Iowa Emergency Foot-and-Mouth Disease Vaccination Plan

IOWA DEPARTMENT OF AGRICULTURE & LAND STEWARDSHIP

This is a draft document focusing on foot-and-mouth disease vaccination strategy and logistics in the state of Iowa and is subject to change. This document does not represent national policy nor any policy of the Iowa Department of Agriculture and Land Stewardship. This document is for planning purposes only and is constantly evolving as new information becomes available.

April 20, 2021

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1. Introduction

The USDA FAD PReP Foot and Mouth Disease Response Plan – Red Book (DRAFT October 2020 offers guidance on key FMD outbreak response strategies for the U.S. including use of vaccine to help control the outbreak. The goal of the Iowa emergency foot-and-mouth disease (FMD) vaccination strategy is to suppress virus replication in high-risk susceptible animals by rapidly vaccinating a high proportion (≥85%) of the at-risk population. This may be achieved through the vaccination of this percentage of premises housing susceptible animals within a defined region. However, the goal is to achieve as close to a 100% vaccination rate as is logistically possible. Later, vaccinated animals may be depopulated, slaughtered, or allowed to live out their useful lives, depending on the extent and epidemiology of the outbreak as well as the need to return the U.S. livestock industry back to normal production.

The use of emergency vaccination to respond to a FMD outbreak within the United States (U.S.) will be determined by the Unified Command, the State Veterinarian of Iowa, and the US Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS) Deputy Administrator, and guided by this plan. The purpose of this plan is:

- to define the purpose and strategy of Iowa's emergency vaccination campaign with the goals of eradicating FMD and returning Iowa, and ultimately the U.S. livestock industry to normal production as rapidly as possible;
- to outline the operational plan of the emergency vaccination campaign so that the Iowa Department of Agriculture and Land Stewardship (IDALS) is prepared to control vaccine quality and accountability, rapidly administer doses to target populations of animals, and maintain traceability of vaccinates; and
- to assist the Unified Command and State Veterinarian in determining vaccine needs and provide a process for requesting appropriate quantities of vaccine from the APHIS VS Deputy Administrator.
- to provide a process for the Unified Command, State Veterinarian, and the APHIS VS Deputy Administrator to rapidly consider and select alternative strategies using

emergency vaccination when it becomes apparent in an FMD response that stamping-out alone will not achieve control, containment, and ultimately eradication of FMD;

This plan is not intended to guide a long-term or routine campaign for wide-spread vaccination throughout all of Iowa. In addition, emergency FMD vaccination is not an appropriate strategy for use during a focal (Type 1) outbreak.

Iowa has a series of standalone foreign animal disease (FAD) plans for common strategies that can be applied to any FAD as well as a disease-specific Iowa FMD Response Plan. These plans can be accessed on the IDALS' website at: https://iowaagriculture.gov/animal-industry-bureau/animal-disease-response.

The Iowa FMD Emergency Vaccination Plan is an addendum to the Iowa FMD Response Plan and it presents the concept of operations for IDALS to implement an emergency vaccination program when there is an announced presumptive or confirmed positive case of FMD in the United States.

2. Situation

Virus biology, host response, population density, and production type of each species in a Vaccination Zone will dictate vaccine prioritization. IDALS officials will consider the following species of FMD-susceptible domesticated animals, listed alphabetically, when determining vaccine strategy:

- Bison
- Camelids
- Captive Cervids
- Cattle
- Goats
- Sheep
- Swine

Biological considerations include that cattle have a low threshold of infection but are moderate shedders of FMD virus while swine have a higher threshold of infection but can amplify the virus. Severity of infection varies depending on the strain and virulence of the virus and age of the animal. Most adult cattle and swine can recover but may not return to full productivity. Morbidity rate is very high in naïve populations, and significant pain and distress occur in some species. As a result of the infection, animals may experience decreased milk yield, permanent hoof damage, and chronic mastitis. Younger calves, piglets and lambs may have a high mortality rate. Clinical signs in adult sheep and goats are usually subtle. American bison and cervids (e.g., deer and elk) can serve as hosts for the virus but their importance in virus transmission, except as fomites, is unclear. Llamas and alpacas do not appear to be very susceptible but can be experimentally infected. Infections in alpacas were suspected during one outbreak, although there are no confirmed cases documented in the field.

3. Requesting Vaccine

i. Process

a. The decision to initiate a vaccine request will be made by the State Veterinarian, in consultation with the Policy Group and the USDA APHIS VS Area Veterinarian in Charge (AVIC) and District Director (DD). At a minimum, the Policy Group will include the State Veterinarian, the IDALS Animal Industries Regulatory Division Director, and the IDALS Incident Commander. Once the decision to request vaccine has been made, the State Veterinarian, AVIC, and DD will provide Iowa's written FMD Vaccination Plan and the Emergency FMD Vaccine Authorization and Request to the USDA APHIS VS FMD Incident Coordination Group (ICG), which will coordinate review and approval of the request by the U.S. Chief Veterinary Officer. The USDA APHIS Emergency FMD Vaccine Authorization and Request form is found in Appendix E of the FAD PReP Foot and Mouth Disease Response Plan – The Red Book (and is in Attachment ii of this document).

b. The decision on how much vaccine to request will be based partially on an estimate of the number and types of cattle and swine (and potentially other susceptible species) in the anticipated vaccination zone(s) (which may include the infected and buffer zones). The FMD Spread Estimator Tool (Attachment viii) can be used to help estimate the appropriate size for vaccination zones. When the vaccination zone(s) are designated, an estimate of the number and type of cattle and swine will be made based on information that IDALS may already have, including but not limited to the number of animal premises within the county(s), or upon the numbers and types of animals found in the most recent USDA NASS data for the affected county(s). The FMD Dose Estimator Tool (Attachment vii) based on the density of livestock in the county can be used to obtain an estimate of FMD vaccine doses that will be needed for the vaccine zone(s). The amount of vaccine to request will depend on the types of animals that the Policy Group prioritizes for vaccination (e.g. all cattle and calves, dairy cows, beef cows, feedlot cattle, all swine, swine reproductive herd, finishing swine, other susceptible species, etc.) and dose requirements for each species (See Attachment ii). If the outbreak occurs in an animal dense area and the FMD Spread Estimator Tool indicates that the virus has a moderate or higher potential to spread, the Iowa State Veterinarian is likely to request a very large amount of vaccine in anticipation of virus spread. For example, if an outbreak occurs in 18 animal dense counties in NW and central Iowa, approximately 14 million doses will be requested.

c. At the direction of the State Veterinarian, the Incident Management Team (IMT) will prepare and enter a resource request into the APHIS Emergency Management Response System (EMRS) and initiate logistics to receive and manage vaccine.

d. All requests from the state for FMD vaccine must be approved by the U.S. Chief Veterinary Officer. To support the request, the State Veterinarian must provide to the USDA APHIS VS FMD ICG Iowa's up-to-date FMD Vaccination Plan and the

Emergency FMD Vaccine Authorization and Request (Attachment ii). The ICG will coordinate review and approval of the request by the U.S. Chief Veterinary Officer.

e. After the initial vaccine request is made, the Incident Management Team will contact all producers within the vaccination zone to determine the current numbers and types of animals housed on each premises. They will also request that the producers complete and sign the FMD Vaccination Management Plan (found in Attachment iii) which includes an agreement to vaccinate for FMD and defines vaccination procedures.

ii. Responsibilities

a. Responsibilities for providing vaccine, storing and distributing vaccine, administering vaccine and animal identification.

i.) The USDA is responsible for providing vaccine and delivering it to the state cold storage site. Individuals authorized by IDALS and USDA are responsible for vaccine activities within the state. Iowa plans to include private Accredited Veterinarians as authorized individuals and is looking into if their fees for the following activities can be covered by the response:

1. Picking up the vaccine from the state distribution point
2. Maintaining the cold chain and chain-of-custody for the vaccine
3. Overseeing administering the vaccine to the animals
4. Ensuring animals are properly identified and data is in an electronic format that can be entered into EMRS.
5. Collecting samples for compliance testing on a specified number of premises after vaccine is administered if requested.

ii.) IDALS is responsible for storing vaccine and distributing it to Authorized/ Accredited Veterinarians to administer to approved animals/herds.

iii.) Authorized/Accredited Veterinarians are responsible for the activities listed above. These activities may be carried out by properly trained individuals working under the authority of the Authorized/Accredited Veterinarian.

iv.) Producers/animal owners are responsible for providing the equipment and personnel to safely handle the animals during vaccination, and properly identifying vaccinated animals/herds. If the response does not pay some or all of the private Accredited Veterinarian's fees described above, the producer/animal owner may be responsible for paying those fees charged by the private Accredited Veterinarian.

v.) Authorized/Accredited Veterinarians and individuals working under their authority are responsible for properly storing and accounting for all vaccine assigned to them.

vi.) Federally and State inspected packer and slaughter establishments are strongly encouraged to record FMD RFID tag information from animals they slaughter and report that to Federal and/or State authorities.

b. Policy Group:

i.) Makes the decision to request vaccine for use in the state.

ii.) Reviews and approves the vaccine request prior to submittal to USDA.

iii.) Reviews and approves any changes to the initial vaccine request, if needed, after notification from USDA on the amount of vaccine doses that the state will receive.

c. FMD Vaccination Advisory Committee:

i.) Receives information on the science behind FMD vaccination and will work to form consensus on priorities for FMD vaccine use before an outbreak.

ii.) As requested, responsible for providing input to the Policy Group on the utilization of a FMD vaccination strategy in Iowa, both before an FMD detection and during an FMD response.

iii.) Prior to an FMD detection, the following groups will select the following number and types of representatives to serve on the committee:

1. Iowa Pork Producers Association:
    a. One association representative
    b. One veterinarian
2. Iowa Cattleman's Association:
    a. One association representative
    b. One veterinarian
3. Iowa State Dairy Association:
    a. One association representative
    b. One veterinarian
4. Other susceptible species:
    a. One association representative
5. IDALS Appointed Representatives:
    a. One representative of the packer/processor industry
    b. One veterinarian with experience with FMD response in another country
6. Iowa State University:
    a. One agriculture economist
    b. One veterinary diagnostic laboratory representative
    c. One foot-and-mouth disease subject matter expert
    d. One Extension and Outreach representative

d. State Veterinarian:

i.) Communicates with states that would be receiving Iowa's vaccinates for processing (e.g. cattle leaving the state for processing) and with states wanting to send vaccinates into Iowa.

1. The draft document "Framework for Interstate Movement Decisions During a Foot and Mouth Disease Outbreak in the United States" (see Appendix i) provides a potential framework for discussion between and among Responsible Regulatory Officials and industry to provide optimal protection from introduction of FMD virus to a new area while

maintaining business continuity for livestock producers and associated industries and safe and wholesome food to consumers.

ii.) Reviews and approves the Operations Section's request for vaccine.

e. State Incident Management Team (IMT):

i.) The Operations Section develops the supplemental information for the vaccine request.

ii.) The Policy Group, with input as requested from the Advisory Committee as well as subject matter experts, makes recommendations on the best use of vaccine, with a focus on containment or slowing the spread of disease, and/or on preserving unique genetic stock or breeding stock needed to regenerate the state/national herd.

iii.) The Vaccine Branch in the Logistics Section will manage vaccine distribution and tracking. Vaccine distribution and use will be tracked in EMRS.

1. Documents, verifies, and reports on the number of vaccine doses delivered to the distribution warehouse.
2. Assists in the management, verification and documentation of the distribution of vaccine from the warehouse to the field.

iv.) The Disease Reporting Branch receives and tracks information through EMRS regarding vaccinates during the response.

v.) Animal Health staff will receive and track information regarding vaccinates (through EMRS) after the IMT is demobilized.

vi.) Communicates with stakeholders, state partner agencies (including local law enforcement and emergency management) and the public via the PIOs

f. State Emergency Management:

i.) Assists with the National Veterinary Stockpile (NVS)-related warehousing where needed and as requested. (Having a liaison in the Policy Group, state emergency management would be aware of the vaccination request as soon as a decision was made to submit such a request.)

ii.) The Point of Distribution Manager, within the Vaccination Branch, will coordinate with premises slated for vaccination, in advance of vaccine delivery, to determine the identity of an Authorized/Accredited Veterinarian to receive their vaccine and oversee administration of their vaccine and to determine if they have infrastructure for cold storage and personnel and infrastructure that can support the vaccination effort. If they do not have an Authorized/Accredited Veterinarian to work with, or the necessary infrastructure and personnel for vaccine administration, logistics personnel will locate the necessary personnel and equipment (e.g., animal handling equipment, refrigerated storage).

g. Authorized and/or Private Accredited Veterinarian

i.) The private Accredited Veterinarians referred to in this document must be Category II Accredited Veterinarians licensed and accredited in Iowa who have been trained in FMD vaccination policies and procedures through the IowaFADefense program. *Note: There are 1,064 Category II Accredited Veterinarians licensed with a business address in Iowa as of January 29, 2021.*

ii.) Helps the producer in the development of a premises-specific Vaccination Management Plan, in coordination with vaccine case manager from the state or USDA (Attachment iii).

iii.) Assists in implementing Iowa's vaccination strategy.

iv.) Documents, verifies, and reports on the number of vaccine doses picked up from the state distribution site and used for each approved premises where vaccines will be administered.

v.) Manages the distribution of vaccine they receive for each premises.

vi.) Oversees and reports on the administration of vaccine to animals, verifying cold chain maintenance, injection, record keeping and animal or group tracking/marking. Makes information available so that authorized EMRS data entry personnel can enter data into EMRS.

vii.) These activities may be carried out by properly trained individuals working under the authority of the Accredited Veterinarian.

viii.) Informs IDALS of any loss of vaccine doses (e.g., a vaccine bottle breaks on a premises, accidental vaccine release from a syringe into the environment, etc.), vaccination of an unintended species/individual animal on the premises, or any deviations of proper cold chain management which may make the vaccine unusable.

ix.) Returns unused vaccines to IDALS.

h. Distribution and Administration Coordinator in the Vaccine Branch:

i.) Locates Authorized/Accredited Veterinarians to oversee vaccination for each premises and any commercial vaccination crews used for the response and provide personnel to assist in vaccine administration.

i. Owner of vaccinates:

i.) Identifies an Accredited Veterinarian to be responsible for vaccination on their premises, provides equipment, supplies and personnel to assist with animal handling, vaccination and animal identification.

ii.) Responsible for paying any fees charged by the private Accredited Veterinarian not paid by the response.

iii.) With the assistance of an Authorized/Accredited Veterinarian, develops a Vaccination Management Plan (Attachment iii) for vaccinates. This plan will address vaccination procedures. It will also detail how the producer tracks vaccinates, offspring born to vaccinates, reports any mortality of vaccinates

and the movement, sale, or harvesting of vaccinates to state animal health officials. This information will be reported to the Disease Surveillance Branch during the response and to the day-to-day permitting staff once the IMT is stood down.

j. State producer organizations (i.e., Pork Association, Cattlemen's Association, Livestock Associations, Dairy Cooperatives, etc.):

i.) Participate in the Advisory Committee.

ii.) Work with state animal health to identify available qualified Accredited Veterinarians, personnel qualified and available to participate in vaccination crews, and necessary equipment if requested by the Producer (both before an outbreak and during a response).

iii.) Work with PIOs, likely form a unified PIO that includes government and industry

4. Utilization of Vaccine

i. Factors to Consider in Utilization of FMD Vaccine

See Appendix ii

ii. Process for Making Vaccine Utilization Decisions

a. During the outbreak the Policy Group will evaluate all available information on the epidemiology of the outbreak, the characteristics of the vaccine, and the quantity and timeliness of vaccine availability to make specific recommendations on priorities for vaccine use to have the greatest impact on controlling the outbreak and minimizing the impact of FMD on animal health and production, the food supply, and the economy. When deciding priorities, the Policy Group will consider the recommendations in the FMD Red Book, Appendix E (See Appendix vii of this document), recommendations from USDA, and the recommendations of the FMD Vaccination Advisory Committee.

b. The size and shape of the Control Area and Vaccination Zone will be established by the Policy Group. The FMD Potential Spread Estimator Tool can be used to assist in estimating the potential for FMD spread and establishing the size and shape of the Vaccination Zone based on specific characteristics of the outbreak. The number of animals in the Vaccination Zone requiring vaccination can be estimated based on information that IDALS may already have, including but not limited to the number of animal premises within the county(s), or upon the numbers and types of animals found in the most recent USDA NASS data for the affected county(s). The FMD dose estimator tool can be used to help estimate the number of doses needed in a vaccination zone.

c. The IC will work with the Operations and Planning Sections to determine appropriate vaccination zones in the event of an FMD outbreak, and reevaluate these designations as needed throughout the outbreak based on the epidemiological situation. The Disease Reporting Officer will designate "at-risk premises" within zones.

d. The Operations Section will implement the decision of the Policy Group and will determine if the allocated vaccine will allow Iowa's vaccination strategy to be implemented and if it can be implemented in a timely manner. If the number of doses available is insufficient to implement either a vaccinate all, or a ring vaccination strategy (vaccinating susceptible animals on non-infected premises in a vaccination zone around the Control Area), the strategy may shift to focusing on a smaller area of coverage or protecting "high value" animals. The strategy may prioritize breeding animals needed to regenerate the state or national herd(s). For example, it takes longer to re-build the beef or dairy herds than swine herds due to gestation time and number of offspring. This strategy may change depending on how much vaccine is available and the timing of availability. High value animals will likely include breeding stock of high genetic value. Vaccinating these animals will result in them being sero-positive for FMD for life. If this impacts their value, that must be considered in the strategy shift. If this latter strategy cannot be effectively applied due to limited vaccine allocated, Iowa may hold the vaccine and focus on depopulating infected and at-risk animals, or isolate them until they recover, in an effort to contain the disease.

e. The Distribution and Administration Coordinator within the Vaccine Branch of the Operations Section will determine if the premises with animals to be vaccinated is ready to receive and administer vaccine. The animals must be contained in an area where they can be safely handled for vaccination, there must be arrangements for adequate biosecurity for the animals and the personnel, and the FMD Vaccination Management Plan (Attachment iii) must be signed and approved. For biosecurity reasons, this will be done remotely by the Distribution and Administration Coordinator by liaising with the Authorized/Accredited Veterinarian that is overseeing administration on the said premises.

f. As the universe of operations needing vaccination is reviewed, operations considered low priority for vaccination (i.e., low risk of infection or transmission or being sent to slaughter soon) may be temporarily bypassed. Examples of low priority operations may include cow-calf and other operations where there is little to no off-site movement and geographic isolation of animals. In these cases, as the vaccination of higher priority operations is concluded, these low priority operations may fall into a queue to receive vaccination or testing to see if the animals were exposed or still naïve.

5. Vaccine Handling

i. Vaccine Receiving, Staging, and Distribution

IDALS alone does not have the physical infrastructure nor human resources to maintain the cold chain required to receive, stage, and then distribute FMD vaccinations. However, to ensure all cold chain requirements are met IDALS will utilize external partners and services to accomplish everything required to successfully move FMD vaccination throughout Iowa, while maintaining storage and handling requirements stipulated by USDA and the vaccine manufacturer. Chain-of-custody will be maintained from the point where vaccine is transferred into the possession of IDALS, to the point of injection into

an animal. From the point of injection, vaccine will be tracked by individual vaccinate or group of vaccinates.

When researching the various cold storage options available in Iowa it became clear that the method selected will be dependent on the storage capacity and capabilities of the external partner(s) at the time of need. Therefore, different options are outlined below, allowing IDALS to pivot as needed on short notice.

However, regardless of which option(s) are selected, IDALS will request as many materials from the USDA NVS as needed to properly maintain the cold chain. This will include requesting mobile refrigeration units as well as packaging materials (if the plan calls for either).

Iowa Department of Public Health (IDPH) Strategic National Stockpile (SNS) Partnership

a. [placeholder until we can further engage with IDPH – in general IDPH has a storage facility in Des Moines with cold storage space where NVS could potentially deliver pallets]

IDALS Contracting with Brick and Mortar Storage Facility

a. The USDA NVS will deliver pallets of FMD vaccine to a centralized cold storage facility in Iowa. The exact location of the facility will depend on the storage capacity of the facility at the time. Options for a centralized cold storage facility, with estimated pricing, are maintained by the head of vaccination branch in the document titled FMD vx cold chain.xlsx

b. When the pallets are delivered, staff at the cold storage facility will scan barcodes (it is critical that vaccines have bar codes affixed for tracking) on each pallet to log their delivery. During this process, the head of the Vaccination Branch will observe and verify receipt and documentation of the vaccines.

c. The Central Warehouse Manager will observe staff at the cold storage facility while they repack and resort pallets. They will work closely with the Distribution and Administration Coordinator to oversee daily shipments of vaccine for field application.

d. The Distribution and Administration Coordinator plans the delivery of the vaccine from the cold storage facility to local points of distribution in the field.

IDALS Contracting with Portable Cold Storage Units

a. Entire or repacked pallets from a centralized location will be delivered to local points of distribution. Local points of distribution will consist of portable refrigeration units rented from an external partner. The following protocol will be utilized to identify an external partner in the locality where needed:

    i.) The head of the Vaccination Branch will liaise with the Iowa Department of Homeland Security and Emergency Management and the respective local

emergency manager for the locality to see if an existing contract/relationship exists with a company renting portable refrigeration units.

ii.) If none exists, the head of the Vaccination Branch will contact an external partner listed in the document titled FMD vx cold chain.xlsx.

b. Once portable refrigeration unit(s) are identified, the head of the Vaccination Branch will liaise with the Iowa Department of Homeland Security and Emergency Management and the respective local emergency manager for the locality to identify a secure site, with the proper access to electrical hookups, to deliver and operate the portable refrigeration unit(s).

c. The Point of Distribution Manager will oversee the delivery of vaccines to the local point(s) of distribution, ensuring proper tracking and documentation.

d. The Point of Distribution Manager will track and document vaccines as they are distributed to Category II Accredited Veterinarians for administration to animals.

Authorized/Accredited veterinarian role

a. Authorized/Accredited Veterinarians overseeing vaccine administration will arrange the pickup of vaccines and official ear tags from the point of distribution (either the brick and mortar storage facility or portable cold storage unit, depending on the final setup). To ensure there is not cross contamination between premises the Authorized/Accredited Veterinarian must select someone that is not going on premises. This person must arrive in a vehicle that has also not been on a livestock premises.

ii. Vaccine Administration

a. Personnel, equipment, facilities and procedures: The Distribution and Administration Coordinator will ensure that everything is in place for successful vaccination at identified premises according to the Premises Vaccination Checklist (Attachment iv), including the identity of the Authorized/Accredited Veterinarian who will receive and manage vaccine for the premises. The producer may need to pay any fees charged by the private Accredited Veterinarian which the response does not cover. The producer is expected to provide the necessary equipment, supplies and personnel to implement the vaccination program if possible. The vaccine will be administered based on pork quality assurance (PQA), beef quality assurance (BQA) and sheep safety and quality assurance (SSQA) standards. IDALS, in collaboration with USDA, may implement serologic testing on some premises to monitor both vaccination compliance and vaccine efficacy. Since the vaccines are DIVA compatible, it will be necessary to test for antibodies to viral structural proteins. The test will be positive if the animals are either vaccinated or infected. A second test for antibodies to non-structural proteins will be essential to determine that the vaccinated animals are not infected with FMD virus. The herd will be negative for antibodies to non-structural proteins if it is not infected with FMD virus.

b. Disposition of partially used FMD vaccine vials

Because of concern that the vaccine vials used on a premises could become contaminated, they should not be taken to another operation. Partially used vaccine vials should be destroyed in a manner that would inactivate any contaminating FMD virus. The FMD vaccine vials from the NVS are expected to contain 100 mls (50 doses). Destroying partially used 50 dose vials would lead to a lot of waste of the very limited supply of vaccine. To avoid this, the Authorized/Accredited Veterinarian should dispense the anticipated number of doses needed (when less than 50 doses) on a farm into a labeled sterile 100 ml vial (with rubber stopper) using a sterile syringe and needle before the vial is taken to a premises for use.

The vial should be labeled indicating:

- True name of the vaccine (from the original vial)
- Manufacturer
- Serial number
- Current date and expiration date
- Number of doses
- Authorized/Accredited Veterinarians name
- Premises that it is designated to be used on

For example, if it is anticipated that 75 doses will be needed on the premises, A full vial of 50 doses plus a partial vial of 25 doses will the taken to the farm. A few extra doses may be included to ensure that enough vaccine is available on the premises.

c. If a producer cannot provide the equipment, supplies and personnel to assist with animal handling, vaccination and animal identification, the producer may be quarantined until such time as they can or a vaccination crew contracted by either USDA APHIS or IDALS may be contracted to vaccinate the animals.

iii. Supplies

a. IDALS will coordinate with industry and individual producers for equipment and supplies to support vaccination. If these sources cannot fill the state's needs, requests for supplies and equipment will be forwarded to the NVS and/or state emergency management.

iv. Biosecurity

a. Biosecurity will play a vital role in controlling and containing FMD on infected or potentially infected premises and in protecting the health of animals on non-infected premises. Infected, Contact, and Suspect Premises are considered infected/contaminated and placed under quarantine. Biocontainment (keeping disease in) is the focus of response activities on these premises. At-Risk, Monitored, and Free Premises are considered locations with no evidence of disease. Bioexclusion (keeping disease out) is the focus for response activities on these premises. Depending on the extent of the outbreak and the type of vaccination strategy being implemented, vaccination may take place on both infected and non-infected premises.

b. Biosecurity approaches are both structural and operational. Structural biosecurity is built into the physical construction and maintenance of a facility. Operational biosecurity involves management practices designed to prevent the introduction and spread of disease agents onto or off of an animal production premises. Existing

biosecurity plans may offer protection against endemic diseases but heightened precautions will be needed in the event of an FMD outbreak.

i.) The Secure Food Supply Plans were developed to aid producers, transporters, and food processors in the event of a foreign animal disease outbreak and contain species-specific guidance, including a checklist for enhanced biosecurity. Guidance can be customized to individual operations and is intended to maintain business continuity on operations with no evidence of infection. Operations should follow the biosecurity guidelines outlined in the Plans to best ensure bioexclusion of FMD during vaccination campaigns. The Plans can be accessed at: www.cfsph.iastate.edu/Secure-Food-Supply/

ii.) The FAD PReP NAHEMS Guidelines: Biosecurity document (see Appendix iv and FAD PReP FMD and CSF Standard Operating Procedures: Biosecurity (see Appendix v) document also provide detailed guidance on biosecurity principles that producers can implement both before and during an FMD outbreak.

c. The Biosecurity Checklist for FMD Vaccination Handling and Administration (Attachment v.) will be available online during a response and given to all Accredited Veterinarians overseeing vaccination

v. Documentation and Tracking

a. If vaccinates move individually, each vaccinate will be tagged/identified individually. If they can move as a group (e.g., pens of cattle in a feedlot, swine in a production system), then the group will be tracked as a lot/group of cattle, swine, etc. As time and availability of resources allow, and if a vaccinate group has not been harvested or euthanized, the individual vaccinates will be tagged. This will lead to a need for fewer tags than doses of vaccine. The options for official identification of vaccinated cattle and pigs are found in Attachment vi.

i.) All movement of vaccinated animals will require permitting which is to be conducted through EMRS.

b. Critical information will be collected for vaccinated animals or lots/groups of animals (see Attachment iii and Attachment iv).

i.) Premises Identification Number.

ii.) Date of vaccination(s) (each time) and vaccine manufacturer and serial number.

iii.) Tag number (individual animal tracking), pen number/ID for lots/groups of animals vaccinated, the number of animals vaccinated and the total number of animals in the lot/group.

c. Vaccinates will be tracked from the time they are vaccinated until they are harvested, depopulated, or die of natural causes and the final disposition reported. Regardless of how a vaccinate leaves a premises, IDALS will be immediately notified. EMRS will be used for tracking of vaccinates.

d. Producers wanting to move vaccinated animals off the premises will need to obtain a permit from the state, prior to moving them off the operation, for the duration of the animal's life.

Acknowledgements:

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References:

Foreign Animal Disease Preparedness & Response Plan (FAD PReP) National Animal Health Emergency Management System (NAHEMS) Guidelines: Vaccination for Contagious Diseases. October 2014. Available at: http://www.cfsph.iastate.edu/pdf/fad-prep-nahems-guidelines-vaccination-for-contagious-diseases

Foreign Animal Disease Preparedness & Response Plan (FAD PReP) National Animal Health Emergency Management System (NAHEMS) Guidelines: Vaccination for Contagious Diseases. Appendix A: Foot-and-Mouth Disease. USDA-APHIS-VS and CFSPH. May 2015. Available at: http://www.cfsph.iastate.edu/DiseaseInfo/disease.php?name=foot-and-mouth-disease.

Foreign Animal Disease Preparedness & Response Plan (FAD PReP) Strategy Document: Classification of Phases and Types of a Foot-and-Mouth Disease Outbreak and Response. March, 2013. Available at: http://www.cfsph.iastate.edu/pdf/phases-and-types-of-an-fmd-outbreak

Draft Framework for Interstate Movement Decisions during a Foot-and-Mouth Disease Outbreak in the U.S. (Appendix i)

Styles, Darrel K. Foot-and-Mouth Disease: General Virology, Epidemiology, and Rational Response Strategies Focused on Vaccination and Testing. USDA-APHIS-VS Foot and Mouth Disease Preparedness: Prioritizing and Managing Vaccination Campaigns Webinar. November 2019.

USDA-APHIS-VS National Training and Exercise Program. Emergency FMD Vaccination Planning Guide and Template v1.0. February 15, 2019.

Attachment i:

Contact List: ***To be added by IDALS***

Attachment ii:

Foot-and-Mouth Disease Response Plan, The Red Book
Appendix E, Part I
Emergency FMD Vaccine Authorization and Request

Animal and Plant Health Inspection Service, Veterinary Services

Surveillance, Preparedness, and Response Services

National Preparedness and Incident Coordination Center

4700 River Rd.

Riverdale, MD 22737

United States Department of Agriculture

Emergency FMD Vaccine Request
And Initial Plan for Vaccination Campaign

FMDvacc_v8_05.03.18

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

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

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

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

Subsequent vaccine orders will be placed via 213RR.

Include a revised version of this document with each 213RR request for vaccine.

Part I – Emergency FMD Vaccine Authorization and Request

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

Projected vaccine dose needs

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

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

Given the table above:

1) Estimate the number of FMD vaccine doses needed for an initial 2-week campaign: 1st 2 wks Click here to enter text..

2) Estimate the number of FMD vaccine doses needed to conduct a 3-month vaccine campaign in your State, if a type 2 FMD Outbreak (moderate regional outbreak) occurs: 3 mos. regional Click here to enter text..

3) Estimate the number of FMD vaccine doses needed to conduct a >6-month vaccine campaign in your State, if a type 4 FMD Outbreak (national outbreak) occurs: 6 mos. national Click here to enter text..

Part II – Emergency FMD Vaccination Plan for the State of

The emergency FMD Vaccination Plan should contain the following elements:

Strategy

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

FMD Response Strategy Click here to enter text.

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

Animal vaccinates Click here to enter text.

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

Anatomical loc. Click here to enter text.

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

Vaccination zones Click here to enter text.

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

Vaccination schedule Click here to enter text.

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

Enforcement strategy Click here to enter text.

Logistics

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

Logs contact Click here to enter text.

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

Cold chain & security Click here to enter text.

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

Documentation/ID Click here to enter text.

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

Vaccine capacity Click here to enter text.

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

Vaccine disposal Click here to enter text.

_____ _____

STATE/TRIBAL ANIMAL HEALTH OFFICIAL SIGNATURE DATE

Attachment iii:

FMD Vaccination Management Plan

(USDA Template)

EXERCISE EXERCISE EXERCISE

Note: This Foot-and-Mouth Disease (FMD) Vaccination Plan template is intended to serve as a guide. It must be amended as necessary to be specific to the single premises identified below. Attach any supplemental materials necessary and reference in each section as applicable.

FMD susceptible animals, as defined for the purpose of this document, include cattle, goats, sheep, swine, bison and captive cervid.

Premises Information Needed		
Premises ID #		
Special ID		
State abbreviation and county		
Herd type	☐ Commercial	☐ Non-commercial
Network System	☐ Integrated	☐ Independent
Premises owner ☐ Check if primary point of contact		
Name of premises		
Phone number of premises		
Address of premises		
Business owner ☐ Check if primary point of contact		
Name of premises		
Phone number of premises		
Address of premises		
Animal owner(s) ☐ Check if primary point of contact		
Name of representative if applicable		
Address and phone number of animal owners (attach list if necessary) ☐ Check if same as above		
Federal or State Official Point of Contact		
Name		
Phone number		

This document is a written herd management agreement developed between USDA APHIS Veterinary Services (VS) and _____ (*Insert State initials*) (hereafter, "the State" or "State") with input from _____ (*Insert animal owner and/or premises owner*) (hereafter, "the Herd Owner"). This herd will be handled in accordance with the Initial State

Response and Containment Plan (ISRCP), the *USDA APHIS Foot and Mouth Disease Response Plan: The Red Book*, and the Code of Federal Regulations (CFR).

SECTION A: PREMISES DESIGNATED FOR FMD VACCINATION

Note: This section applies to premises designated to receive FMD vaccine by VS and the State as part of an official response to an FMD outbreak.

ANIMAL CENSUS

All vaccinated animals and their identification shall be listed in a detailed animal inventory attached to this plan.

Animal Census Date: _____

Type	*Census*	*Age/age range*[1]	*Production purpose*	*Subject to vaccination*	*Animal identification type (select all that apply)*
Beef Cattle	Calves			☐ Yes ☐ No	☐ RFID ☐ Pen/Lot # ☐ Tags ☐ Brand/tattoo ☐ Other: _____
	Adults			☐ Yes ☐ No	☐ RFID ☐ Pen/Lot # ☐ Tags ☐ Brand/tattoo ☐ Other: _____
Dairy Cattle	Calves			☐ Yes ☐ No	☐ RFID ☐ Pen/Lot # ☐ Tags ☐ Brand/tattoo ☐ Other: _____
	Adults			☐ Yes ☐ No	☐ RFID ☐ Pen/Lot # ☐ Tags ☐ Brand/tattoo ☐ Other: _____
Goat				☐ Yes ☐ No	☐ RFID ☐ Pen/Lot # ☐ Tags ☐ Brand/tattoo ☐ Other: _____
Sheep				☐Yes ☐ No	☐ RFID ☐ Pen/Lot # ☐ Tags ☐ Brand/tattoo ☐ Other: _____
Swine	Piglets			☐ Yes ☐ No	☐ RFID ☐ Pen/Lot # ☐ Tags ☐ Brand/tattoo ☐ Other: _____
	Adults			☐ Yes ☐ No	☐ RFID ☐ Pen/Lot # ☐ Tags ☐ Brand/tattoo ☐ Other: _____
Bison				☐ Yes ☐ No	☐ RFID ☐ Pen/Lot # ☐ Tags ☐ Brand/tattoo ☐ Other: _____
Captive Cervid				☐Yes ☐ No	☐ RFID ☐ Pen/Lot # ☐ Tags ☐ Brand/tattoo ☐ Other: _____

[1]For cattle: calves are ≤6 months, adults are >6 months in age; For swine: piglets are ≤21 days, adults are >21 days in age

☐ Check if **no animals** on this premises will be/were vaccinated for FMD.

If checked, specify the reason for not vaccinating animals on this premises (select all that apply):

☐ Owner refusal; reasoning: _____

☐ Other (e.g., inadequate vaccine doses available): _____

Premises designated to receive FMD vaccine, but no vaccine was administered to animals, are **still subject to enhanced biosecurity, movement restrictions, and identification and documentation requirements** as specified below for FMD vaccinated premises. Review these requirements with the Herd Owner and then obtain signatures at the end of this document.

AGREEMENT TO VACCINATE AND PROCEDURES REQUIRED FOLLOWING VACCINATION FOR FMD

This herd will be handled in accordance with the _____ (*Insert name of State's vaccination plan*.)

This agreement allows the premises operated by _____ (*Insert herd owner and/or premises owner*), (hereafter, "the Herd Owner"), to receive FMD vaccine from VS or the State, to administer the FMD vaccine to FMD susceptible animals on the premises, and to maintain accurate inventory and disposition of FMD vaccinated animals on the premises. Inventory of vaccinated animals will be attached to this plan once they have been vaccinated.

_____ (*Insert herd owner and/or premises owner*), may request modifications to these procedures at any time by contacting the Federal or State Official Point of Contact. The procedures in this document will remain in effect until all vaccinated animals are removed for slaughter, die on the premises, are sold under permit to a new owner, or until such time as VS and the State approve modifications to this agreement. Records of disposition of vaccinates shall be maintained for a minimum of 5 years for cattle, sheep, goats, bison and captive cervid and 2 years for swine.

THE MAIN TENETS OF THIS PLAN FOR VACCINATED PREMISES INCLUDE:

- Enhanced biosecurity,
- Movement restrictions,
- Vaccination procedures,
- Identification and documentation requirements, and
- Oversight and compliance.

PRIMARY RESPONSIBILITIES

- *Administering vaccine* will be,
  - the responsibility of ☐ State and/or ☐ Federal agency *(check responsible party/parties)*, and
  - carried out by ☐ premises owner/staff ☐ business owner/staff ☐ premises veterinarian ☐ 3rd party contractor ☐ State and/or ☐ Federal agency (*check all person(s) performing vaccination*), with oversight by VS and the State.
- *Identification and documentation requirements* will be,
  - the responsibility of ☐ premises owner ☐ business owner ☐ animal owner ☐ State and/or ☐ Federal agency *(check responsible party/parties)*, and
  - carried out by ☐ premises owner ☐ business owner ☐ animal owner ☐ 3rd party contractor ☐ State and/or ☐ Federal agency (*check all person(s) responsible for record keeping*), with oversight by VS and the State.

ENHANCED BIOSECURITY

The Herd Owner will have a written, operation-specific biosecurity plan and implement the biosecurity plan continuously.

Does this premises have an approved Secure Food Supply plan in place? Yes ☐ No ☐

If yes, obtain a copy and attach to this herd plan along with the corresponding map describing the premises.

Any significant risk factors for the introduction of FMD must be addressed *prior to* vaccination. If identified risk factors are not addressed, and the premises becomes infected with FMD, VS may not provide indemnity funding for infected herds on that premises.

{Case managers/site managers should list significant risk factors here. Those would include significant biosecurity lapses (to include contact with feral swine), significant rodent or insect activity in the barns, untreated water supplies, garbage feeding, traffic too close to houses (such as rendering, trash trucks, etc.)}

MOVEMENT RESTRICTIONS

The verbal quarantine was issued by _____ (*insert name of animal health official*) on _____ (*insert date*). The written quarantine document was issued on _____ (*insert date*) and receipt was acknowledged by signature of _____ *(insert animal or premises owner, or representative*).

The Herd Owner will always maintain animal enclosures in a condition to prevent the escape of vaccinated animals. If any vaccinated animal escapes from the premises, the Herd Owner must report the escape to VS or the State within 24 hours.

The Herd Owner will not add to or remove from the premises any FMD susceptible animals except under the conditions specified by a movement permit approved by the State, which may require diagnostic testing of animals to be performed.

THE QUARANTINE WILL NOT BE RELEASED BEFORE:

- a determination of the disposition of all FMD-susceptible vaccinate/non-vaccinated animals on the premises has been made and approved by VS and the State,
- diagnostic testing has been performed, if applicable, and
- written notification of quarantine release has been received by the Herd Owner from VS and the State.

VACCINATION PROCEDURES

The Herd Owner will allow vaccination of all susceptible animals on the premises according to the VS and State policy for FMD vaccination administration and for the designated animals on the premises. The policy might include administering multiple vaccine doses to the same animal at different time periods to maintain herd immunity, based on vaccine manufacturer recommendations. The Herd Owner will notify VS or the State promptly if vaccine is unable to be administered to all designated animals on the premises according to the policy. VS and State

policy will be provided to the herd owner prior to vaccination. If the policy changes, the Herd Owner will be notified of the changes.

The Herd Owner will maintain documentation of all vaccinated animals on the premises using the vaccination record system designated by VS and the State. The Herd Owner will review each vaccination record and certify that the information is correct.

The Herd Owner will report immediately any vaccine-associated adverse events, such as illness, injury, or death, to VS or the State.

IDENTIFICATION AND DOCUMENTATION REQUIREMENTS

The Herd Owner will permanently identify and keep records of each vaccinated animal until it is slaughtered, dies on the premises, or leaves the premises under permit to a new owner, according to VS and State FMD vaccinate identification policy and procedures. This policy will be provided to the herd owner prior to vaccination. If the policy changes, the Herd Owner will be notified of the changes.

The Herd Owner will report the death of any vaccinated animal, and the death or addition (i.e., through birth) of any non-vaccinated animals on the premises, to VS or the State as soon as possible, but no later than 7-14 days following the death/addition. The Herd Owner will immediately notify VS and the State of any changes to the premises or business ownership. Records of disposition of vaccinates shall be maintained by the Herd Owner for a minimum of 5 years for cattle, sheep, goats, bison and captive cervid and 2 years for swine.

OVERSIGHT AND COMPLIANCE

The Herd Owner will allow VS or State personnel to enter the premises to inspect vaccinated animals and documents for the purpose of verifying compliance with provisions of this FMD Herd Plan and for diagnostic surveillance purposes.

If VS and the State determine that the Herd Owner has not met the responsibilities of this agreement, VS and/or the State may further restrict the movement of livestock on or off the premises until such time as the owner becomes compliant with the procedures. Further, if the Herd Owner fails to carry out the responsibilities of this agreement, VS and the State may deem the Herd Owner ineligible to receive indemnity payments related to FMD infection.

OWNER/OPERATOR:

Signature: _____ **Date:** _____

As the Category II Accredited Veterinarians for (*Insert herd owner and/or premises owner*), my signature below acknowledges that I will:

1. Document, verify and report vaccine doses obtained from distribution site
2. Maintain and verify cold chain
3. Manage distribution of vaccine for each premises

4. Supervise vaccination of program animals
5. Officially ID vaccinated animals
6. Report vaccinations to USDA/IDALS (EMRS)

Category II Veterinarian [Accreditation number: _____]

*Signature:*_____ Date: _____

☐ **VS INCIDENT COMMANDER** **OR** ☐ **VS DISTRICT DIRECTOR/AREA VETERINARIAN IN CHARGE:**

Signature:_____ **Date:** _____

☐ **STATE INCIDENT COMMANDER** **OR** ☐ **STATE VETERINARIAN:**

Signature:_____ **Date:** _____

Attachment iv:

Premises Vaccination Checklist and Information Management

This checklist should be completed under the authority of an Authorized/Accredited Veterinarian before proceeding to the premises to administer FMD vaccine. The Accredited Veterinarian is authorized by IDALS or USDA officials. As much of this information as possible should be entered by reading bar codes or QR codes. The information in italics should automatically populate the FMD Vaccination Report Form to be filed by the Authorized/Accredited Veterinarian with IDALS and/or the USDA AVIC and/or EMRS.

- *The name, address and contact information of the Authorized or Category II Accredited Veterinarian responsible for receiving FMD vaccine, ensuring it was properly stored, handled, and administered to the appropriate animals, and that the animals or group of animals are properly identified.*
- *Name, address and contact information of the authorized representative of the Authorized/Accredited Veterinarian (if any) responsible for on farm vaccination and animal identification activities.*
- *Name, address and contact information of the animal owner(s).*
- *If applicable, address and contact information of the responsible manager of the premises.*
- *Premises identification number and address of the location of the vaccinated animals.*
- *Manufacturer, serial number, expiration date of FMD vaccine to be used.*
- *Number, species and type of animals to be vaccinated.*
- *Whether the vaccinated animals will be individually identified, or identified by group or lot that must remain together.*

The Authorized/Accredited Veterinarian and the producer responsible for the animals must ensure that the following is in place to enable successful vaccination:

- The owner/manager of the premises assures that sufficient help is available to safely handle the animals to be vaccinated.
- All individuals involved in the vaccination process have been trained on the necessary biosecurity precautions (see biosecurity documents developed for FMD vaccination).
- The owner/manager assures that adequate equipment is available to safely handle the animals during vaccination and animal identification.

- Ensure that necessary supplies will be available (vaccine, syringes, needles, RFID identification tags (if required will be supplied by the USDA), supplies needed for biosecure entry to, and exit from, the premises).
- The FMD Vaccination Management Plan (Attachment iii) must be signed and approved.

Record keeping needs associated with FMD vaccination:

- Vaccine distribution to the Authorized or Category II Accredited DVM (vaccine manufacturer, serial number, expiration date, number of bottles/doses, Date distributed to the DVM)
- Information about the Accredited DVM (name, address, phone, email, State license number, NVAP number)
- Information about the animals and premises to be vaccinated (Premises identification number with latitude and longitude, Owner/manager name, address, phone, email, number, species and type of animals on site, the FMD Vaccination Management Plan)
- Information on vaccine administered and the vaccinated animals should be uploaded into EMRS, or otherwise reported to IDALS and USDA daily (RFID number for individually identified animals, number and description of animals to be identified by group or lot, date of vaccination, dosage)

The information should be compatible and derived from or linked electronically to:

- EMRS
- PIN
- Accredited Veterinarian data base
- State animal health data needs
- Information may include but not limited to group ID or individual animal ID collected at packing plant
- NAHLN lab information collection on submission form
- Producer production record systems
- Control Area coordinates designating premises status and location on maps
- Information gathered on all the premises in the control area, surveillance zone, and vaccination zone as it is collected at the start of the outbreak

Data entry should be:

- Single entry that populates many of the above systems
- As much as possible, data entry by reading QRS or bar codes and RFID tags (DVM info, premises info, vaccine info, etc.) using Orcascan or similar technology on cell phones or iPads.
- Data should be transmitted by an Accredited Veterinarian to a central US database
- RFID tags should be electronically captured

Attachment v.

DRAFT

October 9, 2020

Biosecurity Checklist for Foot and Mouth Disease (FMD) Vaccine Handling and Administration

Introduction

Vaccination for Foot and Mouth Disease (FMD) will be under the authority of USDA. FMD vaccine will be distributed by the Iowa Department of Agriculture and Land Stewardship (IDALS). Livestock owners will be provided with the vaccine through an Accredited Veterinarian and will be responsible for giving it to animals as directed by IDALS and the Accredited Veterinarian. This biosecurity checklist serves as best practices to ensure personnel giving the vaccine do not introduce or spread diseases through their activities. Livestock operations are expected to have put enhanced biosecurity measures in place for personnel, vehicles, and equipment entering or leaving an operation. The livestock operation may have stricter biosecurity practices than listed here and those must be followed by anyone entering/working on/exiting the operation.

Vaccine may be used on livestock infected with FMD but not yet detected, on farms with clinical signs (suppressive vaccination), or not yet exposed to FMD (protective vaccination). In ALL CASES, **people giving FMD vaccine need to follow strict enhanced biosecurity practices when entering, working on, and exiting the premises** to avoid bringing or spreading FMD and other diseases. At a minimum, refer to the Enhanced Biosecurity Checklist and Manual for the specific species/commodity in the Secure Food Supply Plans for further information and training materials. (http://www.cfsph.iastate.edu/Secure-Food-Supply/).

Vaccine Vial Receiving Biosecurity

- Vaccine vials must be maintained at the temperatures recommended on the label.
- Ensure the container(s) with the vaccine vials is able to be disinfected upon crossing the Perimeter Buffer Area (PBA) or Line of Separation (LOS) on the livestock premises.
    - Vaccine bottles must NOT be placed under UV lights unless they are in an unopened box.
- All items that will be used to administer the vaccine should be new, not used on other livestock premises.
    - If reused, they should be capable of being cleaned and disinfected after using around livestock before exiting the LOS or PBA.
- All disposable items used to administer the vaccine should be placed in designated containers (sharps for needles, plastic bags for vaccine vials) and decontaminated before leaving the farm (e.g. incineration).
- Unused vaccine should be handled according to USDA requirements.

Routes of Travel

The Department of Transportation, or a transportation team may inform the vaccination crews of the roads to use to travel to the premises to be vaccinated.

Prior to Arrival

Prior to arrival at every operation, all who enter are required to:

- ☐ Have been trained on biosecurity practices
- ☐ Read and understand all procedures for crossing the LOS and PBA as applicable before arrival.
- ☐ Sign an agreement verifying they have been informed of the biosecurity protocols and will abide by them.
- ☐ Ensure that the inside of their vehicle is clean (free of all animal manure/excrement) and has not become contaminated by soiled clothes, footwear and other items.
- ☐ Have showered and be wearing clean clothing and footwear since last contact with susceptible animals.
- ☐ Not have contact with animals, live or dead, or facilities where they are held after showering.
- ☐ Shower and change into clean clothing and footwear before leaving their residence if living on site.
- ☐ In addition to vaccine and vaccination supplies, gather all equipment needed including PPE, bucket and brush for cleaning boots and equipment, cleaning product, disinfectant, water, hand sanitizer, garbage bags, sealable plastic bags.
- ☐ Meet the requirements of downtime established by the operation (if applicable).

On Arrival

On arrival at the operation, everyone who is going to enter an operation must meet the following requirements:

- ☐ Sign in and complete the entry logbook that includes, at minimum: name, phone number, reason for entry and if they had livestock (cattle, pigs, sheep, goats) contact in the last seven days and describe where that contact occurred (auction, packing plant, exhibition, home, internationally, etc., and City/State. They must also sign to certify that they have showered and changed into clean clothes since last animal contact.
- ☐ Only bring food or drink in containers that can be consumed on site, disposed of safely, or the containers disinfected. Do NOT eat in animal areas.
- ☐ Leave all personal items outside the PBA or LOS unless they can be cleaned and disinfected.
- ☐ All cell phones must be kept in a plastic sealable bag, disinfected prior to crossing the PBA or LOS and disinfected prior to exiting the premises.

Biosecure Entry Procedures

Upon entry of the operation, all who cross the designated Access Point on foot or exit their vehicle inside the PBA or LOS are required to follow the operations clothing/footwear policy which must include, at a minimum:

- ☐ Wearing operation-dedicated clothing or clean coveralls/protective outerwear.
- ☐ Wearing operation-dedicated footwear or disposable or disinfectable footwear.
- ☐ Washing hands and/or wear disposable or disinfectable gloves over clean hands.

Vaccine Administration

- Determine order of vaccine administration and plan movements between groups before starting; or dedicate personnel to one group of animals.
    - Start with the youngest, healthiest animals first, to older, healthy animals. Vaccinate animals that may be carrying diseases last. The Accredited Veterinarian should decide if animals are not healthy enough to be vaccinated.

Biosecure Exit Procedures

Upon exiting the operation, all persons must, at a minimum:

- ☐ Remove protective outerwear and disposable footwear, clean and disinfect footwear, remove gloves, and wash hands before crossing the LOS.

- ☐ All outerwear and footwear should be left on the operation for disposal or cleaning and disinfection. Place all disposable dirty items (e.g., disposable coveralls, boots, and supplies) in a plastic garbage bag to be left on the premises for proper disposal.
    - If this is impossible, place items in a plastic bag, clean and disinfect the outside at the LOS before exiting, and dispose of or launder it in a manner that prevents animal exposure to the items.
- ☐ Follow all vehicle and equipment exit biosecurity protocols recommended in the SFS plans and/or established by the operation.

Resources

Secure Food Supply Information Manual for Enhanced Biosecurity

- Beef: https://securebeef.org/beef-producers/biosecurity/
- Swine: https://www.securepork.org/pork-producers/biosecurity/
- Dairy: https://securemilksupply.org/milk-producers/biosecurity/
- Sheep: https://securesheepwool.org/producers/biosecurity/

FAD PReP: Biosecurity SOP: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/emergency-management/fadprep-sops/ct_sop_biosecurity

USDA FAD PReP: Vaccination for Contagious Diseases Appendix A: Foot and Mouth Disease: http://www.cfsph.iastate.edu/pdf/fad-prep-nahems-appendix-a-vaccination-for-foot-and-mouth-disease

Attachment vi.

DRAFT

Options for Official Identification of FMD Vaccinated Cattle and Swine

Assumptions:

- It may be feasible to have 25 million doses of FMD vaccine available within weeks of the beginning of an FMD outbreak in the U.S.
- There is a need to identify and track all FMD vaccinated animals from the point of vaccination until the end of their life.
- The optimal identification system for FMD vaccinated cattle and swine would be to have RFID ear tags and a visually identifiable permanent indication that they are vaccinated, such as a pink USDA ear tag.
- USDA APHIS has a notice in the Federal Register (Docket No. APHIS-2020-0022) regarding "Use of Radio Frequency Identification Tags as Official Identification in Cattle and Bison". (https://www.federalregister.gov/documents/2020/07/06/2020-14463/use-of-radio-frequency-identification-tags-as-official-identification-in-cattle-and-bison). Some cattle already have RFID tags. USDA has some supply of RFID tags in stock available for use. There are not enough RFID tags in stock to identify all vaccinated cattle that do not already have one.
- The National Veterinary Stockpile has a limited number of metal FMD pink ear tags for use in cattle and swine (and corresponding applicators). There are not enough metal pink FMD tags in stock to identify all cattle and swine that are vaccinated.
- Due to the limited supply of pink metal FMD tags and of RFID tags, the current ability to identify FMD vaccinated animals will probably require a combination of approaches.
- These assumptions may change over time.

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

- If vaccinates can move as a group (e.g., pens of cattle in a feedlot, swine in a production system), then the group will be tracked as a lot/group of cattle, swine, etc. without the need for individual animal identification. This will lead to a need for fewer tags than doses of vaccine. As time and availability of resources allow, and if a vaccinated group has not been harvested or euthanized, the individual vaccinates will be tagged before animals can leave the group.
- If animals in a group may move individually, or as a sub-group, each vaccinate will need to be tagged/identified individually. Possible options for cattle are:

  - Cattle that already have an RFID tag will have their tag number recorded as having been vaccinated. If sufficient tags are available, they will also receive a metal pink FMD vaccinated tag and the number recorded.
  - Cattle without an RFID tag will receive an official RFID tag (if sufficient tags are available) and the tag number will be recorded as having been vaccinated. If sufficient tags are available, they will also receive a metal pink FMD vaccinated tag and the number recorded.
  - Cattle without RFID tags, and for which RFID tags are not available, will receive a metal pink FMD vaccinated tag. The highest priority for the limited number of metal pink FMD vaccinated tags will be cattle without RFID tags. Those cattle will be tracked by the number on the metal tag.
  - If sufficient RFID tags and metal pink FMD vaccinated tags are not available, then vaccinated, individually identified cattle must be identified with ear tags that have unique numbers, are tamper-resistant and have a high retention rate in the animal.

- Possible options for identifying individual FMD vaccinated swine are:
  - Each animal will receive an official metal pink FMD vaccinated ear tag and the number recorded.
  - If sufficient metal pink FMD vaccinated tags are not available, then vaccinated, individually identified swine must receive ear tags that have unique numbers, are tamper-resistant and have a high retention rate in the animal.

Attachment vii.

FMD Dose Estimator Tool

https://content.cfsph.iastate.edu/IDALS-FMD-VAC-PLAN/

Attachment viii.

FMD Spread Estimator Tool

https://content.cfsph.iastate.edu/IDALS-FMD-VAC-PLAN/

Attachment ix.

FMD Vaccine Cold Chain Options

https://content.cfsph.iastate.edu/IDALS-FMD-VAC-PLAN/

Attachment x.

List of Abbreviations

AOS	Active observational surveillance
ARMAR	Agriculture Response Management and Resources Exercise
APHIS	Animal and Plant Health Inspection Service
AVIC	Area Veterinarian in Charge
Cat II	Category II Accredited Veterinarian
DD	District Director
FAD	Foreign Animal Disease
FMD	Foot-and-Mouth Disease
ICG	Incident Coordination Group
IMT	Incident Management Team
MAC	Multi-Agency Coordination
NAHLN	National Animal Health Laboratory Network
NASAHO	National Assembly of State Animal Health Officials
NTEP	National Training and Exercise Program
NVS	National Veterinary Stockpile
SAHO	State Animal Health Official
U.S.	United States
USDA	United States Department of Agriculture
VS	Veterinary Services

Appendix i:

Draft Framework for Interstate Movement Decisions During a Foot-and-Mouth Disease Outbreak in the U.S.

https://content.cfsph.iastate.edu/IDALS-FMD-VAC-PLAN/

Appendix ii:

Factors to Consider for Utilization of FMD Vaccine

Important information can be found in the USDA Foreign Animal Disease Preparedness and Response Plan (FAD PReP)/National Animal Health Emergency Response System (NAHEMS) Guidelines which provide the foundation for a coordinated national, regional, state and local response in an emergency. As such, they are meant to complement non-Federal preparedness activities. These guidelines may be integrated into the preparedness plans of other Federal agencies, State and local agencies, Tribal Nations, United States Territories, and additional groups involved in animal health emergency management activities. Appendix A: Vaccination for Foot-and-Mouth Disease (access at http://www.cfsph.iastate.edu/pdf/fad-prep-nahems-appendix-a-vaccination-for-foot-and-mouth-disease) is a supplement to FAD PReP/NAHEMS Guidelines: Vaccination for Contagious Diseases, and covers the disease-specific strategies and general considerations of FMD vaccination. Both documents are components of APHIS' FAD PReP/NAHEMS Guideline Series, and are designed for use by APHIS Veterinary Services (VS), and other official response personnel in the event of an animal health emergency, such as the natural occurrence or intentional introduction of a highly contagious foreign animal disease in the United States. Additional guidance on priorities for using extremely limited quantity of FMD vaccine most effectively is found in Appendix E of the USDA APHIS FAD PReP Foot and Mouth Disease Response Plan – The Red Book (See Appendix vii of this document).

a. **During an outbreak, USDA will first need to provide outbreak specific information to Iowa to inform their request for vaccine**, including:

   i. Strain(s) of FMD virus involved in the outbreak

      While vaccines against FMD exist, there are seven known serotypes and more than 60 subtypes of the FMD virus and immunity to one serotype does not provide cross protection. Immunity to one subtype may or may not provide protection against related subtypes. Vaccines must be closely matched to the viral strain circulating.

   ii. Vaccines from the NVS that will be effective against the outbreak strain

      1. The potency of the vaccine vs. the outbreak strain will be essential information to inform best use of the vaccine. This will determine the number of doses needed initially to induce immunity (one vs. two) for each species and the frequency of re-vaccination to maintain immunity. This will vary depending on the data available and could be different for vaccines made by different vaccine manufacturers.

      2. In the absence of adequate data documenting otherwise, cattle would likely need one dose of vaccine every 6 months during the outbreak. Pigs would likely need an initial dose, a booster dose at 2 to 4 weeks, and every 6 months. Some high potency vaccines in pigs have been shown to induce adequate immunity after a single dose to well-matched outbreak strains but this strategy would have to be approved by USDA prior to utilization. The anticipated recommendations for vaccine doses for various species are:

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

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

iii. Quantity of vaccine and projected schedule of availability for the U.S.

iv. Age of various species to vaccinate (no maternal antibody vs. with maternal antibody)
Young animals that did not receive passive antibody against the outbreak strain through colostrum can respond to vaccines at a few days of age. The response will likely improve if vaccinated at a few weeks of age. Young animals that receive passive antibody through the colostrum will not respond to the vaccine until the maternal antibody level declines after several weeks and may need 2 or 3 doses to confer herd immunity.

v. Slaughter withdrawal time
The minimum slaughter withdrawal time for all vaccines in the U.S. is 21 days. FMD vaccines using oil adjuvants may have a slaughter withdrawal time as long as 60 days. Currently APHIS and FSIS are in discussion regarding a 21 day withdrawal time for FMD vaccine administered under the authority of an Accredited Veterinarian.

vi. Frequency of re-vaccination
A commonly recommended re-vaccination frequency for cattle and swine is every 6 months during an outbreak. For maintenance of FMD free with vaccination, revaccination annually may be recommended. The recommendation will depend on the potency of the vaccine against the outbreak strain and the epidemiologic situation.

vii. Cold chain dependence of vaccine and data on stability at alternative temperatures
1. Vaccine should always be maintained at recommended temperatures (35.6°F - 46.4°F) until administered to the animal. However, some vaccines have stability data indicating they are still effective if held at higher temperatures for limited times.
2. USDA and/or IDALS officials should make decisions on disposition or use of FMD vaccine that has been outside of the recommended storage temperatures based on stability data provided by the vaccine manufacturer (to the NVS) and consultation with CVB. Any vaccine that has been frozen is not suitable for use.

viii. Whether the vaccine will induce antibodies to non-structural viral proteins and is therefore not suitable for Detecting Infection in Vaccinated Animals (DIVA) through testing for antibody to non-structural proteins.

b. **Factors influencing decisions on prioritizing vaccine allocation must be updated frequently, be based on the situation at hand, and adjustments made accordingly as the**

outbreak progresses. These factors include:

i. Type of outbreak (1 through 6) (See Appendix iii: FAD PReP Strategy Document: Classification of Phases and Types of a Foot-and-Mouth Disease Outbreak and Response) during Phase 2 **on a National level:**

1. **Type 1: Focal FMD Outbreak:** Stamping out without vaccination
2. **Type 2: Moderate Regional FMD Outbreak:** Consider establishing a Containment Vaccination Zone and/or Protection Vaccination Zone with eventual depopulation and disposal, or slaughter, of vaccinated animals.
3. **Type 3: Large Regional FMD Outbreak:** A vaccinate-to-live policy may be considered to reduce the shedding and spread of the virus.
4. **Type 4: Widespread or National FMD Outbreak:** Stamping-out of Infected and Contact Premises may need to be discontinued. A vaccinate-to-live policy may be considered to reduce the shedding and spread of the virus.
5. **Type 5: Catastrophic U.S. FMD Outbreak:** Implement a comprehensive FMD vaccination program once sufficient vaccine becomes available.
6. **Type 6: Catastrophic North American FMD Outbreak:** Work with officials in Canada and Mexico to implement a comprehensive North American FMD control program, including vaccination once sufficient vaccine becomes available.

ii. Status of outbreak in Iowa during Phase 2 (see Appendix iii): Iowa may be in any of these statuses and levels but may request vaccine because of anticipated need for vaccine in the near future. The priority for vaccine allocation by USDA may consider the status in Iowa and in other states.

1. **State Not-Known to be Infected with FMD:** FMD has been confirmed in the U.S., adequate surveillance, epidemiologic investigation, movement controls, and biosecurity (see Appendix iii) are not yet in place to give confidence of absence of FMD virus infection in Iowa (this may take considerable time).
2. **FMD Monitored State:** State has conducted adequate surveillance and epidemiologic investigations and has adequate movement controls and biosecurity in place based on the Secure Food Supply plans to give reasonable confidence there is no FMD virus infection in Iowa. A State may apply to the USDA to receive FMD Monitored status.
3. **FMD Positive State:** FMD infection anywhere in Iowa confirmed by FADDL
   a. **Level 1, Stamping out:** Focal area of infection limited to one or a small number of herds with low to moderate livestock numbers. Epidemiologic investigation and surveillance indicate that FMDV has not spread beyond the initial few premises. The Infected Premises have not had extensive animal movement and are not too large to depopulate quickly. Rapid stamping-out is feasible.
   b. **Level 2, Stamping out with vaccination:** A few focal areas of infection limited to an area with low to moderate livestock numbers on small to medium size premises. Epidemiologic investigation and surveillance indicate FMDV has not spread beyond the Control Area(s) within Iowa. The Infected Premises have not

had extensive animal movement out of the Control Area and are not too large to depopulate quickly.

c. **Level 3, Vaccination with limited stamping out:** Multiple areas of infection are detected in Iowa, or the type, number and/or size of infected and contact herds are too great to depopulate quickly enough to suppress disease spread. Stamping-out of some Infected and Contact Premises may need to be discontinued. Some herds may be allowed to recover. There is a reasonable likelihood that the response strategy, including vaccination, will bring the outbreak under control in Iowa.

d. **Level 4, Vaccination with no stamping out:** Widespread areas of infection are detected involving too many herds or herds that are too large to depopulate quickly enough to suppress disease spread. There are infected herds throughout Iowa or a region of the state, with many newly infected herds identified weekly. The magnitude and speed of spread of FMD infection overwhelms local, state, and federal resources. It becomes impossible to manage Control Areas. Advise all producers to implement strict biosecurity to protect their herds according to the SFS plans and implement biocontainment for infected herds. Begin vaccinating as soon as vaccine becomes available, with a goal of vaccinating all designated susceptible animals in Iowa. Allow all animals that can pass FSIS inspection (including vaccinates and recovered animals) to move to slaughter.

e. **Level 5– Any state that has achieved a ≥95% vaccination rate of designated susceptible animals:** A state, regardless of its FMD infection status that has achieved at least a 95% vaccination rate of designated susceptible animals will be designated by Federal Officials as an FMD vaccinated state. It is not feasible to achieve a 100% vaccination rate in a state because calves and pigs are continually being born and added to the herds and because booster vaccinations will be needed on a designated schedule. It is feasible to achieve a 100% vaccination rate in a herd. An FMD vaccinated herd should have sufficient herd immunity to prevent FMD spread within the herd. An FMD Vaccinated State should have a very low level, or no, FMD virus circulation within the state. Herds that have recovered from FMD infection should be vaccinated to ensure that the herd has uniform herd immunity to suppress FMD virus spread.

c. **Factors that may be considered in determining the appropriate vaccination strategy when an outbreak is not identified in Iowa, but Iowa officials have determined that there is a significant chance of disease introduction**, include:

i. Implementation of a state standstill.

ii. Status of border states related to controlling the movement of susceptible species and fomites.

iii. Proximity of a vaccination ring to a state border (calling for a ring vaccination that crosses a state border may not be a viable strategy since it is dependent on what the cross-border state is doing).

iv. Level of confidence in current delineation of the outbreak extent, nationally.

d. **Factors that may be considered in determining the appropriate vaccination strategy when an outbreak has been identified in Iowa include all of the factors above and**:

i. Livestock industry infected.

ii. Consolidation or integration of the infected industry.

iii. Geographic location of the outbreak.

iv. Priority for vaccine use:
   1. By species
   2. By production phase and sector
   3. By age
   4. Within Control Area, or within vaccination zone around the Control Area

v. Purpose of vaccination: protective or suppressive
   1. Is the herd already infected (suppressive vaccination)?
   2. Are animals or premises epidemiologically linked to this herd infected (if not, then protective vaccination)?
   3. Potential for effective biosecurity to protect this herd?
   4. Has the relevant Secure Food Supply plan been implemented for this herd?
   5. Impact if this herd is not vaccinated and becomes infected?
      a. Protect valuable genetics?
      b. Protect breeding stock to regenerate state/national herd?
      c. Number of animals of each species and stage of production?

vi. Priority for each species and production phase when vaccine supply is limited
   1. Consider prioritizing vaccination of cattle to prevent spread. If cattle are protected by vaccination, pigs may be spared due to their higher infectious dose threshold and likely stricter biosecurity.
   2. Consider employing ring vaccination and or vaccination of related production sites to restrict spread and either depopulate or manage the outbreak inside of the ring or production system. A high rate of vaccination is essential to control the outbreak.
   3. Species other than cattle and swine would not be considered for vaccination during the initial stages of a vaccine response
   4. Consider sending recovered animals to slaughter or return them to production after recovery from infection.
   5. Plan for bull dairy calves on a site not known to be infected (and with no maternal antibody) in a Control Area
      a. Option A: Vaccinate on the farm at 3 weeks of age, hold for at least 2 weeks, then move by permit to another site within or out of the Control Area
      b. Option B: If can't hold them, vaccinate and send by permit to grower site within Control Area
      c. Option C: Euthanize the bull dairy calves and safely dispose of them.

vii. Priority for premises to receive vaccine

1. Premises meeting criteria defined by the Policy Group will receive vaccine allotments first. Regardless, all premises receiving vaccines will need to have a premises identification number (PIN) prior to receiving vaccines. Any premises without a valid PIN will be assigned one before vaccine will be distributed to that site.

viii. Priority for each species and production phase when vaccine supply is sufficient
   1. Only consider depopulating and disposing of animals due to welfare concern
   2. Prioritize vaccination based on production sector susceptibility and needs
   3. Consider employing blanket vaccination behind an advancing vaccine front, for example starting on the outer perimeter of the vaccine area and working in
   4. Long-term vaccination campaign:
      a. If the outbreak lasts ≥6 months, re-vaccination may be necessary and cost may fall on producer
      b. Animal identification and tracking will be crucial for recovery of FMD freedom, perhaps with vaccination.
   5. Recovery
      a. Must conduct surveillance for seropositive animals
         i. USDA and the World Organization for Animal Health (OIE) will determine which vaccines and tests are appropriate for use depending on specific details of the outbreak.
         ii. All seropositive animals should correlate with an identified vaccinate
         iii. Seropositive animals that don't correlate with an ID or have not been vaccinated are problematic for recovery and can hamper trade
         iv. For surveillance to be successful, it will require vaccines that are able to detect infection in vaccinated animals (DIVA). Vaccination protects from clinical signs but may not prevent infection. Naturally infected animals develop antibodies to both structural and non-structural viral proteins (NSPs). Vaccination primarily induces antibodies to only structural proteins. With sufficiently purified vaccine, vaccinated animals will be exposed to most NSPs only if they become naturally infected with a field virus. Thus, tests that detect titers to NSPs can be used to detect vaccinated animals that are also naturally infected (DIVA tests) and determine whether the status of a herd is FMD free or infected, even if the herd has been vaccinated.

ix. Must develop a plan to halt vaccination and work toward seronegative herds/flocks

x. Likelihood that vaccination of this herd will help to protect neighboring premises
   1. Data on neighboring premises will be required (number, species, and age of animals; level of biosecurity; vaccination status, infection status)

Appendix iii:

FAD PReP Strategy Document: Classification of Phases and Types of a Foot-and-Mouth Disease Outbreak and Response

https://www.aphis.usda.gov/animal_health/emergency_management/downloads/phases-and-types-of-an-fmd-outbreak_2013.pdf

Appendix iv:

FAD PReP NAHEMS Guidelines: Biosecurity

https://www.aphis.usda.gov/animal_health/emergency_management/downloads/nahems_guidelines/fadprep_nahems_guidelines_biosecurity.pdf

Appendix v:

FAD PReP Foot-and-Mouth Disease and Classical Swine Fever Standard Operating Procedures: Biosecurity

https://www.aphis.usda.gov/animal_health/emergency_management/downloads/sop/sop_fmdcsf_biosecurity.pdf

Appendix vi:
FAD PReP Foot-and-Mouth Disease Response Plan
The Red Book, October 2020

https://www.aphis.usda.gov/animal_health/emergency_management/downloads/fmd_responseplan.pdf

Appendix vii:
FAD PREP Foot-and-Mouth Disease Response Plan
The Red Book, Appendix E
October 2020

United States Department of Agriculture

FMD Response
FMD Vaccine Prioritization Strategy
October 2020

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

INTRODUCTION

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

BASIC INFORMATION

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

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

GUIDANCE

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

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

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

- How likely it is that the premises has already been exposed (if high, vaccination may not be appropriate);

- Environmental conditions (wind, humidity), that may increase probability of introduction;
- Husbandry conditions and health of the animals;
- Biosecurity on the premises (guarding against the risk of introduction prior to protection); and
- Ability to physically vaccinate (logistics, personnel, identification) in a safe and effective manner.

SPECIFIC INFORMATION

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

Cattle

- Vaccinate cattle preferentially – *they are very easily infected due to low viral threshold of infection. If the number of infected cattle can be minimized through preventative measures and/or lower the viral shed if exposed, then other at-risk species can be spared from vaccination and protected through biosecurity. This approach is especially recommended when supplies of vaccine are limited.*

- Vaccinate calves preferentially – *calves are particularly vulnerable and less likely to survive infection, while adult cattle typically do not experience severe clinical signs. This is especially crucial in situations such as calf ranches housing dairy-heifer replacement and bull dairy calves for beef production.*

- Prioritize dairy operations – *feedlots and cow-calf operations are more likely to recover from FMD infection. Additionally, dairy cattle that do recover rarely achieve pre-infection levels of milk production. Dumping milk from infected dairies is incredibly challenging and not an efficient use of resources. With the narrow profit margins in the dairy industry, this is paramount to financial disaster. Infected dairies also complicate the job of the responders because not only do the cattle have to be managed through depopulation and disposal, but the milk has to be dumped which is especially challenging in states like California that have strict EPA regulations.*

Swine

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

- Farrow operations and Genetic Founder Stock:
  - Farrow operations and genetic founder stock should be prioritized, as it ensures that weaned pigs will have adequate maternal immunity when initially moved into transit.
  - These sows and boars in farrow operations should receive one full dose, followed by a booster in 10 to 14 days and then every 6 months thereafter. This protects this

multiplier stock and ensures that the weaned pigs will have adequate maternal immunity when they are moved into transit or grow-out.
- Genetic operations may want to be vaccinated; these producers need to carefully consider long-term export consequences of implementing emergency vaccination. Vaccinated animals may not be eligible for export of their germplasm or offspring if zoning agreements can be achieved during an outbreak, or export resumes after recovery. If vaccination is elected, then these animals should be vaccinated in the same manner as farrowing operations.

♦ Feeder pigs:

- Feeder pigs may be considered, but only should receive a single dose which should provide adequate protection for 3 months. Before immunity wanes, the animal will hopefully be slaughtered. This is an especially relevant recommendation if vaccine supplies are limited.

Sheep and Goats

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

- The sheep industry is largely concentrated in the west, and while these animals respond to FMD vaccination well, their economic contribution to the economy may not warrant the use of precious vaccine. So if exposed, a managed outbreak followed by harvest (sheep demonstrate minimal clinical signs and clear the infection quickly) may be the best option. However if vaccination is elected, a single dose of 1ml is sufficient to protect for 6 months

- Goats are more problematic. They widely distributed and are found virtually in every state and while there is some large scale goat farming for milk, cheese, and meat, they are largely a cottage industry and found with hobbyists. They have the same response to infection by FMD and the same vaccine dosing regimen as sheep, but whether it is really cost effective to vaccinate goats would depend on the epidemiology of the situation and may be better to allow to recover and harvest as with sheep.

Zoological Species

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

SUMMARY

Tools that may inform vaccine application or even wholesale distribution to States would include this guidance and measures such as national modeling of the outbreak, Such an approach could expose pathways that could result in expansion of the outbreak and suggest where vaccines could be preferentially applied to block further spread. Modeling on a region or State

can help inform local responders but may be insufficient for national responders seeking to prevent outbreak expansion. Therefore, it is important to have as much information as possible prior to modeling including age, production sector, movement networks (including feed commodities), dangerous contacts, and other factors influencing spread.

ADDITIONAL INFORMATION

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