire

This appendix contains a sample epidemiological questionnaire that could be employed in the event of an FMD outbreak.

Sample FMD Epidemiology Questionnaire

Date: _____

Business/farm name: _____

Primary contact: _____

Business address: _____

Business telephone number: _____

Cell telephone number: _____

Fax number: _____

Home telephone number: _____

E-mail address: _____

Secondary contact: _____

Business address: _____

Business telephone number: _____

Cell telephone number: _____

Fax number: _____

Home telephone number: _____

E-mail address: _____

Farm address (911 and Animal Location): _____

City: _____ ZIP code: _____

County: _____ Township: _____

Range: _____ Section: _____

GPS coordinates (decimal degrees): _____

Premises identification number: _____

**The purpose of this epidemiological questionnaire is to help provide premises designations:
Suspect Premises, Contact Premises, At-Risk Premises, or Monitored Premises.**

A. General Information

1. Species on premises: _____
2. Type of premises (commercial or backyard): _____
3. Have you observed feral or wild animals on or near the premises?
 Yes No Don't know
4. Are there backyard premises with susceptible livestock nearby?
 Yes No Don't know
5. Do you have multiple, non-contiguous premises between which you travel and work (yes/no)?
 Yes No
6. Are there contiguous premises with susceptible livestock (not owned by you)?
 Yes No

B. Animal Population on Premises

Species	Males > 1 year	Females > 1 year	< 1 year
Swine			
Sheep/goats			
Cattle			
Other susceptible species			

Non-susceptible species (type and number): _____

C. Trace Back Information. In the last 28 days, did the following movements **onto** the farm occur? Please provide as much accurate information as possible for each unique source.

1. Susceptible animals

Yes Don't know No

If yes,

a. What species? _____

b. How many animals? _____

Source/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Animals tested for FMD prior to movement (Yes/No)	Entered in visitor log (Yes/No)

2. Milk products or byproducts

Yes Don't know No

If yes,

Source/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Milk or product tested for FMD prior to movement (Yes/No)	Entered in visitor log (Yes/No)

3. Feed trucks

Yes Don't know No

If yes,

Source/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

4. Fresh litter/bedding

Yes Don't know No

If yes,

Source/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

5. Manure

Yes Don't know No

If yes,

Source/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

6. Hoof trimmers

Yes Don't know No

Source/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

7. Mortality pickup/renderer

Yes Don't know No

Source/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

Did the driver leave the vehicle while on the premises?

Yes Don't know No

If Yes,

a. What area of the premises did he enter? _____

b. Was driver required to wear outer clothes
and footwear provided by the premises? Yes Don't know No

8. Company vet/service tech

Yes Don't know No

Source/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

9. Non-company vet/consultant

Yes Don't know No

Source/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

10. Construction or service person (e.g., gas, plumbing, pest control)

Yes Don't know No

Source/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

11. Customer/buyer/dealer

Yes Don't know No

Source/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

12. Other producer

Yes Don't know No

Source/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

13. Non-business visitor (friend/neighbor)

Yes Don't know No

Source/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

D. Trace Forward Information. In the last 28 days, did the following movements **off** the farm occur? Please provide as much accurate information as possible for each unique destination.

1. Susceptible animals

Yes Don't know No

If yes,

a. What species? _____

b. How many animals? _____

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Animals tested for FMD prior to movement (Yes/No)	Entered in visitor log (Yes/No)

2. Milk products or byproducts

Yes Don't know No

If yes,

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Milk or product tested for FMD prior to movement (Yes/No)	Entered in visitor log (Yes/No)

3. Feed trucks

Yes Don't know No

If yes,

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

4. Fresh litter/bedding

Yes Don't know No

If yes,

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

5. Manure

Yes Don't know No

If yes,

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

6. Hoof trimmers

Yes Don't know No

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

7. Mortality pickup/renderer

Yes Don't know No

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

Did the driver leave the vehicle while on the premises?

Yes Don't know No

If yes,

- a. What area of the premises did he enter? _____
- b. Was driver required to wear outer clothes
and foot wear provided by the premises? Yes Don't know No

8. Company vet/service tech

Yes Don't know No

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

9. Non-company vet/consultant

Yes Don't know No

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

10. **Construction or service person (e.g., gas, plumbing, pest control)** Yes Don't know No

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

11. **Customer/buyer/dealer** Yes Don't know No

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

12. **Other producer** Yes Don't know No

Destination/ name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

13. **Non-business visitor (friend/neighbor)** Yes Don't know No

Destination/name; date	Truck and equipment C&D before entering (Yes/No)	Truck and equipment C&D when leaving (Yes/No)	Personnel enter livestock areas (Yes/No)	Entered in visitor log (Yes/No)

E. Biosecurity Employee Risk Factors

1. Do any of your personnel work at other premises with susceptible animals or have they visited other premises, feedlots, dairy, processing plants, or livestock slaughtering facilities within the past 28 days? Yes No
If yes, what premises? _____
2. Do any of your workers live with someone who works at another livestock premises, feedlot, dairy, processing plant, slaughter facility, or rendering plant? Yes No
3. Have you hired new personnel during the past 28 days? Yes No
If yes, did they work for another livestock premises before you hired them? Yes No
If yes, where did they work prior to coming to your premises? _____
4. Has an employee from the premises visited a slaughter/rendering facility within the past 28 days? Yes No
If yes, what facility? _____
If yes, did the person clean and disinfect his vehicle? Yes No
If yes, did the person change outer clothes? Yes No
If yes, did the person disinfect footwear or change into footwear assigned to the premises upon return? Yes No
5. Have any of your employees been overseas? Yes No
If yes, where? _____

F. Biosecurity Risk Factors

1. Have wild ruminants been seen on the property in the last 28 days? Yes No
2. Have rodents, dogs, or cats been observed in livestock housing in the past 28 days? Yes No
3. Which of the following **best** describes this farm's usual carcass (normal mortality) disposal method?
 Rendering Burial on site
 Composting on site Incineration on site
 Other specify: _____
4. Do you dispose of livestock for other farms? Yes No
5. Have you maintained all requirements since your last regular biosecurity audit? Yes No
If no, what requirements have not been met? _____

6. What additional biosecurity measures have been implemented? (For example, once the premises have been determined to be within a Control Area, all vehicles, including feed trucks, must be cleaned and disinfected prior to entry and exit.)

- G. Is there any other information that would assist with movement tracing? Have there been any unusual movements for the premises within the last 28 days that were not captured on this form?

Appendix H

Examples of Movement Control Notices

This appendix provides two examples—State and Federal—of halting movement of animals during a disease outbreak.

EXAMPLE—WEST VIRGINIA

Commissioner of Agriculture Halts Poultry Shows and Sales after AI-Positive Flock Discovered in Virginia

Commissioner of Agriculture Gus R. Douglass has ordered a halt to poultry shows and sales throughout West Virginia in response to a turkey flock that tested positive for low pathogenicity avian influenza (LPAI) in Mt. Jackson, Va., just across the West Virginia border.

The strain is not the “bird flu” that has been plaguing Southeast Asia and parts of Europe and poses no threat to human health.

The order applies to any gathering of live birds, including shows at fairs and festivals and sales of poultry. The order is effective Monday, July 9, and will be in place for 30 days unless another positive flock is discovered.

The order does not apply to the commercial industry, which tests every flock for AI before it is moved off the farm to ensure that infected birds are not trucked past other poultry farms.

“Having already dealt with a positive flock in West Virginia earlier this year, we want to take every precaution to protect our poultry industry from a potentially devastating situation,” said Commissioner Douglass.

He also noted that the West Virginia Department of Agriculture is on high alert for any signs of the disease here, and that the industry has been exercising enhanced surveillance protocols since a 2002 AI outbreak that affected West Virginia and Virginia.

Poultry companies on both sides of the border have instructed their growers not to spread litter or move it from their farms until further notice.

According to the Virginia Department of Agriculture and Consumer Services (VDACS), testing over the weekend by the USDA’s National Veterinary Services Laboratory (NVSL) in Ames, Iowa, confirmed the presence of AI antibodies, which indicates possible prior exposure to the virus. The turkeys did not show any signs of illness prior to testing.

Virginia is closely monitoring all poultry operations within a six-mile radius of the affected farm.

NVSL is doing further testing to help identify the virus and hopefully determine its source. VDACS, USDA and the poultry owner are working cooperatively to minimize the possibility that the virus will move beyond this farm.

The affected flock contains 54,000 birds, which will be euthanized as a precaution as soon as possible and composted on-site. While LPAI poses no risk to human health, federal and state policy is to eradicate H5 and H7 subtypes because of their potential to change into more serious types, which have a higher mortality rate among birds.

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

EXAMPLE—FEDERAL

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



Rules and Regulations

Federal Register

Vol. 68, No. 73

Wednesday, April 16, 2003

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 82

[Docket No. 02-117-5]

Exotic Newcastle Disease; Additions to Quarantined Area

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the exotic Newcastle disease regulations by quarantining El Paso and Hudspeth Counties, TX, and Dona Ana, Luna, and Otero Counties, NM, and prohibiting or restricting the movement of birds, poultry, products, and materials that could spread exotic Newcastle disease from the quarantined area. This action is necessary on an emergency basis to prevent the spread of exotic Newcastle disease from the quarantined area.

DATES: This interim rule was effective April 10, 2003. We will consider all comments that we receive on or before June 16, 2003.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 02-117-5, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. 02-117-5. If you use e-mail, address your comment to regulations@aphis.usda.gov. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 02-117-5" on the subject line.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

FOR FURTHER INFORMATION CONTACT: Dr. Aida Boghossian, Senior Staff Veterinarian, Emergency Programs Staff, VS, APHIS, 4700 River Road Unit 41, Riverdale, MD 20737-1231; (301) 734-8073.

SUPPLEMENTARY INFORMATION:

Background

Exotic Newcastle disease (END) is a contagious and fatal viral disease affecting the respiratory, nervous, and digestive systems of birds and poultry. END is so virulent that many birds and poultry die without showing any clinical signs. A death rate of almost 100 percent can occur in unvaccinated poultry flocks. END can infect and cause death even in vaccinated poultry.

The regulations in "Subpart A—Exotic Newcastle Disease (END)" (9 CFR 82.1 through 82.15, referred to below as the regulations) were established to prevent the spread of END in the United States in the event of an outbreak. In § 82.3, paragraph (a) provides that any area where birds or poultry infected with END are located will be designated as a quarantined area, and that a quarantined area is any geographical area, which may be a premises or all or part of a State, deemed by epidemiological evaluation to be sufficient to contain all birds or poultry known to be infected with or exposed to END. Less than an entire State will be designated as a quarantined area only if the State enforces restrictions on intrastate movements from the quarantined area that are at least as stringent as the regulations. The regulations prohibit or restrict the movement of birds, poultry, products,

and materials that could spread END from quarantined areas. Areas quarantined because of END are listed in § 82.3, paragraph (c).

On October 1, 2002, END was confirmed in the State of California. The disease was confirmed in backyard poultry, which are raised on private premises for hobby, exhibition, and personal consumption, and in commercial poultry.

In an interim rule effective on November 21, 2002, and published in the **Federal Register** on November 26, 2002 (67 FR 70674–70675, Docket No. 02-117-1), we amended the regulations in § 82.3(c) by quarantining Los Angeles County, CA, and portions of Riverside and San Bernardino Counties, CA, and restricting the interstate movement of birds, poultry, products, and materials that could spread END from the quarantined area.

In a second interim rule effective on January 7, 2003, and published in the **Federal Register** on January 13, 2003 (68 FR 1515–1517, Docket No. 02-117-2), we further amended § 82.3(c) by adding Imperial, Orange, San Diego, Santa Barbara, and Ventura Counties, CA, and the previously non-quarantined portions of Riverside and San Bernardino Counties, CA, to the list of quarantined areas. Because the Secretary of Agriculture signed a declaration of extraordinary emergency with respect to the END situation in California on January 6, 2003 (see 68 FR 1432, Docket No. 03-001-1, published January 10, 2003), that second interim rule also amended the regulations to provide that the prohibitions and restrictions that apply to the interstate movement of birds, poultry, products, and materials that could spread END will also apply to the intrastate movement of those articles in situations where the Secretary of Agriculture has issued a declaration of extraordinary emergency (new § 82.16).

On January 16, 2003, END was confirmed in backyard poultry on a premises in Las Vegas, NV. Therefore, in a third interim rule effective January 17, 2003, and published in the **Federal Register** on January 24, 2003 (68 FR 3375–3376, Docket No. 02-117-3), we amended § 82.3(c) by quarantining Clark County, NV, and a portion of Nye County, NV, and prohibiting or restricting the movement of birds, poultry, products, and materials that

could spread END from the quarantined area. On January 17, 2003, the Secretary of Agriculture signed a declaration of extraordinary emergency because of END in Nevada (see 68 FR 3507, Docket No. 03-001-2, published January 24, 2003).

On February 4, 2003, END was confirmed in backyard poultry on a premises in the Colorado River Indian Nation in Arizona. Therefore, in a fourth interim rule effective February 10, 2003, and published in the **Federal Register** on February 14, 2003 (68 FR 7412-7413, Docket No. 02-117-4), we amended § 82.3(c) by quarantining La Paz and Yuma Counties, AZ, and a portion of Mohave County, AZ, and prohibiting or restricting the movement of birds, poultry, products, and materials that could spread END from the quarantined area. On February 7, 2003, the Secretary of Agriculture signed a declaration of extraordinary emergency because of END in Arizona (see 68 FR 7338, Docket No. 03-001-3, published February 13, 2003).

On April 9, 2003, END was confirmed in backyard poultry on a premises in El Paso County, TX. Therefore, in this interim rule, we are amending § 82.3(c) by designating El Paso and Hudspeth Counties, TX, and Dona Ana, Luna, and Otero Counties, NM, as a quarantined area and prohibiting or restricting the movement of birds, poultry, products, and materials that could spread END from the quarantined area. As provided for by the regulations in § 82.3(a), this quarantined area encompasses the area where poultry infected with END were located and a surrounding geographical area deemed by epidemiological evaluation to be sufficient to contain all birds or poultry known to be infected with or exposed to END.

Emergency Action

This rulemaking is necessary on an emergency basis to prevent the spread of END. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**.

We will consider comments that we receive during the comment period for this interim rule (see **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review under Executive Order 12866.

This rule amends the regulations by quarantining El Paso and Hudspeth Counties, TX, and Dona Ana, Luna, and Otero Counties, NM, and prohibiting or restricting the movement of birds, poultry, products, and materials that could spread END from the quarantined area. This action is necessary on an emergency basis to prevent the spread of END from the quarantined area.

This emergency situation makes timely compliance with section 604 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) impracticable. We are currently assessing the potential economic effects of this action on small entities. Based on that assessment, we will either certify that the rule will not have a significant economic impact on a substantial number of small entities or publish a final regulatory flexibility analysis.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 82

Animal diseases, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements, Transportation.

■ Accordingly, 9 CFR part 82 is amended as follows:

PART 82—EXOTIC NEWCASTLE DISEASE (END) AND CHLAMYDIOSIS; POULTRY DISEASE CAUSED BY SALMONELLA ENTERITIDIS SEROTYPE ENTERITIDIS

- 1. The authority citation for part 82 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

- 2. In § 82.3, paragraph (c) is amended by adding, in alphabetical order, entries for New Mexico and Texas to read as follows:

§ 82.3 Quarantined areas.

*	*	*	*	*
(c)	*	*	*	*
*	*	*	*	*

New Mexico

Dona Ana County. The entire county.

Luna County. The entire county.

Otero County. The entire county.

Texas

El Paso County. The entire county.

Hudspeth County. The entire county.

Done in Washington, DC, this 10th day of April 2003.

Bobby R. Acord,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03-9322 Filed 4-15-03; 8:45 am]

BILLING CODE 3410-34-P

FARM CREDIT ADMINISTRATION

12 CFR Part 615

RIN 3052-AC05

Funding and Fiscal Affairs, Loan Policies and Operations, and Funding Operations; Capital Adequacy

AGENCY: Farm Credit Administration.

ACTION: Final rule.

SUMMARY: The Farm Credit Administration (FCA or agency) amends its capital adequacy regulations to add a definition of total liabilities for the net collateral ratio calculation, limit the amount of term preferred stock that may count as total surplus, clarify the circumstances in which we may waive disclosure requirements for an issuance of equities by a Farm Credit System (FCS, Farm Credit or System) institution, and make several nonsubstantive technical changes. These amendments update, modify, and clarify certain capital requirements.

EFFECTIVE DATE: This regulation will become effective 30 days after publication in the **Federal Register** during which either or both houses of

Appendix I

Secure Milk Supply Plan

The Secure Milk Supply (SMS) Plan is a public-private-academic collaboration, currently in progress. *The overall goal is to maintain business continuity for dairy producers and processors in an FMD outbreak and to provide a continuous supply of milk and milk products for consumers.*

The SMS Plan will develop processes and procedures that milk producers, processors, and Federal and State agencies agree are feasible. These processes and procedures will allow the safe movement of milk from dairies in an FMD Control Area through a processing plant such that the FMDV does not spread and further impair U.S. ability to export agricultural products.

APHIS has provided funding to examine this issue in detail and develop specific response recommendations. Each group has a set of objectives that will contribute to developing a national SMS Plan. Communication among the researchers throughout development will ensure the final products are complementary and well coordinated. The principal academic investigators are as follows:

- ◆ Center for Food Security and Public Health (CFSPPH), Iowa State University
- ◆ University of California, Davis
- ◆ Center for Animal Health and Food Safety (CAHFS), University of Minnesota.

The SMS Plan has also created four working groups:

1. Milk Movement Matrix
2. Premises Biosecurity
3. Milk Truck Biosecurity
4. Milk Plant Biosecurity.

Each of these groups consists of members of academia and industry, SAHOs, and APHIS officials.

Together, these groups will achieve objectives that contribute to the development of the SMS Plan, including the following:

- ◆ Research on the survival of FMDV in milk and potential methods to transport and process milk in a biosecure way, including the ability to detect FMDV in bulk milk tanks through diagnostic testing
- ◆ Determination of the viability of a Federal and State transport plan for raw milk movement from non-infected premises in an FMD Control Area
- ◆ Socialization of information with stakeholders to obtain feedback and gauge acceptance, particularly on current regulations and critical movement points to minimize FMD spread
- ◆ Analysis of current structure and business practices of the dairy industry to see how they relate to emergency management and business continuity
- ◆ Identification and prioritization of risk assessments for different commodities necessary to support continuity of business efforts for the dairy industry in the event of an FMD outbreak response
- ◆ Engagement of the dairy industry in animal health emergency response planning
- ◆ Engagement of dairy health professionals in national animal health emergency management planning for FMD response.

Appendix J

Information on FMD Vaccines and Vaccination

FMD vaccination is a complex topic, and further information can be found in NAHEMS Guidelines: Vaccination for Contagious Diseases (2010), which has an FMD-specific Appendix A; the FMD Vaccination SOP; and the NVS FMD Countermeasures Working Group document. All of these resources can be found at <https://fadprep.lmi.org>.

MATCHING

Vaccine matching is critical in the success of an emergency vaccination strategy for an FMD outbreak. The OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (2010) Chapter 2.1.5 on FMD provides extensive guidance on vaccine matching. As stated in this chapter, “Vaccination against one serotype of FMDV 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 the FMD virus. However, this is expensive and time consuming: in vitro methods should be considered as alternatives.² Chapter 2.1.5 explains the serological testing that can be conducted to choose an effective vaccine strain and details the enzyme-linked immunosorbent assays (ELISAs), two-dimensional neutralization tests (VNT), or a complement fixation test (CFT). These tests assess the serological relationship between a field isolate and a vaccine virus (*r* value). In addition, it explains how to calculate the expected percentage of protection (EPP).

For the *r* value, with an ELISA test, the following guidelines are used for interpretation:

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

- ◆ 0.4–1.0: Close relationship between field isolate and vaccine strain. A potent vaccine containing the vaccine strain is likely to confer protection.

¹ OIE, *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, Chapter 2.1.5, “Foot-and-Mouth Disease,” 2010, http://www.oie.int/eng/normes/mmanual/2008/pdf/2.01.05_FMD.pdf.

² NVS, *National Veterinary Stockpile Countermeasures Working Group Report: Foot-and-Mouth Disease*, 2007.

-
- ◆ 0.2–0.39: The field isolate is antigenically related to the vaccine strain. The vaccine strain might be suitable for use if no closer match can be found provided that a potent vaccine is used and animals are preferably immunized more than once.
 - ◆ <0.2: The field isolate is only distantly related to the vaccine strain and the vaccine strain is unlikely to protect against challenge with the field isolate.³

POTENCY

In addition to vaccine matching, the potency of the vaccine also contributes to “the range of antigenic cover.”⁴ For example, vaccines that are more potent may give greater protection against heterologous strains, a quicker onset of immunity, and increased protection from viral shedding and transmission. Additional booster vaccines can also increase the antigenic cover of a given vaccine.

The most common test of potency is the 50 percent protective dose (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.”^{5,6} The PD₅₀ is determined in a dose response study in 15 cattle at least 6 months of age given primary vaccination of either one full dose, 1/4 dose, or 1/16 dose (5 cattle per group, with 2 cattle in a control group that is not vaccinated), and subsequently challenged by the inoculation of 10,000 ID₅₀ (50 percent infectious dose) of virulent bovine virus of the same type or subtype as that used to prepare the vaccine. Preferred observed potency is at least 6 PD₅₀ per cattle dose.^{7,8}

An alternative to this test is the PGP test (percentage of protection against generalized foot infection). Seronegative cattle with the same characteristics described above are vaccinated with a manufacturer-suggested volume.^{9,10} Then, these animals and a control group (2 nonvaccinated animals) are challenged 4 weeks or more after vaccination with a fully virulent challenge strain, intradermally onto

³ OIE, *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, 2010.

⁴ OIE, *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, 2010.

⁵ OIE, *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, 2010.

⁶ NVS, *National Veterinary Stockpile Countermeasures Working Group Report: Foot-and-Mouth Disease*, 2007.

⁷ OIE, *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, 2010.

⁸ NVS, *National Veterinary Stockpile Countermeasures Working Group Report: Foot-and-Mouth Disease*, 2007.

⁹ OIE, *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, 2010.

¹⁰ NVS, *National Veterinary Stockpile Countermeasures Working Group Report: Foot-and-Mouth Disease*, 2007.

the surface of the tongue. Unprotected animals will show lesions at sites other than the tongue within 7 days.

Potency tests for other species have not yet been standardized. However, a test similar to the cattle PD₅₀ test can be adopted for pigs.¹¹

STRAINS

The World Reference Laboratory for FMD recommends FMD virus strains that should be included in FMDV antigen banks, most recently in December 2009. High-priority strains, not in order of importance, include¹²

- ◆ O Manisa (covers pan-Asian topotype),
- ◆ O BFS or Campos,
- ◆ A24 Cruzeiro,
- ◆ Asia 1 Shamir,
- ◆ A Iran-05,
- ◆ A22 Iraq, and
- ◆ SAT 2 Saudi Arabia (or equivalent).

The *WRLFMD Quarterly Report October-December 2009* lists the medium and low priority recommendations:

http://www.wrlfmd.org/ref_labs/ref_lab_reports/OIE-FAO%20FMD%20Ref%20Lab%20Report%20Oct-Dec%202009.pdf.

DIVA

One of the most important challenges to vaccination is ensuring that infected and vaccinated animals can be successfully differentiated. NVSL-FADDL uses the 3ABC Prionics ELISA as a herd DIVA test. In the United States, NVSL-FADDL is the only laboratory that currently runs the 3ABC ELISA, though laboratories in the NAHLN may have that capability in the future. (See Subsection 6.4 of this response plan for diagnostic flowcharts.)

Differentiating infected and vaccinated animals on an individual rather than herd basis remains a diagnostic challenge. Subsection 6.4 and the FMD Diagnostics

¹¹ OIE, *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, 2010.

¹² World Reference Laboratory for FMD, *WRLFMD Quarterly Report October-December 2009*, http://www.wrlfmd.org/ref_labs/ref_lab_reports/OIE-FAO%20FMD%20Ref%20Lab%20Report%20Oct-Dec%202009.pdf.

SOP provide information on the diagnostic tests, flow of these tests, and Incident Command responsibilities for DIVA and surveillance in the event of an FMD outbreak in the United States.

Insufficiently purified vaccines may contain low levels of non-structural proteins; vaccine purity is very important for DIVA, particularly when animals must be vaccinated multiple times.¹³ The fact that individual vaccinated cattle infected with FMDV could be asymptomatic carriers without seroconverting to the non-structural proteins (which is the basis of DIVA testing with current diagnostics) is also a concern.¹⁴

CROSS-PROTECTION

Vaccines will not provide cross-protection among different serotypes. Cross-protection against different strains in the same serotype depends on the amount of variation and its potency.¹⁵

IMMUNITY

Onset of Immunity

Inactivated FMD vaccines may decrease viral shedding and clinical signs in cattle and sheep in challenge studies as early as 4 days after vaccination with protection improving for the next 2–3 weeks; swine appear to be more difficult to protect shortly after challenge. Limited studies have reported some protection as soon as 3–4 days after vaccination; however, with more severe challenges, pigs may not be completely protected against disease until 21–28 days after vaccination.¹⁶ An oil adjuvanted product is likely to be used in an emergency vaccination strategy associated with an FMD outbreak in the United States.

Duration of Immunity

With three doses of Al(OH) adjuvanted vaccine, cattle showed immunity (via reduced clinical signs) for up to 3 years. With a single dose of oil emulsion vaccine, cattle remained seropositive with titers believed to be protective for at least 90

¹³ R. P. Kitching, “Identification of foot and mouth disease virus carrier and subclinically infected animals and differentiation from vaccinated animals,” *Rev Sci Tech*, 21(3), 2002, pp. 531–538. Also see NAHEMS Guidelines: Vaccination for Contagious Diseases, Appendix A (2010).

¹⁴ NVS, *National Veterinary Stockpile Countermeasures Working Group Report: Foot-and-Mouth Disease*, 2007.

¹⁵ NVS, *National Veterinary Stockpile Countermeasures Working Group Report: Foot-and-Mouth Disease*, 2007.

¹⁶ NVS, *National Veterinary Stockpile Countermeasures Working Group Report: Foot-and-Mouth Disease*, 2007. Also see NAHEMS Guidelines: Vaccination for Contagious Diseases, Appendix A (2010).

days post-vaccination. Swine challenged with low levels of homologous virus after one dose did not display clinical disease for 7 months.¹⁷ The OIE suggests two inoculations, 2–4 weeks apart, with revaccination every 4–12 months.¹⁸

REFERENCES

- Elsken, L. A., M. Y. Carr, T. S. Frana, et al. "Regulations for vaccines against emerging infections and agrobioterrorism in the United States of America." *Rev. Sci. Tech.*, 26(2), 2007, pp. 429–441.
- Kitching, R.P. "Identification of foot and mouth disease virus carrier and subclinically infected animals and differentiation from vaccinated animals." *Rev Sci Tech.* 21(3), 2002, pp. 531–538.
- Kitching, R. P., and S. Alexandersen. "Clinical variation in foot and mouth disease: pigs." *Rev Sci Tech*, 21(3), 2002, pp. 513–518.
- National Veterinary Stockpile (NVS). *National Veterinary Stockpile Countermeasures Working Group Report: Foot-and-Mouth Disease*. 2007.
- Parida, S., L. Felming, Y. Oh, et al. "Emergency vaccination of sheep against foot-and-mouth disease: significance and detection of subsequent sub-clinical infection." *Vaccine*, 26, 2008, pp. 3469–3479.
- Sutmoller, P., and R. Casas Olascoaga. "Unapparent foot and mouth disease infection (sub-clinical infections and carriers): implications for control." *Rev. sci. tech. Off. Int. Epiz.*, 21(3), 2002, pp. 519–529.
- OIE. *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, Chapter 2.1.5, "Foot-and-Mouth Disease." 2010.
http://www.oie.int/eng/normes/mmanual/2008/pdf/2.01.05_FMD.pdf.

¹⁷ NVS, *National Veterinary Stockpile Countermeasures Working Group Report: Foot-and-Mouth Disease*, 2007.

¹⁸ OIE, *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, 2010.

Appendix K

Glossary

Animal product	Blood or any of its components, bones, bristles, feathers, flesh, offal, skins, and any by product containing any of those components that originated from an animal or bird.
Case	An individual animal infected by FMD virus, with or without clinical signs.
Cloven-hooved animals	Members of the order Artiodactyla. Most are susceptible to infection by FMDV. Includes pigs, deer, sheep, goats, and cattle.
Compartment (compartmentalization)	An animal subpopulation contained in one or more establishments under a common biosecurity management system with a distinct health status with respect to a specific disease or specific diseases for which required surveillance, control, and biosecurity measures have been applied for the purpose of international trade.
Confirmed positive premises	Any premises with at least one confirmed positive case (animal) as specified by the current APHIS definition for FMD; Infected Premises.
Control Area	A Control Area (an Infected Zone and Buffer Zone) has individual premises quarantine for Infected Premises, Suspect Premises, and Contact Premises and movement restrictions for At-Risk Premises and Monitored Premises.
Emergency vaccination	A disease control strategy using the immunization of susceptible animals through the administration of a vaccine comprising antigens appropriate to the disease to be controlled.
Etiology	The causes or origin of disease or the factors that produce or predispose toward a certain disease or disorder.
Euthanasia	The humane destruction of an animal accomplished by a method that produces rapid unconsciousness and subsequent death with a minimum of pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death.

FAD PReP (Foreign Animal Disease Preparedness and Response Plan)	Document used to identify veterinary functions and countermeasures necessary to contain and control a FAD outbreak. It is also used to integrate functions and countermeasures with emergency management systems and operations conducted in joint and unified command by local, State, and Federal personnel.
FMDV infection	<p>For the purposes of international trade, the OIE <i>Terrestrial Animal Health Code</i> Chapter 8.5 deals with not only the occurrence of clinical signs caused by FMDV, but also with the presence of infection with FMDV in the absence of clinical signs. FMDV infection is defined as follows:</p> <ol style="list-style-type: none"> 1. FMDV has been isolated and identified as such from an animal or a product derived from that animal; or 2. Viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of FMDV has been identified in samples from one or more animals, whether showing clinical signs consistent with FMD or not, or epidemiologically linked to a confirmed or suspected outbreak of FMD, or giving cause for suspicion of previous association or contact with FMDV; or 3. Antibodies to structural or nonstructural proteins of FMDV that are not a consequence of vaccination have been identified in one or more animals showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected outbreak of FMD, or giving cause for suspicion of previous association or contact with FMDV.
Fomites	Inanimate objects that can transmit infectious agents from one animal or person to another.
Foreign animal disease	A transboundary animal disease not known to exist in the U.S. animal population.
Incubation period	For the purposes of the OIE <i>Terrestrial Animal Health Code</i> (2010), the incubation period for FMD is 14 days. The incubation period is the longest period that elapses between the introduction of the pathogen into the animal and the first clinical signs of the disease.
Index case	The first or original case identified in a disease outbreak.
Kill	Any procedure which causes the death of an animal.

Mass depopulation	Method by which large numbers of animals must be destroyed quickly and efficiently with as much consideration given to the welfare of the animals as practicable, but where the circumstances and tasks facing those doing the depopulation are understood to be extenuating.
Milk	The normal mammary secretion of milking animals obtained from one or more milkings.
Milk product	The product obtained by any processing of milk.
Modified stamping-out policy	Animal health measures for stamping-out that are not implemented in full.
Mutation (genetic)	Change in the sequence of a cell's genome caused by radiation, viruses, transposons, and mutagenic chemicals, as well as errors during meiosis or replication.
Non-susceptible animal	Animal that does not develop a particular disease when exposed to the causative infectious agent of that disease.
OIE (World Organization for Animal Health)	Organization that collects and publishes information on animal diseases from 177 countries and develops standards for animal health.
Outbreak	The occurrence of cases of a disease that are in excess of what is normally expected in a given population.
Personal protective equipment (PPE)	Clothing and equipment to prevent occupational injuries and diseases through control of exposure to potential hazards in the work place after engineering and administrative controls have been implemented to the fullest extent.
Preemptive slaughter	Depopulation under the competent authority of susceptible animal species in herds or flocks on premises that have been exposed to infection by direct animal-to-animal contact or by indirect contact of a kind likely to cause the transmission of FMD virus prior to the expression of clinical signs.
Premises	A geographically and epidemiologically defined location, including a ranch, farm, stable, or other establishment.
Presumptive positive premises	Premises with at least one presumptive positive case (animal).
Regionalization (also known as zoning)	An animal subpopulation defined primarily on a geographical basis (using natural, artificial, or legal boundaries).

Rendering	Process by which purified fat and protein products are recovered from inedible portions of animals by cooking at high temperatures.
Ruminants	Mammal in the order Artiodactyla, including cattle, goats, sheep, bison, deer, elk, moose, antelope, and others (camelids, giraffes), but not including Suina (pigs, peccaries). For purposes of the OIE <i>Terrestrial Animal Health Code</i> (2010), ruminants do not include the dromedary (<i>Camelus dromedarius</i>).
Slaughter	The killing of an animal or animals for human consumption, often by bleeding.
Stamping-out	Means carrying out under the authority of the Veterinary Authority, on confirmation of a disease, the killing of the animals which are affected and those suspected of being affected in the herd and, where appropriate, those in other herds which have been exposed to infection by direct animal to animal contact, or by indirect contact of a kind likely to cause the transmission of the causal pathogen. All susceptible animals, vaccinated or unvaccinated, on an infected premises should be killed and their carcasses destroyed by burning or burial, or by any other method which will eliminate the spread of infection through the carcasses or products of the animals killed.
Susceptible animal	Any animal that can be infected with and replicate the disease pathogen of concern.
Trace back	The identification of the origin and movements of all animals, animal products, possible fomites, people, possible vectors, and so on that have entered onto an infected premises.
Trace forward	The tracing of all animals, people, fomites, and so on that have left an infected premises. The premises that received the animals or goods should be investigated and kept under surveillance or quarantine.
Vector	An insect or any living carrier that transports an infectious agent from an infected individual to a susceptible individual or its food or immediate surroundings.

Appendix L

Abbreviations

AC	Area Command
AGID	agar-gel immunodiffusion
AHPA	Animal Health Protection Act
AHSM	Animal Health and Surveillance Management
APHIS	Animal and Plant Health Inspection Service
ARP	At-Risk Premises
ARS	Agricultural Research Service
AVIC	area veterinarian in charge
AVMA	American Veterinary Medical Association
BZ	Buffer Zone
C&D	cleaning and disinfection
CA	Control Area
CCC	Commodity Credit Corporation
CEAH	Centers for Epidemiology and Animal Health
CF	Contingency Fund
CFIA	Canadian Food Inspection Agency
CP	Contact Premises
CVB	Center for Veterinary Biologics
CVO	Chief Veterinary Officer of the United States
CVZ	Containment Vaccination Zone
DHS	Department of Homeland Security
DIVA	differentiation of infected from vaccinated animals
DOI	Department of Interior
EITB	enzyme-linked immunoelectrotransfer blot
ELISA	enzyme-linked immunosorbent assay
EMLC	Emergency Management Leadership Council
EMRS	Emergency Management Response System
EPA	Environmental Protection Agency

EQS	Emergency Qualifications System
ESF	Emergency Support Function
FA	Free Area
FAD	foreign animal disease
FAD PReP	Foreign Animal Disease Preparedness and Response Plans
FAS	Foreign Agricultural Service
FEMA	Federal Emergency Management Agency
FFS	Federal-to-Federal support
FMD	foot-and-mouth disease
FMDV	foot-and-mouth disease virus
FP	Free Premises
FSIS	Food Safety Inspection Service
GFRA	Global Foot-and-Mouth Disease Research Alliance
HHS	Health and Human Services
HTST	high temperature—short time pasteurization
ICP	Incident Command Post
ICS	Incident Command System
IMT	incident management team
IP	Infected Premises
IZ	Infected Zone
JIC	Joint Information Center
LIMS	LabWare Laboratory Information Management System
LPA	Legislative and Public Affairs
LPAI	low pathogenic avian influenza
LPBE	liquid phase blocking ELISA
LSRTIS	Licensing, Serial Release, and Testing Information System
MAC	Multiagency Coordination Group
MP	Monitored Premises
NAFMDVB	North American Foot-and-Mouth Disease Vaccine Bank
NAHEMS	National Animal Health Emergency Management System
NAHERC	National Animal Health Emergency Response Corps
NAHLN	National Animal Health Laboratory Network

NASS	National Agricultural Statistics Service
NCAHEM	National Center for Animal Health Emergency Management
NCIE	National Center for Import Export
NIC	National Incident Coordinator
NIMS	National Incident Management System
NPV	negative predictive value
NRF	National Response Framework
NSP	nonstructural protein
NSU	National Surveillance Unit
NVLS	National Veterinary Logistics System
NVS	National Veterinary Stockpile
NVSL	National Veterinary Services Laboratories
NVSL-AMES	NVSL location for FAD diagnostic testing in Ames, IA
NVSL-FADDL	NVSL location for FAD diagnostic testing in Plum Island, NY
OIE	World Health Organization for Animal Health
OSHA	Occupational Safety and Health Administration
PPE	personal protective equipment
PPV	positive predictive value
PVZ	Protection Vaccination Zone
ROSS	Resource Ordering and Status System
rRT-PCR	real-time reverse transcriptase polymerase chain reaction
SAGARPA	Mexican Secretariat of Agriculture and Rural Development
SAHO	State Animal Health Official
SATs	South African Territories (FMD serotypes)
SITC	Smuggling Interdiction and Trade Compliance
SMS	Secure Milk Supply
SOP	standard operating procedure
SP	Suspect Premises
SZ	Surveillance Zone
TAIO	Tool for the Assessment of Intervention Options
TDD	telecommunications device for the deaf
UHT	ultra-high temperature

USDA	U.S. Department of Agriculture
USTR	United States Trade Representative
VDACS	Virginia Department of Agriculture and Consumer Services
VI	virus isolation
VIAA	virus infection association antigen
VNT	virus neutralization test
VP	Vaccinated Premises
VS	Veterinary Services
VSPS	Veterinary Services Process Streamlining
WS	Wildlife Services

Appendix M

References

Note: This appendix lists documents related to FMD response. All related FAD PReP documents listed in Appendix A are also references for this *FMD Response Plan*.

APHIS-USDA. *Summary Response Plan to the Detection of FMD in the United States*. 2008.

APHIS-USDA. *NAHEMS Guidelines, Response Strategies: Highly Contagious Diseases*. 2005. <http://inside.aphis.usda.gov/vs/fadprep.shtml>.

AUSVET. *Australian Veterinary Emergency Plan: Disease Strategy Foot-and-mouth disease*. 2010.
<http://www.animalhealthaustralia.com.au/programs/eadp/ausvetplan/disease-strategies.cfm> .

Canadian Food Inspection Agency (CFIA). *Foot-and-Mouth Disease Hazard Specific Plan*. 2007.
<http://www.inspection.gc.ca/english/animal-health/management/fmdfie/fmdfiee.shtml> .

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

Department for Environment, Food, and Rural Affairs (DEFRA). *Contingency Plan for Exotic Diseases of Animals: Overview of Emergency Preparedness*. 2009.
<http://www.defra.gov.uk/foodfarm/farmanimal/diseases/control/contingency-plan.htm> .

Department for Environment, Food, and Rural Affairs (DEFRA). *Contingency Plan for Exotic Diseases of Animals: Framework Response Plan*. 2009.
<http://www.defra.gov.uk/foodfarm/farmanimal/diseases/control/contingency-plan.htm> .

Department for Environment, Food, and Rural Affairs (DEFRA). *Foot and Mouth Disease: Commonly Asked Questions*. 2009.
<http://www.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/fmd/qanda/index.htm#4> .

Donaldson, A. I. "Quantitative data on airborne FMD virus; its production, carriage and deposition." *Philosophical Transactions of the Royal Society, London (Series B)*, 1983, 302, pp. 529–534.

Donaldson, A. I., K. A. J. Herniman, J. Parker, and R. F. Sellers. "Further investigations on the airborne excretion of foot-and-mouth disease virus." *Journal of Hygiene (Cambridge)*, 1970, 69, pp. 557–564.

Code of Federal Regulations. Title 9, Chapter 1, Part 53.
http://www.access.gpo.gov/nara/cfr/waisidx_10/9cfr53_10.html.

Code of Federal Regulations. Title 9, Chapter 1, Part 94.
http://www.access.gpo.gov/nara/cfr/waisidx_10/9cfr94_10.html.

Elsken, L. A., M. Y. Carr, T. S. Frana, et al. "Regulations for vaccines against emerging infections and agrobioterrorism in the United States of America." *Rev. Sci. Tech.*, 26(2), 2007, pp. 429–441.

Federal Emergency Management Agency (FEMA). *National Response Framework* (NRF). 2008. <http://www.fema.gov/emergency/nrf/>.

Federal Emergency Management Agency (FEMA). *National Incident Management System* (NIMS). 2008. <http://www.fema.gov/emergency/nims/>.

Kitching, R. P. "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.

Kitching, R.P. and Alexandersen, S. "Clinical variation in foot and mouth disease: pigs." *Rev Sci. Tech.*, 21(3), 2002, pp. 513–518.

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

Parida, S., L. Felming, Y. Oh, et al. "Emergency vaccination of sheep against foot-and-mouth disease: significance and detection of subsequent sub-clinical infection." *Vaccine*, 26, 2008, pp. 3469–3479.

Schley, D., D. J. Paton, S. J. Cox, S. Parida, and S. Gubbins. "The effect of vaccination on undetected persistence of foot-and-mouth disease virus in cattle herds and sheep flocks." *Epidemiol. Infect.*, 2009, 137, pp. 1494–1504.

Sellers, R. F. "Quantitative aspects of the spread of foot-and-mouth disease." *Veterinary Bulletin*, 41, 1971, pp. 431–439.

Sellers, R. F., A. I. Donaldson, and K. A. J. Herniman. "Inhalation, persistence and dispersal of foot-and-mouth disease virus by man." *Journal of Hygiene (Cambridge)*, 68, pp. 565–573.

- Spickler, A. R., J. A. Roth, J. Galyon, and J. Lofstedt (Eds). *Emerging and Exotic Diseases of Livestock*, 4th Ed. (Ames, IA: Iowa State University, College of Veterinary Medicine; Center for Food Security and Public Health; Institute for International Cooperation in Animal Biologics, 2010).
- Sutmoller, P. and R. Casas Olascoaga. “Unapparent foot and mouth disease infection (sub-clinical infections and carriers): implications for control.” *Rev. Sci. Tech., Off. Int. Epiz.*, 21(3), 2002, pp. 519–529.
- Tenzin, Dekker A., H. Vernooij, A. Bouma, and A. Stegeman. “Rate of Foot-and-Mouth Disease Virus Transmission by Carriers Quantified from Experimental Data.” *Risk Analysis*, 28(2), 2008, pp. 303–309.
- United States Animal Health Association (USAHA). *Foreign Animal Diseases*. (Boca Raton, FL: Boca Publications Group, 2008).
- World Organization for Animal Health (OIE). *Foot-and-Mouth Disease*. Technical Disease Card. 2010.
http://www.oie.int/eng/maladies/en_technical_diseasecards.htm.
- World Organization for Animal Health (OIE). *Manual of Diagnostic tests and Vaccines for Terrestrial Animals*. Chapter 2.1.5, “Foot-and-Mouth Disease.” 2009. http://www.oie.int/eng/normes/mmanual/2008/pdf/2.01.05_FMD.pdf.
- World Organization for Animal Health (OIE). *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*. 2010.
http://www.oie.int/eng/normes/mmanual/A_summary.htm.
- World Organization for Animal Health (OIE). *Terrestrial Animal Health Code*. Chapter 8.5, “Foot-and-Mouth Disease.” 2010.
http://www.oie.int/eng/normes/mcode/en_chapitre_1.8.5.htm.
- World Organization for Animal Health (OIE). *Terrestrial Animal Health Code*. 2010. http://www.oie.int/eng/normes/mcode/en_sommaire.htm.