United States Government Accountability Office

Report to the Chairman, Committee on Energy and Commerce, House of Representatives

December 2015

EMERGING ANIMAL DISEASES

Actions Needed to Better Position USDA to Address Future Risks

GAO-16-132

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GAO Highlights

Highlights of GAO-16-132, a report to the Chairman, Committee on Energy and Commerce, House of Representatives.

Why GAO Did This Study

Pork is consumed more than any other meat worldwide, and there are numerous other products made with ingredients from pigs, including medical products, such as insulin to treat diabetes. The United States is the world's third-largest producer of pork products. USDA estimated that U.S. pork exports in 2014 were valued at over $6 billion. Two lethal, highly contagious diseases in pigs emerged in the United States in 2013 and 2014, causing the deaths of millions of pigs. The two emerging diseases are collectively known as SECD.

GAO was asked to review federal actions to address SECD outbreaks. This report examines (1) the initial response to the SECD outbreaks, (2) USDA's subsequent actions to manage SECD, and (3) steps USDA has taken to improve its future response to emerging animal diseases. GAO analyzed USDA efforts to collect data about the number and location of infected herds; reviewed federal regulations and USDA animal disease response guidance; and interviewed USDA, state, and industry stakeholders involved in the response and control efforts.

What GAO Recommends

GAO recommends that USDA develop a process to help ensure its guidance for investigation of animal diseases is followed and clarify and document how it will respond to emerging diseases, including defining roles and responsibilities. USDA generally agreed with GAO's recommendations.

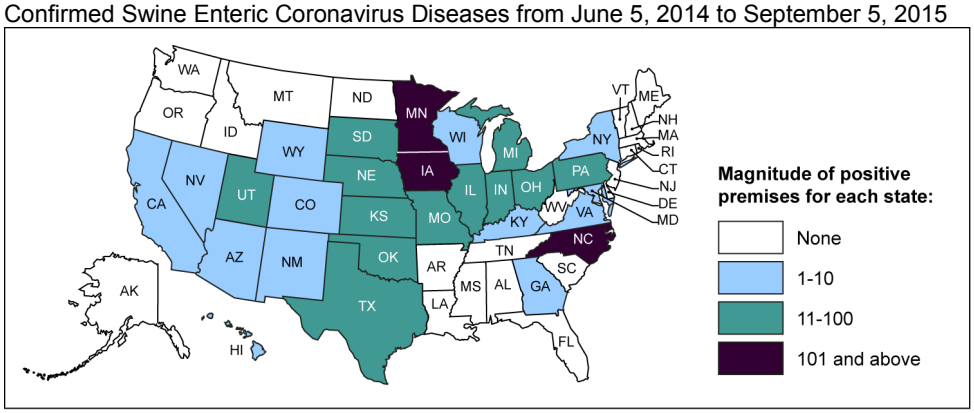
View GAO-16-132. For more information, contact John Neumann at (202) 512-3841 or neumannj@gao.gov or Timothy M. Persons at (202) 512-6412 or personst@gao.gov.

What GAO Found

The U.S. Department of Agriculture (USDA) did not take regulatory action during the initial response to the outbreaks of Swine Enteric Coronavirus Diseases (SECD) beginning in May 2013, when an outbreak was first detected, because the agency did not believe then that such action was necessary. Instead, USDA initially supported swine industry-led efforts. Without regulatory action, such as requiring reporting of infected herds, USDA had limited information about the location of the first infected herds. In addition, USDA officials acknowledged that USDA did not follow its guidance that calls for conducting epidemiological investigations at the onset of outbreaks. As a result, USDA did not conduct timely investigations of the premises with the first infected herds, and the source of disease will likely never be determined. Further, USDA does not have a process to help ensure the guidance is followed. Without such a process, USDA lacks reasonable assurance that the guidance will be followed in the future.

In June 2014, amid concerns about the spread of SECD, USDA issued a federal order requiring reporting of newly infected herds. As a result, USDA has more accurate information about the number and location of such herds, and SECD have been confirmed in 28 U.S. states, as shown below. USDA also provided funding to help manage the diseases.

Confirmed Swine Enteric Coronavirus Diseases from June 5, 2014 to September 5, 2015



Sources: USDA Swine Enteric Coronavirus Disease Situation Report, September 10, 2015; Map Resources (map). | GAO-16-132

To help improve its future response to SECD and other emerging animal diseases—those not known to exist in the United States or which have changed to become a threat—USDA has drafted new guidance. However, it has not defined key aspects of its response such as roles and responsibilities, which according to its strategic plan, are key components of successful collaboration to protect animal health. Without a clearly defined response to such emerging animal diseases, response efforts could be slowed.

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Abbreviations

APHIS	Animal and Plant Health Inspection Service
FDA	Food and Drug Administration
OIE	World Organisation for Animal Health
PDCoV	Porcine Deltacoronavirus
PED	Porcine Epidemic Diarrhea
SECD	Swine Enteric Coronavirus Diseases
USDA	U.S. Department of Agriculture

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

December 15, 2015

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

Two lethal, highly contagious diseases in pigs—Porcine Epidemic Diarrhea (PED) virus and Porcine Deltacoronavirus (PDCoV)—emerged in the United States in 2013 and 2014 respectively. These diseases do not directly affect public health but have resulted in the deaths of millions of pigs. According to the U.S. Department of Agriculture (USDA), the United States is the world's third-largest producer and consumer of pork and pork products. U.S. pork exports in 2014 were valued at over $6 billion, according to USDA's Economic Research Service. Pork is consumed more than any other meat worldwide, and there are numerous other products made with ingredients from pigs, including medical products, such as insulin to treat diabetes and manufacturing goods, such as insulation and rubber.

PED and PDCoV are collectively known as Swine Enteric Coronavirus Diseases (SECD). USDA currently categorizes SECD as emerging animal diseases, which it defines, in part, as any animal disease previously not known to exist in the United States, or any known animal disease which has an unexpected and unexplained increase in morbidity or mortality, or which has changed to become a threat to animal or public health.[1] SECD have also been identified in Canada, Mexico, South America, Europe, and Asia according to USDA documents.[2]

[1]For USDA's complete definition of emerging diseases, see U.S. Department of Agriculture, Animal and Plant Health Inspection Service, *Veterinary Services Proposed Framework for Response to Emerging Animal Diseases In the United States*, July 2, 2014, p. 8.

[2]Some countries, such as Mexico, have placed requirements that live pigs exported from the United States have certification for their PED status, according to USDA's export library website as of October 7, 2015.

USDA has the authority to act to prevent the spread of animal diseases under the Animal Health Protection Act.[3] This act authorizes the Secretary of Agriculture to carry out operations and measures to prevent, detect, control, and eradicate diseases and pests of animals, including emerging diseases, and recognizes that the prevention, detection, control, and eradication of such diseases and pests are essential to protect animal health, the health and welfare of people, economic interests of livestock and related industries, the environment, and interstate and foreign commerce in animals and other articles.

USDA uses an epidemiological approach to understand diseases and, if appropriate, plans actions to control or manage them. Epidemiology examines the spread of disease by time, place, and animal—by herd in SECD context[4]—as well as the mode of transmission and source of entry of disease. In particular, it involves conducting outbreak investigations on the premises where the disease is detected and identifying patterns of geographic distribution to determine factors associated with the onset and spread of disease.[5]

You asked us to review SECD outbreaks and the federal actions taken to address these diseases. This report examines (1) the initial response to the SECD outbreaks; (2) USDA's subsequent actions to manage SECD; and (3) what steps, if any, USDA has taken to improve its future response to emerging animal diseases.

To address all three objectives, we reviewed statutes, regulations, and policies, as well as agency documents related to federal actions on SECD. We also reviewed relevant documents from international animal health organizations to learn about international requirements for SECD.

[3]Animal Health Protection Act, Pub. L. No. 107-171, tit. X, subtit. E, 116 Stat. 494 (codified as amended at 7 U.S.C. §§ 8301-8317).

[4]For SECD, USDA uses the term "premises" as the analytic unit, referring to the group of animals collocated rather than an individual animal. Since premises can also refer to the location of where animals are housed, for the purpose of this report we use the term "herd" when referring to a unit of SECD-infected animals.

[5]The Centers for Disease Control and Prevention defines an outbreak as the occurrence of more cases of a disease, injury, or health condition than the number of cases (or incidents) of disease expected in a given area, or among a specific group, over a particular time period. For an animal disease not known to exist in the United States, the expected number of cases is zero.

We interviewed officials from USDA's Animal and Plant Health Inspection Service's Veterinary Services, which works to protect and improve animal health; the Department of Health and Human Services' Food and Drug Administration's (FDA) Center for Veterinary Medicine, which regulates livestock feed; selected state animal health officials; and three industry associations—American Association of Swine Veterinarians, National Pork Board, and National Pork Producers Council—identified by USDA officials as representing the commercial swine industry.[6] These associations represent the vast majority of the commercial industry, but their views are not generalizable to all swine veterinarians and producers. We interviewed state animal health officials from the 11 states that USDA identified as having the highest number of positive tests for the SECD virus during the initial response to the SECD outbreaks—specifically, Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Carolina, Ohio, and Oklahoma. These states were also among the highest pork producing states as of 2010 and received the highest level of financial assistance to support their SECD activities.[7] These officials' views provide insights into how states perceived USDA's actions to address SECD, but these views cannot be generalized to all 50 states.

In addition, for the first two objectives, we analyzed two USDA data collection efforts to assess the number and location of infected herds. These efforts included (1) initial voluntary positive testing results reported by some diagnostic laboratories from 2013 to June 2014 and (2) mandatory reports of confirmed cases of SECD from June 2014 through September 2015 as reported by swine veterinarians or producers and confirmed by a USDA official.[8] To assess the quality of these two data collection efforts, we reviewed agency documents and interviewed

[6]The American Association of Swine Veterinarians' mission includes increasing the knowledge of swine veterinarians, protecting and promoting the health and well-being of pigs, and advocating science-based approaches to veterinary, industry, and public health issues. The National Pork Board performs industry-related research, promotes pork as a food product, and provides consumer information about pork. The National Pork Producers Council represents U.S. pork producers through proposing legislation, regulations, and trade initiatives and through its political action committee, which support candidates at the state and federal levels who support the U.S. pork industry.

[7]These states all had 128 or more positive testing results for SECD, whereas the next state had fewer than 90 positive testing results. The selected states represent 11 of the top 15 pork producing U.S. states.

[8]USDA collected voluntary data through June 4, 2014. USDA began collecting mandatory reporting data as of June 5, 2014 and, as of September 2015, is still collecting.

officials responsible for collecting and analyzing these data. We found significant problems of completeness with the voluntary positive testing results. For example, the test samples did not consistently include premises information. Without this information, USDA did not know if the test samples were for diagnosing potentially newly infected herds or for retesting herds that had previously been tested positive. However, we found these data sufficiently reliable for the limited purpose of characterizing the increase in SECD-positive testing results. We found the mandatory reports of confirmed cases to be sufficiently reliable for the limited purpose of characterizing the geographic distribution over time within the United States. To understand the spread and source of these diseases, we reviewed four studies from March 2013 to August 2015 in peer-reviewed journals about factors that could contribute to the spread of these diseases in the United States or lead to their entry into the United States.

Further, for the first objective, we reviewed USDA's response from the initial identification of SECD in the United States in May 2013 up to its subsequent approach to these diseases in June 2014. We compared USDA's actions with its guidance for investigating animal disease outbreaks. We also interviewed agency officials from USDA's Animal and Plant Health Inspection Service's Veterinary Services and industry representatives from the American Association of Swine Veterinarians, National Pork Board, and National Pork Producers Council to understand the industry's response to SECD.

For the second objective, we reviewed USDA's actions to manage SECD from June 2014 through September 2015, as well as information on USDA funding for SECD research and actions during that period. We compared these actions with USDA's mission to help ensure the free flow of agricultural trade by keeping U.S. agricultural industries free from pests and diseases. We also compared them with federal standards for internal control, in particular, the standards for monitoring to ensure that the findings of reviews are promptly resolved. We interviewed USDA officials, state veterinarians, and industry representatives—who are stakeholders in USDA's animal disease responses—to learn their views on the usefulness of USDA's actions. We met with academic researchers, government officials, diagnostic laboratory officials, and swine veterinarians in Colorado, Iowa, and Minnesota because these states include key USDA offices or university laboratories that conducted the majority of SECD diagnostic tests. The views of these stakeholders are not generalizable, but they provide perspectives from researchers who specialize in swine diseases, USDA officials who hold key roles in

addressing SECD, swine veterinarians with experience from a state that produces a high number of swine, and diagnostic laboratory officials from laboratories that conducted the majority of SECD diagnostic tests. We also visited Ottawa, Canada, to interview Canadian government officials and industry representatives and better understand the steps they have taken in managing SECD, and to identify any differences from the steps taken in the United States. We selected Canada because it has SECD strains similar to those in the United States,[9] is the largest exporter of live pigs to the United States, and has been active at the national level in managing SECD.

For the third objective, we also reviewed USDA's policies and guidance for investigating, reporting, and responding to animal diseases. We compared information that USDA has communicated about its response to emerging diseases with expectations for collaboration laid out in USDA's Animal and Plant Health Inspection Service's Strategic Plan 2015-2019 and with federal standards for internal control, including control activities and documentation.[10]

We conducted this performance audit from October 2014 to December 2015 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.

Background

According to USDA, SECD are characterized by an acute, rapidly spreading viral diarrhea of pigs.[11] No other species, including humans,

[9]According to the Centers for Disease Control and Prevention website, a strain is defined as a group of organisms of the same species sharing certain hereditary characteristics not typical of the entire species but minor enough not to warrant classification as a separate breed or variety.

[10]U.S. Department of Agriculture, Animal and Plant Health Inspection Service, *Safeguarding the Health and Value of American Agriculture Since 1972, Strategic Plan 2015-2019,* January 30, 2015 and GAO, *Standards for Internal Control in the Federal Government,* GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999).

[11]U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, *Novel Swine Enteric Coronavirus Diseases (SECD), Case Definition*, June 5, 2014.

are known to be affected, and these diseases are not a direct public health threat. Pigs develop varying degrees of diarrhea and loss of appetite depending upon the age of the pig infected. Piglets are the most severely affected and have the highest mortality rates (50 to 80 percent), while growing and adult pigs have the lowest rates (approximately 1 to 3 percent).[12]

PED was first recognized in England in 1971 and has been known to exist in China since 1973. According to USDA's SECD case definition document,[13] China has seen a large increase in outbreaks since 2010, and the emergence of new strains of PED have been attributed to this increase. USDA's case definition document also provides information about the presence or suspected presence of PED and PDCoV in the United States and other countries. For example, the first outbreak of PED in the United States was reported in May 2013. PED has also been reported in Mexico and Canada, as of August 2013 and January 2014, respectively. Further, as of June 2014, PED is thought to be widespread throughout most regions of Western and Central Europe and Southeast Asian countries. In addition, PED is suspected in parts of South America.[14] PDCoV is more recent and less widespread; it was first reported in China in 2012, in the United States in January 2014, and later in Canada according to the document.

USDA's mission includes protecting and improving the health, quality, and marketability of our nation's animals and animal products by working to prevent, control, or eliminate animal diseases, and by monitoring and promoting animal health and productivity. USDA's overall budget request was $23 billion in fiscal year 2015, of which $287 million was budgeted for the agency's animal health efforts, including disease response. USDA comprises multiple organizations that support its animal health mission; see table 1 on the next page for selected organizations and their specific missions and roles.

[12]Ibid.

[13]Ibid. USDA's case definitions establish uniform criteria for reporting purposes and provide general disease information.

[14]According to USDA officials, since there is no international PED reporting requirement, USDA has tracked the spread of SECD in the world through literature reviews.

Table 1: U.S. Department of Agriculture (USDA) Agencies or Organizations with Animal Health Roles

Agency or organization	Roles related to animal health
Animal and Plant Health Inspection Service (APHIS)	Supports USDA's overall mission, including protecting and promoting U.S. agricultural health.
	Within APHIS, **Veterinary Services** protects and improves the health, quality, and marketability of our nation's animals, animal products, by preventing, controlling and eliminating animal diseases, and by monitoring and promoting animal health and productivity. Veterinary Services has several component organizations, including: The **Center for Epidemiology and Animal Health** explores and analyzes animal health and related agricultural issues to facilitate informed decision making in government and industry. The group also partners with the World Organisation for Animal Health to improve international disease surveillance and analytic methods supporting trade decisions.[a] The **Center for Veterinary Biologics** ensures that veterinary biologics—products of biological origin such as vaccines and diagnostic kits—for the diagnosis, prevention, and treatment of animal diseases maintain purity and potency and are safe and effective. **National Veterinary Services Laboratories** ensures that timely and accurate laboratory support is provided by their nationwide animal health diagnostic system by providing diagnostic services, reagents, and training in world-class facilities, among other things. The **National Animal Health Laboratory Network** is organized under the National Veterinary Services Laboratories. It is a multifaceted network composed of sets of laboratories that focus on different diseases, using common testing methods and software platforms to process diagnostic requests and share information. It is a cooperative effort between two USDA agencies—APHIS and the National Institute of Food and Agriculture—and the American Association of Veterinary Laboratory Diagnosticians.
Agricultural Research Service	Develops and applies solutions to the nation's high-priority agricultural problems and disseminates information to, among other things, ensure high-quality, safe food, and other agricultural products.
Economic Research Service	Conducts a research program to inform public and private decision making on economic and policy issues involving food, farming, natural resources, and rural development.
National Institute of Food and Agriculture	Advances knowledge of agriculture, the environment, human health and well-being, and communities by supporting research, education, and extension programs in the Land-Grant University System and other organizations.

Sources: USDA and World Organisation for Animal Health websites and USDA's Foreign Animal Disease Preparedness and Response Plan, February 2014 | GAO-16-132

[a]The World Organisation for Animal Health, of which the United States is a member, is an intergovernmental organization headquartered in Paris, France. The organization, more commonly referred to as the OIE, is responsible for improving animal health worldwide. The OIE requires its 180 member countries to report certain diseases to the organization and other member countries.

In carrying out its animal health mission, USDA participates in surveillance and preparedness, as well as response efforts for animal diseases. Surveillance activities can be conducted to monitor animal health, or in response to a specific disease. Animal disease surveillance consists of collecting, analyzing, and interpreting animal health data to detect diseases early, enable rapid reporting and response during disease outbreaks, and control the spread of disease.[15] According to USDA guidance, the agency also can use such data for accurate risk analysis, which includes assessing present, future, and emerging threats to animal health, and estimating the likelihood of a damaging event and the resulting consequences.

As part of the agency's preparedness and response efforts, USDA has identified certain animal diseases that pose a risk and must be reported if they occur in the United States. Data collected on these diseases are used to estimate their geographic distribution and severity, which inform officials' response efforts. For example, USDA established program diseases to control or eradicate specific diseases that must be reported to federal and state animal health officials. The agency works with federal-state-industry stakeholders to control or eradicate these diseases. USDA describes program diseases as serious zoonotic diseases, diseases that are economically important, or diseases of concern to the livestock, poultry, or aquaculture industries.[16]

Among these program diseases, some are designated as foreign animal diseases, which, in addition to being reported to USDA must be reported to the international community. USDA defines a foreign animal disease as a terrestrial animal disease or pest, or an aquatic animal disease or pest, not known to exist in the United States or its territories. A foreign animal disease may involve livestock, poultry, wildlife, or other animals. The World Organisation for Animal Health (formerly known as the Office of International Epizooties or, more commonly by its previous acronym, OIE) develops the list of internationally reportable animal diseases. This list is used by OIE's 180 member countries when determining trade restrictions

[15]For more information on our past work about livestock and poultry surveillance, see GAO, *Homeland Security: An Overall Strategy Is Needed to Strengthen Disease Surveillance in Livestock and Poultry,* GAO-13-424 (Washington, D.C.: May 21, 2013).

[16]Zoonotic diseases are contagious diseases that spread between animals and humans, according to USDA. U.S. aquaculture industries primarily raise fish and shellfish in captivity.

on animals or animal products that pose a risk to their agricultural industries.[17] According to USDA's guidance about animal diseases, one of the most immediate and severe consequences of an incident of an OIE-Listed animal disease in the United States is the loss of export markets. For example, according to the USDA's Economic Research Service website, as a result of the current outbreak of highly pathogenic avian influenza—an OIE-Listed disease—as of June 2015, 15 countries, including China, Russia, and South Korea, have banned poultry imports from the United States with many other countries placing bans on U.S. states or regions.[18]

Rapid response to diseases can prevent or limit sudden, negative consequences for animal health, economic security, and food security. Additionally, a rapid response can help normal production to resume as quickly as possible. When deciding on and implementing actions to respond to outbreaks of animal disease, USDA collaborates with other federal agencies, state officials, and with industry. For example, USDA works with

- FDA, which, among other things, is responsible for ensuring the safety of feed, to investigate potential feed contamination;
- state animal health officials and state departments of agriculture to assist in disease control efforts such as data collection; and
- industry to implement biosecurity practices that are critical to limiting disease entry and spread.[19] For example, diseases can be introduced or spread to healthy animals via footwear and outerwear, but biosecurity practices such as changing or covering these items before

[17]World Organisation for Animal Health (OIE), *OIE-Listed diseases, infections and infestations in force in 2015*, accessed July 30, 2015, http://www.oie.int/animal-health-in-the-world/oie-listed-diseases-2015/.

[18]U.S. Department of Agriculture, Economic Research Service, *Current Status of HPAI Outbreaks and Trade Bans, and U.S. Poultry and Egg Production, 2014,* updated June 23, 2015*,* accessed September 23, 2015, http://www.ers.usda.gov/topics/animal-products/poultry-eggs/interactive-chart-hpai-status.aspx.

[19]Biosecurity is a series of management practices designed to prevent the introduction or spread of disease agents on an animal production facility. External practices are designed to keep diseases out, and internal practices are designed to keep diseases that do occur from spreading. Some biosecurity practices are designed to do both.

entering premises can help prevent the introduction of disease. Similarly, changing or covering these items after working with infected animals can prevent the spread of disease.

According to USDA's Animal and Plant Health Inspection Service's strategic plan, collaborative efforts are thought to produce more public value than any single agency could produce. Components of these efforts include the identification of roles and responsibilities and mutually agreed upon common outcomes, such as the control or eradication of a disease,[20] as well as joint strategies for achieving the agreed-upon outcome.

USDA Did Not Take Regulatory Action During the Initial Response to the SECD Outbreak, Limiting Its Understanding of the Geographic Distribution, Spread, and Source of the Diseases

USDA did not take regulatory action during the initial response to the SECD outbreak, beginning in May 2013 when the PED virus was first detected, because it did not believe then that such action was necessary to manage the outbreak. By not taking regulatory action, USDA had limited information about the initial geographic distribution of the diseases; their modes of spread; and the locations of the first infected herds, which could have helped identify the source of entry of the diseases in the United States.

[20]For example, USDA, state, and industry stakeholders successfully collaborated to implement a national program that eradicated pseudorabies from U.S. pig herds in 2004. Pseudorabies, also known as Aujeszky's Disease, is an economically devastating disease that can cause up to 100 percent mortality among some pig litters. According to USDA's summary of the Pseudorabies Eradication Program, it was formally initiated in 1989 after years of planning.

USDA Did Not Take Regulatory Action During the Initial Response, Instead Playing a Supporting Role to Industry Efforts

USDA did not take regulatory action during the initial response when SECD were identified in May 2013. According to USDA officials, the agency was reluctant—and did not believe it was necessary—to take regulatory action, such as requiring reporting of infected herds or restricting the movement of pigs. Such action could have had negative financial impacts on the swine industry, according to USDA documents. Instead, the agency initially supported swine industry-led efforts to address SECD.

The agency's decision not to take regulatory action took into account several factors, including that these diseases were not listed as internationally reportable animal diseases, do not pose a threat to people, and were not lethal to all pigs.[21] If USDA had designated these as foreign animal diseases within the United States, the agency might have been expected to impose quarantines, and other countries might have restricted the importation of pigs or pig products. According to USDA guidance for reportable and foreign animal diseases, import restrictions could potentially have severe consequences because U.S. animal agricultural industries are becoming more dependent on exports, and the long-term strategic plans of these industries call for increasing the amount of goods sold abroad.

Moving Pigs

Pigs are often moved among multiple premises at different stages of their life spans to accommodate their growth in size. Typically, pigs are moved by truck and trailer as shown in the picture below. Additionally, the U.S. Department of Agriculture (USDA) estimates that more than 600,000 pigs are transported to slaughter on any given day in the United States.

According to industry representatives and USDA, movement restrictions such as a quarantine lasting more than a week could potentially result in euthanasia of hundreds of thousands or millions of animals, depending on how long the quarantine was in place, since premises may not be able to humanely house pigs larger than they customarily handle.

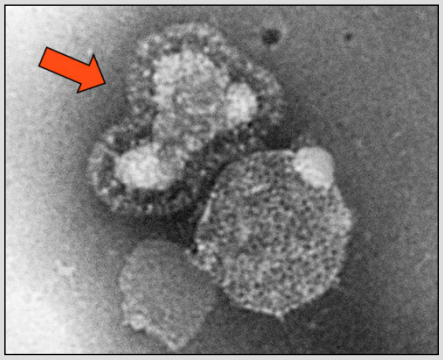
Sources: GAO (analysis); Alex Ramirez, Veterinary Diagnostic and Production Animal Medicine, Iowa State University (photo). | GAO-16-132

Off-loading pigs from a livestock trailer.

[21]While SECD can be lethal to piglets, older pigs can recover from these diseases.

Porcine Epidemic Diarrhea Virus (PED) Strains

The U.S. Department of Agriculture and other researchers have reported on more than one strain of PED presently in the United States. According to recent research, two strains identified in the United States closely resemble the strains of PED virus circulating in China; however, genetic resemblance does not indicate how the virus arrived in the United States.



Sources: GAO (analysis); Iowa State University (image). GAO-16-132

PED virus.

USDA officials told us that, at that time of their decision, varying strains of PED were known and active around the world, and the agency and the swine industry were aware of how PED spread (via fecal contamination). At that time, USDA believed the best course of action was for industry to manage SECD according to an agency announcement about the diseases. USDA officials explained that industry was already leading the response to other swine diseases, such as transmissible gastroenteritis.[22]

The initial response by industry and USDA to the SECD outbreak included efforts to learn more about these diseases. Within 3 months of the first PED diagnosis, one of the main swine industry associations—the National Pork Board—made $800,000 available for research to learn about PED and potential ways to control the disease, such as through promoting maternal (sow) immunity. USDA provided support and collaborated with industry associations in the response. Initial agency support included

- providing diagnostic support through its National Veterinary Services Laboratories to the National Animal Health Laboratory Network;[23]
- providing funding for and participating with industry associations in investigations of herds that became infected without an obvious reason, such as a newly infected herd in a remote area that had no clear connections to another infected herd; and
- compiling and reporting to industry associations positive testing results (indicating infected herds) that were voluntarily reported by

[22]Transmissible gastroenteritis was first identified in the United States in 1946. Industry leads the response to this disease, which is now endemic. Unlike SECD, USDA designates transmissible gastroenteritis as a monitored swine disease and is reportable to the OIE. Veterinarians are to report cases of the disease to the state animal health official, who in turn is to notify USDA in a monthly report if the state has at least one known incident. USDA is to report the presence or absence of this disease in a state to the OIE in an annual and a semiannual report. USDA does not collect location information, does not track the number of infections in each state, and does not take regulatory control measures for this disease.

[23]The National Animal Health Laboratory Network is a cooperative effort between USDA and state and university laboratories. These laboratories perform routine diagnostic tests for animal diseases, as well as targeted surveillance and response testing for foreign animal and emerging diseases.

veterinarians or producers to the National Animal Health Laboratory Network laboratories.

USDA also funded SECD-related research through the regular annual grant cycle of its National Institute of Food and Agriculture, as well as within the Agriculture Research Service. According to several federal, state, industry, and academic stakeholders we interviewed, research funding is important. Several stakeholders explained both industry and federal funding are important to promote research because they typically have different objectives. Generally, industry focuses on research with near-term applicability for producers, such as identifying which disinfectants are most effective in killing viruses. USDA generally supports research that is more broadly intended to further understanding of animal diseases. For example, past USDA work led to a diagnostic tool that was used to confirm the first identification of PED in the United States. The protocol for this tool was provided to the National Animal Health Laboratory Network. This protocol helped veterinary diagnostic laboratories participating in this network develop faster diagnostic tools, which they currently use to identify SECD.

USDA Had Limited Information on SECD Geographic Distribution and Mode of Spread and Cannot Definitively Identify How the Diseases Entered the United States

Because USDA did not take regulatory action, the agency had limited information about the initial geographic distribution of the diseases; their modes of spread; and the locations of the first infected herds, which could have helped identify the source of entry of the diseases in the United States. Further, in part because USDA did not have information about locations of the first infected herds, it did not investigate the first outbreak of SECD at the onset, and the source of entry of SECD into the United States will likely never be determined.

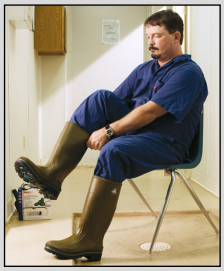
USDA Did Not Know the Initial Geographic Distribution of SECD Because Reporting Was Incomplete

At the onset of SECD in the United States, USDA did not know the geographic distribution because disease reporting was incomplete. State veterinary diagnostic laboratories and swine veterinarians initially identified these diseases and provided USDA with limited information on their geographic distribution by state, but not by premises. According to USDA's Chief Epidemiologist, location information is an important component in understanding how the disease is spread and how to prevent diseases and mitigate their spread. However, USDA did not initially require reporting of infected herds or the exact location of these herds, and swine producers were reluctant to voluntarily share this information with USDA. USDA officials, swine veterinarians, and industry representatives that we interviewed believed that producers' reluctance stemmed partly from concern about whether USDA had the ability or

procedures in place to maintain confidentiality of this information. Swine veterinarians we interviewed told us that producers were also concerned about public perception of these diseases based on past experience with other diseases. Specifically, in 2009, a novel influenza virus with origins in pigs caused a worldwide epidemic and led to substantial losses in pork sales when consumers mistakenly believed they could become infected by eating pork.[24]

Swine Enteric Coronavirus Diseases (SECD) Spread

GAO's review of literature found that there are multiple likely modes for the spread of SECD. Specifically, these studies found that SECD could likely be spread by transport vehicles, people, feed, and air. For example, people involved in transporting pigs can potentially spread virus on their clothing and boots from one location to another. In addition, employees and veterinarians in direct contact with pigs, service people delivering feed or water, maintenance workers, and others who visit premises can carry the virus onto and off of the premises, spreading it inadvertently. As demonstrated in the image below, the National Pork Board recommends biosecurity practices such as changing outerwear and footwear before entering premises with pigs to help mitigate the risk of spreading diseases. For further discussion of the literature review, see appendix I.



Sources: GAO (analysis); National Pork Board (photo). GAO-16-132

Changing into clean boots and coveralls.

According to USDA's summary of SECD testing results, the information USDA received voluntarily from laboratories in the early outbreak of PED, and later for PDCoV, was not useful for determining the number of infected herds.[25] In particular, swine producers did not consistently share information on the location of their premises when submitting samples for testing, and some producers submitted multiple samples at various times from the same premises in an effort to determine if SECD had been eradicated. Without complete location information, USDA did not know if these test samples were for diagnosing potentially newly infected herds, or for retesting herds that had previously tested positive. Additionally, in some cases, the results reported to USDA contained inaccuracies, such as incorrect state locations of the infected herds. For example, USDA officials explained that a swine-producing company could be based in one state, but the premises on which the sample was collected might have been in another state. Further, test samples provided by producers to diagnostic laboratories did not identify the type of swine infected, such as breeding sows, piglets, or pigs ready for slaughter—information useful for understanding the type of animal most susceptible and the impact of these diseases on industry. The laboratories also did not report to USDA the results of negative tests until November 2013, which could have demonstrated where the diseases were not occurring or where the disease occurrence might have been declining.

The limited information USDA received, while incomplete, suggested that the diseases were quickly spreading to multiple states. Specifically, PED was initially diagnosed in 3 states (Indiana, Iowa, and Ohio) in May 2013. The laboratories then diagnosed PED in 10 additional states through

[24]GAO-13-424.

[25]U.S. Department of Agriculture, *Swine Enteric Coronavirus Disease Testing Summary Report: Summary Report for NAHLN Laboratory Testing April 2013 – June 2014 (Prior to the USDA Federal Order),* September 2014.

June 2013 and in about 30 states total through May 2014. Similarly, the limited information for PDCoV suggested that it was present in the same 3 original states as PED in January 2014 (Indiana, Iowa, and Ohio) and had spread to at least 11 additional states through May 2014.[26]

USDA Participated in Efforts to Understand Ways SECD Could Have Spread

Beginning in May 2013, USDA collaborated with universities and industry associations on various efforts to understand how SECD may have spread in the United States. In one instance, USDA personnel provided statistical and technical support for university-based research on the possible airborne transmission of PED and geographic clustering of positive sites. In another effort, USDA personnel contributed to questionnaire development and analysis for a nationwide survey by swine veterinarians of selected swine producers with PED-infected herds; this effort found feed could have been a potential factor in the spread of the disease.[27] In addition, for PDCoV, USDA participated with industry in investigations in April 2014 at premises where the disease was diagnosed in the United States.

[26]USDA reported a fifteenth state with PDCoV, Oklahoma, during the week ending June 1, 2014.

[27]American Association of Swine Veterinarians (AASV), *AASV Interpretation of PEDv Survey Results,* on the website of the American Association of Swine Veterinarians, accessed on November 21, 2014, https://www.aasv.org/aasv%20website/Resources/Diseases/PED/AASVInterpretationPEDvSurvey.pdf.

Porcine Epidemic Diarrhea Virus (PED) in Canada

PED was first reported in Canada in January 2014, 8 months after it was first reported in the United States. Canadian provincial and federal government officials, with help from private swine veterinarians, conducted an immediate epidemiological investigation on the source of the PED and found an association between cases of PED in Canada and a feed ingredient (spray-dried porcine blood plasma) from a U.S. feed distributor. According to Canadian federal government officials, the feed distributor voluntarily removed this feed from the market and the officials believe this change helped reduce the spread of PED in Canada.

Sources: Canadian Food Inspection Agency (information); Map Resources (map). | GAO-16-132

First confirmed case of PED was from Middlesex County, Ontario.

USDA officials explained that there were other actions the agency could have taken to potentially limit the spread. For example, the agency could have imposed a temporary quarantine, restricting movement for a few days. However, these officials told us that, in their opinions, quarantine, depending on its length, could have had negative financial consequences to swine producers. Further, the officials told us that agency actions, such as quarantine, may not have been able to prevent the spread based on the pig industry's reliance on movement. The diseases are highly infectious and, by the time the first SECD was identified in May 2013, diagnostic laboratories later determined that PED had already been spreading, and multiple herds were infected as early as April 2013. After observing what happened in the United States, officials in at least one Canadian province worked with producers to establish voluntary movement restrictions to limit the spread in Canada, according to Canadian swine industry and government officials. Additionally, several Canadian provinces required reporting of infected herds including premises identification numbers. In the United States, these numbers serve as a way to track a farm (or premises) without using specific location information, such as longitude and latitude coordinates or a postal address, to help protect the privacy of the producer.

USDA Did Not Investigate the First Outbreak at the Onset, and the Source of Entry of SECD into the United States Will Likely Never Be Determined

USDA officials told us they missed an opportunity to conduct in-depth epidemiological outbreak investigations at the premises where PED was first diagnosed. Such investigations can help identify how a disease may have entered specific premises and, thus, may help determine how the disease entered the United States. USDA's investigation guidance for emerging animal disease incidents in effect during the first outbreak stated that collecting and analyzing epidemiological information is a

critical element to an investigation.[28] Had USDA followed this guidance, it would have conducted key steps of an outbreak investigation at the onset of the first cases, such as interviewing persons for incident history on the first infected premises near the time of the initial diagnosis and collecting and analyzing other epidemiological data for those incidents. Such an investigation does not guarantee that the source of the outbreak will be determined, but it typically provides some information necessary for such a determination. USDA's Chief Epidemiologist told us that timely outbreak investigations at the first infected premises would have been helpful in collecting more information on the source of entry. Because USDA did not follow its investigation guidance, the source of entry of PED into the United States will likely never be determined.

When asked why USDA did not conduct a timely outbreak investigation at the premises where PED was first diagnosed, senior USDA officials told us that the agency did not have information about locations of the first infected herds—information that would have been gained through regulatory action to require reporting. In addition, agency officials said USDA learned about the disease after it was identified by a laboratory. Officials explained that typically USDA applies its investigation guidance when the agency is contacted to help identify an unknown disease on the premises. One senior USDA official explained that, in the case of PED, USDA chose not to follow its investigation guidance since the disease was already identified—even though the guidance does not provide for an exception in such cases.

USDA's investigation guidance states that employees may not deviate from the directions provided without appropriate justification and supervisory concurrence. USDA officials acknowledged that they did not follow the guidance. USDA currently does not have a process in place that would help ensure this guidance is followed. According to federal standards for internal control, internal control activities help ensure that management directives, such as those incorporated in the investigation guidance, are carried out. The control activities should be effective and efficient in accomplishing the agency's control objectives. One example of

[28]U.S. Department of Agriculture, Veterinary Services Guidance 12001.1, *Policy for Investigating Potential Foreign Animal Disease/Emerging Disease Incidents (FAD/EDI)* (October 25, 2012). The current version of this guidance, 12001.2, updated position titles following the 2013 reorganization of USDA's Veterinary Services and made no changes to the definitions, objectives, elements, or classification of investigations.

a control activity would be establishing a process for documentation of the justification and approval of any deviation from the directions. Without appropriate control activities, USDA cannot have reasonable assurance that the guidance will be followed in future outbreaks.

USDA Subsequently Took Additional Actions to Manage SECD, with Mixed Results, and Identified Potential Preventive Strategies

Amid mounting concerns about the spread of the diseases and the associated economic losses, USDA took additional actions to manage SECD beginning in June 2014. In particular, USDA issued a federal order imposing reporting and planning requirements, and it provided financial assistance to states and producers. USDA cites progress in addressing SECD, but stakeholders we interviewed have questioned the usefulness of some of USDA's actions. In addition, USDA is retrospectively conducting a study of potential ways PED could have entered the United States and has identified potential preventive strategies based on its findings.

USDA Imposed Reporting and Planning Requirements and Provided Financial Assistance to Manage SECD

In June 2014, USDA issued a federal order to help manage the diseases. According to USDA documents, the order followed a winter in which SECD appeared to spread at increasing rates, leading to mounting producer concerns about economic losses from pig deaths. The order includes two basic requirements that remain in place at the time of this report. First, it requires anyone with knowledge of the diseases, including producers, veterinarians, and diagnostic laboratories to report all new SECD incidents to USDA or state animal health officials, providing specific information, including premises identification numbers. It also requires that, before a herd is considered confirmed positive for SECD, the herd with positive testing results also has at least one case of a pig with a history of clinical signs consistent with SECD.[29] According to USDA, routine, standard reporting for SECD helps determine the

[29]USDA established a case definition for a confirmed positive SECD diagnosis to help ensure consistent identification of the diseases. Under the definition, confirmed positive diagnosis requires both a positive testing result and confirmation of clinical signs. Diagnostic tests confirm the presence of the virus but do not necessarily identify if the virus is infective (i.e., can be spread to other animals). Confirming clinical signs is a way for animal health officials to identify if herds testing positive for the virus are ill. Before the order, SECD reporting reflected the number of positive testing results rather than the number of premises with confirmed infected herds in accordance with USDA's case definition.

magnitude of the diseases in the United States and documents progress in managing the diseases. Second, the order requires producers reporting SECD incidents to work with a veterinarian—either their herd veterinarians, or USDA or state animal health officials—to develop herd management plans. These herd management plans, which must be submitted to USDA, list biosecurity practices that the producers will follow to control the spread of disease.[30]

USDA also provided approximately $26 million for a variety of activities to help manage SECD. This funding was budgeted for, among other things,

- cooperative agreements with state animal health offices to support SECD management and control activities related to required reporting;
- financial assistance for diagnostic testing to determine the presence or absence of SECD;
- financial assistance for veterinarians developing the required herd management plans—specifically, reimbursement of $150 per plan;
- financial assistance to producers for biosecurity practices, specifically for purchasing disinfectants for transportation trucks and premises;
- efforts to develop vaccines;
- genomic sequencing of the viruses that cause SECD to better understand their characteristics;[31] and
- internal USDA SECD-related activities, such as staff time for SECD reporting and working with stakeholders.

[30]Examples of these practices include implementing procedures for visitors, employees, and vehicles entering or exiting the premises to help ensure contaminants are not brought into the premises (e.g., visitors and employees may have to shower and change into coveralls and boots, and vehicles may have to be cleaned); cleaning and disinfection of facilities before bringing in new pigs after a disease outbreak; and diagnostic testing to monitor the status of the herd infection and assess efficacy of control strategies.

[31]Genomic sequencing allows scientists to track virus mutation, as well as to better understand the impact of different virus strains for immunity.

USDA Announced Progress in Managing SECD, but Stakeholders We Interviewed Have Questioned the Usefulness of Some USDA Actions

Following its regulatory actions and provision of funding related to SECD, USDA announced progress in managing these diseases. However, stakeholders we interviewed raised concerns about the usefulness of some aspects of USDA's efforts to address SECD. USDA officials explained that, in response to some of these concerns, they have shifted funding to activities that stakeholders found more useful.

USDA Cited Several Achievements in Managing SECD

In December 2014, USDA announced in a public statement that it had made progress addressing SECD and was receiving more accurate and timely information about SECD-infected herds and their locations. According to USDA's announcement, this information allowed animal health officials to better understand how the diseases spread and what measures have been most effective in containing them.[32] More specifically, USDA noted that it had achieved the following in reporting and managing SECD:

- received information quickly and electronically through an improved information technology network with the laboratories, allowing federal and state health officials to better understand the spread of an animal disease outbreak in nearly real time;
- increased the number of diagnostic tests submitted that include the premises identification number, allowing for more accurate monitoring of current disease incidence and spread;
- granted two conditional licenses for vaccines developed for SECD; and
- improved its ability to detect new viruses and changes to existing viruses through genomic sequencing.

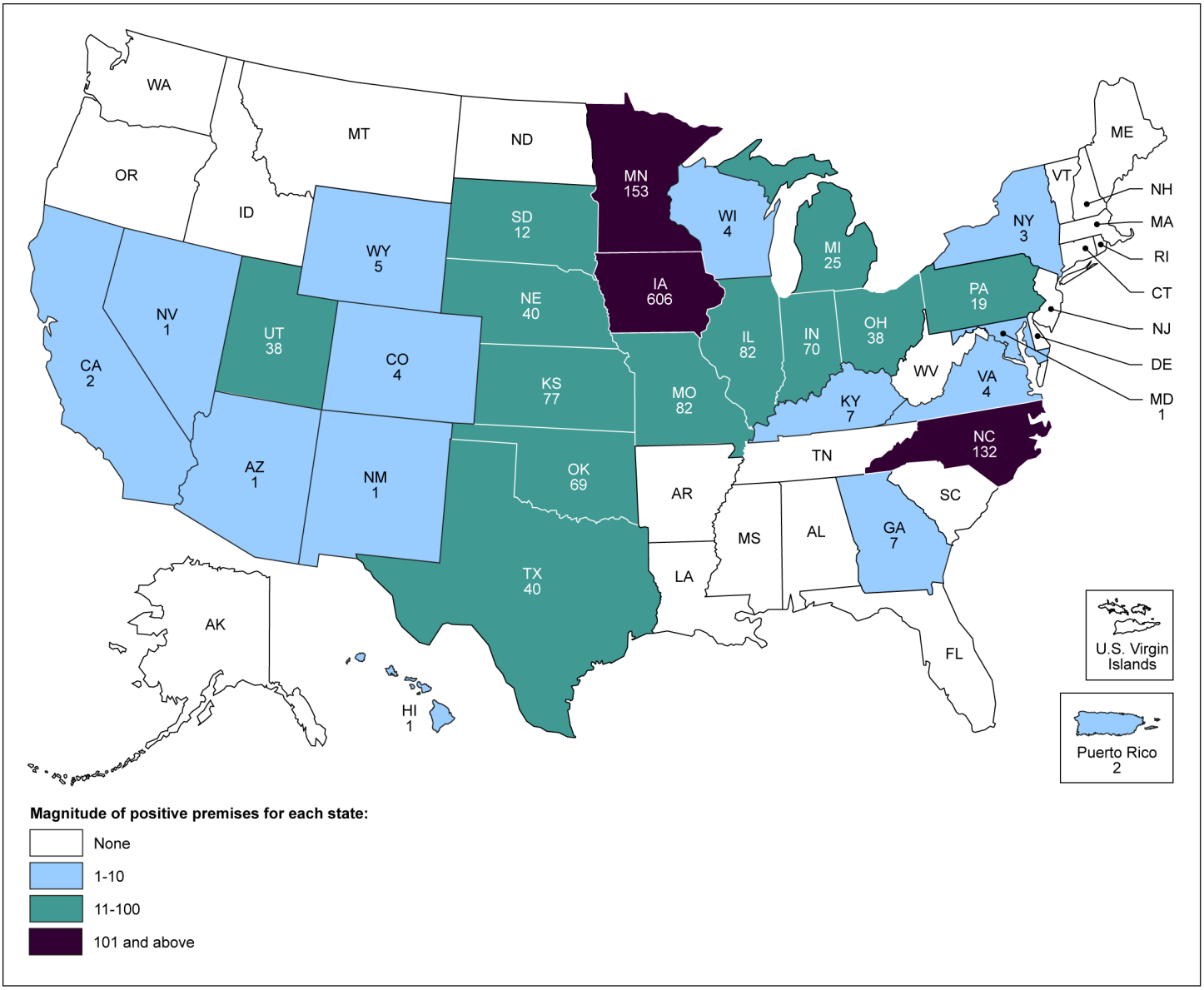
Several state, industry, and federal stakeholders we interviewed told us that providing financial assistance for diagnostic testing and requiring reporting were the most important USDA actions for helping to manage these diseases. Several stakeholders also said that these actions improved information available about the geographic distribution of

[32]This information may also allow veterinarians and swine producers to better understand these diseases.

SECD. According to USDA's Chief Epidemiologist, frequent diagnostic testing demonstrated whether biosecurity practices to reduce the risk of spread were working. The federal order's requirement to report positive SECD incidents requiring specific information, including premises identification numbers, has resulted in USDA having more accurate data on the frequency and date of new SECD incidents, and on the location of infected herds. According to a USDA report on these diseases, the agency can use premises identification numbers to identify whether a herd was previously reported as infected to avoid double counting infected herds, and USDA officials commented that the required information also assists officials in contacting producers to confirm clinical signs of illness.[33] USDA can now more accurately report on the number of new infections and on infections by state. As shown in figures 1 and 2 on the next pages, from June 5, 2014, through September 5, 2015, PED-infected premises have been confirmed in 28 U.S. states and 1 U.S. territory and PDCoV-infected premises have been confirmed in 15 U.S. states.

[33]Producers often submit numerous samples for multiple reasons, such as to confirm the presence of these diseases among their herds; to test whether control efforts or new biosecurity practices are effective in keeping these diseases out of herds (i.e., confirm the absence of the diseases); and to test new pigs, which will be introduced to their premises, to confirm that the new pigs are not infected.

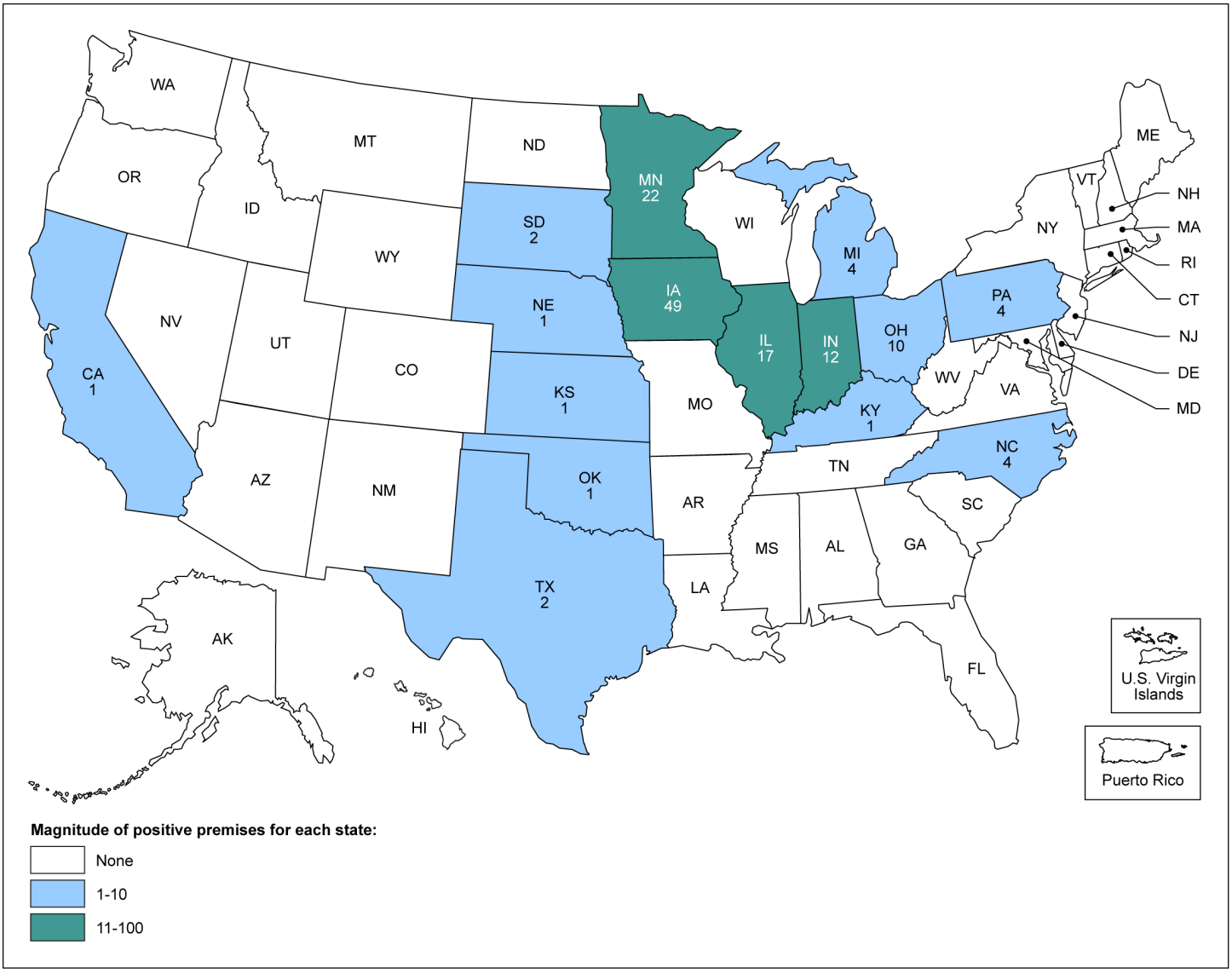
Figure 1: Cumulative Number of Confirmed Porcine Epidemic Diarrhea (PED)-Positive Premises Reported to the U.S. Department of Agriculture, June 5, 2014 through September 5, 2015



Sources: USDA Swine Enteric Coronavirus Disease Situation Report, September 10, 2015; Map Resources (map). | GAO-16-132

Note: Numbers include all confirmed PED-positive premises, including premises that have also been confirmed positive for Porcine Deltacoronavirus (PDCoV). Approximately 4 percent of the PED-positive premises were also confirmed positive for PDCoV. The numbers represent the raw counts of premises rather than the percentage of PED-positive premises in each state.

Figure 2: Cumulative Number of Confirmed Porcine Deltacoronavirus (PDCoV)-Positive Premises Reported to the U.S. Department of Agriculture, June 5, 2014 through September 5, 2015



Sources: USDA Swine Enteric Coronavirus Disease Situation Report, September 10, 2015; Map Resources (map). | GAO-16-132

Note: Numbers include all confirmed PDCoV-positive premises, including premises that have also been confirmed positive for Porcine Epidemic Diarrhea (PED). Approximately 44 percent of the PDCoV-positive premises were also confirmed positive for PED. The numbers represent the raw counts of premises rather than the percentage of PDCoV-positive premises in each state.

More Than Pork

Pigs produced in the United States have more uses than supplying pork, according to the U.S. Department of Agriculture. For example, several human medical treatments such as heparin are developed from pig by-products. Heparin, which can prevent blood clot formation, growth, and movement, is extracted from pig intestines. It is used in several medical procedures, including open heart surgery, kidney dialysis, and catheterization.

Sources: U.S. Department of Agriculture (information); Art Explosion (image). | GAO-16-132

USDA reported in September 2015 that, since June 2014, cumulatively, 1,599 premises have been confirmed as having herds infected with SECD. More specifically, within these premises 1,468 herds have been infected with PED, 73 herds have been infected with PDCoV, and 58 herds have been infected with both PED and PDCoV. From June 2014 through September 2015, about 40 percent of infected U.S. herds were in Iowa, the top swine-producing state. Using industry estimates, USDA reported in June 2014, that these diseases have caused approximately 7 million pig deaths, mainly among piglets, in the United States,[34] with PED causing the majority of these deaths.

Stakeholders We Interviewed Raised Concerns about the Usefulness of Some Aspects of USDA's Efforts to Address SECD

Some aspects of USDA's efforts to address SECD were not as well received as the financial assistance for diagnostic testing and the reporting requirements, according to stakeholders in our review. For example, stakeholders we interviewed told us veterinarians did not seek the $150 dollar financial assistance USDA offered for each herd management plan developed to help control the spread of disease on premises with SECD-infected herd because the effort associated with obtaining the assistance was not worth the amount received. According to data provided by USDA, less than 16 percent of the funds originally budgeted for reimbursing veterinarians had been obligated as of August 2015. Additionally, according to several state officials and industry

[34]Because USDA has not conducted its own assessment on the number of SECD-related pig deaths, the industry estimate provides an order of magnitude estimate. We neither reviewed nor assessed the reliability of industry's estimate of 7 million pig deaths; the number of deaths may be significantly higher or lower than the estimate.

representatives and a USDA official responsible for the funds, many producers were not applying for financial assistance for their biosecurity practices. As of August 2015, less than $1 million of the $11.2 million initially budgeted for biosecurity payments had been obligated according to the data USDA provided. State officials and industry representatives explained that producers were not seeking this assistance for various reasons, including that the effort associated with obtaining financial assistance was not worth the amount received; the assistance was limited to purchasing disinfectants; and the assistance was available only to producers with herds that tested positive after the federal order was issued.

USDA officials explained that they, therefore, shifted funds from this category to cover other activities, such as diagnostic testing, in response to stakeholder concerns. USDA initially budgeted $2.4 million for diagnostic testing. However, according to USDA officials, laboratories and industry representatives requested that the agency treat SECD diagnostic testing similar to testing for other reportable animal diseases and reimburse diagnostic laboratories for all tests, not only tests with positive results for infection. As a result, USDA increased the amount of financial assistance available for diagnostic testing within a few weeks of announcing its funding for SECD activities and, as of August 2015, about $10 million has been obligated for diagnostic testing. See table 2 for the initial funding amounts for SECD activities and obligated amounts by activity as of August 2015.

Table 2: U.S. Department of Agriculture (USDA) Funding for Activities to Manage Swine Enteric Coronavirus Diseases (SECD)

Dollars in millions

Proposed recipient	Activity	Initial funding as of June 2014	Obligated funds as of August 2015
National Animal Health Laboratory Network diagnostic laboratories	Diagnostic testing	$2.4	$10.0
State animal health departments	Support management and control activities related to required reporting	2.4	2.1
Herd veterinarians	Assist with development and monitoring of herd management plans and sample collection	0.5	0.1
Producers (with infected herds)	Cost-share funding to support biosecurity practices	11.2	1.0
USDA Agricultural Research Service	Support development of vaccines	3.9	3.9
National Animal Health Laboratory Network diagnostic laboratories	Genomic sequencing for newly positive herds	1.5	1.3
USDA Animal and Plant Health Inspection Service	Support SECD activities and the distribution of SECD program funds to combat these diseases	4.3	0.3
Total		**$26.2**	**$18.7**

Source: USDA data for SECD-related funds. | GAO-16-132

Note: GAO rounded amounts to the nearest one hundred thousand.

Regarding other USDA actions, nonfederal stakeholders—including industry representatives, private veterinarians, and academics—told us that further work is needed for the conditionally approved PED vaccines to be effective in preventing new herds from getting infected. As a result, some stakeholders we interviewed said these conditional vaccines are used on a limited basis or in conjunction with a traditional disease control method known as "feedback."[35] However, immunity from feedback or vaccines is not lifelong, and reoccurrences may occur. In addition, some state animal health officials noted that it would be helpful if USDA's information system for tracking infected herds automatically notified them of new infections in their state, similar to how USDA's officials are

[35]Feedback is the process of grinding up the intestinal contents and feces of infected dead piglets and feeding it to sows (breeding pigs) and replacement gilts (young pigs that will become sows) to induce immunity.

notified. Some of these state officials explained that automatic notification could assist them in conducting their disease response activities. For example, officials may need to collect additional information from producers of infected herds to complete documentation of herd management plans and obtain additional samples to monitor herds' disease status. Currently, after the first incident in the state, to learn about subsequent incidents, a state official could either access USDA's information system to check if there have been any new incidents within the state or could contact each laboratory to request direct notification of new incidents, according to USDA officials we interviewed.

USDA Is Retrospectively Conducting Studies on Likely Sources of Entry for SECD and Identified a Strategy to Address Potential Biosecurity Gaps

While USDA was unable to definitively identify how either PED or PDCoV entered the United States, in September 2015, USDA released a retrospective study of numerous potential ways SECD could have entered the United States.[36] This retrospective root cause study began almost a year after laboratories diagnosed PED in the first known infected herd.[37]

This retrospective root cause study indicates that the use of transport carrier totes is the most plausible potential source of entry based on the criteria the agency used when evaluating how PED may have entered the United States.[38] These totes are large, flexible sacks with a capacity of more than 1,000 pounds that are used to carry dry products. USDA determined that these totes were generally not cleaned before being reused for a number of purposes, including distributing pet food treats and shipping pig feed ingredients, such as organic soybeans, to the United States.[39] The study explained that organic soybeans are a product

[36]U.S. Department of Agriculture, Animal and Plant Health Inspection Service, *Swine Enteric Coronavirus Introduction to the United States: Root Cause Investigation Report* (September 24, 2015).

[37]The study acknowledges that there are limitations as a result of it being conducted a year after the onset of the outbreaks, such as the source of epidemiological data collected for the study are veterinarians' recollection of information regarding the outbreak a year earlier.

[38]For the purposes of USDA's investigation, a scenario had to explain transit through four segments of travel in order to be plausible: (1) the product or person carrying the U.S. outbreak virus had to be contaminated in the origin country, (2) the virus had to remain viable and infectious in transit to the United States, (3) the virus had to have means of dispersion to at least six geographically distinct locations in the United States in approximately 2 weeks, and (4) the virus had to reach farms and infect pigs.

[39]Producers may include pet food treats as part of a pig's diet.

imported from China that can be fertilized with swine manure and are frequently shipped in totes. Because the study identified totes as a potential gap in U.S. border biosecurity, USDA has initiated further research into totes to provide evidence to support the study's findings. Specifically, USDA is conducting tests to confirm that cross contamination between the totes and feed ingredients can occur and that the virus can survive during long transit times. According to a USDA official, the results demonstrate that the PED virus can survive on the totes for at least 5 weeks at room temperature and at least 10 weeks at 39 degrees Fahrenheit. According to the retrospective root cause study, the agency is also working with the Department of Homeland Security's U.S. Customs and Border Protection to test samples of organic soybean shipments to determine whether they are a possible source of PED virus.[40]

The retrospective root cause study also identified two preventive strategies that could mitigate the potential risk related to totes: (1) not reusing these totes or (2) identifying appropriate cleaning and disinfection procedures for the totes before their reuse to transport products into the United States. USDA has communicated findings of the study to FDA, which, among other things, is responsible for ensuring the safety of feed, and to stakeholders in the feed and swine industry, who, according to USDA, could mitigate risks prior to exposure of animals.

USDA Has Not Defined Key Aspects of Its Future Response to Emerging Animal Diseases

To improve its future response to emerging animal diseases, USDA has drafted new guidance and a proposed list of reportable diseases but has not defined key aspects of its response. More specifically, USDA has drafted guidance for responding to emerging animal diseases and has proposed a comprehensive list of animal diseases that must be reported by anyone with knowledge of the diseases. However, USDA has not defined roles and responsibilities or criteria for actions that are included in its response to emerging diseases.

[40]USDA and the Department of Homeland Security are partners in the effort to protect American agriculture against the introduction of pests and diseases at our nation's ports of entry. USDA determines what agricultural products are admissible into the United States and what products pose a risk and should be prohibited or restricted entry. The Department of Homeland Security's U.S. Customs and Border Protection then enforces these agricultural rules and regulations at ports of entry.

USDA Has Drafted Guidance and an Associated List of Reportable Diseases to Improve Its Approach for Responding to Emerging Animal Diseases

USDA has drafted new guidance for responding to emerging animal diseases;[41] according to a USDA summary document, the agency developed this guidance as a result of its experience with SECD and to improve the agency's response to future diseases.[42] USDA made this guidance available for public comment from October 16, 2014, through January 16, 2015. The draft guidance describes USDA's goals for addressing emerging diseases as (1) undertake global awareness of, assessment of, and preparedness for animal diseases or pathogens not currently in the United States that may be of animal or public health concern or have trade implications; (2) detect, identify, and characterize disease events; (3) communicate findings and inform stakeholders; and (4) respond quickly to minimize the impact of disease events. This draft guidance also refers to existing USDA guidance for conducting investigations and reporting results for emerging animal disease events.[43]

In conjunction with the draft guidance, USDA also released a "Proposed National List of Reportable Animal Diseases."[44] According to USDA's description of the proposed list, it is intended to, among other things, facilitate the response to an emerging animal disease in the United States. In the list, USDA identifies specific animal diseases and their proposed monitoring and reporting requirements, which would also apply to emerging animal diseases either currently on the list or newly identified. Any individuals, including producers and laboratory personnel, who have any knowledge of an incident of any of the listed diseases that USDA categorizes as "notifiable" would be required to comply with these reporting requirements; currently no individuals beyond accredited veterinarians are specifically required to report to USDA, according to the list. Agency officials we interviewed told us that expanding the reporting

[41]U.S. Department of Agriculture, Animal and Plant Health Inspection Service, *Veterinary Services Proposed Framework for Response to Emerging Animal Diseases in the United States*, July 2014.

[42]U.S. Department of Agriculture, *Summary of the National List of Reportable Animal Diseases and National Framework for Emerging Disease Response for the Secretary's Advisory Committee on Animal Health*, April 2015.

[43]U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, VS Guidance Document 12001.2, *Policy for the Investigation of Potential Foreign Animal Disease/Emerging Disease Incidents (FAD/EDI),* June 5, 2014.

[44]U.S. Department of Agriculture, Animal and Plant Health Inspection Service, *Proposal for a U.S. National List of Reportable Animal Diseases (NLRAD)—Concept Paper*, July 2014.

requirement to all knowledgeable individuals closes a reporting gap for disease incidents where no accredited veterinarian examined the animal or conducted the testing.

USDA Has Not Defined or Communicated Key Aspects of Its Approach for Responding to Emerging Animal Diseases

USDA's draft guidance has not defined or communicated key aspects of its response to emerging diseases, including when the agency would take a lead role, what the agency's responsibilities would be, and examples of what circumstances may trigger actions such as euthanasia or quarantines. In contrast, USDA has defined and communicated such aspects of its response to foreign animal diseases. For example, USDA's guidance for responding to foreign animal diseases provides information on roles and responsibilities, the scope of regulatory intervention, the criteria used in the selection of a response strategy, and examples of actions taken under different strategies. In addition, for several foreign animal diseases, USDA has created specific response plans that include examples of different types of responses to different levels of outbreaks.[45]

According to a senior USDA official who was involved in the drafting of the emerging diseases draft guidance, this guidance is intended to be broadly applicable and not as detailed as the guidance for foreign animal diseases. In addition, the characteristics of each emerging disease could vary dramatically, and creating a decision tree, for example, to show what actions to take could be difficult because of a high number of different potential scenarios. We recognize that defining the response to every emerging disease can be challenging because of the many unknowns. However, in its draft guidance, the agency has not included general information on key aspects of its response to emerging diseases, such as roles and responsibilities of the various involved stakeholders, potential response strategies, and what may trigger different types of actions. This information could facilitate rapid, effective decision making.

USDA's Animal and Plant Health Inspection Service stated in its 2015-2019 Strategic Plan that protecting the health, welfare, and value of America's agriculture and natural resources requires coordinated and collaborative efforts, and that identifying roles and responsibilities is a key component of successful collaboration. Agency officials we interviewed

[45]USDA has specific response plans for classical swine fever; foot-and-mouth disease; highly pathogenic avian influenza; and Newcastle disease, which is an acute, rapidly spreading and usually fatal viral infection of poultry.

agreed that they believe developing additional information on roles and responsibilities, potential response strategies, and what may trigger different types of actions would be feasible and useful. In a summary document that USDA released about its draft guidance on responding to emerging diseases, USDA noted that, for SECD, the options for responding to these diseases and how decisions would be made were not clear.[46] Industry representatives we interviewed said that they did not know how USDA would address the diseases and what role industry would have, which led to concerns about sharing information about SECD incidents with USDA and how USDA would use this information. Without more information on USDA's approach, the representatives said they may not be receptive to USDA taking the lead in addressing future emerging animal diseases. The National Pork Board announced in November 2014 that it would provide $15 million for a swine health information center to better prepare industry for the next emerging swine disease.

Absence of a clearly defined agency response to emerging animal diseases is also inconsistent with federal standards for internal control. USDA guidance primarily lists the goals of USDA in responding to emerging diseases and does little to explain how these goals will be achieved. Under these federal standards, control activities are the policies, procedures, techniques, and mechanisms that enforce management's directives; these activities help ensure that actions are taken to address risks. Appropriate documentation is an example of a control activity. The standards state that internal control needs to be clearly documented, and the documentation should be readily available for examination. The documentation should appear in management directives, administrative policies, or operating manuals.[47] Without a clearly defined and documented response to emerging animal diseases, response efforts could be slowed as agency staff and other stakeholders may not be able to quickly identify the appropriate actions to take.

Conclusions

The recent outbreaks of SECD have heightened awareness of the need to better prepare for emerging animal diseases. USDA, the states, and

[46]U.S. Department of Agriculture, *Summary of the National List of Reportable Animal Diseases and National Framework for Emerging Disease Response for the Secretary's Advisory Committee on Animal Health*, April 2015.

[47]GAO/AIMD-00-21.3.1, 11 and 15.

the swine industry are making considerable efforts to ensure that, in the future, the response to such diseases will be swift and effective—which can be paramount for preventing or limiting sudden, negative consequences for animal health, economic security, and food security. While much has been accomplished, opportunities remain to improve USDA's ability to respond to the risks posed by emerging animal diseases. In particular, unless USDA clarifies how it intends to respond to such diseases, stakeholders may not be receptive to USDA leadership and agency staff may not know their options for managing future outbreaks or how to decide among these options. Additionally, USDA currently does not have a process in place that, consistent with standards for internal control, would help ensure its guidance for investigation of foreign or emerging animal diseases is followed. Until USDA develops such a process, it cannot have reasonable assurance that the guidance will be followed in future outbreaks.

Recommendations for Executive Action

To improve USDA's ability to respond to and protect against future emerging animal diseases, we recommend that the Secretary of Agriculture direct the Administrator of the Animal and Plant Health Inspection Service to take the following two actions:

- Clarify and document how the agency will respond to emerging diseases including defining key aspects of its response, such as roles and responsibilities, potential response strategies, and what may trigger different types of actions.
- Develop a process to help ensure that its guidance for investigation of foreign or emerging animal diseases is followed, such as a process for documentation of the justification and approval of any deviation from the directions.

Agency Comments and Our Evaluation

We provided a draft of this report to USDA for review and comment. USDA provided written comments, which are summarized below and reproduced in appendix II. In its comments, USDA agreed with the intent of our recommendations and described actions or plans to address them.

More specifically, to clarify and document how the agency will respond to emerging diseases, USDA noted that its new draft guidance for responding to emerging animal diseases was made available for public comment and stated that it will revise this guidance as needed. USDA

also stated that, for each of the goals within this guidance, APHIS is developing further direction to clarify roles and responsibilities, potential responses, and possible triggers.

To develop a process to help ensure that its guidance for investigation of foreign or emerging diseases is followed, USDA stated that the intended refinement and expansion of the guidance for responding to emerging animal diseases will address when and how emerging diseases may be investigated differently from the procedures in its current investigation guidance.

In our draft, we also included a recommendation to develop a process to address deficiencies identified by USDA's root cause retrospective study or demonstrate the findings do not warrant management action to reduce the likelihood of entry of future animal diseases into the United States. We have removed this recommendation because, in its written comments, USDA provided new information on actions it has recently taken to address it. Specifically, USDA identified two approaches to mitigate potential risks identified in the study. First, USDA stated that, prior to the release of the study, APHIS consulted with FDA, which has regulatory jurisdiction over feed and feed facilities, to discuss potential regulatory controls under the Food Safety and Modernization Act.[48] In particular, USDA noted a rule FDA enacted in September 2015 to implement provisions of this act that requires registered animal food facilities to develop a food safety plan, perform an analysis on hazards associated with the animal food and the facility, and implement measures to control these hazards. USDA stated that these regulatory controls are believed to address the risks identified in the study related to the entry of animal diseases into the United States. We believe that this is a reasonable assessment of the new regulatory controls. Second, USDA has communicated findings of the study to stakeholders in the feed and swine industry, who, according to USDA, could mitigate risks prior to exposure of animals. USDA provided us with documentation supporting its statement about meeting recently with FDA and industry, and we verified with a senior swine industry official that USDA presented findings of its study to the swine industry prior to its release. In light of these recent activities, we no longer believe that there is a need for a

[48]The FDA Food Safety and Modernization Act was signed into law by President Obama on January 4, 2011. It shifts the focus from responding to contamination to preventing it.

recommendation to develop a process to address deficiencies identified in the root cause analysis report, and we removed it accordingly.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees, the Secretary of Agriculture, and other interested parties. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff members have any questions about this report, please contact John Neumann at (202) 512-3841 or neumannj@gao.gov, or Timothy M. Persons at (202) 512-6412 or personst@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.

Sincerely yours,

John Neumann
Director, Natural Resources and Environment

Timothy M. Persons, Ph.D.
Chief Scientist

Appendix I: GAO Review of Studies on the Spread of Porcine Epidemic Diarrhea

We identified and reviewed four studies published between March 2013 and August 2015 in peer-reviewed journals that examined factors that may have contributed to the spread of Porcine Epidemic Diarrhea (PED) in the United States.[1] University researchers, swine veterinarians, and pork producers collaborated on these studies. None of the four studies we reviewed found evidence of a definitive cause of PED spread. However, the studies showed that it is plausible for PED viruses to be spread by air, feed, transport vehicles, or people. See table 3 below for a summary of the studies.

Table 3: Factors Identified by Peer-Reviewed Studies That May Have Contributed to the Spread of Porcine Epidemic Diarrhea (PED) in the United States

Studies listed were published between March 2013 and August 2015

Factor(s)	Study
Airborne transmission	Carmen Alonso, Dane P. Goede, Robert B. Morrison, Peter R. Davies, Albert Rovira, Douglas G. Marthaler, and Montserrat Torremorell. "Evidence of infectivity of airborne porcine epidemic diarrhea virus and detection of airborne viral RNA at long distances from infected herds." *Veterinary Research*, vol. 45, no. 73 (2014). **Description:** Laboratory- and site-based study of eight sites in Oklahoma in July 2013 to determine PED airborne infectivity. **Results:** PED genetic material was detected in the air and was transported long distances (10 miles), but did not result in PED infection.
Feed	Andrew S. Bowman, Roger A. Krogwold, Todd Price, Matt Davis, and Steven J. Moeller. "Investigating the introduction of porcine epidemic diarrhea virus into an Ohio swine operation." *BMC Veterinary Research*, vol. 11, no. 38 (2015). **Description:** Epidemiological investigation of a swine operation in Ohio in January 2014. **Results:** Feed pellets collected from unopened bags at the affected operation sites tested positive for PED using genetic analysis, but did not result in PED infection.

[1]We identified no such studies for the other Swine Enteric Coronavirus Disease, Porcine Deltacoronavirus. Studies published in peer-reviewed journals have been vetted by scholars in the field for quality and importance of research. To identify studies that examined factors that may have contributed to the spread of Porcine Epidemic Diarrhea (PED) in the United States, we conducted a literature search of reviewed peer-reviewed scientific journals including the following: Emerging Infectious Diseases, Veterinary Research, and BMC Veterinary Research. We reviewed the methodologies and results of the studies.

Factor(s)	Study
Feed	Scott Dee, Travis Clement, Adam Schelkopf, Joel Nerem, David Knudsen, Jane Christopher-Hennings, and Eric Nelson. "An evaluation of contaminated complete feed as a vehicle for porcine epidemic diarrhea virus infection of naïve pigs following consumption via natural feeding behavior: proof of concept." *BMC Veterinary Research*, vol. 10, no. 176 (2014). **Description:** On-farm detection of PED in feed at three sites in parts of Iowa and Minnesota in January 2014. **Results:** Material collected from inside feed bins during a PED outbreak tested positive for PED and was infectious when fed to pigs, indicating that PED-infected food could be a vehicle of infection.
People, transport vehicles	James Lowe, Phillip Gauger, Karen Harmon, Jianqiang Zhang, Joseph Connor, Paul Yeske, Timothy Loula, Ian Levis, Luc Dufresne, and Rodger Main. "Role of Transportation in Spread of Porcine Epidemic Diarrhea Virus Infection, United States." *Emerging Infectious Diseases*, vol. 20, no. 5 (2014). **Description:** On-site testing of 575 trailers hauling pigs to 6 harvest (slaughter) facilities in central United States in June 2013 for contamination before, at, and after pigs were unloaded. **Results:** Trucks not contaminated at arrival were contaminated in the unloading process. Staff stepping into the slaughter facility and then into the truck during unloading could contaminate the vehicle indicating that people can play a role in the spread of the virus as well as the vehicles.

Source: GAO analysis. | GAO-16-132

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

United States Department of Agriculture

Office of the Secretary
Washington D.C. 20250

NOV 2 4 2015

Mr. John Neumann
Director, Natural Resources and Environment
U.S. Government Accountability Office
441 G Street N.W.
Washington, D.C. 20548

Dear Mr. Neumann:

Thank you for allowing the United States Department of Agriculture (USDA) the opportunity to review and comment on the U.S. Government Accountability Office's (GAO) Draft Report titled "Emerging Animal Disease: Actions Needed to Better Position USDA to Address Future Risks (GAO 16-132). We have addressed the GAO Recommendations.

To improve USDA's ability to respond to and protect against future emerging animal diseases, GAO recommends that the Secretary of Agriculture direct the Administrator of the Animal and Plant Health Inspection Service (APHIS) to take the following three actions (listed in bold):

Clarify and document how the agency will respond to emerging diseases including defining key aspects of its response, such as roles and responsibilities, potential response strategies, and what may trigger different types of actions.

USDA Response: USDA agrees with the intent of this Recommendation. In October 2014, APHIS posted a document on its website titled "Veterinary Services Proposed Framework for Response to Emerging Animal Diseases In the United States." The framework described four goals for addressing emerging diseases:

1. Undertake global awareness, assessment, and preparedness for animal diseases or pathogens not currently in the United States that may be of animal or public health concern or have trade implications;
2. Detect, identify, and characterize disease events;
3. Communicate findings and inform stakeholders; and
4. Respond quickly to minimize the impact of disease events.

APHIS' Veterinary Services (VS) follows this framework when identifying and evaluating emerging disease events and defining the appropriate responses. Emerging diseases, by definition, do not fit into any category that APHIS has previously defined; they are not endemic, they are not covered by an established APHIS animal health program, and they are not on the list of recognized foreign animal diseases. For that reason, APHIS' approach must be flexible and evaluate potential impacts of the disease before developing an appropriate response.

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APHIS invited public comments on the framework and will revise it as needed. Further, APHIS is developing implementation guidance for each of the four goals that will clarify roles and responsibilities, potential responses, and possible triggers. The guidance will be completed by December 30, 2016.

Develop a process to help ensure that its guidance for investigation of foreign or emerging animal diseases is followed, such as a process for documentation of the justification and approval of any deviation from the directions.

USDA Response: USDA agrees with the intent of this Recommendation. APHIS has procedures in place for responding to foreign animal diseases, documented in the FAD-Prep manuals and VS Guidance Document 12001.2 titled "Policy for the Investigation of Potential Foreign Animal Disease/Emerging Disease Incidents (FAD/EDI)." APHIS follows Guidance Document 12001.2 when disease is reported on farm and an investigation is initiated to evaluate the situation. Federal or State trained Foreign Animal Disease Diagnosticians (FADD) collect appropriate information and laboratory samples as indicated, and documentation that procedures are followed and results are finalized occurs through data and reports that are entered into the APHIS Emergency Management Reporting System.

While 12001.2 covers both foreign animal diseases and emerging disease incidents, there is a clear distinction between the two. An emerging disease is "not yet known or characterized" and may not result in an immediate additional on-farm investigation as is standard for a suspected foreign animal disease. The first finding of a SECD virus in the United States was at a university diagnostic laboratory and not from a request for a FADD to evaluate an on-farm situation. USDA initially determined that the appropriate action was to support swine industry-led efforts, thus providing the approval to supersede 12001.2. However, discussions with the swine industry did not result in consensus for on-farm investigations conducted by State or Federal officials.

Flexibility is necessary in evaluating and responding to emerging diseases. Future emerging issues may appear as industry trends or syndromes that would warrant broader epidemiologic study rather than individual farm investigations of acutely reported disease symptoms.

For newly emerging diseases, the further expansion and refinement APHIS intends to undertake on the emerging disease framework, to be completed by December 30, 2016, will address when and how emerging diseases may be investigated differently from the current Guidance 12001.2.

Develop a process to address deficiencies identified by USDA's root cause retrospective study or demonstrate the findings do not warrant management action to reduce the likelihood of the entry of future animal diseases into the United States.

USDA Response: USDA agrees with the intent of this Recommendation. USDA has identified two approaches to mitigate the potential risks identified in the study: 1) regulatory controls enacted by the Food and Drug Administration (FDA) under the Food Safety and Modernization Act (FSMA) are believed to address entry risk as part of the required hazard analysis, and 2) widespread communication of findings to feed and swine industry target management opportunities to further mitigate risks prior to of exposure of animals.

Because the FDA has regulatory jurisdiction of feed and feed facilities, APHIS consulted FDA to review the root cause study prior to its release for potential regulatory mitigations under FSMA. FDA noted its new rule "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals," enacted in September 2015, under FSMA requires animal food facilities, required to register with FDA as food facilities, to develop a food safety plan and perform a hazard analysis to identify known or reasonably foreseeable hazards associated with the animal food and the facility. In the analysis, the facility needs to consider such aspects as the ingredients, the manufacturing processes, the formulations, and the intended use of the animal food. If hazards are identified, the facility needs to implement measures to control those hazards.

After completion of the root cause investigation, APHIS developed communication strategies to disseminate the results of the report and empower stakeholders in the swine and feed industry to act upon the findings. The strategy included: 1) presentations and stakeholder meetings with both swine and feed industry representatives; 2) notification through the APHIS Stakeholder registry; 3) posting the report on the APHIS external website; and 4) preparation of a manuscript in the peer reviewed literature describing the root cause investigation and findings of virus stability in tote material studies. Summaries of the report appeared shortly after its release in most industry journals and reporting websites. This wide dissemination of the study findings provides information for both the producer and feed industries to enact management practices that mitigate virus entry to the animal herds.

Again, thank you for the opportunity to comment on this GAO Draft Report.

Sincerely,

Edward Avalos
Under Secretary
Marketing and Regulatory Programs

Appendix III: GAO Contacts and Staff Acknowledgments

GAO Contacts

John Neumann, (202) 512-3841 or neumannj@gao.gov.
Timothy M. Persons, (202) 512-6412 or personst@gao.gov.

Staff Acknowledgments

In addition to the individual named above, Mary Denigan-Macauley (Assistant Director), Sushil Sharma (Assistant Director), Leslie Ashton, Kevin Bray, Mark Braza, Allen Chan, Barbara El Osta, Cynthia Norris, Dan Royer, Amber Sinclair, and Elaine Vaurio made key contributions to this report.