FMD vaccination is a complicated and technical issue. This document provides basic information, introducing the challenges of FMD vaccine usage.

Why Do We Need FMD Vaccine (and Vaccination Strategies)?

There are critical reasons for considering vaccination strategies in an FMD outbreak in the United States. In particular, vaccination would be favored over stamping-out (as an exclusive strategy for anything beyond a small, focal outbreak) because

- there is a lack of capacity and capability to rapidly depopulate and appropriately dispose of large numbers of carcasses;
- vaccination lessens negative economic impacts to producers and can protect the health of production animals;
- vaccination can help to preserve genetic stock; and
- solely implementing a stamping-out strategy extends the duration of an outbreak, increasing costs and disrupting the food supply chain for key commodities—including milk, meat, and cheese—especially for domestic consumption.

FMD Vaccine Complexities

There are a number of challenges in planning for FMD emergency vaccination, specifically related to the vaccine, itself.

- ***Antigenic diversity:*** Antigenic diversity of the different serotypes and topotypes means that there is not a single FMD vaccine, but 20 to 25 different vaccines (just to cover the high priority topotypes). Vaccination against one serotype does not cross-protect against other serotypes, and may also fail to protect fully or at all against other strains of the same serotype. This makes it particularly difficult to estimate the quantity of vaccine needed of any one particular topotype.
- ***Production Locale:*** Per current U.S. law, no live FMD virus may be introduced for any purpose into any part of the mainland of the United States, by commercial manufacturers or federal entities (21 U.S.C. 113A). As such, there is no conventional, killed virus FMD production (which requires live FMD virus) in the United States. To date, the only FMD vaccine development in the United States is with a genetically modified, non-infectious version of the FMD virus. The Secretary authorized its movement to the U.S. mainland in 2018 for continued vaccine development and study.
- ***Novel Technologies:*** Novel vaccine technologies on a variety of different platforms are currently being pursued both commercially and within Federal-government research institutions. However, they are in various stages of development and licensing; only one novel vaccine (an adenovirus-vectored A24 topotype) has been licensed by the USDA APHIS Center for Veterinary Biologics for use in the United States.

Vaccine Banking

There are currently two mechanisms by which the United States is supplied with FMD vaccine: the North American Foot-and-Mouth Disease Vaccine Bank (NAFMDVB) and the National Animal Vaccine and Veterinary Countermeasures Bank (NAVVCB).The NAVVCB was established by the Agriculture Improvement Act of 2018 (“The Farm Bill”) and makes a much larger number of vaccine doses available to the United States. In July 2020, APHIS announced a $27.1 million initial purchase of FMD vaccine for the NAVVCB. This is the first step toward the U.S. goal of banking 10-25 million doses of each of the 10-12 highest risk strains of FMD.

These Banks contain quantities of vaccine stored as vaccine antigen concentrate (VAC) encompassing a range of representative FMD types/subtypes that will be converted into finished vaccine at the time of the outbreak. Vaccines produced from VAC are high-potency inactivated vaccines (meaning they do not contain live virus), are compatible for differentiating infected and vaccinated animals (DIVA), and are shown to be effective in cattle, swine, sheep and goats.

Capabilities Required to Use FMD Vaccine in an Outbreak

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

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

Image: Copyright OIE 2018 [World Organisation for Animal Health]
Foot and Mouth Disease Vaccination and Post-vaccination Monitoring

Vaccination Planning Assumptions

APHIS believes that an efficient, overall approach to protecting the U.S. livestock industry in an FMD outbreak can be developed. Although the vaccination aspect of preparedness presents unique challenges, these can be overcome with advance planning and collaboration among all stakeholders. The following statements provide common ground for further collaboration and coordination around FMD vaccine.

- The use of emergency vaccination will be determined by the Unified Incident Command, the State Animal Health Official(s), and the Veterinary Services Deputy Administrator (U.S. Chief Veterinary Officer).
- Once a decision has been made to vaccinate, APHIS will place the order for the first shipment (ie, the maximum number of doses available, up to 2.5 million).
- The bank holding a matching strain will deliver finished vaccine 10-14 days post-order. If the vaccine is from the NAVVCB, subsequent shipments of 2.5 million each 10-14 days may also be available.
- The delivery period of 10-14 days will allow APHIS and States to assess the extent of the outbreak and for States to prepare and submit their Emergency Vaccine Requests and Plans.
- The production cycle for vaccine is approximately 14 weeks; thus, there may be a gap in vaccine receipt once initial quantities are exhausted.

Prioritizing Vaccine Use

Given the highly populated nature and mobility of livestock in the United States, it is unlikely that enough FMD vaccine will be available to vaccinate all (or most) susceptible animals, even in a moderate FMD outbreak. Determining which premises and animal groups should be considered for vaccination will depend upon multiple variables. In general, though, APHIS recommends planning for a protective emergency vaccination strategy targeted in at-risk areas, to reduce the outbreak size and protect susceptible animals from infection using emergency vaccination with the deliberate intent to maintain vaccinates for the duration of their usefulness. Thus, for planning purposes,

- Vaccinate cattle preferentially; calves which are particularly vulnerable; prioritize dairy operations; vaccinating large feed lots may depend on vaccine availability.
- Swine have a higher threshold of infection and might be protected through increased biosecurity.
- If vaccinating swine, prioritize farrow operations and genetic founder stock (require booster in 10-14 days); feeder pigs should only receive a single dose for 3-month immunity.
- Do not plan to vaccinate sheep and goats, but do recognize them as potentially spreading the virus through sub-clinical infection.
- Do not plan to vaccinate zoological species.

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

Next Steps

What are your goals for an FMD response?

What do you need to do to bolster preparedness?

Can you efficiently manage distribution of vaccine doses from the warehouse to the farm?

For More Information

Please visit **www.aphis.usda.gov/fadprep**.

- *FMD Disease Response Plan: The Red Book*
- FMD Ready Reference Guides
- *FMD Vaccination Policy*
- *FMD Vaccination Prioritization Strategy*
- *National Animal Health Emergency Management System (NAHEMS): Vaccination for Contagious Diseases, Appendix A: Foot and Mouth Disease.*