



RESOLUTION NUMBER: 1 APPROVED

SOURCE: USAHA/AAVLD COMMITTEE ON ANIMAL Emergency Management

SUBJECT MATTER: National Foot-and-Mouth Disease Preparedness

BACKGROUND INFORMATION:

Foot-and-Mouth disease (FMD) is the most contagious and economically destructive disease of livestock. A FMD event in the United States would have severe, profound, and long lasting negative impact on the United States agriculture and general economy. The United States Department of Agriculture (USDA) estimates that economic losses due to an FMD event in the United States would range from \$15 billion to \$100 billion per year (Source: USDA FMD Vaccination Policy in the United States, September 2014). Recent experiences in the United States with foreign animal disease outbreaks, such as porcine epidemic diarrhea virus (PEDv) and H5 type highly pathogenic avian influenza (HPAI), underscore the need for preparedness in dealing with high consequence animal diseases impacting agriculture. In collaboration with animal agriculture stakeholders, allied industries, academia, state and other federal agencies, the USDA continues to make progress on FMD preparedness and response planning.

Outdated notions of FMD disease mitigation through culling-to-control methods are not practical for the scale and sophistication of animal agriculture in the United States. Emergency FMD surveillance, vaccination, control, and elimination strategies together provide the most timely and viable option for minimizing the economic impact of the disease. In the event of an FMD outbreak in North America that becomes endemic, control of the disease with vaccination will be essential to assure some level of continuity of business operations to sustain short and long-term viability for United States livestock producers, as well as maintaining sufficient numbers of vaccinated commercial and purebred breeding stock to re-build the national herds.

The September 2014 USDA FMD Vaccination Policy states the following:

The goal (of this Policy) is to advance preparedness by facilitating discussion, if not consensus, among our many partners to identify what level of preparedness is adequate and cost effective when considering:

- *Procuring and maintaining a sufficient amount of vaccine for a large-scale emergency vaccination effort is extremely costly.*
- *Vaccine quantity currently available to USDA is sufficient to respond to a small, focal outbreak in an area that is not livestock-dense.*
- *FMD virus strains are sufficiently different so vaccinating against one strain may not protect against different strains, even if they are related.*
- *FMD vaccine cannot be currently produced in the United States (21 U.S.C. 113A). The current vaccine antigen concentrate (VAC) held by the North American FMD Vaccine Bank must be shipped abroad to be finished into vaccine.*
- *VAC currently held by the North American FMD Vaccine Bank is intended to be shared by the United States, Canada, and Mexico. For VAC currently held by the North American FMD Vaccine Bank, the vaccine manufacturers can produce 2.5 million doses in 21 days upon receiving the VAC. For additional vaccine (created from a master seed and not currently stored as VAC), vaccine production can take as long as 14 weeks.*

In working with our stakeholders, USDA APHIS believes that an efficient, overall approach to protect the Nation's livestock industry in an FMD outbreak can be developed. Although the vaccination aspect of preparedness presents unique challenges, these can be overcome with adequate advance planning and consideration of the capabilities and opportunities that public-private partnerships and cost-sharing can afford.

RESOLUTION:

The United States Animal Health Association urges the United States Secretary of Agriculture to include adequate funding for Fiscal Year 2017 for an optimized Foot-and-Mouth Disease (FMD) vaccine bank to support continuity of business operations by the United States livestock industry in the face of a major FMD outbreak. The budget should include:

1. Funds for a managed FMD antigen bank located offshore (in compliance with 21 U.S.C. 113 A), with sufficient antigen diversity to provide timely access to FMD vaccines protecting against all strains currently circulating in the world; and
2. Contracts for surge production capacity to rapidly produce the millions of doses of vaccine that would be required to mitigate an extensive FMD outbreak in the United States.

INTERIM RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Veterinary Services recognizes the concerns of the U.S. Animal Health Association and appreciates the opportunity to respond.

APHIS does not have funds to procure vaccine antigen concentrate in the quantities required to address an extensive Foot-and-Mouth Disease (FMD) outbreak in the United States and is unlikely to get this funding in a single fiscal year. Therefore, the agency must work towards this goal over the coming years. APHIS has discussed the possibility for public-private partnership to fund an adequate FMD vaccine bank for the United States

The North American Foot-and-Mouth Disease Vaccine Bank is in the process of modernizing operations to include in future contracts 1) storing vaccine antigen concentrate at manufacturing production site overseas, and 2) pursuing buy-back options for vaccine antigen concentrate that are due to expire after a period of time.

To assess what funding may be needed for greater vaccine capacity, APHIS intends to issue a "sources sought notice" from vaccine manufacturers, with a goal of identifying which companies can supply the types of vaccine needed, in the amounts needed, in the timeframe needed. The information received from the vaccine manufacturing companies will help APHIS prepare and plan for the future. To purchase vaccine, APHIS would solicit proposals through normal contracting channels.

APHIS will hold meetings with stakeholders and vaccine experts in 2016 and 2017 to discuss priorities and funding options.