

FMD vaccine 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, in anything beyond a small, focal FMD outbreak, stamping-out (as an exclusive strategy) is not viable or sustainable because

- ◆ there is a lack of capacity and capability to rapidly depopulate and appropriately dispose of large numbers of carcasses;
- ◆ the cost of implementing a total stamping-out strategy is inordinately high;
- ◆ there would be severe economic losses for producers, from the loss of production animals;
- ◆ there would be further losses to producers from the destruction of genetic stock; and
- ◆ there would be a lengthier interruption in the food supply chain for key commodities—including milk, meat, and cheese—especially for domestic consumption.



FMD Vaccine Challenges

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

- ◆ **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.
- ◆ **Overseas production:** 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.

Key Advantages and Disadvantages of Commercial, Emergency, and Novel Vaccine for an FMD Outbreak in the United States

Advantages and Disadvantages	Emergency (High Potency) Vaccine	Commercial Vaccine	Novel Technologies (such as Adenovirus)
<i>Advantages</i>	<ul style="list-style-type: none"> ◆ Reduces time to onset of immunity. ◆ Reduces FMD virus shedding in cattle. ◆ Requires fewer boosters for protection. 	<ul style="list-style-type: none"> ◆ May be available in larger quantities. ◆ Can be delivered quickly. ◆ Lower cost. ◆ Sufficient to contain outbreak with movement restrictions. 	<ul style="list-style-type: none"> ◆ Subunit, recombinant DNA vaccines not using live FMD virus can be produced on U.S. mainland.
<i>Disadvantages</i>	<ul style="list-style-type: none"> ◆ Requires storage of vaccine antigen concentration (VAC). ◆ Delay in delivery of finished vaccine. ◆ Cost. ◆ Limited availability. ◆ Cannot be produced on U.S. mainland (live FMD virus). 	<ul style="list-style-type: none"> ◆ Requires multiple boosters in shorter intervals. ◆ Does not reduce FMD virus shedding as much as emergency vaccine. ◆ Longer time to onset of immunity. ◆ Cannot be produced on U.S. mainland (live FMD virus). 	<ul style="list-style-type: none"> ◆ Less data regarding onset of immunity, duration of immunity, and protection. ◆ Highly limited availability. ◆ Cost.

North American FMD Vaccine Bank (NAFMDVB)

The United States participates in the NAFMDVB with Canada and Mexico. The NAFMDVB holds VAC for an FMD outbreak in the United States, Canada, and/or Mexico. This VAC, if needed in an outbreak, will be reformulated to finished vaccine by the manufacturer.

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 the following:

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

Imperative for Additional Capabilities

- ◆ **Economic estimates of an FMD outbreak in the United States:** An outbreak of FMD in the United States would have catastrophic consequences for the multi-billion dollar livestock industry; FMD is a threat to economic security and infrastructure as well as animal health. Economic estimates suggest that a U.S. outbreak would likely cost billions of dollars. In a recent estimate by Hayes (2012), with a focus on the pork industry, an estimated economic impact was \$12.8 billion dollars, annually, for 10 years (\$128 billion in total). Carpenter et al. (2011), for an outbreak in California, offered a median national loss in national agricultural surplus (including direct and indirect costs) from \$2.3 to \$69 billion.
- ◆ **Recent worldwide FMD outbreaks:** Recent experiences in FMD free countries, particularly Japan and South Korea, also suggest the need for effective and implementable emergency vaccination strategies to control an outbreak. In 2010, Japan was able to contain and eradicate FMD using a combination of stamping-out, strict movement controls, and vaccination. Initially, Japan tried to eradicate FMD by stamping-out infected and contact animals, in coordination with strict movement restrictions. However, the government modified this strategy to use emergency vaccination because it was not possible to depopulate animals quickly enough to halt FMD transmission. In South Korea (2010—2011), a stamping-out strategy was also initially attempted. South Korean officials depopulated approximately 3 million swine and 150,000 cattle before electing to vaccinate the entire national herd.
- ◆ **Uniqueness of U.S. animal agriculture:** It is important to remember that a single state in the United States may have as many animals as the entire country of South Korea. In fact, 35 of 50 States have susceptible livestock populations in excess of 1 million animals; 10 States have populations in excess of 5 million animals; and 4 States have more than 10 million animals.

Questions You Should Ask Your Organization

- ◆ **What are your goals for an FMD response?**
- ◆ **What strategies do you think will work for your industry/State/region?**
- ◆ **What do you need to do to bolster preparedness?**



For More Information

- ◆ National Animal Health Emergency Management System (NAHEMS): Vaccination for Contagious Diseases, Appendix A: Foot and Mouth Disease.
- ◆ Center for Food Security and Public Health, Iowa State University: http://www.cfsph.iastate.edu/Vaccines/disease_list.php?disease=foot-and-mouth-disease&lang=en.
- ◆ World Organization for Animal Health: *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, Chapter 2.1.5 (2012). www.oie.int.
- ◆ The World Reference Laboratory for Foot-and-Mouth Disease (WRLFMD): www.wrlfmd.org.

