



March 2019

# FOOT-AND-MOUTH DISEASE

## USDA's Efforts to Prepare for a Potential Outbreak Could Be Strengthened

# GAO Highlights

Highlights of [GAO-19-103](#), a report to congressional requesters

## Why GAO Did This Study

FMD is a highly contagious viral disease that causes painful lesions on the hooves and mouths of some livestock, making it difficult for them to stand or eat, thus greatly reducing meat and milk production. The United States has not had an FMD outbreak since 1929, but FMD is present in much of the world. An FMD outbreak in the United States could have serious economic impacts, in part because trade partners would likely halt all imports of U.S. livestock and livestock products until the disease was eradicated. These imports were valued at more than \$19 billion in 2017.

GAO was asked to review USDA's efforts to prepare for an FMD outbreak. This report examines (1) USDA's planned approach for responding to an FMD outbreak; (2) challenges USDA would face in pursuing its response goals; and (3) how USDA identifies, prioritizes, and monitors corrective actions to mitigate the challenges. GAO observed a USDA FMD preparedness exercise; reviewed agency documents and nongeneralizable questionnaire responses from 29 respondents from federal and state government, livestock industries, and universities; and interviewed officials from federal and state governments and representatives of livestock industries and universities.

## What GAO Recommends

GAO is recommending that USDA follow its procedures to prioritize and monitor the completion of corrective actions that the agency has identified for FMD preparedness. USDA agreed with these recommendations, and described actions it will take to implement them.

View [GAO-19-103](#). For more information, contact Steve D. Morris at (202) 512-3841 or [smorris@gao.gov](mailto:smorris@gao.gov).

March 2019

# FOOT-AND-MOUTH DISEASE

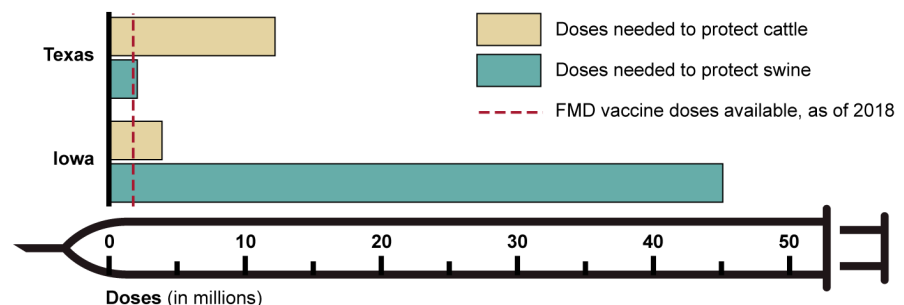
## USDA's Efforts to Prepare for a Potential Outbreak Could Be Strengthened

### What GAO Found

The U.S. Department of Agriculture's (USDA) planned approach for responding to an outbreak of foot-and-mouth disease (FMD) includes several strategies. These strategies generally rely on killing infected and susceptible animals, vaccinating uninfected animals, or a combination of both approaches. USDA would implement one or more of the strategies, depending on factors such as the outbreak's size and the resources available, according to agency documents.

USDA would likely face significant challenges in pursuing its response goals of detecting, controlling, and containing FMD quickly; eradicating FMD while seeking to stabilize industry and the economy; and facilitating continuity of commerce in uninfected animals. GAO identified challenges in 11 areas—including allocating a limited supply of FMD vaccine—based on its review of USDA documents, responses to GAO's questionnaire, and interviews with agency officials and others with expertise on FMD. According to USDA, the agency may not have a sufficient supply of FMD vaccine to control more than a small outbreak because of limited resources to obtain vaccine. As shown below, the current vaccine supply would be sufficient to protect about 14 percent of Texas's cattle or about 4 percent of Iowa's swine; these states' cattle and swine populations are the nation's largest. The Agriculture Improvement Act of 2018 includes a provision to increase the FMD vaccine supply.

**Foot-and-Mouth Disease (FMD) Vaccine Doses Needed to Protect Cattle and Swine in Texas and Iowa, Compared with Vaccine Doses Available, 2018**



Source: GAO analysis of data from the National Agricultural Statistics Service and the North American Foot-and-Mouth Disease Vaccine Bank. | [GAO-19-103](#)

USDA has identified dozens of corrective actions to mitigate the challenges of responding to an FMD outbreak, as called for in USDA procedures, but has not prioritized these corrective actions or monitored their completion, as also called for in its procedures. USDA has identified the corrective actions through exercises simulating FMD outbreaks, surveys, and lessons learned from other foreign animal disease outbreaks. However, USDA has not completed all of the corrective actions, including actions related to vaccination. Agency officials stated that they have not completed such corrective actions because they have been responding to outbreaks of other animal diseases and have limited resources. Without following agency procedures to prioritize and monitor corrective actions, USDA cannot ensure that it is allocating its resources to the most beneficial actions to prepare for a possible FMD outbreak.

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## Abbreviations

APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
avian influenza	highly pathogenic avian influenza
DHS	Department of Homeland Security
FMD	foot-and-mouth disease
Red Book	<i>Foot-and-Mouth Disease Response Plan: The Red Book</i>
SOP	standard operating procedures
USDA	U.S. Department of Agriculture
vaccine bank	North American FMD Vaccine Bank

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March 12, 2019

The Honorable Pat Roberts  
Chairman  
Committee on Agriculture, Nutrition, and Forestry  
United States Senate

The Honorable Gary C. Peters  
Ranking Member  
Committee on Homeland Security and Governmental Affairs  
United States Senate

Foot-and-mouth disease (FMD) is a highly contagious viral disease that causes painful lesions on the hooves and inside the mouths of some species of livestock, making it difficult for them to stand or eat, thus greatly reducing production of meat or milk. The virus affects domestic and wild cloven-hoofed animals, such as cattle, swine, sheep, goats, bison, and deer. There are no known cases of FMD in the United States as of January 2019, but it is present in more than two-thirds of countries in the world, so it could be introduced here either accidentally or intentionally as an act of terrorism, according to documents from the U.S. Department of Agriculture (USDA).<sup>1</sup> An FMD outbreak in the United States could severely harm the economy, largely because of trade repercussions from loss of our nation's "FMD-free" status. If the United States lost this status, trading partners would likely be unwilling to accept our exports until the United States is declared FMD-free again.<sup>2</sup> As a result, USDA expects that in an FMD outbreak, all exports of cattle, swine, sheep, goats, and uncooked products from these animals would temporarily stop. Beef exports in 2017 were valued at about \$7 billion, and pork exports were valued at about \$6 billion, according to the U.S. Meat Export Federation. Depending on the extent and duration of an FMD

<sup>1</sup>U.S. Department of Agriculture, *Foot-and-Mouth Disease Response Plan: The Red Book* (Riverdale, Md.: September 2014). This is the most recent version of USDA's FMD Response Plan.

<sup>2</sup>The World Organisation for Animal Health classifies member countries, including the United States, as FMD-free if they meet certain criteria including no reported cases of FMD in the previous 12 months. The international community generally places a higher value on products from countries classified as FMD-free. Countries without this status are restricted in their ability to trade animals and animal products to other countries. Even if a country is classified as FMD-free after recovering from an outbreak, other countries may decide to continue restricting trade.

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outbreak, it could have a significant effect on these exports, as well as the larger agricultural economy.

USDA is responsible for preparing for an outbreak of FMD in the United States and coordinating a response if an outbreak occurs, in partnership with the Department of Homeland Security (DHS), individual states, and industry. USDA's goals for its FMD response are to (1) detect, control, and contain FMD as quickly as possible; (2) eradicate FMD using strategies to stabilize animal agriculture, the food supply, the economy, and to protect public health; and (3) provide science- and risk-based approaches and systems to facilitate continuity of commerce in uninfected animals.<sup>3</sup>

Some countries have addressed FMD outbreaks in the past by killing and disposing of infected and susceptible animals, otherwise known as stamping out. However, South Korea and Japan stamped out millions of swine and cattle in recent FMD outbreaks but still struggled to contain the virus. U.S. livestock industries operate on a much larger scale than those in either South Korea or Japan, which could make stamping out an outbreak here more difficult. Some countries have used vaccination in conjunction with stamping out to control FMD.

You asked us to review USDA's efforts to prepare for an FMD outbreak. This report (1) describes USDA's planned approach for responding to an FMD outbreak; (2) identifies what challenges, if any, USDA would face in pursuing its FMD response goals; and (3) examines how USDA identifies, prioritizes, and monitors corrective actions to mitigate these challenges.

To describe USDA's planned approach for responding to an FMD outbreak, we reviewed relevant legislation and USDA strategy and guidance documents. We also interviewed USDA officials at the agency's headquarters, laboratories, center for epidemiology and animal health, and center for veterinary biologics.<sup>4</sup> We selected these officials to interview because of their knowledge about USDA's planned approach, their involvement in preparing for an FMD outbreak, and the roles they would play in responding to such an outbreak.

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<sup>3</sup>The FMD response goals are the same as the larger strategic response goals for USDA response to any foreign animal disease outbreak. See U.S. Department of Agriculture, *Foot-and-Mouth Disease Response Plan: The Red Book*.

<sup>4</sup>Epidemiology is the study of the distribution of disease in populations and of factors that determine its occurrence.

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To identify what challenges, if any, USDA would face in pursuing its FMD response goals, we first came up with a list of potential challenge areas. To develop the list of potential challenge areas, we reviewed USDA documents, reports about FMD outbreaks in other countries, and after-action reports from 41 preparedness exercises in the United States from 2007 to 2018 in which officials practiced responding to simulated FMD outbreaks and identified emerging challenges.<sup>5</sup> We also interviewed USDA headquarters staff and field staff in Iowa (the state with the most livestock); USDA laboratory officials; state animal health officials in California, Colorado, Iowa, and North Carolina; representatives from four different livestock industries; and others with expertise in this area. We selected the individuals to interview based on their knowledge about challenges that USDA could face in pursuing its FMD response goals, their central role in preparing for an FMD outbreak, and recommendations from other interviewees, as well as diversity in geographic location. We also visited a swine farm and cattle feedlot in Iowa and interviewed the owners. We selected a swine farm and cattle feedlot to visit because swine and cattle were the livestock industries with the greatest populations of animals in the United States in 2016. We identified a list of 11 potential challenge areas, including vaccination.

To confirm the significance of the challenge areas, we sent a questionnaire with the list of potential challenge areas to four categories of individuals: federal government officials, state government officials, livestock industry representatives, and academic researchers. Within the categories, we selected individuals from relevant units within USDA and DHS, states with relatively high livestock populations, different livestock industries (beef cattle, dairy cattle, swine, and sheep), and academic researchers with relevant expertise. We asked the recipients whether USDA would face a significant challenge in each of the 11 areas and whether they knew of other challenge areas we had not listed. We defined significant to mean a challenge that is sufficiently great or important enough to be worthy of USDA action. We sent the questionnaire to 39 recipients and received responses from 29. Since we used a nonprobability sample, the results are not generalizable to all government officials, livestock industry representatives, or FMD experts, but the responses helped confirm the list of 11 challenge areas and provided illustrative information about each one.

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<sup>5</sup>After-action reports and associated improvement plans summarize areas for improvement and corrective actions identified in preparedness exercises and real-world response events.



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We reviewed challenges related to vaccination for FMD in greater depth than other challenges because of the significant role vaccination could play if reliance solely on stamping out is not feasible. Specifically, we visited DHS's Plum Island Animal Disease Center on Plum Island, New York, where we interviewed officials from USDA's Foreign Animal Disease Diagnostic Laboratory and others about challenges related to FMD vaccination. We also reviewed agency documents on the topic and interviewed other officials from USDA, universities, states, and industry groups about issues related to FMD vaccination. Further, we interviewed officials from the vaccine company that currently produces the majority of FMD vaccine available for use in the United States and a company that has exclusive rights to use a modified version of the FMD virus to produce FMD vaccine in the future.

To determine how USDA identifies, prioritizes, and monitors corrective actions to mitigate the challenges, we reviewed related USDA guidance and other agency documents, observed an FMD preparedness exercise,<sup>6</sup> reviewed after-action reports from 41 previous FMD preparedness exercises, and interviewed USDA officials. The FMD preparedness exercises were sponsored by USDA, DHS, and state governments, and ranged from small-scale exercises focused on narrow response tasks to large-scale exercises in which participants practiced a wide range of response activities in a simulated outbreak. We reviewed USDA's procedures for evaluation and improvement planning to understand how the agency is to identify, prioritize, and monitor corrective actions. To determine whether USDA was consistently following these procedures, we reviewed the 41 after-action reports for FMD preparedness exercises and interviewed agency officials about corrective actions identified in the reports and steps the agency has taken to prioritize and monitor progress on the actions. We reviewed agency documents and interviewed agency officials about examples of corrective actions that USDA has identified and taken or not yet taken. We also reviewed USDA after-action reports for outbreaks of highly pathogenic avian influenza (avian influenza) and reviewed USDA's database of related corrective actions to learn how the agency identified, prioritized, and monitored actions to mitigate challenges for that disease. To assess the overall reliability of the database to use information from this database in our report, we reviewed

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<sup>6</sup>The exercise took place from May 7 through 10, 2018. It was sponsored by USDA with varied levels of participation from federal, state, and local agencies, as well as industry representatives, participating from the locations where they would be in an actual outbreak.

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management controls over the information systems that maintain the data, and we interviewed USDA officials who manage the database. We determined that the database was sufficiently reliable to allow us to describe the contents of the database and general status of corrective actions. For further details on our objectives, scope, and methodology, see appendix I.

We conducted this performance audit from May 2017 to March 2019 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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## Background

This section provides an overview of FMD, as well as information on the potential impact of an outbreak in the United States; USDA activities to respond to outbreaks of diseases, including FMD; federal, state, tribal, and industry roles in FMD control; and FMD vaccines.

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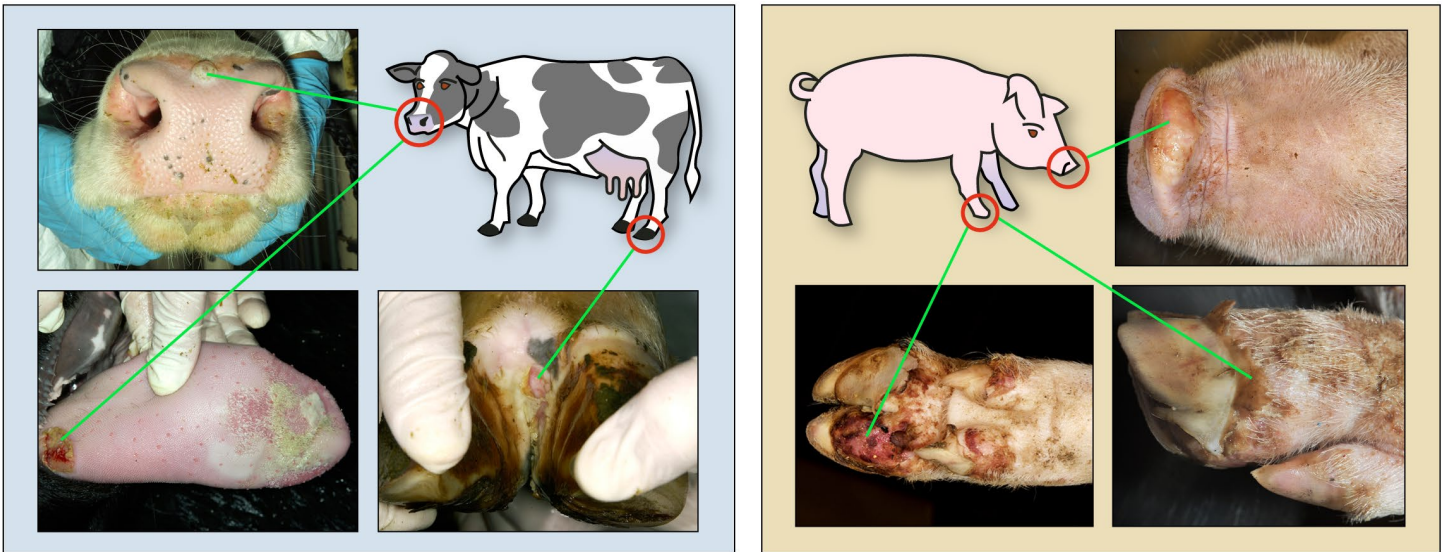
## Overview of FMD

FMD is a highly contagious viral disease that causes fever and painful lesions on cloven-hoofed animals' hooves, mouths, and udders (see fig. 1). These debilitating effects, rather than high mortality rates, are responsible for severe productivity losses associated with FMD. The disease generally does not infect humans and is not considered a public health or food safety threat.<sup>7</sup> Young animals may die from the virus, while most adult animals recover. However, livestock infected with FMD have severely diminished meat and milk production.

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<sup>7</sup>FMD infections in humans are very rare: about 40 cases have been diagnosed since 1921, according to USDA. The disease in humans is generally mild, short-lived, and self-limiting. FMD differs from hand, foot, and mouth disease of humans.

**Figure 1: Examples of Foot-and-Mouth Disease Lesions on Cow and Swine**

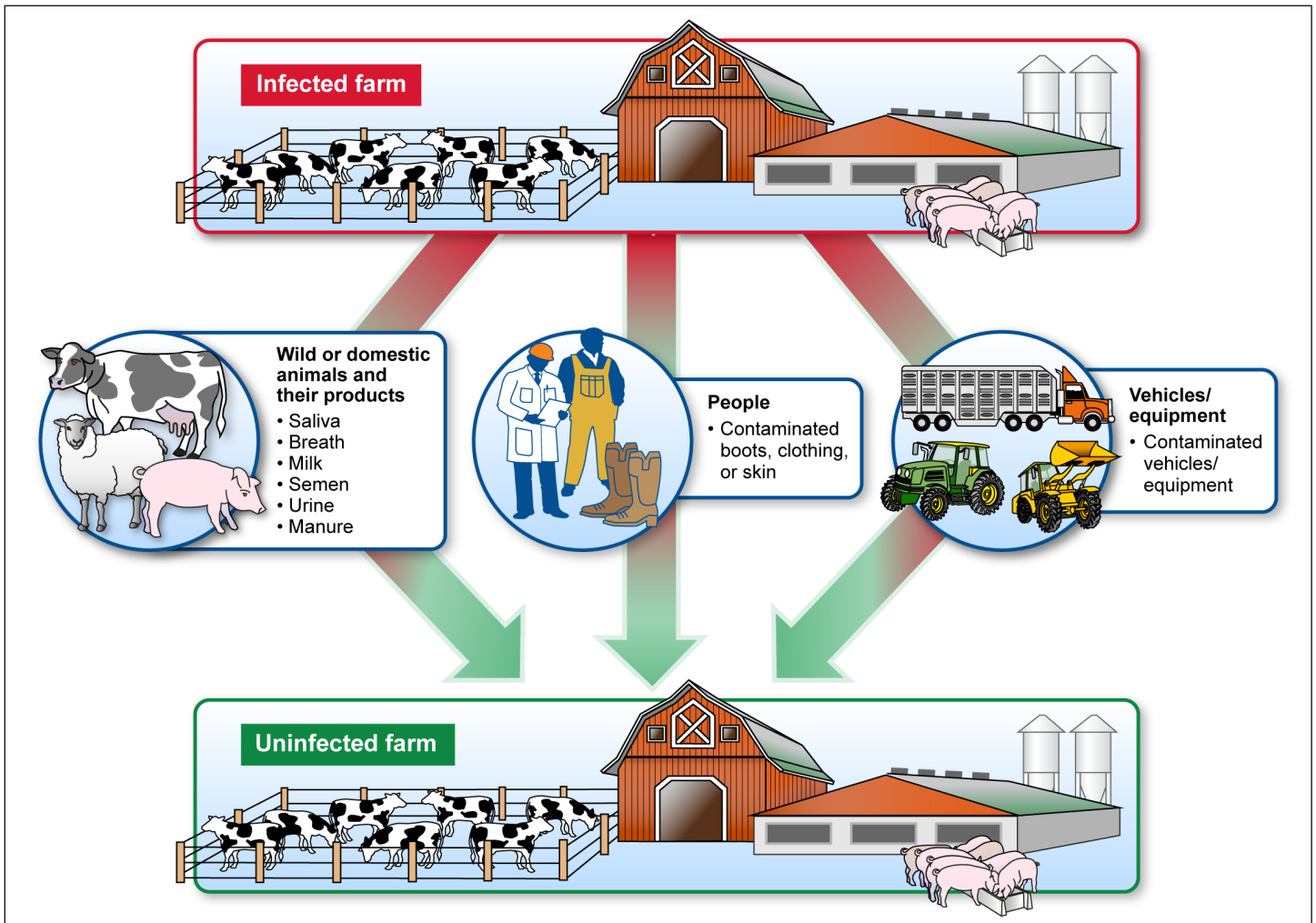


Sources: Plum Island Animal Disease Center (photos); GAO (illustrations). | GAO-19-103

FMD virus can be found in all secretions and excretions from infected animals, including in breath, saliva, milk, urine, feces, and semen, as well as in the fluid from the lesions.<sup>8</sup> Animals can release the virus for up to 4 days before showing visible signs of infection, and FMD can spread from one animal species to another. The virus itself can survive in the environment for many months and can spread when healthy animals come into contact with infected animals or via contaminated vehicles, equipment, clothes, feed, or animal products, as shown in figure 2.

<sup>8</sup>In cattle, the virus generally spreads through breath, and in pigs, it generally spreads through saliva or skin lesions.

**Figure 2: Ways in Which Foot-and-Mouth Disease Can Spread between Farms**



Sources: U.S. Department of Agriculture; GAO. | GAO-19-103

Note: FMD can also spread in other ways, such as when susceptible animals are fed raw or improperly cooked garbage (food waste) containing infected animal products or when they drink contaminated water.

The United States has not had an FMD outbreak since 1929, but the disease could be introduced here from countries in Africa, Asia, Eastern Europe, or South America where it is present. The United States is vulnerable to FMD transmission, given the large size and mobility of the U.S. livestock sector. In 2018, the United States had about 94 million head of cattle, 74 million swine, 5 million sheep, and more than 2 million goats. Many of these livestock are concentrated in major livestock-producing states such as Texas and Iowa, but livestock are present in

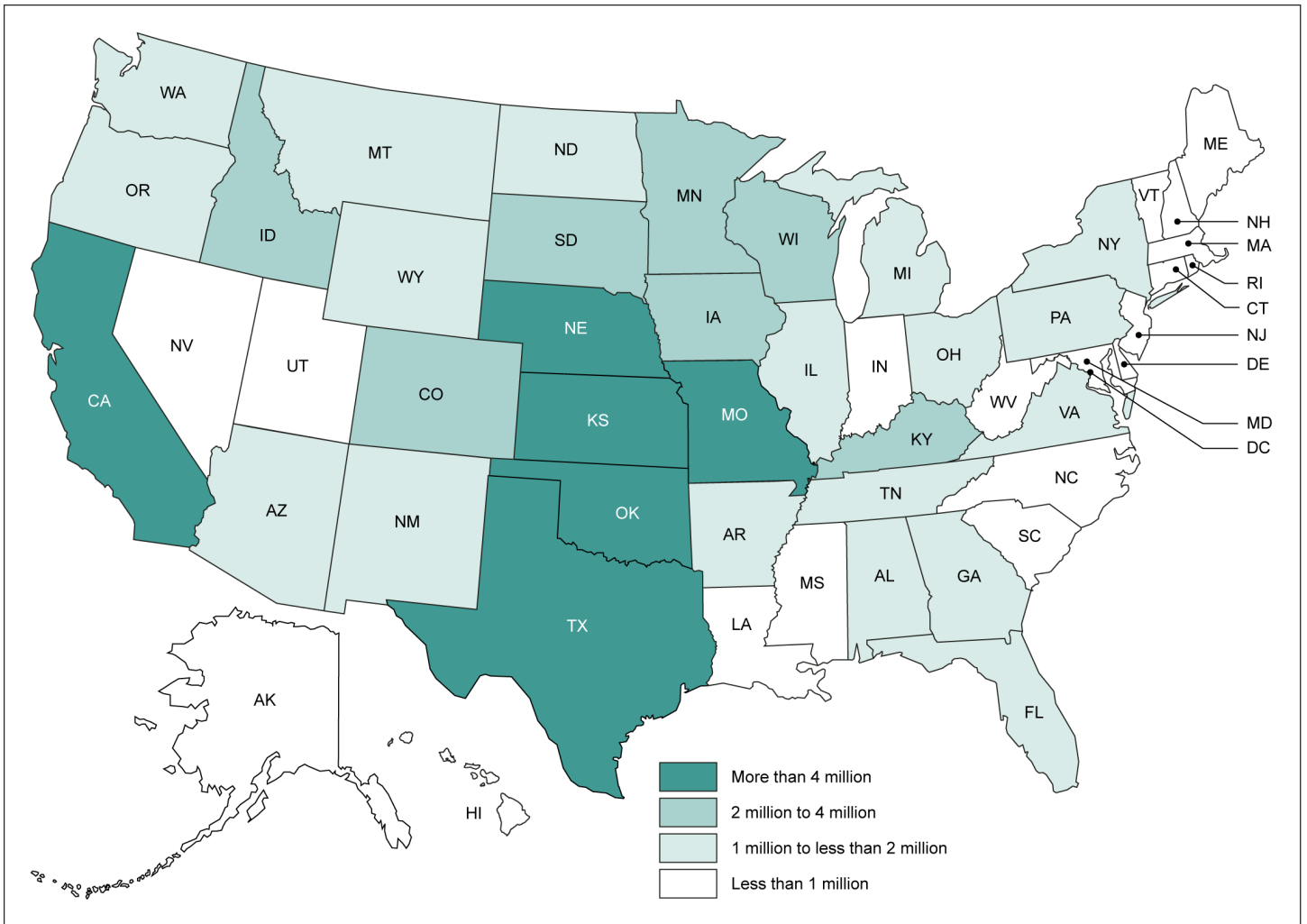
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every state. (See figs. 3 and 4 for the populations of cattle and swine by state.) According to USDA documents, a large percentage of livestock in the United States are kept on large farms, ranches, or feedlots (i.e., areas or buildings where livestock are fed and fattened up), some with capacity for 50,000 to 100,000 or more animals. Livestock are transported daily to feeding facilities, markets, slaughter plants, and other farms or ranches. For example, swine are often moved among multiple premises at different stages of their life spans to accommodate their growth in size, among other things. According to the swine industry, approximately 1 million swine are on the road every day in transit to various stages of the production process.<sup>9</sup>

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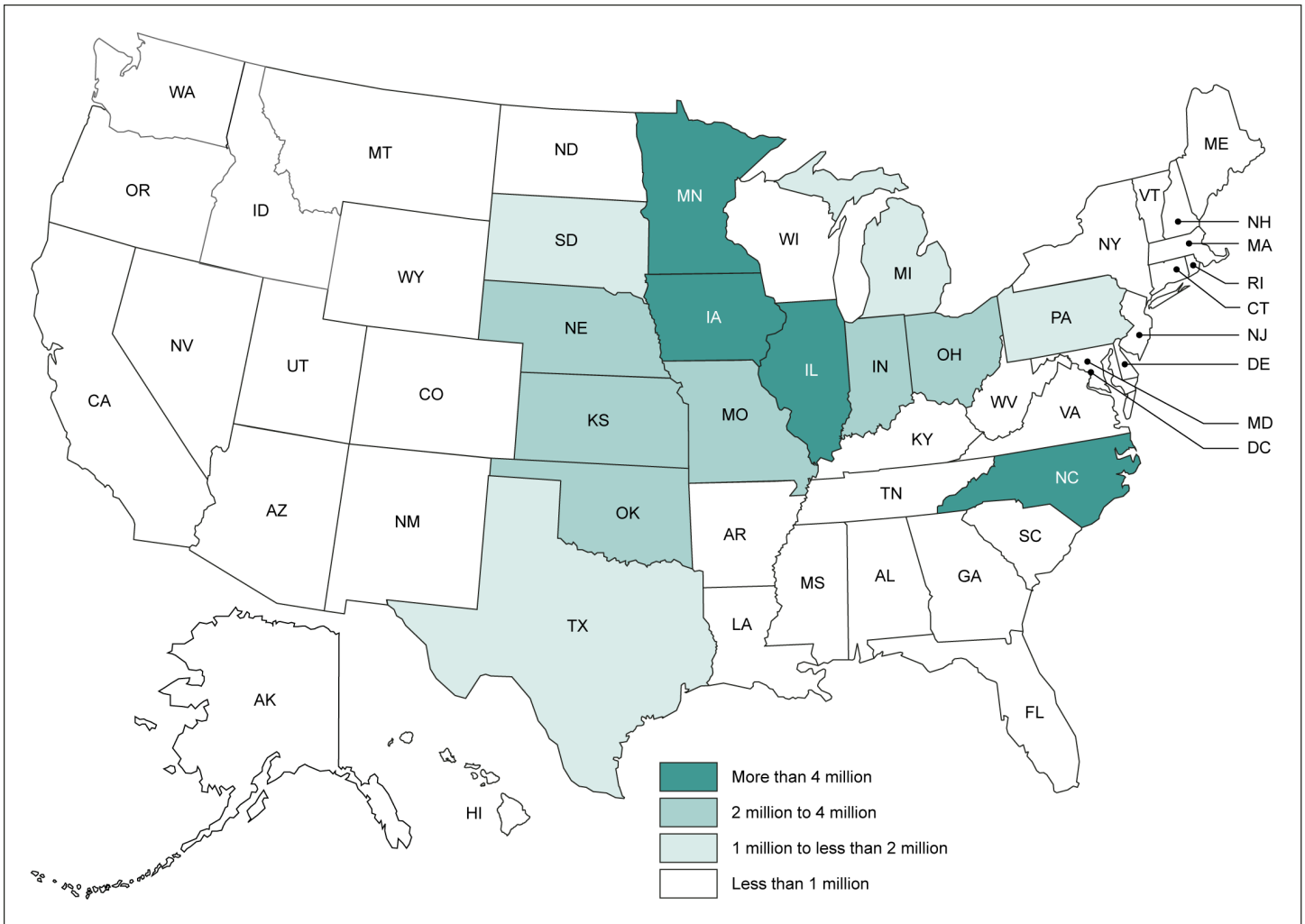
<sup>9</sup>Center for Food Security and Public Health, *Secure Pork Supply (SPS) Plan for Continuity of Business* (Ames, Iowa: August 2017).

**Figure 3: Cattle Population by State in 2018**



Sources: GAO analysis of U.S. Department of Agriculture National Agricultural Statistics Service data; Map Resources (map). | GAO-19-103

**Figure 4: Swine Population by State in 2017**



Sources: GAO analysis of U.S. Department of Agriculture National Agricultural Statistics Service data; Map Resources (map). | GAO-19-103

## Potential Impact of FMD Outbreak

An FMD outbreak in the United States could have serious economic consequences. A 2001 outbreak of FMD in the United Kingdom, for example, resulted in the killing of more than 6 million animals, with direct costs of more than \$3 billion to the public sector and more than \$5 billion

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to the private sector.<sup>10</sup> The extent of economic damage in the United States would depend primarily on the duration and geographic extent of the outbreak, the extent of trade disruptions, and how consumers reacted to the disease and associated control measures, according to USDA. In a large and long-lasting outbreak, control measures such as killing animals and halting the transportation of animals could cause significant losses for livestock operations. In addition, trade disruptions could have an enormous impact because U.S. exports of livestock, meat, and dairy products—together valued at more than \$19 billion in 2017 based on estimates from the U.S. Meat Export Federation and the U.S. Dairy Export Council—would likely stop or be sharply reduced. In addition, domestic consumers might be reluctant to purchase meat and animal products such as milk during an FMD outbreak, even though the products would be safe for people to consume, according to USDA.

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## USDA Activities to Respond to Outbreaks

Partly to protect the economic interests of the U.S. livestock industry, the Animal Health Protection Act authorizes USDA to detect, control, and eradicate diseases in livestock.<sup>11</sup> USDA's Animal and Plant Health Inspection Service (APHIS) is the lead agency for responding to outbreaks of foreign animal diseases, including FMD.<sup>12</sup> According to APHIS, in responding to an outbreak of FMD or any foreign animal disease, APHIS, in coordination with state and industry partners, would conduct the following activities, among others:

- **Surveillance.** Observing animals for visible signs of disease and analyzing data on locations and numbers of disease cases to detect premises with the disease, determine the size and extent of an outbreak, and determine whether outbreak control measures are working.

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<sup>10</sup>According to the United Kingdom's National Audit Office, tourism suffered a significant financial impact from the outbreak because potential visitors to Britain's countryside were deterred by the initial blanket closure of footpaths by local authorities and by media images of mass incineration of animal carcasses. National Audit Office, Comptroller and Auditor General, *The 2001 Outbreak of Foot and Mouth Disease*, HC 939 Session 2001-2002 (London: June 21, 2002).

<sup>11</sup>Farm Security and Rural Investment Act of 2002. Pub. L. No. 107-171, tit. X, subtit. E, §§ 10402, 10406 (codified as amended at (7 U.S.C. §§ 8302, 8306)).

<sup>12</sup>According to USDA, a foreign animal disease is a transboundary animal disease not known to exist in the U.S. animal population.



### Biosecurity

Biosecurity measures, which help minimize disease spread, include the following: placing signs indicating precautions personnel and visitors must follow; establishing sign-in procedures at entry points; removing dirt from boots and disinfecting them prior to entering a facility; using disposable personal protective equipment, such as Tyvek suits, gloves, masks, and boots, when entering premises; disposing of contaminated items properly; designating “clean” and “dirty” storage areas in vehicles; and controlling movement on and off premises.



Clean boots and coveralls.

Source: U.S. Department of Agriculture. | GAO-19-103

- **Epidemiologic tracing.** Gathering and analyzing data on cases of a disease, premises with such cases, movement of infected animals, and their potential contact with uninfected animals to locate other animals or premises with the disease, understand the outbreak’s rate and direction of spread, and investigate the source of the outbreak.
- **Diagnostic testing.** Conducting approved and validated assessments of samples taken from animals to identify infected animals or to demonstrate that healthy animals are free of disease.
- **Applying quarantines and stop-movement orders.** Restricting the movement of infected or potentially infected animals, animal products, and contaminated items to prevent the virus from spreading to healthy animals.
- **Employing biosecurity measures.** Taking steps, such as cleaning and disinfecting trucks that travel between premises, to contain the virus on infected premises and prevent it from spreading via objects or equipment that can carry infection.<sup>13</sup>
- **Stamping out and vaccination.** Killing infected animals and vaccinating uninfected animals—for example in buffer zones around infected premises—to limit the spread of the virus.
- **Compensating owners.** Paying owners fair market value for animals and equipment that the government determines must be destroyed to limit disease spread.

To help prepare for a potential FMD outbreak, APHIS and its partners conduct preparedness exercises in which officials practice responding to simulated FMD outbreaks. Such exercises range from small-scale, narrowly scoped exercises to full-scale, broadly scoped exercises. For example, some exercises focus on specific response tasks such as electronic messaging between laboratories or shipping response supplies to the field, and involve relatively few people for less than a day. Other exercises simulate a wide range of response activities that APHIS and its partners would use in an FMD outbreak, involve dozens of people from different agencies and industry organizations in locations across the country, and last for multiple days.

Multiple units within APHIS carry out these preparedness and response activities at the agency’s headquarters in Maryland; field offices in 27

<sup>13</sup>Biosecurity refers to procedures intended to protect humans or animals from exposure to disease, pests, or harmful biological agents.

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states and Puerto Rico; and the National Veterinary Services Laboratories in Ames, Iowa, and on Plum Island, New York.<sup>14</sup> APHIS's Foreign Animal Disease Diagnostic Laboratory on Plum Island, New York, develops and performs diagnostic tests for foreign animal diseases, including FMD.

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### Federal, State, Tribal, and Industry Roles Related to FMD Control

APHIS also works with federal agencies within and outside of USDA, along with states, tribes, and academic and industry partners—all of which have roles related to FMD control, as discussed below.

- **USDA's Food Safety and Inspection Service** is responsible for the safety of meat, poultry, and egg products. Agency officials assigned to slaughter establishments examine animals before processing to look for visible symptoms of FMD, among other things.
- **USDA's Agricultural Research Service** conducts research on agricultural problems of high national priority, including the FMD virus and FMD vaccine.<sup>15</sup>
- **USDA's National Institute of Food and Agriculture** invests in and conducts agricultural research, education, and extension to help solve national challenges in agriculture, food, the environment, and communities. The agency has funded modeling of FMD spread and research on potential economic impacts.
- **DHS** has funded research on FMD vaccine and development of response decisions tools, training, and equipment; sponsored preparedness exercises; and developed emergency plans, among other things. In an FMD outbreak, DHS may assume the lead for coordination of federal resources if the Secretary of Agriculture requests assistance from DHS. The Secretary of Homeland Security, in coordination with the Secretaries of Agriculture, Health and Human Services, the Attorney General, and the Administrator of the Environmental Protection Agency, is to ensure that the combined federal, state, and local response capabilities are adequate to

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<sup>14</sup>The National Bio and Agro-defense Facility, currently under construction in Manhattan, Kansas, will replace Plum Island's outdated facilities.

<sup>15</sup>USDA's National Institute of Food and Agriculture also supports and funds agricultural research, along with education and extension programs.

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respond quickly and effectively to a major disease outbreak, among other things, affecting the national agriculture or food infrastructure.<sup>16</sup>

- The **Department of the Interior** carries out disease surveillance of wild animals and coordinates surveillance activities with state fish and wildlife agencies, among other things. The Department of the Interior's U.S. Geological Service conducts research on wildlife diseases, including FMD, and if needed in an FMD outbreak, would administer diagnostic tests for wildlife.
- The **Federal Bureau of Investigation** coordinates the federal investigation of criminal activities through the Joint Terrorism Task Force. If animals, livestock, or poultry are suspected targets of a terrorist attack, or if any evidence suggests a foreign animal disease may have been or could be intentionally introduced, USDA notifies the Federal Bureau of Investigation to investigate.
- **State governments** prepare plans for foreign animal diseases, including FMD; conduct preparedness exercises; and would play a key role in a response effort. In an FMD outbreak, a state animal health official and an APHIS field official would co-lead initial response efforts. For example, state governments might take immediate actions, such as applying quarantines and stop-movement orders.
- **Tribal governments**, like state governments, would play a key role in initial response efforts and conduct activities similar to those of state governments.
- The **National Animal Health Laboratory Network** is a partnership of 59 federal, state, and university-associated animal health laboratories throughout the United States, of which 45 are approved to administer diagnostic tests for FMD.
- **Livestock industry organizations** support communication and education efforts with their members and the public, participate in FMD preparedness exercises, and have helped develop some FMD planning documents.

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## FMD Vaccines

As part of its response to an FMD outbreak, APHIS may access vaccine through the North American Foot-and-Mouth Disease Vaccine Bank (vaccine bank), which is jointly administered by the United States,

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<sup>16</sup>*Defense of United States Agriculture and Food*, Homeland Security Presidential Directive/HSPD-9, (Jan. 30, 2004).

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Mexico, and Canada.<sup>17</sup> Because finished vaccines have a short shelf life, the vaccine bank manages a supply of vaccine concentrate, which can be stored at extremely cold temperatures for about 5 years. Some of the concentrate is stored at the Foreign Animal Disease Diagnostic Laboratory on Plum Island, New York, and some at the manufacturer's facilities in Lyon, France.<sup>18</sup> During an FMD outbreak, the manufacturer would convert the concentrate into finished vaccine and ship it to the United States. For the concentrate stored in the United States, the vaccine bank would need to first ship it to the manufacturer overseas. APHIS's National Veterinary Stockpile coordinates logistics planning, particularly for catastrophic outbreaks, and would be responsible for delivering the finished vaccine to affected states, according to USDA planning documents.

The FMD virus has seven distinct variations, or serotypes, and more than 60 subtypes within the serotypes, according to USDA documents.<sup>19</sup> FMD vaccine should be as closely matched to the outbreak subtype as possible to provide more effective protection, according to USDA officials and a document on FMD vaccination. A vaccine for one FMD subtype may also provide good or partial immunity to other closely related subtypes, but it would not generally protect against other serotypes. The vaccine bank has concentrate for a number of FMD subtypes that pose the greatest risk to North American livestock based on recommendations from the World Reference Laboratory for FMD.<sup>20</sup>

We have previously reported on APHIS's management of foreign animal diseases, including FMD. For example, in May 2015, we recommended that USDA assess and address its veterinarian workforce needs for

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<sup>17</sup>The United States contributes 70 percent of the bank's funding, Mexico provides 20 percent, and Canada provides 10 percent. Each country is to have access to a percentage of FMD vaccine equal to the percentage of its contribution, according to the vaccine bank guidelines.

<sup>18</sup>FMD vaccine manufacturers are located overseas because of a statutory prohibition against having live FMD virus on the U.S. mainland. This prohibition does not apply to FMD vaccine concentrate, which does not contain live virus.

<sup>19</sup>Subtypes of FMD are closely related groups of individual strains, also known as topotypes, of the virus. A serotype is one way to group subtypes with similar surface structures.

<sup>20</sup>The World Reference Laboratory for FMD is located at the Pirbright Institute in the United Kingdom. USDA does not publish the exact inventory of the vaccine bank for national security reasons.

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emergency response to an outbreak of an animal disease such as FMD.<sup>21</sup> USDA agreed, in part, with the recommendation, and in 2017 hired additional veterinarians. The agency is currently building a model to develop workforce estimates for a large-scale FMD outbreak, according to agency officials.

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## USDA's Planned Approach Calls for Outbreak-Specific Strategies, Using Overarching Guidance to Implement the Strategies

USDA's planned approach for responding to an FMD outbreak relies on several different strategies emphasizing stamping out, vaccination, or both, depending on factors such as the size of the outbreak. To aid agency officials in implementing the strategies, USDA has developed overarching guidance for responding to animal disease outbreaks and detailed procedures for many response activities.

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## USDA's FMD Response Strategies Emphasize Stamping Out or Vaccination, Depending on Factors Such as Outbreak Size and Resource Availability

USDA's APHIS has developed several different, but not mutually exclusive, outbreak response strategies that the agency will consider to control and eradicate FMD in an outbreak as part of its planned approach, according to USDA documents and officials. These strategies rely on stamping out—killing and disposing of—infected and susceptible animals, vaccination of uninfected animals, or both. For strategies involving vaccination, options include killing and disposing of vaccinated animals (vaccinate-to-kill), allowing the animals to be slaughtered and their meat processed (vaccinate-to-slaughter), or allowing the animals to live out their useful lifespan (vaccinate-to-live).<sup>22</sup> Response strategies would likely change as an outbreak unfolds, and might also vary by region or type of animal affected, according to APHIS planning documents.

Over time, USDA's FMD planned approach has evolved from relying solely on stamping out to including vaccination strategies as it became apparent that in many potential scenarios, reliance on stamping out alone

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<sup>21</sup>GAO, *Federal Veterinarians: Efforts Needed to Improve Workforce Planning*, GAO-15-495 (Washington, D.C.: May 26, 2015).

<sup>22</sup>During an FMD outbreak, USDA might vaccinate animals that would later be slaughtered or killed to prevent them from transmitting the disease in the interim.

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would not be effective or feasible. Specifically, in 2010, USDA's *Foot-and-Mouth Disease Response Plan: The Red Book* (Red Book) first stated that APHIS would consider vaccination strategies such as vaccinate-to-slaughter and vaccinate-to-live.<sup>23</sup> In 2014 APHIS updated the Red Book with the addition of a vaccinate-to-kill strategy to better distinguish what would happen to animals if they were not eligible for slaughter. By 2016, USDA had determined that complete stamping out of anything beyond a small FMD outbreak was not a viable, effective, or sustainable response strategy for the United States, according to USDA's FMD vaccination policy.<sup>24</sup>

Experiences in preparedness exercises and foreign outbreaks of FMD influenced a shift in USDA's planned approach toward vaccination strategies. In 2010, Japan and South Korea both experienced FMD outbreaks and initially relied on stamping out combined with strict movement restrictions. Japan stamped out about 300,000 cattle and swine, and South Korea stamped out about 150,000 cattle and 3 million swine—a third of the country's total swine population. Despite these efforts, FMD continued to spread in both countries until they implemented vaccination strategies, according to USDA documents. A 2007 FMD preparedness exercise, sponsored by the Texas Animal Health Commission and USDA, found that killing and disposing of infected animals in a livestock-dense area like the Texas panhandle would not be feasible in a timely manner because of the large number of animals on infected premises (e.g., 50,000 to 75,000 head of cattle on large cattle feedlots). USDA learned that having vaccination strategies in place would be necessary to effectively respond to an FMD outbreak.

If an FMD outbreak occurred, APHIS would select a response strategy or multiple strategies, or it would modify strategies to achieve its FMD response goals based on the unique circumstances of the outbreak, according to agency planning documents.<sup>25</sup> APHIS would do so in consultation with affected states and tribes, and if the agency chose to

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<sup>23</sup>U.S. Department of Agriculture, *Foot-and-Mouth Disease Response Plan: The Red Book*.

<sup>24</sup>This did not require a change to the Red Book because it was a determination about how USDA would apply its strategies, according to a USDA official.

<sup>25</sup>The FMD response goals are to (1) detect, control, and contain FMD as quickly as possible; (2) eradicate FMD using strategies to stabilize animal agriculture, the food supply, the economy, and to protect public health; and (3) provide science- and risk-based approaches and systems to facilitate continuity of commerce in uninfected animals.

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use vaccine, states would request it from USDA.<sup>26</sup> According to agency planning documents we reviewed, APHIS would consider a number of factors when deciding on its approach, including the following:

- FMD vaccine availability;
- consequences of the outbreak (e.g., trade restrictions or loss of valuable genetic stock);
- public acceptance of response strategy or strategies;
- scale of the outbreak (i.e., number and size of infected premises);
- rate of outbreak spread;
- location of initial outbreak (e.g., isolated ranch versus livestock-producing area);
- movement of animals (number of locations that infected or potentially infected animals have traveled to or through); and
- federal and state resources available to implement response strategies.

Resource needs vary among strategies and generally increase with the scale of an outbreak, according to USDA planning documents. Having the necessary resources available to implement a stamping-out response strategy would include having qualified personnel to kill animals in accordance with accepted protocols and having appropriate disposal facilities. To implement strategies involving vaccination, APHIS would need a sufficient quantity of vaccine, the resources for distributing and administering the vaccine, and the diagnostic tests necessary to distinguish between vaccinated and infected animals, according to USDA's FMD vaccination policy. If the scale of an outbreak were small,<sup>27</sup> and APHIS had access to sufficient resources, agency officials would likely implement a stamping-out strategy in an attempt to quickly stop the production of virus in infected animals and limit the outbreak's spread, according to agency planning documents. However, these planning documents indicate that if the outbreak grew to a moderate regional, large

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<sup>26</sup>The use of emergency vaccination will be determined by the Unified Command, state animal health officials, and APHIS's Veterinary Services Deputy Administrator (U.S. Chief Veterinary Officer), according to USDA documents.

<sup>27</sup>USDA defines a focal FMD outbreak—what we call a small outbreak—as “limited to one State or small region with low to moderate livestock numbers on relatively small premises.”

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regional, national, or catastrophic scale,<sup>28</sup> the resources required for killing all infected and potentially infected animals, disposing of carcasses, and paying compensation to livestock owners would quickly multiply, and APHIS policy calls for strategies focused on vaccination, according to USDA documents.

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### USDA Has Developed a Range of Documents to Guide Its FMD Response Strategies

Over time, USDA's APHIS has developed various documents to guide its response to FMD, including overarching guidance for responding to FMD and other foreign animal diseases, procedures with in-depth operational details, and plans to secure the nation's food supply. To aid agency officials in implementing FMD response strategies broadly, APHIS has developed FMD response plans and guidance for responding to foreign animal disease outbreaks more generally. For example, the Red Book describes USDA's FMD response strategies; identifies the capabilities needed to respond to an FMD outbreak; and provides guidance on the critical activities required during the response, including time frames for these activities. The Red Book is intended for responders at all levels of government and industry partners. For example, if a state official or a livestock owner wanted to know the steps to test and confirm a positive case of FMD, the Red Book explains the process and has a flowchart to illustrate the steps. APHIS also has developed response manuals that provide guidance relevant to foreign animal disease outbreaks, including FMD. For example, a manual on roles and coordination provides an overview of USDA's framework for incident management, funding, communication strategies, relationships, and authorities during a foreign animal disease outbreak, including an FMD outbreak.<sup>29</sup> APHIS also has produced ready reference guides that condense guidance material from

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<sup>28</sup>USDA defines a moderate regional FMD outbreak as "A few focal areas of infection limited to a region with low to moderate livestock numbers on small to medium size premises." USDA defines a large regional FMD outbreak as one in which "Multiple areas of infection in a region, or the type, number and/or size of infected and contact herds are too great to depopulate quickly enough to suppress disease spread." USDA defines a widespread or national FMD outbreak as one in which "Widespread areas of infection are detected involving too many herds or herds that are too large to depopulate quickly enough to suppress disease spread." USDA defines a catastrophic FMD outbreak as one in which "Widespread areas of infection are detected involving a large portion of the United States."

<sup>29</sup>U.S. Department of Agriculture, *APHIS Foreign Animal Disease Framework: Roles and Coordination* (Washington, D.C.: September 2016).



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these broader documents into short summary documents for training and education purposes.<sup>30</sup>

In addition, APHIS has developed standard operating procedures (SOP) for many response activities. Some SOPs are specific to an FMD outbreak, and others provide more general instruction on activities to respond to foreign animal diseases. The FMD biosecurity SOP, for example, describes steps responders at all levels of government and industry partners can take to help prevent the spread of the virus, such as protocols for putting on and taking off personal protective equipment (e.g., coverall suits, boots, and gloves); standards for separating “clean” and “dirty” zones in vehicles and on premises; and instructions for cleaning and disinfecting vehicles before arrival at and after departure from different premises.<sup>31</sup>

Many of the more general SOPs have proven useful during outbreaks of other animal diseases and exercises simulating FMD outbreaks, according to APHIS and state government officials, and APHIS has revised them to incorporate lessons learned. For example, one state animal health official said that during the 2014 avian influenza outbreak, the SOP for disposing of poultry carcasses through composting was initially insufficient because the poultry industry had not previously been composting in all states.<sup>32</sup> To improve consistency across states, APHIS updated protocols during the outbreak and created composting protocols for avian influenza-infected flocks and livestock to supplement the agency’s disposal SOP, which addresses carcass disposal for foreign

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<sup>30</sup>For example the *Ready Reference Guide—Overview of the FMD Response Plan: The Red Book* includes information on the goals of FMD response, the epidemiological principles that will guide the response effort, the different strategies that may be used, and the factors influencing which FMD strategy is chosen. The *Ready Reference Guide—Quarantine, Movement Control, and Continuity of Business* provides information on how these critical activities will be managed in order to control and contain the FMD virus in an outbreak while facilitating the movement of uninfected animals and uncontaminated animal products. See U.S. Department of Agriculture, *Ready Reference Guide—Overview of the FMD Response Plan: The Red Book* (Washington, D.C.: November 2015), and *Ready Reference Guide—Quarantine, Movement Control, and Continuity of Business* (Washington, D.C.: December 2015).

<sup>31</sup>U.S. Department of Agriculture, *Standard Operating Procedures: 9. Biosecurity*, Draft (Riverdale, M.D.: November 2013).

<sup>32</sup>The first detection of highly pathogenic avian influenza occurred in December 2014. Additional associated detections occurred through June 2015. In this report, we refer to those events as the 2014 outbreak.

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animal diseases generally.<sup>33</sup> These composting protocols expanded on and clarified guidance to be used in subsequent outbreaks. In addition, APHIS held training on composting procedures for birds and on large animal composting, which could be part of an FMD response.

USDA, in coordination with industry, state, federal, and academic representatives, has also developed supply plans to secure the nation's food supply and keep businesses operating during an FMD outbreak while managing the risk of spreading the virus, which would decrease the economic impact of an outbreak. To date, USDA and its industry and university partners have developed Secure Milk Supply and Secure Pork Supply plans and have partially completed a Secure Beef Supply plan.<sup>34</sup> These plans guide industry on managing uninfected premises and uninfected animals during an FMD or other foreign animal disease outbreak. For example, the Secure Milk Supply plan has guidance on what producers can do to continue moving shipments of milk during an outbreak, including how to implement enhanced biosecurity plans to prevent the spread of FMD to their facilities. The sheep industry is currently developing its own secure food and wool supply plan, according to industry representatives.

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<sup>33</sup>U.S. Department of Agriculture, *Standard Operating Procedures–14. Disposal* (Washington, D.C.: January 2014).

<sup>34</sup>Center for Food Security and Public Health, *Secure Milk Supply (SMS) Plan for Continuity of Business* (Ames, Iowa: August 2017); *Secure Pork Supply (SPS) Plan for Continuity of Business* (Ames, Iowa: August 2017); and *Secure Beef Supply (SBS) Plan for Continuity of Business* (Ames, Iowa: August 2017).

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## USDA Would Likely Face Significant Challenges in Pursuing Its FMD Response Goals, Particularly regarding Vaccination

USDA would likely face significant challenges in pursuing its FMD response goals of detecting, controlling, and containing FMD as quickly as possible; eradicating FMD using strategies that seek to stabilize animal agriculture industries and the economy; and facilitating continuity of commerce in uninfected animals. We identified 11 challenge areas, based on our review of USDA documents, interviews with agency officials and others with expertise with FMD, and 29 responses to our questionnaire.<sup>35</sup> A majority of respondents indicated that in 10 of the 11 areas USDA would face challenges that are significant—that is, important enough to be worthy of USDA action. (See app. I, fig. 7, for a summary of the responses.) For the 11th area, which is communication and coordination, opinions were split on whether the area would present significant challenges. The 11 challenge areas, which sometimes overlap or fall outside of USDA's direct control, are described below. Examples of actions USDA is taking to address these challenges are described later in this report.

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## Surveillance

USDA would likely face surveillance challenges that could delay detection of the first cases in an FMD outbreak. A majority (22 of 29) of respondents to our questionnaire indicated that USDA would face significant challenges in this area. FMD can spread without detection for the following reasons:

- there is no active surveillance for FMD,<sup>36</sup>
- animals may not have visible signs until up to 4 days after becoming infected,
- signs can be difficult to notice in some species, and
- infected wild animals could go undetected and spread the virus.

For initial detection of an FMD outbreak, USDA relies on passive surveillance, waiting for producers or veterinarians to notice and report

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<sup>35</sup>We received responses from federal government officials, state government officials, industry representatives, and academic researchers. For further details on our questionnaire and responses, see app. I.

<sup>36</sup>Active surveillance involves actively looking for signs or seeking clinical diagnoses for specific disease agents in specific populations. In contrast, passive surveillance relies on astute clinicians and other existing systems to detect signs or symptoms of disease outbreaks, which often trigger further investigation to identify and characterize disease outbreaks.

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visible signs. In contrast, for initial detection of other diseases, such as bovine spongiform encephalopathy (commonly known as mad cow disease), USDA has active surveillance programs in which animals are routinely tested regardless of visible signs.<sup>37</sup> According to USDA officials, the cost and resources required to conduct active surveillance for initial detection of an FMD outbreak would not be justified because the United States has not had an FMD outbreak for decades and there is a risk that false positives could create unnecessary disruptions. However, the officials said the agency would likely use active surveillance during an outbreak.

Passive surveillance, however, may not allow for timely detection of the initial cases of FMD, particularly in sheep. FMD infection in sheep often causes only mild signs or symptoms, such as an elevated temperature or loose stool, and in some cases will not cause any overt signs or symptoms at all, even though the animal may be spreading the virus, according to representatives of the sheep industry. Therefore, an FMD outbreak could become widespread before USDA detects the first cases.

Even if responders are able to detect FMD in domesticated animals before an outbreak becomes widespread, wild animals may become infected and spread the virus, posing additional challenges for USDA and its partners. For example, the U.S. population of feral swine, which are susceptible to FMD, is estimated at 6 million and is rapidly expanding, according to APHIS. Detecting and controlling infected wild animals could be extremely difficult, according to agency officials, and if not controlled, these populations could serve as carriers for the disease. In addition, limitations in diagnostic capabilities, discussed below, could hamper the availability of data needed for surveillance, such as accurate information on new cases of FMD.

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## Diagnostic Capabilities

USDA would likely face challenges related to its capability to diagnose FMD. Such challenges include the lack of validated population-level diagnostic tests and potentially insufficient resources to collect samples and perform diagnostic testing in a large outbreak.<sup>38</sup> A majority (24 of 29) of respondents to our questionnaire indicated that USDA would face

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<sup>37</sup>USDA samples approximately 40,000 animals each year for bovine spongiform encephalopathy to meet requirements of the World Organisation for Animal Health.

<sup>38</sup>Population-level diagnostic tests involve testing samples from many animals at once.

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significant challenges in this area. Currently, during an FMD outbreak, USDA would rely on individual animal testing, given that it has not validated any diagnostic tests that can be used for a group or population of animals, according to USDA's surveillance SOP. If an FMD outbreak expands, the ability to test a large number of animals quickly with minimal resources would be useful for USDA. In a 2017 study of the potential uses of a bulk milk test for FMD in dairy cattle, for example, USDA found that 720 bulk milk tests could replace over 35,000 individual animal tests with the same level of confidence in disease status. However, the study identifies additional work needed to implement bulk milk tests.

USDA and state officials investigate suspected cases of FMD on previously uninfected premises, according to USDA documents. To do so, USDA or state officials travel to the suspected premises—sometimes over long distances—collect samples from the animal or animals, and send them to a qualified laboratory for diagnostic testing.<sup>39</sup> During an outbreak, massive quantities of diagnostic testing may need to be conducted, straining the capacity of federal and state laboratories that are qualified to investigate suspected cases of FMD, and potentially causing delays in detecting infected premises, according to both an after-action report for a preparedness exercise and agency officials. In addition, USDA officials we interviewed expressed concern that diagnostic kits used for these individual animal tests would be in short supply during an outbreak and said that they do not currently know how much time it would take for manufacturers to produce more. In the event of a large FMD outbreak, delays in getting diagnostic results could slow USDA's ability to detect, control, and contain an outbreak.

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## Information Management

USDA would likely face challenges in the area of information management during an outbreak, including incompatible data systems at the state and federal levels or between diagnostic laboratories and USDA and responders who lack familiarity with USDA data systems. A majority (20 of 29) of respondents to our questionnaire indicated that USDA would face significant challenges in this area.

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<sup>39</sup>For an FMD investigation, agency officials must send one sample to one of USDA's National Veterinary Services Laboratories, where laboratory officials would administer confirmatory tests. Agency officials may also send a second sample to one of the 45 National Animal Health Laboratory Network laboratories approved to conduct FMD diagnostic testing.

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USDA and state data systems track information on registered livestock premises and animals. In addition, USDA has an emergency response database for collecting and analyzing data on disease outbreaks and managing response resources. However, state data systems cannot always communicate directly with USDA's data systems because they use different software, according to two state animal health officials. Such impediments to communication could delay information sharing about the location of infected and susceptible animals. One industry representative said that such delays could prolong decisions about permits for uninfected animals to move, disrupting industries' continuity of business. According to an academic researcher, interruptions in movement of animals could cause processing facilities to either close, operate at a diminished capacity, or be overwhelmed by a backlog of animals once movement is restarted, leading to animal welfare concerns. These disruptions could present challenges for USDA to facilitate continuity of commerce in uninfected animals, one of its response goals.

USDA's ability to control an outbreak could also be impaired if responders lack familiarity with USDA data systems. For example, according to a USDA after-action report, during the 2014 avian influenza outbreak, some responders were unfamiliar with USDA's system for entering outbreak response information, resulting in incorrect usage or underutilization of the system. As a result, USDA's overall response was slower than it would have been if timely information had been available.

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## Animal Traceability

USDA would likely face challenges related to the traceability of animals (i.e., the ability to trace their locations and movements) after an outbreak was detected. We found that these challenges result from insufficient use of identification numbers for livestock premises (such as farms and ranches) and individual animals to enable tracing of infected, exposed, and susceptible animals, and from identification numbers that cannot be easily read (e.g., because they are not electronic). A majority (25 of 29) of respondents to our questionnaire indicated that USDA would face significant challenges in this area. In an outbreak, responders would use premises and animal identification numbers, if available, to trace the location and movements of infected animals to identify other animals that may have been exposed. They would also use the identification numbers to locate all susceptible animals in the region, in order to notify owners about the outbreak and any response measures in place, such as stop-movement orders. These activities would be hampered without the identification numbers. For example, Iowa and Texas regulations do not require producers to register all of their animals with the state. Also,

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record keeping varies at individual farms and ranches, where some producers have electronic records, but others have no written records or rely on hand-written paper documents, according to USDA documents. Searching through records by hand at individual farms could take days rather than the hours that it would take if the records were electronic, according to a USDA planning document. Without timely and accurate tracing through the use of premises and animal identification numbers, USDA may face challenges controlling and containing an FMD outbreak and facilitating continuity of commerce in uninfected animals.

In addition, some animals have identification numbers on ear tags that must be read visually, which could slow USDA's efforts to control and contain an outbreak. In an outbreak, responders would need to inspect animals with such ear tags to manually read and record the identification numbers for individual animals. In contrast, for animals with electronic tags, responders could use electronic readers, which can accurately read identification numbers for a group of animals from a distance of up to 12 feet, according to a 2016 USDA study on electronic identification for livestock.<sup>40</sup> One industry representative said that the beef cattle industry has not widely implemented electronic identification because it is difficult for many operators to justify the added cost of purchasing and attaching an electronic tag for each animal.<sup>41</sup>

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## Biosecurity

In an FMD outbreak, USDA would likely face biosecurity challenges including lack of sufficient biosecurity on some premises, difficulty in implementing biosecurity measures for certain species, and lack of documentation (such as a written plan) specifying what measures are currently in place. A majority (20 of 29) of respondents to our questionnaire indicated that USDA would face significant challenges in this area. If sufficient biosecurity measures are not consistently in place on farms, ranches, and feedlots, people and vehicles may inadvertently spread the FMD virus when they travel among premises, impeding USDA's ability to control and contain an outbreak. For example during the 2001 FMD outbreak in the United Kingdom, poor biosecurity and livestock owners' movements between scattered farms led to the introduction of

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<sup>40</sup>U.S. Department of Agriculture, *Ultra-High Radio Frequency Identification Demonstration Project Summary and State Reports* (Washington, D.C.: August 2016).

<sup>41</sup>In the dairy industry, it is more common to use electronic animal identification, according to an industry representative. For example, dairy cattle often have electronic tags to track data on cows' milk production, health, and genetics.

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FMD in previously uninfected areas, according to a 2002 report by the United Kingdom's National Audit Office.<sup>42</sup>

Some livestock owners have not implemented extensive biosecurity measures on their premises, in part because they have not experienced a recent animal disease outbreak and measures may be difficult or expensive to implement, according to an industry representative. In addition, it may be difficult to implement biosecurity measures for certain species. For example, cattle feedlots operate outdoors and may have unrestricted points of entry and exit, so it can be more difficult and costly to control access and implement other biosecurity measures.

In addition, even if producers have biosecurity measures in place, these measures may not be sufficiently documented to facilitate continuity of commerce in uninfected animals. According to USDA guidance documents, during an FMD outbreak, premises in areas with movement restrictions will be required to obtain permits to move any animals or animal products. To obtain such a permit, producers must show that they are not contributing to the spread of disease or putting their animals at risk of exposure, and producers without documented biosecurity plans may face delays moving their animals. According to swine industry representatives, even swine farms with biosecurity procedures do not always document such procedures or the steps they have taken.

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## Depopulation

USDA would likely face depopulation challenges during an FMD outbreak, including limited capability for killing large numbers of animals in a timely manner and difficulties owing to the large size of some animals affected by FMD.<sup>43</sup> A majority (22 of 29) of respondents to our questionnaire indicated that USDA would face significant challenges in this area. For example, USDA officials said killing animals in large feedlots—which can hold 50,000 or more animals—would quickly overwhelm resources, such as the staff and equipment required to kill animals. USDA policy calls for depopulating infected premises within 24 hours, but this may not be feasible on large livestock operations because the animals have to be killed individually, which would be time-consuming

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<sup>42</sup>National Audit Office, Comptroller and Auditor General, *The 2001 Outbreak of Foot and Mouth Disease*.

<sup>43</sup>Depopulation is the killing of animals in large numbers in response to an animal disease outbreak.



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according to an industry representative.<sup>44</sup> If infected premises are not quickly depopulated, animals will continue producing the virus and increase the risk of infecting animals on additional premises, hampering USDA's ability to control and contain an outbreak. Rapid depopulation of infected swine is particularly critical to containing the spread of an outbreak because swine are known as amplifiers of FMD virus, producing and excreting 3,000 times more virus than cattle or sheep, according to USDA documents.

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## Carcass Disposal

USDA would likely face disposal challenges during an FMD outbreak, including the feasibility and logistics of disposing of a large number of animal carcasses, public concern about disposal options, and the environmental impacts of disposal. A majority (25 of 29) of respondents to our questionnaire indicated that USDA would face significant challenges in this area.

In a large FMD outbreak, millions of cattle could be affected. It is possible that FMD can survive for several months on a frozen carcass, according to USDA documents, so if such carcasses are not disposed of properly, they could pose a risk for spreading FMD, hampering USDA's efforts to control and contain an outbreak. Disposing of the carcasses of a 50,000-head herd of cattle from a large feedlot would be a massive effort: the total weight for disposal could be as much as 30,000 tons, or about 1,500 dump truck loads to move all the animals to disposal sites, according to an industry representative. One state animal health official stated that disposal of one or two herds may be possible, but if an outbreak were more widespread, the state would quickly run out of options.

In addition, certain disposal strategies, such as incinerating large piles of carcasses, may cause a negative public reaction, according to an industry representative, USDA's disposal SOP, and state animal health officials. Figure 5 illustrates carcass disposal during a 2001 FMD outbreak in the United Kingdom, where the government implemented a policy of stamping out all susceptible animals within 3 kilometers of known FMD cases. In reaction to the policy, the public staged protests, and

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<sup>44</sup>For example, a 2007 after-action report for an FMD preparedness exercise estimated that it could take 3 minutes per head to kill cattle. At this rate, and with 10 sites operating 24 hours a day, it would take 11.5 days to depopulate 55,000 head of cattle. See The CNA Corporation, *Operation Palo Duro: Policy and Decision-making in Response to an FMD Outbreak* (May 2007).

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businesses in rural areas lost customers who stayed away because of the striking images in the media, according to a 2002 report by the University of Newcastle.<sup>45</sup>

**Figure 5: Livestock Carcass Disposal in the United Kingdom during the 2001 Foot-and-Mouth Disease Outbreak**



Source: Dr. Pam Hullinger, Director of the California Animal Health and Food Safety Laboratory. | GAO-19-103

Finally, carcass disposal can create environmental impacts, such as when a burial site contaminates the groundwater or incineration contaminates the air. In general, states regulate disposal, including such things as the timing (e.g., within 24 hours of an animal's death) and the method of disposal (e.g., prohibiting outdoor incineration or specifying that up to 7 cattle may be buried per acre per year). In an FMD outbreak, large numbers of carcasses could make it difficult to comply with such regulations.

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## Resources

USDA would likely face resource challenges in pursuing its FMD response goals, including insufficient numbers of incident responders to effectively implement USDA strategies in a medium or large outbreak, as well as insufficient resources devoted to preparedness planning in some states. A majority (23 of 29) of respondents to our questionnaire indicated that USDA would face significant challenges in this area.

During the 2014 avian influenza outbreak, there were difficulties quickly providing response resources, such as personnel and equipment, to

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<sup>45</sup>Centre for Rural Economy, University of Newcastle, *Coping with Crisis in Cumbria: Consequences of Foot and Mouth Disease* (Newcastle, United Kingdom: January 2002).

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rapidly stamp out affected flocks, according to a USDA after-action report. According to an academic researcher, an FMD outbreak would be significantly more difficult to handle than recent avian influenza outbreaks. One state official noted that in his state there is not enough of a workforce to adequately respond to an outbreak, and there is no assigned workforce at the local level. For example, this official noted that his state employed only two veterinarians and a few animal health technicians to collect samples for testing in the event of an FMD outbreak. Other state animal health officials expressed concern that states and counties will have difficulty fielding adequate workforces to inspect animal transport vehicles and implement stop-movement orders.

Insufficient preparedness planning in some states could also hamper response efforts, according to a response to our questionnaire from an academic researcher with expertise in FMD preparedness. Some states have not allocated resources to develop FMD response plans, including, for example, the conditions that would trigger a stop-movement order. States typically control intrastate movement under the state's authority, and if states delay issuing stop-movement orders, it may be more difficult for USDA to control and contain an outbreak.

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## Communication and Coordination

Communication and coordination may be an area where USDA could face challenges during an FMD outbreak because of ineffective external or internal communications and unclear roles and responsibilities. Responses to our questionnaire in all categories (federal and state government officials, industry representatives, and academic researchers) were mixed about whether communication and coordination was an area with significant challenges. Specifically, 11 respondents said it was an area with significant challenges, 12 said it was not, and 6 were unsure. One industry respondent who said that the area was not a challenge cited a team of industry representatives that is working with USDA and states to prepare for an FMD outbreak. On the other hand, during a 2016 FMD preparedness exercise in Texas, coordination between USDA and other participants was at times inadequate. For example, during the exercise USDA and the Texas Animal Health Commission shared leadership of the response effort, and some respondents cited frustration with this top-down leadership structure because they were accustomed to emergency management practices and protocols designed for incidents such as natural disaster response efforts, which are generally initiated at the local level. Participants commented that they were confused about who did what and said that coordination needs to be improved between USDA and local

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governments, according to an after-action report.<sup>46</sup> Also, communication across participating agencies broke down. For example, information from USDA on stop-movement orders, the size of the quarantine zone, and the number of sites quarantined did not reach all stakeholders in a timely manner, according to an after-action report.

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## Appraisal and Compensation

Compensating livestock owners for animals or equipment that the government determines must be destroyed to limit the spread of FMD would likely pose various challenges for the agency. USDA would provide the owners with up to 100 percent of the expenses of purchase, destruction, and disposition of animals or materials required to be destroyed, based on the agency's appraisal of the fair market value. Doing so would likely pose various challenges for the agency, according to USDA and state government officials. A majority (19 of 29) of respondents to our questionnaire indicated that USDA would face significant challenges in this area. Such challenges include uncertainties about fair appraisal methods (especially when an outbreak has caused livestock prices to decline), owners resisting killing their animals if compensation rates are too low, and the potentially massive scale of compensation payments. According to USDA economists, if trade restrictions were imposed during an FMD outbreak, the fair market value of animals and their products would likely drop as a result of oversupply. USDA's response to the outbreak could be slowed if producers brought legal challenges to stop the stamping out of their herds because they were not satisfied with compensation levels, a scenario that took place in a 2018 USDA-led exercise simulating the first few days of an FMD outbreak. Moreover, in a widespread FMD outbreak, the scale of federal compensation payments could be substantial. For example, in the 2001 United Kingdom FMD outbreak, compensation costs were estimated at over \$1 billion for the killing of about 6 million animals. Given the larger size of the livestock industry in the United States, federal compensation costs could be much higher, depending on the number of animals killed as part of the response.

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## Vaccination

USDA would likely face challenges related to vaccination, an area of particular importance given vaccination's central role in USDA's strategies

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<sup>46</sup>Federal Emergency Management Agency, *Palo Duro II Functional Exercise After-Action Report* (September 2016).

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for pursuing its response goals. All 29 respondents to our questionnaire agreed that the challenges USDA faces related to vaccination are significant. In particular, USDA does not have access to sufficient vaccine to achieve its response goals under many potential outbreak scenarios, and there is not consensus about how to allocate the limited supply, according to USDA officials and documents. Other challenges in this area relate to the timing and logistics of obtaining, distributing, and administering vaccine and to scientific, procedural, and infrastructure issues in vaccine production.

### Limited Supplies of Vaccine

Supplies of FMD vaccine concentrate in the vaccine bank may be sufficient to help control and eradicate a small, localized outbreak, but it is unlikely that they would be sufficient to stop a larger outbreak, according to USDA planning documents and officials. With a vaccine that is matched to the appropriate FMD subtype, a single dose can protect cattle for 6 months, and two doses are required to provide the same protection to swine. APHIS's 2016 FMD vaccination policy states that 25 million doses for each of 10 subtypes of the virus is an appropriate minimum target to have available.<sup>47</sup> However, the United States currently has access to only 1.75 million doses of each subtype available in the vaccine bank, according to USDA documents.<sup>48</sup> In the United States, there are 24 states in which the number of livestock exceeds the doses available in the vaccine bank, according to USDA documents. In a 2016 report to Congress, USDA stated that the cost to reach its target of 25 million doses would be about \$125 million, which would be about 10 percent of APHIS's budgetary resources in fiscal year 2016. In addition, because the vaccine concentrate has a 5-year shelf life, USDA would incur costs to routinely replace the supply of concentrate, according to agency officials. The Agriculture Improvement Act of 2018 contains a provision that directs the Secretary of Agriculture to establish a national animal vaccine and veterinary countermeasures bank, and to prioritize the acquisition and

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<sup>47</sup>U.S. Department of Agriculture, *Foot-and-Mouth Disease Vaccination Policy in the United States* (Washington, D.C.: September 2016).

<sup>48</sup>The vaccine bank contains 2.5 million doses of several subtypes, including the most common circulating FMD subtypes, and the United States is entitled to 70 percent of those doses, with Mexico and Canada dividing the rest. USDA does not publish the exact inventory for national security reasons.

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maintenance of sufficient quantities of FMD vaccine and accompanying diagnostic products.<sup>49</sup>

The need for additional FMD vaccine was reinforced by a 2016 survey of states by USDA and Iowa State University. On the basis of responses from 32 state animal health officials, the authors estimated that in a widespread or national outbreak, states would plan to use on average 4.2 million doses during the first 14 weeks of the outbreak.<sup>50</sup> Based on these estimates, a vaccine request from a single state could greatly exceed the 1.75 million doses available per subtype in the vaccine bank's supply.

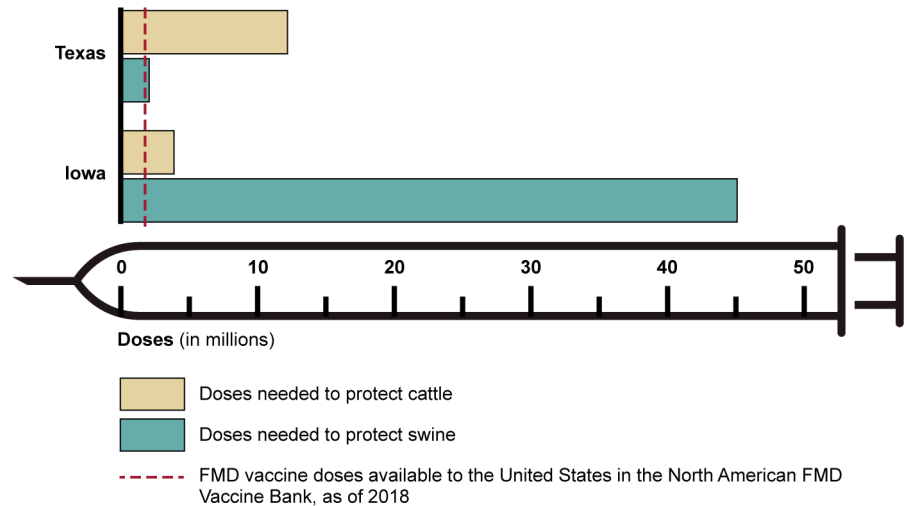
Moreover, if an FMD outbreak occurred in Texas or Iowa, the states with the largest cattle and swine populations, respectively, the available vaccine supply would provide a single dose for about 14 percent of Texas's 12.3 million cattle or the required two doses for about 4 percent of Iowa's 22.8 million swine. Texas's and Iowa's cattle and swine populations together make up about 24 percent of the combined population of cattle and swine nationwide. Figure 6 illustrates the vaccine doses needed to protect cattle and swine in Texas and Iowa compared with the currently available FMD vaccine bank supply of 1.75 million doses per subtype.

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<sup>49</sup>Agriculture Improvement Act of 2018, Pub. L. No. 115-334 § 12101(c), 132 Stat. 4490, 4938 (amending 7 U.S.C. § 8308a(c)). To pay for the national vaccine bank and other activities under a new national animal disease preparedness and response program, the Agriculture Improvement Act of 2018, among other things, directs the Secretary to make available from the funds of the Commodity Credit Corporation \$120 million for fiscal years 2019 through 2022 and \$30 million annually for fiscal year 2023 and each fiscal year thereafter, and authorizes the appropriation of additional sums for fiscal years 2019 through 2023. Pub. L. No. 115-334 § 12101(d) (amending 7 U.S.C. § 8308a(d)).

<sup>50</sup>On the basis of the 32 responses, the median number of vaccine doses that states would plan to use is 2 million, and the range is 8,000 to 20 million.

**Figure 6: Foot-and-Mouth Disease (FMD) Vaccine Doses Needed to Protect Cattle and Swine in Texas and Iowa Compared with Vaccine Bank Doses Available, 2018**



Source: GAO analysis of data from the National Agricultural Statistics Service and the North American FMD Vaccine Bank. GAO-19-103

In addition, because of the large number of FMD subtypes present around the world, and because the FMD virus is constantly mutating, it is possible that an FMD subtype could be introduced in the United States that is not covered by vaccines currently in the vaccine bank. According to a representative from an FMD vaccine manufacturer, producing a vaccine for a new subtype of FMD could take from 6 to 18 months, depending on whether the subtype was known and other factors.

**Lack of Consensus on Vaccine Allocation**

Because of the limited supply of vaccine and the potentially high demand for it, USDA would likely face the challenge of deciding how to allocate it in an FMD outbreak. In a 2016 survey of 13 industry veterinarians, there was no consensus within the beef, dairy, and swine industries about priorities for the vaccine.<sup>51</sup> Specifically, USDA and Iowa State University asked the veterinarians to rank the importance of vaccinating various populations (e.g., bull studs, lactating cows, and boar studs) within the beef, dairy, and swine industries, assuming there was only enough vaccine to vaccinate 25 to 50 percent of animals in a specified area. The

<sup>51</sup>U.S. Department of Agriculture, *Workshop on Foot and Mouth Disease Vaccine: Surge Capacity and Priorities for Emergency Use, Final Report* (Riverdale, Md.: Dec. 15, 2016). USDA and Iowa State University sent the survey to 23 industry veterinarians and 13 responded.

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responses varied widely, with high and low rankings for nearly every population of animals.<sup>52</sup>

## Timing and Logistics

The timing and logistics of obtaining, distributing, and administering the FMD vaccine could also pose challenges. The timing to reformulate the banked vaccine would pose challenges for USDA in an outbreak, according to respondents to our questionnaire. In addition, in March 2005, we found that USDA would not be able to deploy vaccines rapidly enough to contain a widespread FMD outbreak.<sup>53</sup> After USDA requests FMD vaccine from the vaccine bank, vaccine manufacturers could take from 4 to 13 days to finish and ship all of the requested vaccine to the United States, during which time the virus could spread within the livestock population, according to USDA documents. If the vaccine bank's supply of concentrate is exhausted during an outbreak and more is needed, manufacturers may take several months to produce it, according to a vaccine manufacturer.

After obtaining the vaccine, USDA would distribute it to affected states, and the states would distribute it to veterinarians, producers, or others who would be responsible for administering vaccine, according to USDA and state FMD vaccination documents. Many states do not currently have vaccination plans in place and may not have identified the warehousing locations, staff needs, and tracking required to efficiently distribute FMD vaccine, according to agency and state government officials, which could slow USDA's efforts to contain and control an outbreak. States with vaccination plans may be able to more quickly and effectively distribute and administer FMD vaccine during an outbreak. For example, California has a vaccination plan that details how it would receive, distribute, and administer FMD vaccine while maintaining the appropriate temperatures and documentation.<sup>54</sup> The plan includes details such as the supplies needed for administering FMD vaccine to cattle.

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<sup>52</sup>In the survey, veterinarians were asked to only respond to questions about the animal species and industries with which they were most familiar. For each of the animal populations that respondents ranked, there were 4 to 7 responses.

<sup>53</sup>In the report, we recommended that USDA examine the costs and benefits of developing supplies of ready-to-use vaccines that can be quickly deployed against animal diseases of primary concern. USDA has taken steps to examine these costs and benefits. GAO, *Homeland Security: Much Is Being Done to Protect Agriculture from a Terrorist Attack, but Important Challenges Remain*, [GAO-05-214](#) (Washington, D.C.: Mar. 8, 2005).

<sup>54</sup>To remain effective until it is administered, vaccine must be kept at specific, cold temperatures during transportation and storage.



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## Scientific, Procedural, and Infrastructure Issues

USDA faces challenges in obtaining vaccine and using it in a response effort because of scientific, procedural, and infrastructure challenges related to the vaccine and its production. There are very few vaccine manufacturers in the world with the capacity to produce most of the FMD vaccine subtypes and meet the quality standards required by the United States, according to agency officials. Further, there is currently no production capacity for FMD vaccine in the United States because dedicated infrastructure is not in place to produce vaccines without live virus. There is a statutory prohibition against working with live FMD virus on the U.S. mainland, absent a permit granted by the Secretary of Agriculture, and live virus is needed to produce conventional vaccines.<sup>55</sup> To work within this constraint, USDA's Agricultural Research Service (ARS) and DHS developed new technologies to produce vaccine using modified versions of the virus that are unable to cause or transmit disease. The agencies transferred these technologies to vaccine companies that are investing in their development, according to USDA officials.

In 2018, the Secretary of Agriculture announced that vaccine companies could apply for permits to work with a specific modified, noninfectious version of the FMD virus on the mainland. One company has exclusive rights to use this modified version, which was developed and patented by ARS. The company plans to produce FMD vaccine in the United States, but it could take several years to license the initial product, complete the necessary permitting procedures, and build manufacturing infrastructure, according to USDA documents and a company official.<sup>56</sup>

Using FMD vaccine to respond to an outbreak presents additional challenges that are related to limitations of FMD vaccines. Specifically, animals may take up to 28 days after vaccination to develop protective immunity to FMD, depending on the species, potency of vaccine, and other factors. Even after 28 days, some vaccinated animals may not be

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<sup>55</sup>21 U.S.C. § 113a.

<sup>56</sup>The Secretary of Agriculture can issue a permit for use of live virus on the mainland for research and study if the Secretary determines that it is necessary and in the public interest. 21 U.S.C. §113a.

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fully immune to FMD and may continue spreading the virus despite having no visible signs of infection, according to USDA documents.<sup>57</sup>

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## USDA Has Identified Actions to Mitigate Challenges in Responding to FMD but Has Not Prioritized or Monitored Their Completion

To mitigate challenges in responding to potential FMD outbreaks, USDA's APHIS has identified corrective actions through preparedness exercises, surveys, and lessons learned in other outbreaks, as called for in its SOPs. However, APHIS generally does not follow its SOPs for prioritizing or monitoring the completion of these actions.

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## USDA Has Used Preparedness Exercises, Surveys, and Lessons Learned in Other Outbreaks to Identify Actions to Mitigate FMD Challenges

A USDA SOP outlines a process for identifying corrective actions to improve the agency's preparedness for outbreaks of foreign animal diseases.<sup>58</sup> According to the SOP, APHIS is to identify corrective actions after preparedness exercises and animal disease incidents. Consistent with this SOP, APHIS identifies corrective actions for FMD preparedness through exercises simulating FMD outbreaks, surveys of agency officials and others, and lessons learned from outbreaks of other diseases. More specifically, see the following:

- APHIS sponsors FMD preparedness exercises and participates in some such exercises that other federal or state agencies sponsor. After an exercise, the sponsoring agency generally prepares an after-action report that specifies corrective actions, and may include a responsible party for and a date for completing each action. APHIS has after-action reports for more than 40 FMD preparedness exercises that it sponsored or participated in from 2007 through 2018, which include corrective actions for USDA and APHIS.

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<sup>57</sup>According to a 2010 ARS study, 50 percent of cattle that receive FMD vaccines nonetheless become persistently infected, which could pose challenges for recovering from an outbreak. Finding solutions to these limitations is a primary objective of ARS scientists, according to an ARS program direction memo.

<sup>58</sup>U.S. Department of Agriculture, *Standard Operating Procedures: 23.b Evaluation and Improvement Planning*, Foreign Animal Disease Preparedness and Response Plan, version 2.0 (August 2018).

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- APHIS conducts annual surveys of its staff and others—including state government officials, industry representatives, and academics—to identify corrective actions related to preparedness and response training needs.
  - APHIS identifies corrective actions for FMD preparedness based on lessons learned after outbreaks of other diseases. For example, some of the actions that APHIS identified after outbreaks of avian influenza, such as improving a database used for emergency response, could also help the agency mitigate challenges it would face in an FMD outbreak, according to agency officials.

APHIS has identified dozens of corrective actions in all 11 of the areas where we identified challenges for USDA in pursuing its FMD response goals. APHIS has taken corrective actions in each area. For example, to help mitigate the challenge of insufficient biosecurity on some premises, the agency partnered with Iowa State University to offer producers across the nation training on developing enhanced biosecurity plans for implementation during a foreign animal disease outbreak. However, APHIS has not yet taken some other corrective actions that it has identified.

According to agency officials and experts we interviewed, these corrective actions can help mitigate, but may not completely resolve, the challenges identified. Some challenges may be outside USDA's control to fully resolve. For example, the logistical challenges of carcass disposal could be overwhelming in a large-scale outbreak, which could generate thousands of tons of carcasses. A corrective action calling for training on carcass management may help educate FMD responders about disposal methods or preventing environmental impacts; however, such training may not fully resolve the challenge.

Table 1 shows examples of corrective actions identified by USDA in after-action reports, planning documents, other agency documents, or interviews, which the agency has taken or not yet taken for the 11 challenge areas we identified.

**Table 1: Examples of Identified Corrective Actions Taken or Not Yet Taken by the U.S. Department of Agriculture (USDA) to Mitigate Challenges for Foot-and-Mouth Disease (FMD) Response**

<b>Challenge area</b>	<b>Examples of corrective actions identified and taken to mitigate challenge</b>	<b>Examples of corrective actions identified but not yet taken</b>
Surveillance	USDA's Animal and Plant Health Inspection Service (APHIS) piloted a project in 2014 and 2015 conducting active surveillance for FMD in swine. Through the pilot project, APHIS identified issues that must be addressed before implementing such a system more broadly.	Finalize detailed outbreak surveillance protocols for use during an outbreak.
Diagnostic capabilities	APHIS identified potential uses for a bulk-tank milk test and an oral fluid test, which would enable population-level diagnostic testing of dairy cattle and swine.  The National Animal Health Laboratory Network determined the maximum number of FMD diagnostic tests it could run when operating at full capacity and trained laboratory technicians to train others about diagnostic testing, so they can meet the surge capacity needs of an outbreak.	Validate and implement a bulk-tank milk test for dairy cattle and an oral fluid test for swine.  Complete a memorandum of understanding between APHIS and USDA's Agricultural Research Service to provide additional capability to run diagnostic tests in an outbreak.
Information management	APHIS provided training for its staff and state officials on how to use the agency's emergency response database.	Improve information management infrastructure and increase number of information management staff.  Provide additional training and preparedness exercises on information management for APHIS and state officials.
Animal traceability	APHIS established a state-federal working group that developed proposals in April 2018 to improve animal identification and traceability for cattle.	Implement the working group's three overarching goals for improving traceability: advancing electronic data-sharing among states, USDA, industry, and veterinarians; increasing the use of electronic identification; and enhancing the ability to trace animals from birth to slaughter.
Biosecurity	APHIS partnered with Iowa State University to offer web-based training for livestock producers as well as federal and state government officials across the nation on implementing enhanced biosecurity during a foreign animal disease outbreak, such as FMD.	In partnership with industry and others, complete Secure Food Supply Plan for beef, including guidance and templates to help producers implement enhanced biosecurity measures.
Depopulation	APHIS began holding a series of teleconferences between agency officials and state agriculture and environmental officials to discuss depopulation, carcass management, and related issues.	Review state and industry depopulation capabilities for FMD.  Develop just-in-time training for contractors who could be hired for depopulation.
Carcass disposal	During a May 2018 preparedness exercise, APHIS deployed a carcass management calculator, which served as a basis for limiting the number of farms on which stamping out would be used.  In 2018, APHIS provided web-based training on carcass management to its field staff, state officials, and industry representatives.	Deploy web-based dashboard with tools, calculators, resources, and training for external stakeholders on disposal methods and associated risks.

Challenge area	Examples of corrective actions identified and taken to mitigate challenge	Examples of corrective actions identified but not yet taken
Resources	<p>In May 2016, APHIS signed the International Animal Health Emergency Reserve agreement (with Australia, Canada, Ireland, New Zealand, and the United Kingdom), enabling participating countries to share emergency response teams and personnel as needed during animal disease outbreaks.</p> <p>APHIS developed a process for mobilizing its voluntary emergency ready response corps, a group of APHIS staff who volunteer to respond to emergency incidents as needed.</p>	<p>Increase the number of volunteers in the voluntary emergency ready response corps.</p>
Communication and coordination	<p>APHIS provided web-based training for its staff, state officials, and industry representatives on USDA's public communications policy.</p> <p>APHIS developed a general communications plan for emergency situations.</p>	<p>Develop a specific communications plan for a large-scale outbreak.</p> <p>Conduct a preparedness exercise to test the coordination structure among federal agencies.</p>
Appraisal and compensation	<p>APHIS developed a draft compensation payment process for its May 2018 FMD preparedness exercise.</p> <p>APHIS delivered livestock appraisal and compensation training to agency officials in the field.</p> <p>APHIS updated compensation calculators for cattle and swine.</p>	<p>Continue developing options for a compensation payment process that could be used during an FMD outbreak.</p>
FMD vaccination	<p>USDA authorized a modified form of the FMD virus to be on the U.S. mainland, enabling certain vaccines to be produced in the United States once permits and infrastructure are in place.</p> <p>The North American Foot-and-Mouth Disease Vaccine Bank revised contracts with manufacturers to speed access to vaccine in an outbreak.</p> <p>APHIS used predictive models to evaluate different vaccination strategies.</p> <p>APHIS's National Veterinary Stockpile developed a logistical plan in 2011 for distributing FMD vaccine to the field and held preparedness exercises from 2008 through 2018 to inform and test the plan.</p>	<p>Acquire access to additional vaccine.</p> <p>Develop a process for prioritizing and allocating vaccine.</p> <p>Work with states to develop procedures for implementing a vaccination strategy.</p> <p>Continue using FMD predictive models to evaluate vaccination strategies under various outbreak scenarios.</p>

Source: GAO analysis of USDA documents and interviews with agency officials. | GAO-19-103

Note: For each of the challenge areas, USDA has generally identified and taken multiple corrective actions, and identified multiple other corrective actions that it has not yet taken. This table provides examples of corrective actions for each challenge area. We included these examples of corrective actions for illustrative purposes.

Some of the corrective actions that USDA has identified and taken relate to the challenge area of vaccination. For example, to help speed access to vaccine, in 2018, the Secretary of Agriculture announced that vaccine companies could apply for permits to enable them to develop and produce certain types of FMD vaccine in the United States in the future, thereby avoiding delays from producing the vaccine overseas and shipping it here. Also, APHIS officials have used an FMD predictive model to evaluate the effectiveness of different vaccination schemes at the state level, and they told us that they plan to conduct a similar analysis at the national level. The results could help inform USDA's

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vaccine prioritization decisions in advance of an outbreak, according to the officials.

USDA has also begun implementing other corrective actions that have been identified related to FMD vaccination, although more work remains. For example, in February 2009, we recommended—and USDA agreed—that it should detail in a contingency response plan how a response using vaccines would be implemented.<sup>59</sup> Similarly, after-action reports for 2013 and 2016 preparedness exercises highlighted the need for procedures to guide the implementation of FMD vaccination strategies. APHIS has taken or planned several steps to help address this need:

- In 2009, APHIS began drafting vaccine implementation procedures but realized that the national procedures needed to be developed in collaboration with states because of variation among states in their predominant industries, agriculture infrastructure, and government resources. When more states have developed vaccination implementation procedures, APHIS may revise and finalize the national procedures originally drafted in 2009, according to agency officials.
- APHIS's National Veterinary Stockpile developed plans in 2009 and 2011 outlining how some aspects of a vaccination strategy would be implemented.<sup>60</sup> Specifically, in 2009 it developed a template that states and tribes can use to develop their own plans, and in 2011 it prepared a logistical plan for distributing FMD vaccine to the field. The National Veterinary Stockpile also held preparedness exercises from 2008 to 2018 for states and tribes to practice requesting, receiving, and delivering the vaccine and to obtain information that could help APHIS develop national vaccination procedures.
- From 2011 to 2018, APHIS and the California Department of Food and Agriculture worked together to draft detailed procedures for implementing an FMD vaccination strategy in California. The draft procedures and related planning documents are intended to serve as templates to help other states develop such procedures, according to agency officials. APHIS also piloted a workshop on FMD vaccination

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<sup>59</sup>GAO, *Veterinarian Workforce: Actions Are Needed to Ensure Sufficient Capacity for Protecting Public and Animal Health*, [GAO-09-178](#) (Washington, D.C.: Feb. 4, 2009).

<sup>60</sup>APHIS's National Veterinary Stockpile coordinates logistics planning, particularly for catastrophic outbreaks, and would be responsible for delivering the finished vaccine to affected states after receiving it from the vaccine bank.

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planning in October 2018 and plans to hold related preparedness exercises with states from 2019 to 2021.

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### APHIS Does Not Consistently Follow Its Procedures for Prioritizing Corrective Actions and Monitoring Their Completion

Although APHIS has identified dozens of corrective actions for FMD preparedness, it has not consistently followed its SOP for prioritizing all of the actions and monitoring progress in implementing them. Specifically, once corrective actions have been identified, APHIS's SOP calls for prioritizing the actions in an improvement plan, and monitoring the actions to track their completion. APHIS has sometimes designated actions related to FMD vaccination as high priority during annual management meetings, but not all corrective actions have been prioritized, according to agency officials. For example, a 2016 corrective action called for USDA to conduct an exercise to explore roles, responsibilities, and activities related to recovery from a large-scale animal disease outbreak. However, as of December 2018, this action has not been prioritized in an improvement plan, according to the after-action report and an agency official.

In addition, corrective actions have sometimes been identified multiple times without being tracked to completion. For example, an after-action report for a 2007 exercise found that a process for making vaccine-allocation decisions was needed and suggested that a vaccine advisory group could assist with doing so. A 2014 after-action report stated that processes governing vaccine prioritization and allocation were not clear and identified a corrective action calling for USDA to develop a federal-level doctrine for vaccine prioritization and allocation. USDA's 2016 FMD vaccination policy states that APHIS, in coordination with state, local, and industry stakeholders, should consider developing processes, procedures, and strategies for prioritizing the use of currently available vaccine in an outbreak. However, APHIS has not developed processes, procedures, or strategies for prioritizing and allocating its supply of FMD vaccine, according to agency officials. The officials said they have not developed such a process because of limited resources and competing priorities. Also, it would require participation from state and industry stakeholders, and given the small quantity of FMD vaccine relative to the large number of susceptible animals in the country, the stakeholders have had little incentive to devote the necessary time to the issue, according to agency officials.

More generally, agency officials told us that the agency has not prioritized or monitored completion of some corrective actions because they have been responding to actual outbreaks of animal and plant diseases. They

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also noted that they have limited resources for FMD preparedness, which may make it difficult for them to complete all of the corrective actions that have been identified. However, for avian influenza preparedness, APHIS compiled and prioritized more than 300 corrective actions in a database and tracked more than 200 of them to completion. Through this process, it completed nearly all of the 111 high-priority actions and over 100 moderate-priority actions, according to its database as of May 2018. For example after the 2014 avian influenza outbreak, APHIS completed corrective actions that improved its response to a subsequent outbreak in 2016, according to agency documents. The corrective actions addressed such issues as how to quickly depopulate and dispose of infected poultry and efficiently compensate affected producers. APHIS continues to monitor its progress in implementing the remaining corrective actions for that disease, according to agency officials.

APHIS's SOP calls for prioritizing corrective actions to identify the most beneficial use of resources. The SOP also calls for monitoring corrective actions to track their completion so that APHIS can improve its response capabilities and correct problems or deficiencies identified in exercises or incidents. Without following its SOP to prioritize corrective actions for FMD preparedness, APHIS cannot ensure that it is allocating its limited resources toward implementing the most beneficial actions. And without following its SOP for monitoring the corrective actions, APHIS cannot ensure that the highest-priority actions are completed.

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## Conclusions

APHIS has taken important steps to prepare for an FMD outbreak and to mitigate challenges it may face in responding to one. For example, the agency has developed an extensive collection of strategy and guidance documents, held FMD preparedness exercises to practice response activities, and identified dozens of corrective actions and completed some of these actions. However, APHIS has not yet completed other corrective actions, including actions that have been identified multiple times, such as developing a process for prioritizing and allocating the limited supply of FMD vaccine.

APHIS has an SOP for prioritizing and monitoring corrective actions. By following this SOP for avian influenza preparedness, the agency succeeded in prioritizing more than 300 corrective actions and tracking over 200 corrective actions to completion, including nearly all high-priority actions. In contrast, for FMD preparedness, APHIS has not consistently prioritized or monitored the corrective actions it has identified. Without following its SOP to prioritize and monitor corrective actions for FMD



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preparedness, APHIS cannot ensure that it is allocating its limited resources to the most beneficial actions to prepare for a possible FMD outbreak.

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## Recommendations for Executive Action

We are making the following two recommendations to USDA:

- The Administrator of the Animal and Plant Health Inspection Service should follow the agency's SOP to prioritize corrective actions for FMD preparedness. (Recommendation 1)
- The Administrator of the Animal and Plant Health Inspection Service should follow the agency's SOP to monitor progress and track completion of corrective actions for FMD preparedness. (Recommendation 2)

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## Agency Comments

We provided a draft of this report to USDA and DHS for review and comment. USDA provided comments, reproduced in appendix II, in which it agreed with our recommendations. In addition, USDA and DHS provided technical comments, which we incorporated as appropriate.

In response to our recommendations, USDA said that, starting in the second quarter of fiscal year 2019, APHIS will implement the agency's SOP and prioritize corrective actions to be tracked in its corrective actions database, as we recommended. USDA also said that, starting in the third quarter of fiscal year 2019, APHIS will assess and update the items related to FMD in its corrective actions database, as we recommended. In addition, USDA said that APHIS will track accomplishments it makes under a related provision of the Agriculture Improvement Act of 2018.

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We are sending copies of this report to the appropriate congressional committees, the Secretary of Agriculture, the Secretary of Homeland Security, and other interested parties. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

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If you or your staff have any questions about this report, please contact me at (202) 512-3841 or [morriss@gao.gov](mailto:morriss@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix III.

A handwritten signature in black ink that reads "Steve D. Morris". The signature is written in a cursive style with a large, stylized "S" and "M".

Steve D. Morris  
Director, Natural Resources and Environment

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# Appendix I: Objectives, Scope, and Methodology

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This report (1) describes the U.S. Department of Agriculture's (USDA) planned approach for responding to a foot-and-mouth disease (FMD) outbreak; (2) identifies what challenges, if any, USDA would face in pursuing its FMD response goals; and (3) examines how USDA identifies, prioritizes, and monitors corrective actions to mitigate these challenges.

To describe USDA's planned approach for responding to an FMD outbreak, we reviewed relevant legislation and USDA strategy and guidance documents. We also interviewed officials from USDA's Animal and Plant Health Inspection Service (APHIS) at the agency's headquarters in Riverdale, Maryland; laboratories on Plum Island, New York, and in Ames, Iowa; center for epidemiology and animal health in Fort Collins, Colorado; and center for veterinary biologics in Ames, Iowa; and officials from the Department of Homeland Security (DHS) and the Agricultural Research Service (ARS) at DHS's Plum Island Animal Disease Center on Plum Island, New York. We selected these officials to interview because of their knowledge about USDA's planned approach, their involvement in preparing for an FMD outbreak, and the roles they would play in responding to such an outbreak.

To identify what challenges, if any, USDA would face in pursuing its FMD response goals, we first came up with a list of potential challenge areas. To develop the list of potential challenge areas, we reviewed USDA documents, reports about FMD outbreaks in other countries, and after-action reports from 41 preparedness exercises in the United States from 2007 to 2018 in which officials practiced responding to simulated FMD outbreaks and identified emerging challenges.<sup>1</sup> The preparedness exercises included small-scale as well as large-scale ones with a variety of participants, durations, and response activities. We also interviewed APHIS headquarters staff and field staff in Iowa (the state with the most livestock); APHIS and ARS laboratory officials; state animal health officials in California, Colorado, Iowa, and North Carolina; representatives from the beef cattle, dairy cattle, swine, and sheep industries; and academic researchers with expertise in this area. We selected the individuals to interview based on their knowledge about challenges that USDA could face in pursuing its FMD response goals, their central role in preparing for an FMD outbreak, and recommendations from other interviewees, as well as diversity in geographic location. We also visited a

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<sup>1</sup>After-action reports and associated improvement plans summarize areas for improvement and corrective actions identified in preparedness exercises and real world response events.

swine farm and cattle feedlot in Iowa and interviewed the owners. We selected a swine farm and cattle feedlot to visit because swine and cattle were the livestock industries with the greatest populations of animals in the United States in 2016. We identified a list of 11 potential challenge areas.

To confirm the significance of the challenge areas, we used a questionnaire with the list of potential challenge areas. To select the questionnaire recipients, we identified four categories of people who are knowledgeable about challenges that USDA could face in pursuing its FMD response goals, including those who could be involved in a response effort. The four categories are (1) federal government officials, (2) state government officials, (3) livestock industry representatives, and (4) academic researchers with expertise in FMD preparedness. For categories with multiple individuals, we selected individuals to represent relevant units within APHIS, ARS, and DHS (e.g. headquarters; field offices; laboratories; surveillance, preparedness and response services; and science, technology, and analysis services); different livestock industries (beef cattle, dairy cattle, swine, and sheep); and states with relatively high livestock populations. We asked the recipients whether USDA would face a significant challenge in each of the 11 areas and whether they knew of other challenge areas we had not listed. We defined significant to mean a challenge that is sufficiently great or important enough to be worthy of USDA action to address the challenge.

We initially sent the questionnaire with potential challenges to 39 recipients. Two federal officials had retired from their positions, so we sent the list to their replacements. Of the 39 recipients, we received responses from 28. We also included an additional response that APHIS provided from an official who we had not initially contacted and who had relevant expertise, for a total of 29 responses. Despite two follow-up attempts, we did not receive responses from 11 recipients, including both recipients from ARS, 5 of the 18 from APHIS, 3 of the 10 state animal health officials, and 1 of the 2 national animal health laboratory network officials (these are affiliated with universities). Figure 7 shows the categories of respondents and their responses in each of the 11 challenge areas.

**Figure 7: Responses Indicating Whether USDA Would Face Significant Challenges in 11 Areas, When Responding to a Foot-and-Mouth Disease Outbreak**

Respondent category (number of responses)	Response	Challenge area										
		Surveillance	Diagnostic capabilities	Information management	Animal traceability	Biosecurity	Depopulation	Carcass disposal	Resources	Communication and coordination	Appraisal and compensation	Vaccination
Federal government officials (15)	Yes	11	12	9	13	10	11	12	11	4	7	15
	No	2	3	1	0	1	1	0	0	5	2	0
	Unsure <sup>a</sup>	2	0	5	2	4	3	3	4	6	6	0
State government officials (7)	Yes	5	6	5	6	6	6	7	6	4	6	7
	No	2	0	0	1	0	1	0	0	3	0	0
	Unsure <sup>a</sup>	0	1	2	0	1	0	0	1	0	1	0
Industry representatives (4)	Yes	3	4	4	4	2	3	3	4	1	4	4
	No	1	0	0	0	2	1	1	0	3	0	0
	Unsure <sup>a</sup>	0	0	0	0	0	0	0	0	0	0	0
Academic researchers (3)	Yes	3	2	2	2	2	2	3	2	2	2	3
	No	0	1	1	1	1	1	0	1	1	1	0
	Unsure <sup>a</sup>	0	0	0	0	0	0	0	0	0	0	0
<b>Total (29)</b>	<b>Yes</b>	<b>22</b>	<b>24</b>	<b>20</b>	<b>25</b>	<b>20</b>	<b>22</b>	<b>25</b>	<b>23</b>	<b>11</b>	<b>19</b>	<b>29</b>
	<b>No</b>	<b>5</b>	<b>4</b>	<b>2</b>	<b>2</b>	<b>4</b>	<b>4</b>	<b>1</b>	<b>1</b>	<b>12</b>	<b>3</b>	<b>0</b>
	<b>Unsure<sup>a</sup></b>	<b>2</b>	<b>1</b>	<b>7</b>	<b>2</b>	<b>5</b>	<b>3</b>	<b>3</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>0</b>

Source: GAO analysis of questionnaire responses. | GAO-19-103

<sup>a</sup>The unsure response includes responses of unsure or of no basis to judge.

Since we used a nonprobability sample, the results are not generalizable to all government officials, livestock industry officials, or FMD experts, but the responses helped confirm the list of 11 challenge areas and provided illustrative information about each one.

We reviewed challenges related to vaccination for FMD in greater depth than other challenges because of the significant role vaccination could play if reliance solely on stamping out is not feasible. Specifically, we visited DHS’s Plum Island Animal Disease Center on Plum Island, New York, where we interviewed officials from USDA’s Foreign Animal Disease Diagnostic Laboratory and the Agricultural Research Service, as

well as DHS officials, about challenges related to FMD vaccination. We also reviewed agency documents on the topic and interviewed other officials from USDA, the North American Vaccine Bank, universities, states, and industry groups about issues related to FMD vaccination. Further, we interviewed officials from the vaccine company that currently produces the majority of FMD vaccine available for use in the United States and a company that has rights to use a modified version of the FMD virus to produce FMD vaccine in the future.

To determine how USDA identifies, prioritizes, and monitors corrective actions to mitigate the challenges, we reviewed APHIS and DHS guidance on evaluation and improvement planning and other agency documents, observed an FMD preparedness exercise, reviewed after-action reports from 41 FMD preparedness exercises conducted from 2007 through 2018, and interviewed USDA officials. We reviewed APHIS's and DHS's procedures for evaluation and improvement planning to understand how APHIS is to identify, prioritize, and monitor corrective actions. To determine whether APHIS was consistently following these procedures, we observed the preparedness exercise at APHIS's Riverdale, Maryland, office;<sup>2</sup> reviewed a preliminary after-action report for that exercise; and reviewed after-action reports for the 41 other preparedness exercises. We interviewed APHIS officials about corrective actions identified in the after-action reports and what steps the agency has taken to prioritize the actions and monitor their progress. We reviewed agency documents about these procedures and about actions USDA has taken and identified but not yet taken to mitigate challenges. To find examples of corrective actions that USDA has identified and taken or not yet taken, we reviewed after-action reports for the 41 preparedness exercises; APHIS's 2018-2020 training and exercise plan for its veterinary services emergency preparedness and response unit; and other agency documents, such as contracts and plans, and interviewed agency officials. The examples of corrective actions in table 1 are illustrative only and do not include or represent all of the actions that USDA has identified. We sent a draft table of examples to APHIS officials and incorporated their comments as appropriate.

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<sup>2</sup>The Agriculture Response Management and Resources Exercise was held from May 7 through May 10, 2018. The exercise was sponsored by USDA with varied levels of participation from federal, state, and local agencies, as well as industry representatives, participating from the locations where they would be in an actual outbreak.

We also reviewed a GAO report on USDA's management of highly pathogenic avian influenza (avian influenza) outbreaks; interviewed agency officials; reviewed USDA after-action reports for avian influenza outbreaks; and reviewed USDA's database of related corrective actions to learn how the agency identifies, prioritizes, and monitors actions to mitigate challenges for that disease.<sup>3</sup> To assess the overall reliability of that database to use information from the database in our report, we reviewed management controls over the information systems that maintain the data and interviewed USDA officials who manage the database. We determined that the database was sufficiently reliable to describe the contents of the database and general status of corrective actions.

We conducted this performance audit from May 2017 to March 2019 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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<sup>3</sup>GAO, *Avian Influenza: USDA Has Taken Actions to Reduce Risks but Needs a Plan to Evaluate Its Efforts*, [GAO-17-360](#) (Washington, D.C.: Apr. 13, 2017).

# Appendix II: Comments from U. S. Department of Agriculture



United States Department of Agriculture

United States  
Department of  
Agriculture

Marketing and  
Regulatory  
Programs

Washington, DC  
20250

Mr. Steve D. Morris, Director  
Natural Resources and Environment  
Government Accountability Office  
441 G Street N.W.  
Washington, DC 20548

FEB 21 2019

Dear Mr. Morris:

Thank you for providing the United States Department of Agriculture (USDA) the opportunity to comment on the Government Accountability Office's (GAO) Draft Report, "Foot-and-Mouth Disease: USDA's Efforts to Prepare for a Potential Outbreak Could Be Strengthened (GAO 19-103). We have addressed the two Recommendations made to USDA.

USDA and the Animal and Plant Health Inspection Service (APHIS) fully understand the necessity for the planning and preparedness for Food-and-Mouth Disease (FMD). APHIS has taken steps to ensure effective emergency preparedness and response systems are viable. In the APHIS Strategic Plan for Fiscal Year 2019-2023, APHIS addresses its tactics related to FMD, to include partnering with stakeholders and customers to evaluate response options and update response plans, adjusting for changing agricultural production systems and societal expectations (such as, the potential for expanded use of vaccination as a response tool for FMD).

#### **GAO Recommendation #1**

**GAO recommends that the Administrator of the Animal and Plant Health Inspection Service (APHIS) should follow the agency's SOP to prioritize corrective actions for preparedness.**

#### **USDA Response**

USDA agrees with the GAO recommendation to follow the agency's SOP to prioritize corrective actions for FMD preparedness. Starting in the second quarter of Fiscal Year 2019, APHIS' Veterinary Services program area will implement the "USDA, Standard Operating Procedures (SOP) 23.b Evaluation and Improvement Planning, Foreign Animal Disease Preparedness and Response Plan," dated August 2018. APHIS will also prioritize corrective actions to be tracked in the Corrective Action Program Tracker.

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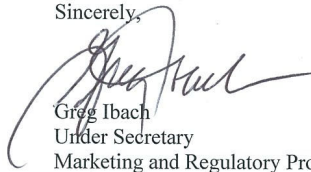
**GAO Recommendation #2**

**GAO recommends that the Administrator of the Animal and Plant Health Inspection Service should follow the agency's SOP to monitor progress and track completion of corrective actions for FMD preparedness.**

**USDA Response**

USDA agrees with the GAO recommendation to follow the agency's SOP to monitor progress and track completion of corrective actions for FMD preparedness. Starting in the third quarter of Fiscal Year 2019, and beyond, Veterinary Services will assess and update the Corrective Action Program Tracker items for FMD, also tracking FMD preparedness projects and progress accomplished as part of the 2018 Farm Bill SEC. 12101 Animal Disease Prevention and Management.

Sincerely,



Greg Ibach  
Under Secretary  
Marketing and Regulatory Programs

An Equal Opportunity Provider and Employer

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# Appendix III: GAO Contact and Staff Acknowledgments

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## GAO Contact

Steve D. Morris, (202) 512-3841 or [morriss@gao.gov](mailto:morriss@gao.gov)

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## Staff Acknowledgments

In addition to the contact named above, Nico Sloss (Assistant Director), Kevin Bray, Emily Christoff, Mary Denigan-Macauley, Christine Feehan, Jesse Lamarre-Vincent, Cynthia Norris, Anne Rhodes-Kline, and Amber Sinclair made key contributions to this report. Ross Campbell, Barb El Osta, Kathryn Godfrey, Hayden Huang, and Dan Royer also made important contributions to this report.

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# Related GAO Products

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*Foot-and-Mouth Disease: USDA's Evaluations of Foreign Animal Health Systems Could Benefit from Better Guidance and Greater Transparency.* [GAO-17-373](#). Washington, D.C.: April 28, 2017.

*Avian Influenza: USDA Has Taken Actions to Reduce Risks but Needs a Plan to Evaluate Its Efforts.* [GAO-17-360](#). Washington, D.C.: April 13, 2017.

*Emerging Animal Diseases: Actions Needed to Better Position USDA to Address Future Risks.* [GAO-16-132](#). Washington, D.C.: December 15, 2015.

*Federal Veterinarians: Efforts Needed to Improve Workforce Planning.* [GAO-15-495](#). Washington, D.C.: May 26, 2015.

*Homeland Security: An Overall Strategy Is Needed to Strengthen Disease Surveillance in Livestock and Poultry.* [GAO-13-424](#). Washington, D.C.: May 21, 2013.

*Veterinarian Workforce: Actions Are Needed to Ensure Sufficient Capacity for Protecting Public and Animal Health.* [GAO-09-178](#). Washington, D.C.: February 4, 2009.

*High-Containment Biosafety Laboratories: DHS Lacks Evidence to Conclude That Foot-and-Mouth Disease Research Can Be Done Safely on the U.S. Mainland.* [GAO-08-821T](#). Washington, D.C.: May 22, 2008.

*National Animal Identification System: USDA Needs to Resolve Several Key Implementation Issues to Achieve Rapid and Effective Disease Traceback.* [GAO-07-592](#). Washington, D.C.: July 6, 2007.

*Avian Influenza: USDA Has Taken Important Steps to Prepare for Outbreaks, but Better Planning Could Improve Response.* [GAO-07-652](#). Washington, D.C.: June 11, 2007.

*Homeland Security: Much Is Being Done to Protect Agriculture from a Terrorist Attack, but Important Challenges Remain.* [GAO-05-214](#). Washington, D.C.: March 8, 2005.

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