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Report to Congressional Requesters

April 2017

AVIAN INFLUENZA

USDA Has Taken Actions to Reduce Risks but Needs a Plan to Evaluate Its Efforts

GAO-17-360

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GAO Highlights

Highlights of GAO-17-360, a report to congressional requesters

Why GAO Did This Study

Avian influenza is an extremely infectious and potentially fatal disease in poultry. In 2014 and 2016, two outbreaks of avian influenza led to the deaths of millions of poultry in 15 states and prompted emergency spending to control the disease. While the health risk to humans is low, humans have been infected with these viruses, sometimes fatally. A spike in fatal human infections in Asia began in late 2016.

GAO was asked to review several issues related to avian influenza. This report examines (1) how outbreaks of avian influenza have affected human health, animal health, and the U.S. economy, (2) the extent to which USDA has taken actions to address any lessons learned from its responses to the outbreaks in 2014 and 2016, and how it plans to evaluate the actions' effectiveness, and (3) ongoing challenges and associated issues, if any, federal agencies face in their efforts to mitigate the potential harmful effects of avian influenza. GAO reviewed global and domestic data on the effects of avian influenza and USDA reports and corrective action data associated with its responses to the recent outbreaks, and interviewed federal officials and stakeholders from state agencies and the poultry industry.

What GAO Recommends

GAO recommends that USDA develop a plan for evaluating the effectiveness of the corrective actions it has taken. USDA agreed with GAO's recommendation.

View GAO-17-360. For more information, contact Steve Morris at (202) 512-3841 or morriss@gao.gov.

What GAO Found

When avian influenza outbreaks occur, they can have significant effects on human and animal health and the U.S. economy. With regard to human health, avian influenza rarely affects humans, but the World Health Organization estimates that two particular types of the virus have caused more than 2,100 human infections and more than 800 deaths since 1997, primarily in Asia and the Middle East. With regard to animal health, avian influenza outbreaks can lead to large numbers of poultry deaths as a result of efforts to control and prevent the spread of the disease. For example, from December 2014 to June 2015, more than 50 million birds were destroyed in the largest outbreak in U.S. history. The effect of avian influenza on the health of other animal species varies. Swine are susceptible to both avian and human influenza viruses that, if mixed, could create a new virus to which humans are vulnerable. An outbreak can also have significant economic consequences; for example, the economic impacts of the 2014 outbreak in the United States have been estimated to range from $1.0 to $3.3 billion.

USDA identified 15 areas with lessons learned from its responses to the 2014 and 2016 outbreaks of avian influenza and 308 associated corrective actions. For example, one lesson learned in the area of depopulation (mass culling of flocks) is that there were not enough skilled personnel available for depopulating infected poultry, leading to delays and possibly increasing the spread of disease. USDA has identified as completed about 70 percent of the 308 corrective actions to address all of the lessons learned. However, the agency has not evaluated the extent to which completed corrective actions—such as encouraging states to form depopulation teams—have helped resolve the problems identified, and it does not have plans for doing so. GAO has previously found that agencies may use evaluations to ascertain the success of corrective actions, and that a well-developed plan for conducting evaluations can help ensure that agencies obtain the information necessary to make effective program and policy decisions. Such a plan would help USDA ascertain the effectiveness of the actions it took to resolve problems identified during recent outbreaks.

On the basis of GAO's analysis of federal efforts to respond to outbreaks and of stakeholders' views, GAO identified ongoing challenges and associated issues that federal agencies face in mitigating the potential harmful effects of avian influenza. For example:

- One challenge is that federal efforts to protect poultry from avian influenza rely on voluntary actions by a wide range of poultry producers to take routine preventative measures—known as biosecurity— to protect their flocks from disease. USDA has two major initiatives under way to encourage improvements to biosecurity.
- An associated issue that federal agencies face is that the chickens used to produce the eggs needed to manufacture critical human influenza vaccine are susceptible to influenza outbreaks. The Department of Health and Human Services is supporting the development of new vaccine manufacturing technologies to reduce reliance on eggs.

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Abbreviations

APHIS	Animal and Plant Health Inspection Service
CDC	Centers for Disease Control and Prevention
CFIA	Canadian Food Inspection Agency
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
Interior	Department of the Interior
USDA	U.S. Department of Agriculture

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April 13, 2017

The Honorable Greg Walden
Chairman
The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Tim Murphy
Chairman
The Honorable Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

The Honorable Fred Upton
House of Representatives

Avian influenza is a highly infectious and, in some circumstances, fatal disease in poultry, including chickens, turkeys, ducks, geese, and other domesticated fowl. Most avian influenza viruses have low pathogenicity, meaning that they cause no signs or only minor clinical signs of infection in poultry. In contrast, highly pathogenic avian influenza can cause a high death rate in poultry.[1] Two separate outbreaks of highly pathogenic avian influenza in the United States, one in 2014 and another in 2016, led to the deaths of millions of domesticated poultry in 15 states, caused economic losses for the U.S. poultry industry, and prompted emergency government spending on control measures.[2] According to the Department

[1]U.S. Department of Agriculture (USDA) regulations define highly pathogenic avian influenza as (1) any influenza virus that kills at least 75 percent of eight 4- to 6-week-old susceptible chickens within 10 days following intravenous inoculation with 0.2 ml of a 1:10 dilution of a bacteria-free, infectious allantoic fluid; (2) any H5 or H7 virus that does not meet the criteria in paragraph (1) of this definition, but has an amino acid sequence at the hemagglutinin cleavage site that is compatible with highly pathogenic avian influenza viruses; or (3) any influenza virus that is not an H5 or H7 subtype and that kills one to five chickens and grows in cell culture in the absence of trypsin. 9 C.F.R. § 53.1.

[2]The first detection of highly pathogenic avian influenza in 2014 occurred in December of that year. Additional associated detections occurred through June 2015. In this report, we refer to those events as the 2014 outbreak. The 2016 outbreak concerned detections of highly pathogenic avian influenza in January of that year.

of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC), while the risk posed to the general public by the avian influenza viruses that circulated in the 2014 and 2016 outbreaks was low, people in other countries have been infected, sometimes fatally, by similar viruses. For example, a similar avian influenza virus caused a spike in human infections and fatalities in China in late 2016 and early 2017, particularly among people in direct contact with poultry. The U.S. outbreaks did not cause infections in humans. However, we previously found in June 2007 that health experts were concerned that if a subtype of avian influenza develops the capacity to spread easily from person to person, a pandemic could occur.[3] According to the World Health Organization, controlling the virus in poultry is the principal way to reduce opportunities for human infection and, therefore, for a pandemic to emerge.

The U.S. Department of Agriculture (USDA) is responsible for acting to prevent, control, and eradicate any disease or pest of livestock, including foreign animal diseases such as highly pathogenic avian influenza, in domestic livestock and poultry.[4] In doing so, USDA typically partners with states and industry in eradicating such diseases, with the agency's level of involvement dependent upon states' preparedness and the size of the outbreak. USDA's Animal and Plant Health Inspection Service (APHIS), state and local animal health officials, and the poultry industry collaborate to eradicate avian influenza by, for example, depopulating (culling) affected poultry flocks to halt spread of the disease, cleaning and disinfecting premises and equipment, and testing for the presence of the virus. USDA compensates—indemnifies—poultry producers for birds and eggs lost to the disease and pays for cleaning, disinfection, and testing.[5]

[3]GAO, *Avian Influenza: USDA Has Taken Important Steps to Prepare for Outbreaks, but Better Planning Could Improve Response,* GAO-07-652 (Washington, D.C.: June 11, 2007). According to the CDC, there are four types of influenza viruses: A, B, C and D. Human influenza A and B viruses cause seasonal epidemics of disease almost every winter in the United States. The emergence of a new and very different influenza A virus to infect people can cause an influenza pandemic. Influenza type C infections generally cause a mild respiratory illness in people and are not thought to cause epidemics. Influenza D viruses primarily affect cattle and are not known to infect or cause illness in people. Pandemics happen when new (novel) influenza A viruses emerge that are able to easily infect humans and spread from person to person in an efficient and sustained way.

[4]A foreign animal disease is a transboundary animal disease not known to normally exist in the U.S. animal population, according to USDA's *Highly Pathogenic Avian Influenza Response Plan: The Red Book (Draft August 2015)*.

[5]Unless otherwise noted, we use the term "poultry producer" to refer to those who raise and manage poultry, regardless of whether they own the birds.

CDC collaborates with USDA and with state and local public health agencies to monitor people who are involved in activities to control and eradicate an outbreak to determine whether they experience influenza-like illness that may be associated with an outbreak in poultry. The Department of the Interior's (Interior) U.S. Geological Survey and U.S. Fish and Wildlife Service collaborate with USDA, HHS, state and local governments, and private interests to conduct surveillance of wild birds and other animals for avian influenza.[6]

You asked us to review several issues related to avian influenza. Our objectives were to (1) provide information on how avian influenza has affected human health, animal health, and the U.S. economy; (2) examine the extent to which USDA has taken actions to address any lessons learned from its responses to the avian influenza outbreaks in 2014 and 2016 and how it plans to evaluate the effectiveness of such actions; and (3) identify what ongoing challenges and associated issues, if any, federal agencies face in their efforts to mitigate the potential harmful effects of avian influenza.

To provide information on how avian influenza has affected human health, animal health, and the U.S. economy, we reviewed data from the CDC, World Health Organization, and World Organisation for Animal Health, among other sources. Specifically, to provide information on human health, we reviewed global and U.S. data on avian influenza-related human mortality and morbidity dating back to 1918, the first recorded pandemic of probable avian origin. Regarding animal health, we reviewed USDA data and scientific literature on highly pathogenic avian influenza outbreaks among poultry dating back to 1924, the first recorded outbreak of highly pathogenic avian influenza in the United States. For low pathogenic avian influenza outbreaks among poultry, we obtained USDA data starting in 2002 that were readily available in proceedings of the U.S. Animal Health Association's annual meetings. For information regarding influenza in other mammals, we reviewed agency information, scientific literature, and interviewed federal, state, and industry officials. For wild birds, we reviewed scientific literature on federal monitoring from

[6]These agencies are members of The Interagency Steering Committee for Surveillance for Highly Pathogenic Avian Influenza in Wild Birds. According to the committee's June 2015 strategic plan, the committee will facilitate a coordinated and cooperative approach among federal and state agencies and other cooperators to surveil wild birds for the presence of avian influenza viruses in the United States. Surveillance methods include investigation of morbidity and mortality events, surveillance of live wild birds and hunter-harvested birds, and environmental sampling.

2006 to 2011 and monitoring data from 2014 to 2016, when Interior's U.S. Geological Survey and USDA began their current wild bird surveillance program. Regarding impacts on the U.S. economy, we focused on the 2014 outbreak of highly pathogenic avian influenza since it was the largest recent outbreak. We reviewed a variety of economic literature for information on the estimated costs of the 2014 outbreak to U.S. agriculture and consumers. We obtained data on USDA obligations for its responses to that outbreak, the January 2016 outbreak, and a May 2016 low pathogenic avian influenza outbreak. To assess the reliability of the data sources noted above, we reviewed the data and supporting documentation and interviewed officials familiar with the data, and we determined that the data were sufficiently reliable for providing information on the effects of avian influenza on human and animal health and the economy. We also asked for observations on the federal responses to the outbreaks of avian influenza through interviews with officials from USDA, HHS, Interior, and state and industry representatives in six states. We selected the six states—California, Indiana, Iowa, Minnesota, North Carolina, and Ohio—either because they were affected by the 2014 and 2016 highly pathogenic avian influenza outbreaks or because they have large poultry industries.[7]

To examine the extent to which USDA has taken actions to address any lessons learned from its responses to the 2014 and 2016 avian influenza outbreaks and how it plans to evaluate the effectiveness of such actions, we reviewed USDA's after action reports of its responses to the 2014 outbreak in western and midwestern states and the 2016 outbreak in Indiana.[8] We also reviewed USDA's Corrective Action Program database for tracking the agency's progress in completing tasks identified in its after action reports and USDA documentation of specific steps taken in response to lessons learned. To examine USDA's tracking of corrective actions in the database, we conducted an in-depth review of a nongeneralizable sample of 10 corrective actions listed in the database.

[7]California, Iowa, and Minnesota were directly affected by the outbreak of highly pathogenic avian influenza that began in 2014. Indiana was directly affected by the outbreak that began in 2016. North Carolina and Ohio were not directly affected by those outbreaks but have large poultry industries. In 2015, North Carolina ranked among the top five U.S. states for turkey and broiler production, while Ohio ranked in the top five for egg production.

[8]According to USDA guidance on evaluation and improvement planning, after action reports summarize key information from exercises and responses. Such a report includes feedback, lessons learned, and analysis of a response and is usually developed in conjunction with a plan for improvement.

For this sample, we randomly selected actions from each of six preparedness and response areas that fit within the scope of our overall review and that USDA classified in its database as priority 1 items with a status of "closed," "completed," or "in progress."[9] We requested and reviewed agency documents and information from officials describing the steps taken to close, complete, or make progress on the actions in our sample. Our review of this sample of actions provides general information about the steps USDA has taken related to these 10 actions; however, the results from this sample are not generalizable to all corrective actions in the database. To assess the overall reliability of the Corrective Action Program database for use in our report, we reviewed management controls over the information systems that maintain the data and interviewed USDA officials who manage the database. We determined that the database was sufficiently reliable to describe the general status of corrective actions and to provide examples of specific actions identified for addressing lessons learned.

To determine what ongoing challenges and associated issues, if any, federal agencies face in their efforts to mitigate the potential harmful effects of avian influenza, we reviewed our prior findings and recommendations on preparing for and responding to animal diseases; the views of stakeholders from the six selected states about challenges related to federal efforts to mitigate the potential harmful effects of highly pathogenic avian influenza; and other sources of information related to wildlife surveillance, domestic poultry and swine surveillance, biosecurity measures to reduce the risk of disease, depopulation of poultry, disposal of poultry carcasses, vaccines for poultry, research on disease transmission and prevention, and protecting the egg supply for human vaccine production. We selected these categories on the basis of preliminary discussions with agency officials and industry representatives and our 2007 report on avian influenza. We gathered the views of stakeholders through interviews with 6 state veterinarians; 10 state public health officials, including public health veterinarians and epidemiologists; and 6 poultry industry representatives from the six states selected. We also interviewed an official from the Canadian Food Inspection Agency (CFIA) about the responses to 2014 and 2015 outbreaks of highly pathogenic avian influenza in British Columbia and Ontario that involved the same viruses that caused the U.S. outbreaks.

[9]USDA defined priority 1 corrective actions as those that would have immediate, critical implications for a future outbreak and that could be completed in less than 1 year.

We conducted this performance audit from March 2016 to March 2017 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

This section provides information on avian influenza viruses; avian influenza transmission in and between humans and animals; commercial and noncommercial poultry production in the United States; our prior work on avian influenza; and the responsibilities that USDA, HHS, and Interior have with respect to avian influenza response, research, surveillance, and other related activities.

Avian Influenza Viruses

Avian influenza is caused by a "Type A" influenza virus (influenza A). Avian-origin influenza viruses are broadly categorized based on a combination of two groups of proteins on the surface of the influenza A virus: hemagglutinin or "H" proteins, of which there are 16 (H1-H16), and neuraminidase or "N" proteins, of which there are 9 (N1-N9). Many different combinations of "H" and "N" proteins are possible. Each H and N combination is considered a different subtype, and related viruses within a subtype may be referred to as a lineage. Avian influenza viruses can be divided into two groups based on the specific genetic features and severity of the disease they cause in 4- to 8-week old chickens in a laboratory setting: low pathogenic and the more severe highly pathogenic. Influenza A has the potential to cause human pandemics, regardless of its pathogenicity in poultry.

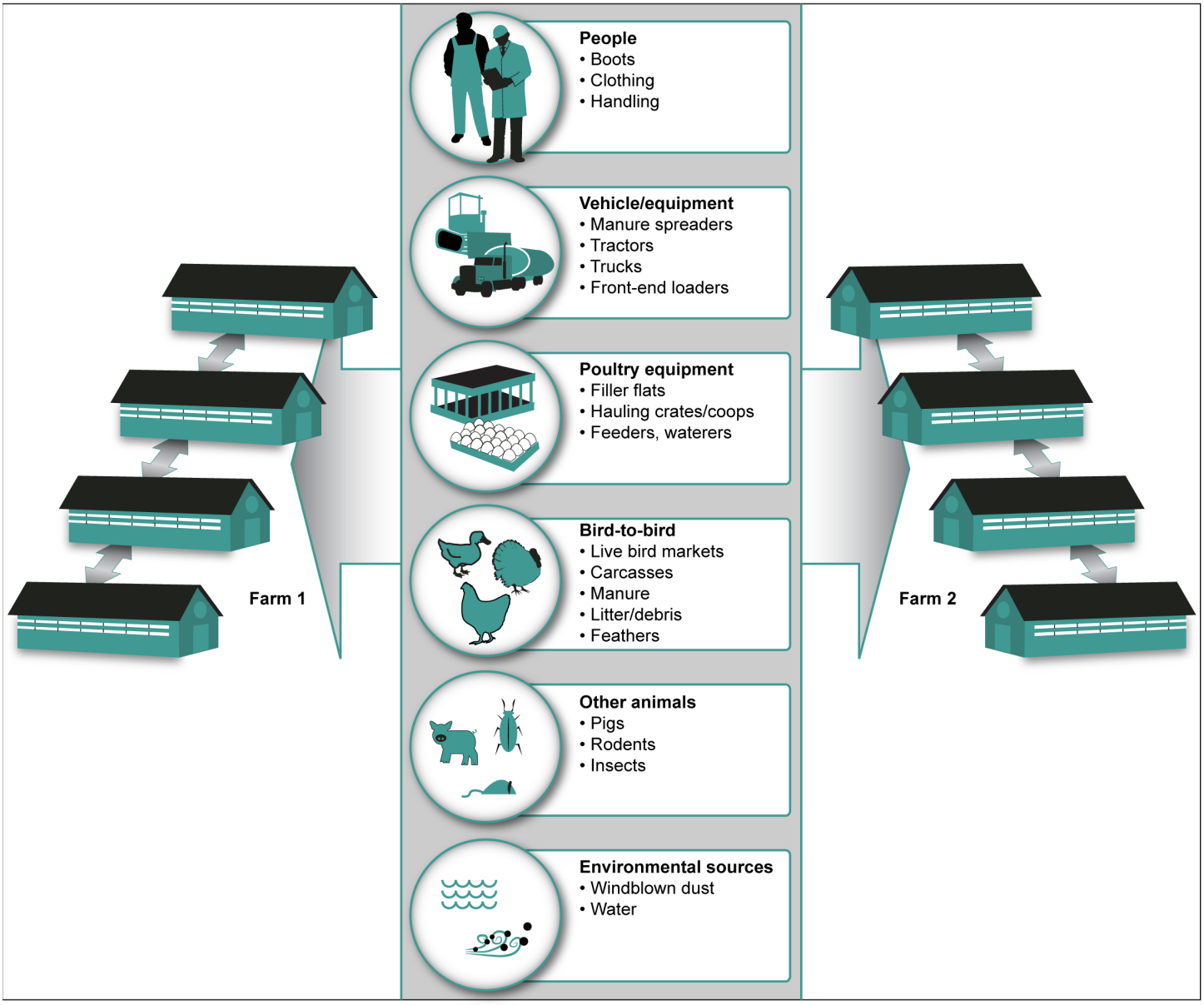
Avian Influenza Transmission

Wild aquatic birds—such as waterfowl, gulls, and shorebirds—are the natural hosts for influenza A viruses.[10] Direct or indirect contact with infected wild birds can expose poultry to avian influenza viruses. Similarly, infected poultry may spread avian influenza into wild bird populations. Avian influenza viruses can also be moved from place to place—including between farms—by people, equipment, vehicles, feed,

[10]Swayne, David E., ed. *Animal Influenza*, 2nd Ed. (Hoboken, N.J.: John Wiley & Sons, 2017).

insects, rodents and other animals, water, and wind-blown dust as shown in figure 1. Poultry producers may implement biosecurity measures to reduce the risk that diseases such as avian influenza will be transmitted to their flocks. For example, producers may disinfect vehicles arriving at and leaving a farm or direct employees to disinfect boots and hands before entering a poultry barn. During an outbreak in poultry, additional biosecurity measures may be used to prevent the disease from further spreading. For example, USDA personnel and contractors working to control an outbreak would be expected to restrict their movements among locations to prevent carrying the virus to an uninfected site.

Figure 1: Ways in Which Avian Influenza Can Spread among Poultry Farms



Sources: U.S. Department of Agriculture and GAO. | GAO-17-360

One form of highly pathogenic avian influenza has become endemic in several countries, including China, Indonesia, and Vietnam; this means that the virus has become entrenched in poultry populations in those countries. USDA considers highly pathogenic avian influenza a "foreign

animal disease" in the United States, meaning U.S. poultry are normally free from the disease. The United States, as a member of the World Organisation for Animal Health, has agreed (through USDA), along with other member countries, to notify the organization and its members of any detection of highly pathogenic avian influenza.[11] Member countries also agree to report cases of low pathogenic H5 or H7 avian influenza found in poultry or other birds because these viruses have the potential to mutate to a highly pathogenic form in poultry and may infect other species. When a country's poultry tests positive for "notifiable" avian influenza, its international trading partners may restrict trade with that country until the partners believe the virus is eradicated—an outcome that can take many months to achieve. Therefore, when a flock is infected with notifiable H5 or H7 avian influenza, the goal of the poultry industry and government agencies is to control and eradicate the virus as rapidly as possible in order to prevent its spread and regain the confidence of trading partners that any future imports of poultry or poultry products will be virus free. To this end, USDA and other federal, state, and industry partners aim to act quickly in the affected area to, among other things: (1) quarantine susceptible animals; (2) implement biosecurity measures; (3) depopulate infected and exposed birds; (4) dispose of contaminated and potentially contaminated materials, including animal carcasses; and (5) clean and disinfect the infected premises. Once the virus is eradicated, USDA, states, and the poultry industry resume routine surveillance for notifiable avian influenza.

Poultry in the United States

According to USDA's Economic Research Service, the U.S. poultry industry is the world's largest producer and second-largest exporter of poultry. The most recent Census of Agriculture reported 233,770 poultry farms in the United States in 2012, but the U.S. poultry industry consists, in large part, of a relatively small number of large companies that own all aspects of the production process—from the hatchery to the processing

[11]The World Organisation for Animal Health, of which the United States is a member, is an intergovernmental organization responsible for improving animal health worldwide and ensuring trade. It requires its 180 member countries to report certain diseases to the organization and other member countries.

facility.[12] The most common types of poultry raised commercially are chickens for consumption (broilers) and chickens that lay eggs (layers), as well as turkeys. There are also poultry that are genetic breeding stock and whose main function is to produce offspring that facilitate mass production and are economical to raise. Additionally, there are poultry raised specifically for producing eggs to make human vaccines. Commercial poultry operations typically raise tens of thousands of birds in confined poultry houses. Such operations can include multiple houses located close to each other. Because of the environment in which commercial birds are raised, if one bird becomes infected with a notifiable avian influenza, hundreds of thousands of birds can be exposed and will need to be depopulated.

In addition to poultry raised commercially, numerous types of birds are raised in backyards, with flocks of up to 1,000 birds. These "backyard birds" are typically chickens used for personal egg production and consumption; they also can include game birds, such as quail and pheasant. These birds may roam free or be confined to a poultry house. In addition, there are birds in live bird markets—facilities that sell live poultry, typically slaughtered on-site, to the general public—and some are sold at auctions and swap meets.

Our Related Prior Work

In a June 2007 report, we found that USDA had made important strides to prepare for highly pathogenic avian influenza outbreaks but that incomplete planning and other unresolved issues could slow a response.[13] There were several unresolved issues at the time that, absent advance consideration, could hinder response. For example, we found that disposal of carcasses and materials infected with highly pathogenic avian influenza could be problematic because operators of landfills were reluctant to accept materials infected with even low pathogenic avian influenza because of the perceived human health risk. To increase the likelihood of rapidly containing a highly pathogenic avian influenza outbreak, we made seven recommendations to USDA, including that the

[12]For example, according to a 2014 report by USDA, broiler production and processing is carried out within tightly integrated production complexes operated by firms called integrators. In 2012, 20 integrators together accounted for 96 percent of all broilers produced in the United States, and the top 3 accounted for 50 percent. U.S. Department of Agriculture, Economic Research Service, *Technology, Organization, and Financial Performance in U.S. Broiler Production* (Washington, D.C.: June 2014).

[13]GAO-07-652.

agency develop a response plan that identifies critical tasks for responding to an outbreak and address concerns about antiviral medication for humans. USDA generally agreed with our recommendations and took action to implement all seven recommendations. (A list of prior related GAO work is included at the end of this report.)

Federal Agencies' Roles in Avian Influenza Response, Research, Surveillance, and Other Related Activities

Multiple organizations within USDA support its animal health mission. When notifiable avian influenza outbreaks occur, APHIS is the lead agency within USDA for preventing and responding to animal disease outbreaks. USDA derives its authority to carry out operations and measures to prevent, detect, control, and eradicate notifiable avian influenza, among other diseases, from the Animal Health Protection Act.[14] The act authorizes the Secretary of Agriculture to hold, seize, quarantine, treat, destroy, or dispose of any animal, means of conveyance, or object that can harbor the disease, or to restrict their movement in interstate commerce. The act also authorizes the Secretary to transfer necessary funds from other USDA appropriations or available funds to manage an emergency in which a disease of livestock threatens any segment of agricultural production in the United States, in order to arrest, control, eradicate, or prevent the spread of the disease. USDA's Wildlife Services, a program unit within APHIS, conducts research on wildlife diseases, such as avian influenza, that may affect agriculture and human health and safety. USDA's Agricultural Research Service conducts research on, among other things, poultry diseases and vaccines for those diseases. For example, the agency published a report in 2014 on experts' analyses of gaps in knowledge about influenzas in poultry and other animals and about effective countermeasures to control and mitigate outbreaks of disease.[15]

HHS is responsible for, among other things, research on human disease, disease surveillance, and vaccine production and distribution. Within HHS, the Influenza Division of CDC's National Center for Immunization and Respiratory Diseases conducts surveillance of influenza in humans, including human infections caused by viruses with animal origins; the

[14]Pub. L, No. 107-171, tit. X, subtit. E, §§ 10401-10418 (codified as amended at (7 U.S.C. §§ 8301-8318)).

[15]U.S. Department of Agriculture, Agricultural Research Service, *Animal Influenza Viruses: Gap Analysis Workshop Report* (Washington, D.C.: 2014).

division also conducts laboratory studies on influenza viruses of concern to characterize them and assess their risks to humans. HHS's Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety and efficacy of veterinary drugs and medical devices and by licensing biological products that are safe, pure, and potent, including vaccines for pandemic influenza. In addition, FDA is responsible for ensuring the safety and proper labeling of more than 80 percent of the U.S. food supply.

In cooperation with USDA's Wildlife Services program and state agencies, Interior participates in the federal government's surveillance of wild migratory birds for the presence of avian influenza and provides leadership and support in the area of wildlife disease research and diagnostics. Interior's U.S. Geological Survey maintains the National Wildlife Health Center, which identifies, controls, and prevents wildlife losses from diseases; conducts research to understand the impact of diseases on wildlife populations; and devises methods to more effectively manage these disease threats. (See app. I for more detail on the roles of federal departments and their component agencies as related to avian influenza.)

Avian Influenza Has Harmed Human Health, Animal Health, and the U.S. Economy

Avian influenza viruses have harmed global human and animal health and the U.S. economy. These viruses rarely infect humans, but some viruses may have high rates of mortality when they do. Avian influenza outbreaks have led to the deaths of hundreds of millions of domesticated poultry in dozens of countries, either directly or through depopulation to prevent spread of the disease. The 2014 and 2016 outbreaks among U.S. poultry led to costs to the federal government of about $930 million and additional costs to the U.S. economy of an estimated $1 billion or more.

Avian Influenza Rarely Infects Humans, but the Mortality Rate for Those Infected Has Been Relatively High

As of March 2017, two lineages of avian influenza—Asian H5N1, which emerged in 1997, and a new strain of H7N9, which emerged in 2013—have together infected more than 2,100 humans and killed more than 900, primarily in Asia and Africa. Neither lineage has developed the capacity to be easily transmissible from birds to humans or from person to person. However, there have been other instances in which influenza A viruses of avian origin have become more easily transmissible and have caused global pandemics that led to large numbers of fatalities in the United States and around the world. Table 1 summarizes occurrences of fatal influenza A infections in humans that are known to have or are suspected of having an avian origin. The likelihood that an influenza A

virus of avian origin will evolve into a form easily transmissible among humans is small, according to officials from HHS, but if such a change occurs, it could lead to serious disease among humans and possibly another pandemic. For example, the World Health Organization has expressed concern that the Asian lineage H5N1 and H7N9 viruses that have sporadically infected humans in Asia, Northern Africa, and the Middle East could evolve to become more easily transmissible to or between humans and lead to serious disease or another pandemic. According to CDC's website, of the novel influenza A viruses that are of special concern to public health, the agency rates the Asian lineage H7N9 virus as having the greatest potential to cause a pandemic, as well as potentially posing the greatest risk to severely impact public health.

Table 1: Occurrences of Influenza A in Humans, from 1918 to March 2017

Years	Place of origin	Extent	Influenza subtype[a]	Reported number of human deaths	Resulted in a pandemic[b]
1918	Europe and the United States	Worldwide	Probable avian influenza (H1N1)	50 million-100 million worldwide; 675,000 in the United States	Yes
1957-58	East Asia	Worldwide	Avian influenza (H2N2)	1.1 million worldwide, 116,000 in the United States	Yes
1968-1969	Southeast Asia	Worldwide	Avian influenza (H3N2)	1 million worldwide, 100,000 in the United States	Yes
1997	Hong Kong	China	Avian influenza (H5N1)	6	No
2003-Mar. 2017[c]	China	Asia, Middle East, and Africa[d]	Avian influenza (H5N1)	453	No
2009-2010	United States	Worldwide	Quadruple reassortant influenza (H1N1)[e]	Up to 575,000 worldwide, up to 18,000 in the United States	Yes
2013-Mar. 2017[c]	China	Asia[f]	Avian influenza (H7N9)	At least 489	No
2014-Mar. 2017[c]	China	China	Avian influenza (H5N6)	6	No

Sources: Centers for Disease Control and Prevention (CDC) and World Health Organization. | GAO-17-360

[a]Avian influenza is a Type A influenza. Influenza A can infect animals and humans and can also cause pandemics. There are many different subtypes of avian-origin influenza A viruses. These subtypes are classified based on a combination of two groups of proteins on the surface of the influenza A virus: hemagglutinin or "H" proteins, of which there are 16 (H1-H16), and neuraminidase or "N" proteins, of which there are 9 (N1-N9). Many different combinations of "H" and "N" proteins are possible. Each combination is considered a subtype, and related viruses within a subtype may be referred to as a lineage.

[b]An influenza pandemic is a global outbreak of a new influenza A virus in humans, while an outbreak is the occurrence of cases of disease in excess of what would normally be expected in a defined community, geographical area, or season.

[c]Data for these occurrences of avian influenza are as of March 16, 2017.

[d]In January 2014, a traveler who had recently returned to Canada from China died from H5N1 infection. That was the only reported case of H5N1 infection in North America as of Dec. 19, 2016.

[e]According to CDC, the 2009 H1N1 influenza is a "quadruple reassortant" virus because while each separate gene segment of the virus has been found in pigs, the individual gene segments of the virus originated from humans, birds, North American pigs, and Eurasian pigs.

[f]Some cases of H7N9 have been reported outside of mainland China, but most of these infections have occurred among people who had traveled to mainland China before becoming ill.

Outbreaks of Avian Influenza Have Killed Millions of Poultry Worldwide but Caused Few Fatalities in Other Species

Avian influenza outbreaks—both highly pathogenic and low pathogenic—have led to the deaths of hundreds of millions of domesticated poultry in dozens of countries, either directly or through depopulation to prevent spread of the disease.[16] For example, the H5N1 highly pathogenic avian influenza outbreak that led to human fatalities in China in 1997 also led to the deaths of an estimated 220 million birds in China and Hong Kong.[17] In the United States, outbreaks of highly pathogenic avian influenza have led to the deaths of more than 67 million birds since 1983, with the most recent outbreaks beginning in December 2014 and ending in June 2015 and, in unrelated incidents, in January 2016 and March 2017. (See table 2 for details of known outbreaks of highly pathogenic avian influenza in commercial U.S. poultry.)

[16]Swayne, David E., ed. *Avian Influenza* (Ames, Iowa: Blackwell Publishing, 2008).

[17]Swayne, *Avian Influenza*.

Table 2: Known Highly Pathogenic Avian Influenza Outbreaks in Commercial U.S. Poultry from 1924 to March 2017

Year(s) of outbreak	State(s)	Origin	Highly pathogenic avian influenza subtype(s)	Reported number and type of birds depopulated[a]
1924-1925	New York, New Jersey, Pennsylvania, Connecticut, Illinois, Indiana, Michigan, Missouri, and West Virginia	Live bird market	H7	Up to 600,000 in New York City alone
1929	New Jersey	Uncertain; possibly introduced by imported European partridges	Uncertain	Uncertain, "four flocks."
1983-1984	Pennsylvania, Virginia, and New Jersey	Live bird market[b]	H5N2	17 million chickens, turkeys, guinea fowl, and partridges
2004	Texas	Live bird market	H5N2	6,600 broilers
2014-2015	Arkansas , California, Idaho, Indiana, Iowa, Kansas, Minnesota, Missouri, Montana, Nebraska, North Dakota, Oregon, South Dakota, Washington, and Wisconsin.	Wild birds	H5N2 and H5N8	7.4 million turkeys, 43 million layers, and 120,000 from "mixed flocks"
2016	Indiana[c]	Wild birds	H7N8	62,109 turkeys
2017	Tennessee	Unknown	H7N9	129,000 broiler breeders

Sources: GAO analysis of U.S. Department of Agriculture and World Organisation for Animal Health data and D.A. Halvorson, "Prevention and management of avian influenza outbreaks: experiences from the United States of America," *Revue scientifique et technique (International Office of Epizootics)* vol. 28, no. 1 (2009): 359-369. | GAO-17-360

[a]Broilers are chickens raised for consumption. Layers are chickens that lay eggs.

[b]A live bird market is any facility—including botanica, poultry store, or custom slaughter—that sells live poultry for on-site slaughter or for off-site ritual use. A botanica is an establishment that sells supplies and some types of poultry or livestock (or both) for sacrificial religions such as Santería and Vodou.

[c]The Indiana outbreak was restricted in size and scope to a single county and 12 premises. This table reports on poultry at sites associated with highly pathogenic avian influenza. In all, more than 414,000 birds were affected.

Highly Pathogenic Avian Influenza in Canada

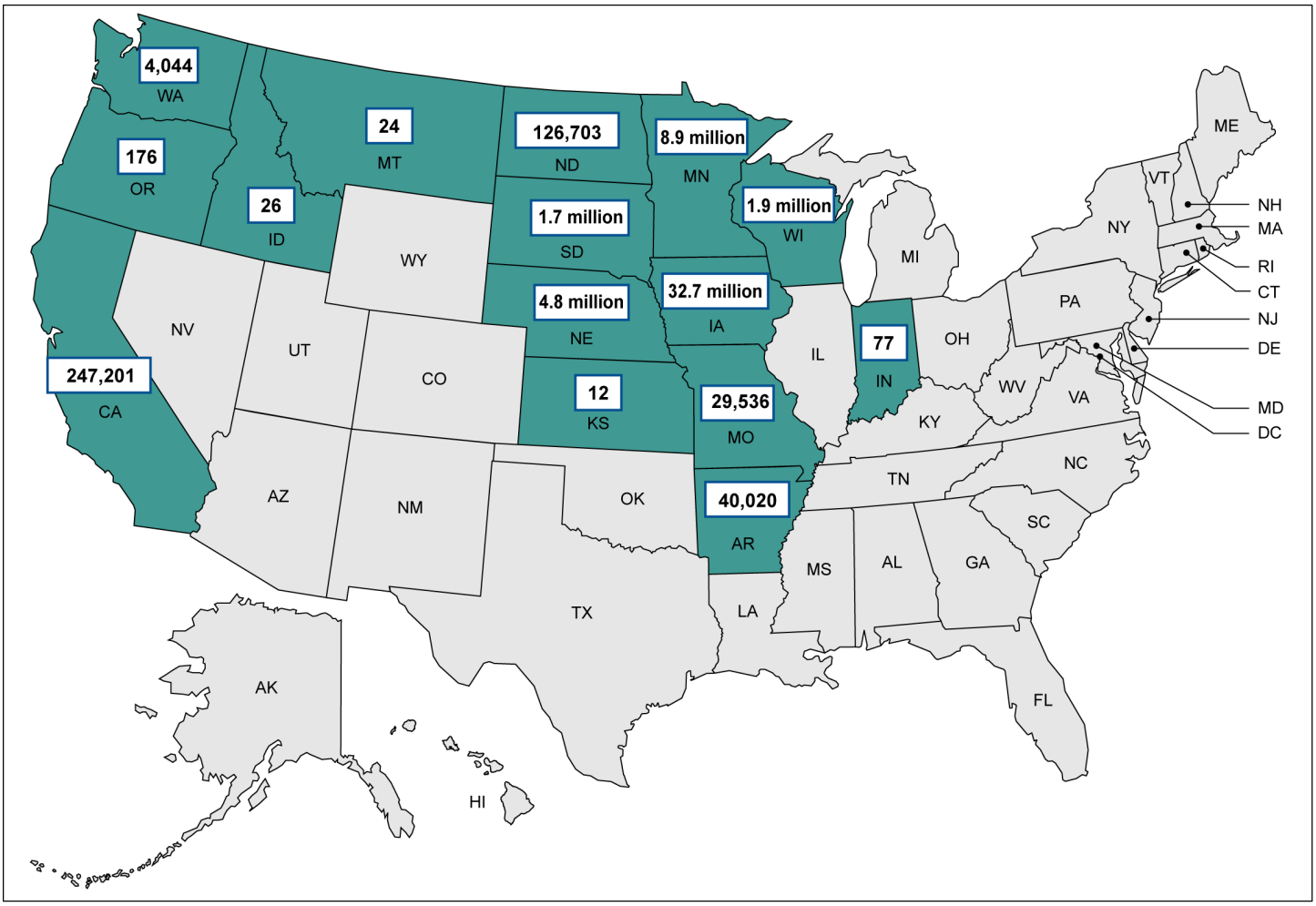
Avian influenza is an extremely infectious and, in some circumstances, fatal disease in poultry, including chickens and turkeys. Avian influenza viruses are classified as either "low pathogenic" or "highly pathogenic" based on their genetic features and the severity of the disease they cause in poultry. Beginning in early December 2014, the Canadian Food Inspection Agency (CFIA), which leads responses to avian influenza outbreaks in Canada, learned of highly pathogenic avian influenza on 13 poultry farms in British Columbia; these included turkey and chicken farms. To eradicate the virus, CFIA depopulated 240,000 birds. Wild birds migrating along the Pacific Flyway were the most likely cause of the outbreak, according to CFIA. In April 2015, CFIA identified highly pathogenic avian influenza in 1 chicken farm and 2 turkey farms in Ontario. The agency controlled the virus by depopulating 79,700 birds. According to a CFIA official, two characteristics of the Canadian poultry industry that facilitate the adopting of biosecurity measures in poultry farms helped limit the size of the 2014 and 2015 Canadian outbreaks. First, poultry farms in Canada are relatively small compared with those in the United States, which reduces the number of birds infected and the chance that influenza will replicate and spread. Second, Canadian poultry companies are not heavily integrated; therefore there is little movement of birds, feed, equipment, and people that could carry the virus from one farm to another.

Source: GAO analysis of CFIA documents and interview with agency official; Map Resources (map). | GAO-17-360

USDA identified the first U.S. cases of the 2014 outbreak of highly pathogenic avian influenza H5 viruses in captive wild birds or backyard flocks in Washington and Oregon in December 2014 and in Idaho the following month. Also in December 2014, USDA identified another subtype, H5N8, in Washington and Oregon. By the time USDA and its state and industry partners eradicated the diseases in June 2015, the related H5N2 and H5N8 viruses had infected poultry flocks on 232 farms in 15 states, with the largest number of affected farms being in Minnesota (110 farms) and Iowa (77 farms).[18] (See fig. 2 for a map showing the 15 states and the approximate number of birds killed or depopulated as a result of the outbreak that began in 2014.)

[18]The infected farms included commercial and backyard flocks.

Figure 2: Approximate Number of Birds Killed as a Result of the 2014 Outbreak of Highly Pathogenic Avian Influenza, by State



Sources: U.S. Department of Agriculture, Map Resources (map). | GAO-17-360

In January 2016, USDA confirmed the presence of an unrelated highly pathogenic avian influenza virus, subtype H7N8, in a commercial turkey flock in Indiana. USDA also found the low pathogenic form of the virus at 8 other nearby commercial turkey farms. About 414,000 birds were depopulated as part of the effort to eradicate the viruses. By May 2016, the viruses were controlled and all producers were permitted to restock (i.e., replace the poultry lost to the disease with new birds). In March 2017, USDA confirmed the presence of another highly pathogenic avian influenza virus, subtype H7N9, in commercial chicken flocks in Tennessee. About 129,000 birds were depopulated as part of the effort to

control the virus. Notably, the influenza virus in Tennessee was not the same H7N9 virus that has caused human infections and fatalities in Asia.

While low pathogenic avian influenza may not cause high mortality in poultry, flocks that are infected with H5 or H7 subtypes of low pathogenic avian influenza are often depopulated because those subtypes have the potential to mutate and become highly pathogenic. This happened in the 2016 outbreak in Indiana, when low pathogenic H7N8 avian influenza became highly pathogenic in a commercial turkey flock. Outbreaks of low pathogenic avian influenza in U.S. commercial poultry flocks have led to the deaths—through depopulation—of more than 6 million birds from 2002 through March 2017, as shown in table 3. In addition, according to USDA officials, the agency has documented low pathogenic H5 and H7 avian influenza viruses 23 times in live bird markets from 2002 through 2016.

Table 3: Low Pathogenic Avian Influenza Outbreaks in U.S. Commercial Poultry, from 2002 to March 2017

State(s)	Low pathogenic avian influenza subtype	Year of outbreak[a]	Reported number and type of birds depopulated[b]
Virginia/North Carolina/ West Virginia	H7N2	2002	4.7 million turkeys, including breeders, and chicken broilers, breeders, and layers
Texas	H5N3	2002	Layers
California	H5N2	2002	Turkey breeders
Connecticut	H7N2	2003	100,000 layers
Rhode Island	H7N2	2003	30,000 layers
Delaware	H7N2	2004	84,000 broilers
Maryland	H7N2	2004	328,000 broilers
Texas	H7N3	2004	51,000 breeder chickens
Nebraska	H7N9	2007	145,000 turkeys
Virginia	H5N1	2007	54,000 turkeys
West Virginia	H5N2	2007	25,600 turkeys
Idaho	H5N8	2008	30,300 game birds
Arkansas	H7N3	2008	16,000 breeder chickens
Minnesota	H7N9	2009	500,000 turkeys
Kentucky	H7N9	2009	20,000 broiler breeders
Missouri	H7N3	2011	29,000 turkeys
Minnesota	H7N9	2011	3,000 turkeys
Arkansas	H7N7	2013	9,800 broiler breeders
California	H5	2014	95,000 quail and 21,000 Peking ducks
Indiana[c]	H7N8	2016	352,114 turkeys and layers
Missouri	H5N1	2016	39,000 turkeys
Wisconsin	H5N2	2017	84,000 turkeys held in quarantine
Alabama, Georgia, and Tennessee	H7N9	2017	100,585 broiler breeders and backyard birds
Kentucky	H7N9	2017	24,700 broiler breeders and backyard birds

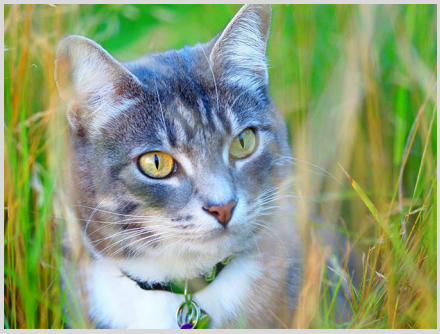
Sources: U.S. Department of Agriculture and U.S. Animal Health Association. | GAO-17-360

[a]We selected 2002 as the starting date for this table because data from the U.S. Department of Agriculture were readily available from that year forward in proceedings of the U.S. Animal Health Association's annual meetings.

[b]Broilers are chickens raised for consumption. Layers are chickens that lay eggs. Breeders produce offspring that facilitate mass production. Game birds are those raised for hunting.

[c]The Indiana outbreak was restricted in size and scope to a single county and 12 premises. This table reports on poultry at sites associated with low pathogenic avian influenza. In all, more than 414,000 birds were affected.

Cats Infected with Avian Influenza in New York City Animal Shelters



According to the Centers for Disease Control and Prevention (CDC), in November 2016, a low pathogenic avian influenza A (H7N2) virus infected cats in New York City animal shelters. Some affected cats showed mild flu-like symptoms such as sneezing or runny noses, and 450 were quarantined until they no longer showed symptoms of infection. A veterinarian collecting respiratory samples from exposed cats contracted the virus and subsequently recovered. According to CDC's website, known human infections with H7N2 are uncommon and have not led to deaths. However, the agency noted that finding avian influenza virus in an unexpected animal, such as a cat, is always concerning because it means the virus has changed in a way that may pose a new health threat.

Source: CDC. Cosmic Photography (photo). | GAO-17-360

The effect of avian influenza on the health of other animal species varies. Avian influenza generally causes few signs of illness and is rarely fatal when it circulates in waterfowl and shorebirds. Because wild birds are rarely sickened by the virus, they are able to move it efficiently along migratory flyways. Interior officials told us, however, that incidents in which wild birds have been killed by highly pathogenic avian influenza have become more common; these officials noted in particular incidents in Asia involving the H7N9 virus. According to the World Health Organization, some mammal species, including swine, can be infected with avian influenza but may show few, if any, observable symptoms, and others, such as ferrets, may experience high morbidity and mortality.[19] Infections in waterfowl and swine are of concern because they can spread the virus to poultry and humans, according to the World Organisation for Animal Health.[20] Swine can also serve as "mixing vessels" in which different influenza viruses come into contact, exchange genetic material, and possibly produce a new virus that is more easily transmissible to or between humans.[21] The H1N1 virus that emerged in 2009 contained gene segments from swine, avian, and human influenza viruses. According to the World Health Organization, the virus caused a global pandemic with up to 550,000 human deaths worldwide from April 2009 to April 2010; the CDC estimates that up to 18,000 of those human deaths occurred in the United States.[22] In addition, a 1976 outbreak of H1N1 swine influenza at Fort Dix, New Jersey, infected up to 230 humans and killed 1 person. More recently, according to CDC documents, more than 360 people in the United States were infected with influenza A (H3N2) variant influenza from August 2011 through September 2016, with one fatality.[23] Also according to CDC, these infections have mostly been associated with prolonged exposure to pigs at agricultural fairs.

[19]Other species known to be susceptible to avian influenza include whales, horses, seals, dogs, cats, tigers, skunks, rats, mice, and weasels.

[20]World Organisation for Animal Health, "Avian Influenza," http://www.oie.int/fileadmin/home/eng/media_center/docs/pdf/disease_cards/ai-en.pdf, downloaded Oct. 12, 2016.

[21]Shinde, et al., "Triple-Reassortant Swine Influenza A (H1) in Humans in the United States, 2005-2009," *New England Journal of Medicine,* vol. 360, no. 25 (June 18, 2009).

[22]Shinde, et al., "Triple-Reassortant Swine Influenza A (H1) in Humans in the United States, 2005-2009."

[23]Influenza viruses that normally circulate in pigs are called "variant" viruses when they are found in people.

Recent Outbreaks Have Cost the Federal Government and the U.S. Economy Billions of Dollars

Outbreaks of avian influenza in poultry in the United States in 2014 and 2016 cost the federal government about $930 million, according to USDA documents, and the 2014 outbreak cost the economy from $1 billion to $3.3 billion, according to two studies by USDA and a private firm. According to USDA budget documents for fiscal years 2015 and 2016, the agency obligated a total of about $869 million for the responses to the 2014 outbreak in 15 states, the January 2016 outbreak in Indiana, and a May 2016 outbreak of low pathogenic avian influenza in Missouri. As shown in table 4, the largest portion of these obligations was for response operations, including depopulation, disposal, composting, and cleaning and disinfection. Indemnity payments to poultry producers were another large category of obligations. Nearly all of the funds were transferred from the Commodity Credit Corporation.[24]

Table 4: U.S. Department of Agriculture (USDA) Obligations for Responses to Avian Influenza Outbreaks from 2014 to 2016

Type of obligation	Obligations through June 30, 2016 (in millions of dollars)
Response operations: depopulation, disposal, composting, cleaning and disinfection, biosecurity, and site management	626.7
Indemnity payments to poultry producers	206.4
Responders' salaries	25.4
Diagnostic tests and surveillance	3.4
State cooperative agreements[a]	7.4
TOTAL	**$869.3**

Source: U.S. Department of Agriculture | GAO-17-360

[a]USDA provides cooperative agreement funding to states, tribal nations, and others for surveillance, monitoring, and prevention and control activities.

In addition, USDA obligated about $60 million in funds transferred from the Commodity Credit Corporation in fiscal year 2015 on fixed costs—such as salaries, benefits, and supplies—and other activities related to preparing for the possible return of the virus in the fall of 2015, such as wild bird surveillance and vaccine research.

[24]The Commodity Credit Corporation is a government-owned and operated entity that was created to stabilize, support, and protect farm income and prices. The entity also helps maintain balanced and adequate supplies of agricultural commodities and aids in their orderly distribution.

With respect to the U.S. economy, two separate analyses have examined and produced national estimates of the economic impacts from the highly pathogenic avian influenza outbreak that began in 2014.[25] A national analysis conducted by USDA economists measured the 2014 outbreak's impact to U.S. livestock and feed sectors, including poultry and poultry products, at $1 billion.[26] The estimates in the analysis take into consideration producer and consumer behavior as prices and production changed in response to the reduction in production and the trade embargoes linked to the outbreak. The effects were measured throughout the course of the outbreak, allowing for estimates based on changes over time. According to this analysis, U.S. turkey producers lost an estimated $214 million in sales (a decline of 6.8 percent from 2014 levels), and broiler producers lost $276 million (a decline of 1.5 percent from 2014).[27]

While broilers were only negligibly affected by the virus, as separately reported by APHIS, the sector still suffered losses because of large decreases in demand from countries that extended full or partial bans on poultry and poultry products, including broilers, from the United States. In addition, because crops (e.g., corn and soybeans) are essential to the poultry sector, those commodities also experienced losses estimated at $373 million because of the reduction in number of birds fed. On the other hand, the reduced egg supply caused by the outbreak raised the price of eggs for consumers and, according to the analysis, led to an increase of $53 million in sales for U.S. egg and layer producers (an increase of 26.7 percent from 2015 levels).[28]

[25]For the purpose of our review, we did not include studies that did not estimate the national impact of the highly pathogenic avian influenza outbreaks.

[26]Johansson, Robert C. et al., "Government Spending to Control Highly Pathogenic Avian Influenza," *Choices*, vol. 31, no. 2 (2nd Quarter 2016); and Seitzinger, Ann Hillberg, and Philip L. Paarlberg, "Regionalization of the 2014 and 2015 Highly Pathogenic Avian Influenza Outbreaks," *Choices*, vol. 31, no. 2 (2nd Quarter 2016). The analysis used a quarterly partial equilibrium economic model of the U.S. feed and livestock agricultural sector. For more information on estimating the economic impacts of disease outbreaks, see Paarlberg, P.L., et al., *Economic Impacts of Foreign Animal Disease,* Economic Research Report 57 (Washington, D.C.: U.S. Department of Agriculture, Economic Research Service, May 2008).

[27]The analysis also estimated losses of $45.9 million in value added throughout the turkey sector and losses of $150.3 million in value added throughout the broiler sector. Value-added losses refer to losses to participants in the sector other than the producers.

[28]The analysis also estimated a gain of $16.2 million in value added throughout the egg sector.

The second national analysis contained a preliminary estimate of $3.3 billion in total economy-wide losses through June 29, 2015, from the 2014 outbreak of highly pathogenic avian influenza.[29] This included direct losses to the turkey and egg processing sectors of $1.6 billion, with losses of $530 million for turkeys and $1.04 billion for laying hens. The $3.3 billion estimate included macroeconomic impacts due to losses to other indirect sectors, such as retail and foodservice, but did not include activities such as clean-up, restocking, or future lost production while the producer prepares to resume production at a pre-disease level.[30] Also, unlike the first analysis noted above, this analysis did not include consumer or producer responses to changes in prices or production, such as increases in egg prices due to production losses.

Starting from the beginning of the avian influenza outbreak in December 2014, 18 trading partner nations imposed bans on all shipments of U.S. poultry and products, and 38 trading partners imposed partial, or regional, bans on shipments from states or parts of states experiencing outbreaks. According to USDA officials, as of January 2017, China, Kyrgyzstan, Russia, and Thailand continued to impose national bans on U.S. poultry imports that were attributed to concerns about highly pathogenic avian influenza, and Jamaica had imposed a state ban on U.S. poultry imports from several Midwestern states. Total U.S. poultry and product exports declined in value from about $6.4 billion in 2014 to $4.9 billion in 2015.[31] The largest of these declines was from the U.S. broiler meat industry, which fell from $4.1 billion to $3.0 billion over that period. While a USDA report attributed part of this decline in exports to a strong U.S. dollar, the report also noted that the avian influenza outbreak that began in 2014 caused the poultry industry to lose market share to other poultry exporters such as Brazil.[32] According to a September 2016 USDA report, export levels of broiler chickens—the largest poultry export sector—were

[29]Elam, Thomas E., "Economic Losses from the 2015 Highly Pathogenic Avian Flu Outbreak," FarmEcon LLC (June 29, 2015).

[30]The author applied a multiplier of 2.1, from the University of Minnesota, to the estimated $1.6 billion in direct losses to turkey and egg processing sectors to arrive at the estimate of $3.3 billion in losses to the economy.

[31]Foreign Agriculture Service, Global Agricultural Trade System Online, Standard Query of all poultry and product exports from the U.S. to the world, https://apps.fas.usda.gov/gats/default.aspx. February 2017.

[32]U.S. Department of Agriculture, Foreign Agricultural Service, *Livestock & Poultry: World Markets and Trade* (Washington, D.C.: April 2016).

modestly rebounding in 2016 from the levels that followed the end of the highly pathogenic avian influenza outbreak in 2015, although these 2016 levels were still at their lowest since 2011.[33] In addition, according to the USDA report, turkey exports remained weak compared to the pre-avian influenza trends, and egg exports in July 2016 were 6 percent lower than the previous year. USDA noted that some major importing countries had lifted trade bans since the 2014 outbreak and that other factors, such as the strength of the dollar, have also affected exports. USDA officials involved in the response also said that the negative effect on U.S. poultry exports was partially mitigated by the fact that some countries imposed regional, rather than national, bans on U.S. poultry products. In addition, the agency's implementation of secure food supply plans allowed poultry producers to move non-infected products during the outbreaks.[34] A goal of these plans is to continue business operations from locations that are not infected with disease.

After the March 2017 detections of highly pathogenic H7N9 avian influenza in two commercial flocks in Lincoln County, Tennessee, numerous countries imposed trade restrictions on U.S. poultry exports. For example, the Republic of Congo (Brazzaville) imposed restrictions on poultry imports from the entire United States. Some countries, such as South Africa, Taiwan, and Uruguay, placed restrictions on poultry imports from the entire state of Tennessee while others, such as Jamaica and the European Union, imposed restrictions on certain geographic areas or counties. Similarly, after detections of low pathogenic avian influenza in March 2017, countries placed restrictions on imported poultry from all or parts of Alabama, Georgia, Kentucky, and Wisconsin.

[33]U.S. Department of Agriculture, Economic Research Service, *Livestock, Dairy, and Poultry Outlook* (Washington, D.C.: Sept. 16, 2016).

[34]Secure food supply plans are guidance documents that describe the requirements and processes by which non-infected producers can qualify for a permit to move non-infected animal products within, out of, and into animal disease outbreak control areas. These plans exist in final or draft forms for the broiler, egg, and turkey sectors. The plans were developed through a collaborative effort among USDA and other federal and state agencies, industry, and academia. For example, the Egg Sector Working Group participated in a private-public-academic partnership to develop practical and implementable solutions for market continuity during an outbreak of highly pathogenic avian influenza.

USDA Has Taken Corrective Actions to Address Lessons Learned but Does Not Have Plans to Evaluate Their Effectiveness

USDA identified lessons learned from its responses to the 2014 and 2016 highly pathogenic avian influenza outbreaks and has taken numerous corrective actions to address them. However, USDA does not have plans for evaluating the extent to which the corrective actions have helped resolve the problems that they were intended to address.

USDA Has Identified Lessons Learned from the 2014 and 2016 Outbreaks and Taken Numerous Corrective Actions

After the outbreaks of highly pathogenic avian influenza in 2014 and 2016, USDA identified lessons learned related to its response activities and has taken numerous corrective actions to address those lessons learned.[35] To identify the lessons learned from both the widespread outbreak that began in 2014 and the limited 2016 outbreak in Indiana, USDA proactively collected feedback about its performance during and after the outbreaks from federal and state animal health officials and from industry representatives involved in the responses. The agency then summarized this feedback into after action reports that included observations about strengths and weaknesses in the responses. The identified lessons learned covered a wide range of response areas, including the depopulation of infected birds, disposal of bird carcasses, and surveillance of flocks for infection. For example, according to USDA documents, rapid depopulation is critical to help prevent or mitigate the spread of the disease by eliminating infected, exposed, or potentially exposed animals. However, USDA noted that during the 2014 outbreak, there were substantial delays in completing depopulation, with producers reporting that it took as long as 11 days to begin depopulation on many premises.

USDA developed a corrective action program to identify, prioritize, and implement corrective actions that are intended to address the root causes of the lessons learned. The agency identified 308 corrective actions across 15 response areas and created a corrective action database to track the actions (see table 5 for the list of 15 response areas and

[35]According to Homeland Security Exercise and Evaluation Program guidance, corrective actions are concrete, actionable steps that are intended to resolve gaps and shortcomings experienced during emergency response exercises and real-world incidents.

examples of lessons learned and corrective actions associated with each area.)

Table 5: Examples of Lessons Learned and Corrective Actions U.S. Department of Agriculture (USDA) Identified after Its Responses to the 2014 and 2016 Outbreaks of Highly Pathogenic Avian Influenza

		Example		
Response area	**Number of corrective actions under response area**	**Lesson learned**	**Corrective action to address lesson learned**	**Status of corrective action, according to USDA's database, as of January 2017[a]**
Appraisal and compensation	8	Indemnity calculators did not capture all costs accurately.	Update indemnity calculators.	Complete/ongoing
Biosecurity	23	Producers reported biosecurity infractions by contracted response teams, potentially leading to further disease spread.	Develop biosecurity training materials for contracted response teams and post on USDA website.	Complete
Communication	54	USDA responders did not have established relationships with local officials in some response areas, leading to coordination or logistics issues.	Develop a protocol for contacting and meeting local officials to address any concerns, ideally before response operations begin.	In progress
Continuity of business[b]	5	Collaboration has been lacking between industry and agricultural policy leaders regarding ways to mitigate disruptions to the domestic animal food supply during a disease outbreak.	Consider assisting with development of secure food supply plans for all segments of the poultry industry and coordinating the updates of existing plans based on experiences from the outbreaks.[c]	Complete
Diagnostics	9	Some laboratories did not have the capability to make diagnostic test results available electronically, leading to delays in reporting results.	Increase electronic messaging capabilities at laboratories.	In progress
Disposal	10	Available guidance for composting dead bird carcasses was insufficient, leading USDA to contract with external composting experts who were sometimes unfamiliar with composting large quantities of bird carcasses.	Identify and train USDA personnel as composting experts to advise producers in the event of an outbreak.	Complete
Epidemiological investigation and tracing[d]	5	Better epidemiological information gathering at the outset of the incident would have improved operational decision making.	Hone initial information-gathering instruments by developing a mini-questionnaire to collect and communicate epidemiological information.	Complete

Response area	Number of corrective actions under response area	Example		
		Lesson learned	Corrective action to address lesson learned	Status of corrective action, according to USDA's database, as of January 2017[a]
Finance	8	Better defined roles and responsibilities for cost control and contract management are needed to ensure that funding or finance issues are resolved.	Develop a standard operating procedure on the reporting of the status of funds and finalize a finance coordination plan.	In progress
Health and safety and personal protective equipment	14	Safety officers were not always notified of safety and health hazards in a timely manner.	Develop a consistent procedure for reporting all safety and health hazards and incidents to the site supervisor and then to the safety officer as soon as practicably possible.	In progress
Incident management[e]	81	Transitions between response teams in states with prolonged response operations were difficult due to non-standardized positions and protocols.	Institute a 2-day transfer period for rotating response teams.	Complete
Information management	36	Some responders were unfamiliar with USDA's electronic record-keeping system for animal disease outbreaks, resulting in incorrect use or underuse of the system.	Develop standard reports and maps for use by responders.	Complete
Logistics	36	There was not a standardized approach for USDA response teams to track equipment and personnel, leading to risk of miscounting or not deploying resources.	Develop a job aid that describes check-in and check-out procedures for equipment and personnel.	In progress
Mass depopulation and euthanasia	13	There were not enough skilled personnel available for depopulation of infected domesticated poultry, leading to delays in depopulation and possible increased disease transmission.	Encourage states to form depopulation teams that can be deployed in an outbreak by providing guidance and training.	Complete
Surveillance	3	Surveillance sampling of commercial flocks did not always identify infected birds prior to widespread illness.	Collaborate with industry to evaluate and improve existing sampling procedures.	In progress
Vaccination	3	A national vaccination strategy that outlines how and when USDA would use vaccines needs to be further defined.	Develop clear and simple messages about the use of vaccines and implications for food safety and human health.	Complete
Total	**308**	—	—	—

Source: GAO summary of U.S. Department of Agriculture corrective action program database. | GAO-17-360

Note: For the response areas, USDA identified multiple lessons learned and corrective actions to address those lessons learned. This table provides examples of lessons learned and corrective

actions for each response area. We selected examples of lessons learned and corrective actions that we believe clearly illustrate the nature of the response area.

[a]The status of "complete" indicates that a corrective action was completed by some action. "Closed" indicates USDA determined that a corrective action was not applicable or advisable, was duplicative, or was subsumed in another lesson learned and no longer requires action. "Complete/ongoing" indicates that an initial task has been satisfied but that activities related to the recommendation will be ongoing, according to USDA officials.

[b]Continuity of business involves managing non-infected poultry operations and products during an outbreak to help the agriculture and food industries maintain typical business or return to business during and after a disease response.

[c]Secure food supply plans are guidance documents that describe the requirements and processes by which non-infected producers can qualify for a permit to move non-infected animal products within, out of, and into animal disease outbreak control areas. These plans exist or are under development for certain sectors of the poultry sector, such as the broiler, turkey, and egg sectors. The plans were developed through a collaborative effort among USDA and other federal and state agencies, industry, and academia.

[d]Epidemiological investigation and tracing involves examining the spread of disease by time, place, and animal, 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.

[e]Incident management involves the overall coordination and organization of the response, such as establishing and maintaining response teams in the field and nationwide.

USDA prioritized the corrective actions according to their implications for future outbreaks and, for the highest priority actions, their time frame for completion. Specifically, USDA defined priority 1 corrective actions as those that would have immediate, critical implications for a future outbreak and that could be completed in less than 1 year; priority 2 actions as those that would have positive implications for a future outbreak or would have immediate, important implications but that may not be completed within 1 year; and priority 3 actions as those that are under consideration or that would have less critical implications for a future outbreak.

According to our review and summary of USDA's corrective action database, the agency has marked as completed about 70 percent of its corrective actions, including about 86 percent of the priority 1 actions (see

table 6).[36] As of January 2017, USDA did not have time frames for completing about 82 percent of the uncompleted priority 2 and priority 3 corrective actions. For example, USDA has not established a time frame for completing a priority 2 corrective action related to depopulation that calls for the agency to develop training materials for contracted responders to help ensure there are enough skilled personnel available for depopulation. This action is marked as "in progress" in the database. When we raised this issue during the course of our review, USDA officials responsible for the database said they are working with the groups in charge of taking corrective actions to identify time frames for the remaining priority 2 and priority 3 actions, but they said that it is complex and difficult to do so in light of other agency disease response activities. For example, they said that responding to an outbreak of New World screwworm in Florida in fall 2016 had caused the agency to pause some of its efforts to address corrective actions from the highly pathogenic avian influenza outbreaks.[37] Nonetheless, agency officials acknowledged that time frames are important and said they will continue to develop them.

[36]We are defining completed actions as those in USDA's corrective action database with a status of "complete," which indicates that a corrective action was completed by some action; "closed," which indicates USDA determined that a corrective action was not applicable or advisable, was duplicative, or was subsumed in another lesson learned and no longer requires action; and "complete/ongoing," which indicates that an initial task has been satisfied but that activities related to the recommendation will be ongoing, according to USDA officials. Examples of these activities include training, biosecurity messaging, and investigating alternative depopulation methods, according to USDA officials. According to the corrective action database, as of January 2017, about 47 percent of the corrective actions were marked as "complete," about 16 percent were marked as "closed," and about 7 percent were marked as "complete/ongoing." In addition, about 28 percent were marked as "in progress" and 1 percent as "not initiated." (The total does not add to 100 percent due to rounding).

[37]According to a USDA fact sheet, New World screwworms (*Cochliomyia hominivorax*) are fly larvae (maggots) that can infest livestock and other warm-blooded animals, including humans. They most often enter an animal through an open wound and feed on the animal's living flesh. If not treated, infestations can be fatal. While New World screwworm has not been widely present in the United States since the 1960s, it is still found in most of South America and in five Caribbean countries. If this pest became established in the United States again, it could cause more than $1 billion in losses for the country's livestock industry.

Table 6: Number of Corrective Actions U.S. Department of Agriculture (USDA) Identified Based on Lessons Learned From Its Responses to the 2014 and 2016 Outbreaks of Highly Pathogenic Avian Influenza, and Percent Completed

Priority	Number of corrective actions	Percent marked as completed, as of January 2017[a]
1	121	86
2	141	55
3	46	78
Total	**308**	**—**

Source: U.S. Department of Agriculture corrective action program database. | GAO-17-360

Note: USDA defined priority 1 corrective actions as those that would have immediate, critical implications for a future outbreak and that could be completed in less than 1 year; priority 2 actions as those that would have positive implications for a future outbreak or would have immediate, important implications but that may not be completed within 1 year; and priority 3 actions as those that are under consideration or that would have less critical implications for a future outbreak.

[a]We are defining completed actions as those in USDA's corrective action database with a status of "complete," which indicates that a corrective action was completed by some action; "closed," which indicates USDA determined that a corrective action was not applicable or advisable, was duplicative, or was subsumed in another lesson learned and no longer requires action; and "complete/ongoing," which indicates that an individual recommendation has been satisfied but that activities related to the recommendation will be ongoing, according to USDA officials.

USDA Does Not Have Plans to Evaluate the Effectiveness of its Corrective Actions

USDA has taken steps to implement corrective actions, but it does not have plans to evaluate the extent to which completed corrective actions have effectively helped to resolve the problems the agency identified in its responses to the recent outbreaks. We have previously found that agencies may use evaluations to ascertain the success of corrective actions, and that a well-developed plan for conducting evaluations can help ensure that agencies obtain the information necessary to make effective program and policy decisions.[38] An evaluation plan should include, among other things, evaluative criteria or comparisons, or how or on what basis program performance will be judged or evaluated. We also found that one approach agencies can use to evaluate changes in events that occur infrequently and unpredictably, such as disease outbreaks, is to conduct simulations or exercises to assess how well an agency's plans anticipate the nature of its threats and vulnerabilities. Homeland Security Exercise and Evaluation Program guidance, which USDA officials told us they used in developing the corrective action program, states that agencies should put in place a system to test and validate corrective

[38]GAO, *Designing Evaluations: 2012 Revision*, GAO-12-208G (Washington, D.C.: Jan. 31, 2012) and *Tax Administration: IRS Needs to Strengthen Its Approach for Evaluating the SRFMI Data-Sharing Pilot Program*, GAO-09-45 (Washington, D.C.: Nov. 7, 2008).

actions that have been implemented.[39] This guidance states that agencies can identify the corrective actions that require validation and then conduct exercises to test whether those corrective actions have led to improvements.[40]

In our review of a nongeneralizable sample of 10 completed corrective actions designated as priority 1, it was unclear to what extent such actions were effective because, while USDA marked in its database that it had completed the corrective actions, it had not evaluated the extent to which these actions achieved the desired outcome. For example, one lesson learned that USDA identified was that many producers lack a strong culture of biosecurity. However, although USDA completed corrective actions associated with that lesson—creating a joint biosecurity website with the U.S. Poultry and Egg Association and putting greater emphasis on biosecurity in conferences with producers—it did not evaluate to what extent taking these actions created a strong culture of biosecurity among producers. In another lesson learned, USDA identified that states and producers encountered impediments in transporting bird carcasses to landfills, such as federal and state rules restricting the movement of bird carcasses along transportation routes in close proximity to other producers. USDA completed corrective actions associated with that lesson—providing guidance, training, and encouragement to states and producers to develop disposal plans—but did not evaluate to what extent taking these actions helped overcome the impediments observed. In addition, depopulation experts we interviewed raised concerns about whether USDA's planned and completed corrective actions will effectively address the challenges with depopulation experienced during the 2014 and 2016 outbreaks. For example, these experts questioned whether a sufficient number of federal employees and contracted responders have been trained in using depopulation equipment to address a lesson

[39]The Homeland Security Exercise and Evaluation Program provides a set of guiding principles for national preparedness exercises, including principles for exercise evaluation and improvement planning. The Department of Homeland Security's Federal Emergency Management Agency issued guidance for the program in 2013. The Department of Homeland Security, *Homeland Security Exercise and Evaluation Program (HSEEP)* (Washington, D.C.: April 2013).

[40]According to the Homeland Security Exercise and Evaluation Program guidance, exercises are instruments to train for, assess, practice, and improve performance in prevention, mitigation, response, and recovery capabilities in a risk-free environment. Exercises can be used for testing and validating policies, plans, procedures, training, equipment, and interagency agreements, among other things.

learned that there were not enough skilled personnel available for depopulation during recent outbreaks.

USDA documents state that the 2016 outbreak provided an opportunity to see that some of the corrective actions taken following the 2014 outbreak resulted in an improved response. For example, according to USDA's after action report on the 2016 outbreak, the changes that USDA made to the process for compensating poultry producers for losses after the 2014 outbreak resulted in a faster and more efficient process during the 2016 outbreak. Nonetheless, USDA officials acknowledged that they are not certain whether completing other corrective actions will be sufficient to address the lessons learned from both outbreaks. They acknowledged the importance of evaluating corrective actions to determine whether additional steps are needed but said that the agency does not yet have plans to do so. Agency officials also told us that evaluating the effectiveness of these corrective actions will need to be a continuous process and should be considered within the broader context of USDA's emergency preparedness for disease response. For example, USDA officials told us they intend to incorporate lessons learned and corrective actions from the agency's response to the 2016 New World screwworm outbreak into the corrective action database for highly pathogenic avian influenza, so that the database becomes a broader tool that the agency can use to track corrective actions related to its overall disease response efforts. By developing a plan for evaluating completed corrective actions and, as part of this plan, considering whether any completed corrective actions require validation through simulations or exercises, USDA could better determine the effectiveness of these actions.

Federal Agencies Face Ongoing Challenges and Associated Issues in Their Efforts to Mitigate the Potential Harmful Effects of Avian Influenza

On the basis of stakeholders' views and our analysis of federal efforts to respond to outbreaks, we identified ongoing challenges and associated issues that federal agencies face in mitigating the potential harmful effects of avian influenza. These challenges are in protecting domesticated poultry from the threat of avian influenza that circulates naturally in wild birds and in relying on voluntary actions by a wide range of poultry producers to prevent poultry flocks from becoming infected. Federal agencies also face other issues associated with mitigating the potential harmful effects of avian influenza: the virus could infect poultry needed to produce eggs used in manufacturing critical human vaccines against pandemic influenza, and federal funding will soon be exhausted for a voluntary surveillance program that gathers information about the presence of influenza viruses in swine that could pose a threat to human health.

Ongoing Challenges that Federal Agencies Face in Mitigating the Potential Harmful Effects of Avian Influenza

We identified two ongoing challenges that federal agencies face in mitigating the potential harmful effects of avian influenza. First, federal agencies are challenged in protecting domesticated poultry from avian influenza because the disease naturally circulates in migratory birds, which may spread the disease. Second, federal efforts to prevent poultry flocks from infection are challenged because these efforts rely on voluntary biosecurity measures by poultry producers.

Protecting Domesticated Poultry from the Threat of Avian Influenza Carried by Wild Birds Is a Challenge

Federal agencies face an ongoing challenge in protecting domesticated poultry from avian influenza because the disease naturally circulates in migratory birds, such as ducks and geese, which are hard to control and which may come into contact with poultry. Because of their migratory behavior, wild birds infected with avian influenza can spread the disease across long distances, including from as far away as Asia. Federal agencies and others are authorized under the Migratory Bird Treaty Act to sample ducks, geese, and other migratory birds to confirm the presence of an infectious disease, including influenza.[41] According to Interior officials, the Act also provides agencies the authority to control migratory birds infected with avian influenza, but the officials noted that experience has shown that such efforts are ineffective. As reported in a text on avian influenza, humans have had and will continue to have minimal impact on control of low pathogenic avian influenza viruses in wild bird populations.[42]

[41]Migratory Bird Treaty Act, ch. 128, 40 Stat. 755 (1918) (codified as amended at 16 U.S.C. §§ 703-712). The Act prohibits, among other things, the selling, transporting, or importing of migratory birds, their eggs, parts, and nests, except when specifically authorized by regulation.

[42]Swayne, *Avian Influenza*.

Use of Vaccines to Eradicate Avian Influenza

According to the U.S. Department of Agriculture (USDA), poultry vaccination has been part of control or eradication programs for avian influenza viruses in a number of countries. Effective vaccination can decrease transmission between animals by decreasing their susceptibility to infection and reducing the amount of virus an infected animal may shed. Vaccination has been used in some successful eradication campaigns for low pathogenic avian influenza outbreaks in the United States but never for highly pathogenic avian influenza outbreaks such as those that occurred in 2014 and 2016, according to USDA.

Stakeholders we interviewed characterized the decision to use poultry vaccines to control and eradicate the 2014 and 2016 outbreaks as having both scientific and economic components. From a scientific perspective, a vaccine needs to be able to protect against a specific influenza virus to be effective and merit use. In June 2015, USDA announced that the vaccines available at the time were not well matched to the virus that was infecting poultry in numerous states. As an example of the economic implications of vaccines, USDA also announced in June 2015 that significant trading partners had indicated that, if USDA began vaccinating, they would ban all U.S. poultry and egg exports until they could complete a risk assessment. For these and other reasons, USDA decided against using vaccines. USDA's Agricultural Research Service continues to develop enhanced vaccines for use in poultry against avian influenza. A 2014 USDA report concluded the poultry industry needs highly effective vaccines that can prevent transmission and that can be mass-delivered in water, in eggs, or in feed.

Source: GAO analysis of USDA documents and interviews with stakeholders. | GAO-17-360

Although federal agencies are unlikely to control avian influenza viruses in wild birds, they can monitor the viruses circulating in this population. Specifically, USDA, Interior's U.S. Geological Survey and U.S. Fish and Wildlife Service, and state and tribal agencies collaborated on a national program for wild bird surveillance that sampled more than 283,000 wild birds from April 2006 through March 2011, when the program ended.[43] The federal effort resumed in December 2014 in response to the outbreaks of highly pathogenic avian influenza on the West Coast of North America. In response to the outbreaks, personnel from USDA and Interior re-convened the Interagency Wild Bird Avian Influenza Steering Committee in January 2015. The Steering Committee developed a wild bird surveillance plan for avian influenzas that may pose a threat to human health or domestic poultry.[44] The plan encourages federal and state agencies and others to use a variety of sampling methods to test live and dead wild birds for avian influenza. According to data recorded as of March 24, 2017, the surveillance program had collected test results from more than 88,000 wild birds since December 2014. The data for that time period show that the program detected 102 cases (about 0.12 percent) of highly pathogenic avian influenza from the same lineage that caused the 2014 and 2016 outbreaks in the United States (see app. II for details on the results of this surveillance program). On the other hand, monthly detection rates for low pathogenic avian influenza A viruses in wild birds were often above 10 percent for those tested. According to USDA and Interior officials, continued monitoring of wild birds will help identify the presence of avian influenza subtypes and help agencies to mitigate the persistent challenge that wild birds pose to domesticated poultry. The state veterinarians we interviewed from California, Indiana, Iowa, Minnesota, North Carolina, and Ohio generally agreed with the need for wildlife surveillance.

[43]Bevins, Sarah N., et al. "Large-Scale Avian Influenza Surveillance in Wild Birds throughout the United States," *PLoS ONE,* vol. 9, no. 8: e104360 (August 12, 2014). doi:10.1371/journal.pone.0104360.

[44]The Interagency Steering Committee for Surveillance for Highly Pathogenic Avian Influenza in Wild Birds, *Early Detection and Monitoring for Avian Influenzas of Significance in Wild Birds: A U.S. Interagency Strategic Plan* (Washington, D.C.: June 2015).

Reliance on Voluntary Actions by a Wide Range of Poultry Producers to Prevent Flocks from Avian Influenza Infections Is a Challenge

Federal efforts to ensure routine biosecurity and prevent poultry flocks from becoming infected with avian influenza face an ongoing challenge because these efforts depend on voluntary actions by a wide range of poultry producers. While USDA's approach to addressing this challenge varies for different types of poultry producers, such as those who manage large commercial operations and those who manage small backyard flocks, the approach primarily relies on using incentives and education to promote voluntary actions.

According to USDA officials, state stakeholders, and poultry industry representatives we interviewed, sound biosecurity practices are important for all types of poultry facilities. This is also evident from the 2014 and 2016 outbreaks of highly pathogenic avian influenza, which affected large commercial and small backyard flocks, including turkeys, laying hens, and ducks. USDA found that lapses in routine preventative biosecurity allowed the initial introduction of disease and enabled it to spread from farm to farm. To gather information on biosecurity practices, USDA analyzed self-assessments completed by 850 poultry producers on the status of their biosecurity practices. While large producers generally indicated more frequently than small producers that they had certain practices in place, the nongeneralizable data showed that important practices were not consistently in place. For example, less than 60 percent of respondents had biosecurity officers or training in place. According to USDA's self-assessment document, biosecurity officers and training could help reduce the threat of infection by improving biosecurity practices. Similarly, less than 60 percent of respondents had delineated lines of separation in their facilities to reduce the risk of contamination. Lines of separation are intended to reduce the risk that contaminated materials come into contact with poultry. In addition, less than 60 percent of respondents said that they had practices in place for personnel to shower or change into clean clothes immediately prior to arriving at a poultry site, or upon arrival, to reduce the risk of introducing an avian influenza virus.

While USDA can impose biosecurity measures during its response to an emergency, the agency does not have the authority to require producers to routinely employ preventative biosecurity measures. Instead, USDA relies on producers to take voluntary action to prevent the introduction of avian influenza and other diseases. Toward that end, USDA recently initiated two interrelated efforts—independent of the corrective action program described above—that may help overcome this challenge among commercial farms. In addition, USDA has continued its efforts, through public education and outreach, to encourage backyard poultry farmers to practice biosecurity.

USDA's first initiative to improve biosecurity involves linking producers' eligibility for indemnity payments to a biosecurity plan. Specifically, USDA issued an interim rule in February 2016 requiring large poultry producers seeking indemnity payments in the future to provide a statement that, at the time highly pathogenic avian influenza was detected in their facilities, they had in place and were following a written biosecurity plan to address the potential spread of the virus.[45] According to USDA officials, this regulatory change provides a strong incentive to members of the poultry industry to have a biosecurity plan in place. As of February 2017, USDA continues to operate under the interim rule issued in February 2016.

The second and related initiative concerns changes to the National Poultry Improvement Plan. According to USDA officials, poultry industry representatives who commented on the interim indemnity rulemaking suggested that the agency use the National Poultry Improvement Plan to promote biosecurity. The improvement plan is a voluntary program administered by USDA under which participating commercial poultry flocks are tested to ensure they are free from diseases, including H5 and H7 subtypes of avian influenza. If a flock tests negative for avian influenza, USDA certifies to trading partners and others that the flock is free of the disease. In September 2016, delegates to the program—who included poultry industry representatives—gave interim approval to add a set of 14 biosecurity principles to the plan's national program standards.[46] The biosecurity principles call for, among other things, training poultry producers about biosecurity; taking steps to protect against infection from wild birds, rodents, and insects; cleaning vehicles and equipment to reduce risk; and managing manure and litter to prevent the exposure of susceptible poultry to disease agents. Those principles would apply to the poultry producers who participate in the program; according to USDA officials, most commercial poultry producers participate. According to USDA officials, these initiatives will encourage commercial producers to adopt preventative biosecurity measures.

[45]81 Fed. Reg. 6745, (Feb. 9, 2016).

[46]The National Poultry Improvement Plan delegates are elected by a representative group of participating industry members and are certified by the state agency. It is recommended that the delegates be plan participants. Each cooperating state is entitled to one official delegate for each of several types of poultry production in which the state has at least one participant. The types of poultry production include egg-type chickens, meat-type chickens, turkeys, other types of poultry, waterfowl, game birds, and others.

Commercial poultry flocks may also be raised outdoors and thus are at greater risk of contact with wild birds infected with avian influenza. For example, turkeys and chickens must have access to outdoor space to be certified by USDA as organically raised.[47] Organically raised poultry are a rapidly growing segment of the industry, according to USDA documents.[48] Stakeholders told us that they were concerned that producers of organically raised poultry do not have to follow the same biosecurity principle—namely, keeping birds indoors—that producers of conventional poultry are encouraged to follow. USDA has acknowledged that organically raised birds are at a greater risk than birds raised indoors. USDA's policy is that if it is determined that temporary confinement of birds is needed to protect the health, safety, and welfare of organic flocks, then producers and certifiers may work together to determine an appropriate method and duration of confinement of such flocks without a loss of organic certification.

Stakeholders we interviewed told us backyard poultry flocks are a concern for contracting and spreading avian influenzas to commercial poultry because these flocks are raised outdoors and are more likely to come into contact with wild birds.[49] According to USDA's website, raising backyard poultry is a growing trend across the United States. USDA manages the "Biosecurity for Birds" campaign to help raise awareness among backyard, hobby, and pet bird owners about the risks of avian influenza. The biosecurity principles that USDA promotes to backyard poultry producers include separating the domesticated flock from other birds, including game birds and wild waterfowl, because the latter can carry disease. According to an agency document, USDA works cooperatively with state animal health officials and the poultry industry to look for disease in breeding flocks, in backyard poultry, and at live bird

[47]82 Fed. Reg. 7042, (Jan. 19, 2017). Subsequent to the publication of this final rule, USDA announced a 60-day delay of the rule's effective date, consistent with the memorandum of January 20, 2017, from the Assistant to the President and Chief of Staff, entitled, *Regulatory Freeze Pending Review.* 82 Fed. Reg. 9967, (Feb. 9, 2017).

[48]According to USDA's April 2016 *Federal Register* announcement of proposed amendments to the National Organic Program, data from the Organic Trade Association indicate that U.S. sales of organic eggs reached $514 million in 2014, an increase of 17 percent over the previous year. 81 Fed. Reg. 21956 (Apr. 13, 2016). In 2014, U.S. organic poultry sales grew nearly 13 percent, to $453 million. USDA stated that there were an estimated 722 organic egg producers and 245 organic broiler operations in the United States.

[49]Our 2007 report on avian influenza also noted concerns about backyard flocks being a source of infection in commercial flocks. See GAO-07-652.

markets, livestock auctions, poultry dealer locations, and small bird sales, fairs, and shows.

Federal Agencies Face Other Issues Associated with Mitigating the Potential Harmful Effects of Avian Influenza

We identified two other issues that federal agencies face associated with mitigating the potential harmful effects of avian influenza. First, outbreaks of the disease threaten the poultry that produce the eggs used in the production of human pandemic influenza vaccine. Second, funding for a voluntary surveillance program that gathers data on influenza A viruses in swine that could pose a threat to human health will be exhausted in fiscal year 2017.

Poultry Used to Produce Critical Human Vaccine Are Susceptible to Influenza Outbreaks

Protecting the chickens that lay the eggs needed to produce human pandemic influenza vaccines is an issue for federal agencies because these birds, like others, are susceptible to avian influenza. HHS has an obligation under the National Strategy for Pandemic Influenza to promote capabilities that assure a pandemic vaccine can be produced at a U.S.-licensed influenza vaccine facility at any time of the year, without limitations imposed by the availability of essential supplies. Pandemic influenza vaccines may be manufactured using several technologies. To date, the most commonly used technology has relied on fertilized eggs as a raw material.[50] According to HHS officials, 90 to 95 percent of the current national stockpile of pandemic influenza vaccines is derived from eggs. According to an HHS official, the agency has a stockpile of egg-based and cell-based pre-pandemic influenza vaccines supplied by four companies. Of the four companies, however, only one has an egg-based vaccine manufacturing facility in the United States. If an influenza pandemic is declared, according to this official, the U.S. government may not be able to rely on foreign countries to allow exports of pandemic vaccine because each country will likely prioritize those vaccines for its own population. Therefore, the U.S. government considers the one U.S.-based company as the only dependable manufacturer for producing egg-based vaccine for rapid pandemic mitigation.

This company contracts with suppliers to provide it with the necessary egg supply. HHS officials and company representatives told us that the company has an egg production network that includes flocks located on numerous farms. According to company officials, protecting the

[50]Making influenza vaccine using egg-based technology—typically used to produce both seasonal and pandemic influenza vaccines for the U.S. market—involves growing virus cultures in fertilized chicken eggs.

company's current network of egg suppliers is critical because the company cannot rely on other suppliers for eggs if its own network is compromised; the officials told us the company would not be able to make vaccine with eggs raised outside its control.

According to HHS officials, the agency recognizes that avian influenza poses a risk to the production of pandemic influenza vaccines. To address that risk, HHS has contracted with the company to protect the egg supply chain and ensure a year-round supply of vaccine-quality fertilized eggs for the company to use in its vaccine manufacturing process. HHS awarded the current 3-year, $42 million contract for a year-round supply of eggs in September 2014. The contract requires that the company have a risk management plan; the company's plan contains both a physical security program and a biosecurity program to provide protection against man-made and natural threats.

HHS officials said they are confident that the company's biosecurity program is sound. According to company representatives, the company mitigates risks by limiting the density of the birds on each farm and by using farms that are not in close proximity. In addition, company employees routinely audit the flocks and incubation facilities, and the company periodically tests the flocks of layer hens for avian influenza using USDA's National Poultry Improvement Plan testing procedures. Furthermore, according to HHS officials, the agency conducts annual security audits of a portion of the facilities in the company's network.

According to company representatives, the company has standard operating procedures for biosecurity in its network of egg suppliers that are based on state department of agriculture guidelines. Company representatives said that because the company contracts with its suppliers and can require specific conditions, it has more control over what is done on the farms and in the incubation facilities than it does with farms that only comply with either USDA or state agriculture department requirements. While the 2014 and 2016 outbreaks did not affect this egg supply, a previous outbreak of highly pathogenic avian influenza caused the deaths of laying hens and reduced the supply of eggs used to produce human vaccines by about 50 percent.

HHS has sought to diversify vaccine production through technologies that are not egg-based. Specifically, HHS has promoted technologies known

as cell-based and recombinant technologies to produce vaccine.[51] According to agency officials, these technologies will help offset the risk avian influenza poses to vaccine production. We have reported separately on federal efforts to diversify the pandemic vaccine supply.[52] According to HHS's website, three Centers for Innovation in Advanced Development and Manufacturing—in Maryland, North Carolina, and Texas—will provide a significant domestic infrastructure in the United States capable of producing medical countermeasures to protect Americans from the health impacts of bioterrorism as well as pandemic influenza and other diseases.[53] However, the centers are not yet able to manufacture the contracted quantity of pandemic influenza vaccine. According to HHS's Office of the Assistant Secretary for Preparedness and Response, as of February 2017, it was yet to be determined when the three CIADMs would be fully operational, but contractor officials indicated that one of the three is expected to become fully operational in 2017.

[51]Cell-based technology uses cells other than eggs, such as those originally derived from the kidney cells of monkeys or canines, infected with influenza virus for the production of the vaccine. Recombinant technology uses specific protein(s) or genes from the influenza virus instead of the entire virus as the antigen for the vaccine. This technology can use cells from mammals as the medium for producing the influenza vaccine as well as cells from other sources, such as from bacteria, yeast, insects, or plants. For more information on cell-based and recombinant technologies, see GAO, *Influenza Vaccine: Federal Investments in Alternative Technologies and Challenges to Development and Licensure*, GAO-11-435 (Washington, D.C.: June 27, 2011).

[52]GAO, *National Preparedness: HHS Has Funded Flexible Manufacturing Activities for Medical Countermeasures, but It Is Too Soon to Assess Their Effect*, GAO-14-329 (Washington, D.C.: Mar. 31, 2014).

[53]According to HHS's website (https://www.medicalcountermeasures.gov/barda/core-services/ciadm.aspx), these centers also address concerns raised by the President's Council of Advisors on Science and Technology in the August 2010 Report to the President on Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza, which called for flexible, nimble, and modern vaccine manufacturing technologies. Among the findings of the President's Council was that "current influenza vaccines are prepared from materials grown in chicken eggs, a cumbersome method that appears outmoded in a world dominated by production of many viral vaccines in cell culture or by new vaccines designed with recombinant DNA methods." However, the council's report did not comment on the threat that avian influenza could pose to the egg supply.

Funding for a Federal Effort to Monitor Swine for Influenza That Could Threaten Human Health Will Run Out in Fiscal Year 2017

USDA and HHS have collaborated to monitor swine for influenza A viruses because swine may act as a "mixing vessel" in which influenza viruses recombine to pose new threats to human health. However, the agencies face the issue that funding for a voluntary surveillance program will be exhausted in fiscal year 2017. According to HHS officials, this surveillance program is the only federal source of data for understanding the types of influenza circulating in swine. Because influenza is endemic in swine worldwide, swine producers are not required to report the disease to USDA, and USDA is not required to report swine influenza to the World Organisation for Animal Health. However, since 2009, when H1N1 swine-origin influenza caused a global human pandemic, USDA has used funding from HHS to collect voluntary data from the U.S. swine industry on the incidence of swine influenza.[54] As we reported in May 2013, there are limitations in the reliability of the data collected by this voluntary program; in particular, it may not accurately represent all of the conditions circulating across the country.[55] Nevertheless, this program has provided useful data on the presence of various subtypes of influenza virus in swine herds, according to HHS and USDA officials. Moreover, representatives from the pork industry we interviewed stated the surveillance data are beneficial to both public and animal health. However, according to USDA officials, funding for the swine surveillance program is expected to be fully expended in fiscal year 2017. USDA officials said that the agency will once again seek additional funding for the program in fiscal year 2018 and beyond, through appropriated funding, but that funding beyond fiscal year 2017 is uncertain. In addition, the U.S. Animal Health Association provided support for the program's continuation through a 2016 resolution asking Congress to appropriate funding for the swine surveillance program; furthermore, according to its representative, the National Pork Producers Council has advocated for continued funding for the program. According to HHS officials, the agency will continue to be supportive of USDA's efforts to continue the program. It is too early to say whether USDA will continue to gather data on influenza in swine beyond fiscal year 2017.

[54]According to a USDA document, HHS transferred $25.75 million to APHIS to support the surveillance program.

[55]For more information, 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).

Conclusions

The federal government has taken important steps to mitigate the significant risks posed by avian influenza to the health of humans, animals, and the economy. However, experience in the United States and around the world has shown that it is challenging to protect domesticated poultry from infection and control the disease when it does strike. USDA proactively identified numerous lessons learned, across a wide range of response areas, from the 2014 and 2016 outbreaks of avian influenza, and it identified more than 300 associated corrective actions. USDA has marked as completed about 70 percent of these actions, but it does not have plans for evaluating the extent to which its completed corrective actions have effectively helped to resolve the problems the agency identified in its responses to the 2014 and 2016 outbreaks. By developing a plan for evaluating completed corrective actions and, as part of this plan, considering whether any completed corrective actions require validation through simulations or exercises, USDA could better assess the effectiveness of these actions. This is particularly important in light of new outbreaks among commercial poultry in 2017 that continue to challenge the nation's efforts to control this devastating disease.

Recommendation for Executive Action

We recommend that the Secretary of Agriculture direct the Administrator of the Animal and Plant Health Inspection Service to develop a plan for evaluating completed corrective actions to determine their effectiveness and, as appropriate, consider whether any completed corrective actions require validation through simulations or exercises.

Agency Comments

We provided a draft of this report to USDA, HHS, and Interior for review and comment. USDA provided written comments on the draft, which are presented in appendix III, and provided technical comments, which we incorporated as appropriate. USDA agreed with our recommendation. HHS and Interior did not provide written comments but provided technical comments, which we incorporated as appropriate.

In its written comments, USDA said that APHIS agreed with our recommendation to develop a plan for evaluating completed corrective actions to determine their effectiveness. Further, USDA said that APHIS will incorporate simulations and exercises in its plan and that, in the event of an actual outbreak, APHIS will evaluate the effectiveness of the response through an after action report. Finally, USDA said that APHIS will continually review the criteria and hierarchy of corrective actions, both completed and ongoing, with respect to avian influenza policies,

emergency management activities, and critical communications with states, tribes, poultry producers, and poultry industry partners.

As agreed with your offices, 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, the Secretary of Health and Human Services, the Secretary of the Interior, 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 me at (202) 512-3841 or morriss@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.

Steve D. Morris
Director, Natural Resources and Environment

Appendix I: Selected Agencies with Responsibilities Related to Avian Influenza

Numerous federal agencies have responsibilities related to reducing the risks posed by avian influenza to human health, animal health, and the economy. Table 7 provides a summary of those responsibilities for agencies within the U.S. Department of Agriculture, the Department of Health and Human Services, and the Department of the Interior.

Table 7: Selected Agencies with Responsibilities Related to Avian Influenza and Its Effects on Human and Animal Health

Department	Component agency	Summary of relevant responsibilities
U.S. Department of Agriculture (USDA)	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 and animal products by preventing, controlling, and eliminating animal diseases, and by monitoring and promoting animal health and productivity. Within Veterinary Services, **Surveillance, Preparedness and Response Services** focuses on animal health needs and carries out functions ranging from early awareness and surveillance to the development and field implementation of animal health programs and emergency response; **National Import Export Services** conducts import and export activities, from policy setting to inspection at ports of entry; and **Science, Technology and Analysis Services** brings together the following science centers to support Veterinary Services in meeting its mission responsibilities: • 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. **Wildlife Services**, through its operational program and the National Wildlife Research Center, employs veterinarians, biologists, and epidemiologists to research and mitigate damage caused by wildlife to public health and safety, agriculture, and natural resources, including diseases in wildlife.

Department	Component agency	Summary of relevant responsibilities
	Agricultural Research Service	Veterinarians and scientists in the Agricultural Research Service do research to support diagnostic testing, vaccines, disease management systems, and farm biosecurity measures, among other tools, to help national efforts to detect, control, and eradicate animal diseases of national priority.
	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.
Department of Health and Human Services (HHS)	Office of the Assistant Secretary for Preparedness and Response	Within the Office of the Assistant Secretary for Preparedness and Response, the **Biomedical Advanced Research and Development Authority**—established by the Pandemic and All-Hazards Preparedness Act[b]—coordinates advanced research and development, manufacturing, and initial procurement of medical countermeasures for chemical, biological, radiological, and nuclear threats, pandemic influenza, and emerging infectious diseases into the Strategic National Stockpile, which is the national repository for medications, medical supplies, and equipment for use in a public health emergency. As part of these responsibilities, the Authority oversees HHS's efforts to develop flexible manufacturing capabilities for medical countermeasures to respond to public health emergencies.
	Centers for Disease Control and Prevention (CDC)	CDC develops strategies for conducting surveillance of diseases in humans, including collaborating with USDA and other agencies to monitor zoonotic diseases. CDC conducts laboratory studies of influenza viruses with pandemic potential to assess their potential risks to humans and to inform pre-pandemic vaccine stockpile decision making. The **Influenza Division o**f the CDC **National Center for Immunization and Respiratory Diseases** conducts surveillance of influenza in humans, including human infections of influenza of animal origin. Researchers use surveillance information to monitor influenza trends and improve rapid reporting and identification of novel influenzas of animal origin to which humans might not have immunity. Researchers also use surveillance to guide the development of diagnostic tests and vaccines.
	Food and Drug Administration (FDA)	FDA is responsible for protecting the public health by ensuring the safety and efficacy of veterinary drugs and medical devices and by licensing biological products that are safe, pure, and potent, including vaccines for pandemic influenza. In addition, FDA is responsible for ensuring the safety and proper labeling of more than 80 percent of the U.S. food supply. FDA's role includes assessing emerging infectious disease threats that may require FDA to take action. FDA works with industry partners and other stakeholders to speed the development, availability, and timely access to critical medical products, e.g., increasing vaccine production if a particularly virulent strain of influenza begins to spread.

Department	Component agency	Summary of relevant responsibilities
Department of the Interior	United States Fish and Wildlife Service	The Fish and Wildlife Service assists with collecting samples for testing birds and hunter-captured animals in its refuges. The Fish and Wildlife Service works with other federal and state agencies to monitor bird populations for the earliest possible detection of the avian influenza virus if it enters this country.
	United States Geological Survey	Interior coordinates the federal government's surveillance of wild migratory birds for the presence of highly pathogenic avian influenza virus, coordinates federal surveillance with related surveillance activities of state fish and wildlife agencies, and provides leadership and support in the area of wildlife disease research and diagnostics to federal and state natural resource agencies. Interior's U.S. Geological Survey maintains the **National Wildlife Health Center**, which identifies, controls, and prevents wildlife losses from diseases as well as conducts research to understand the impact of diseases on wildlife populations; the center also devises methods to more effectively manage these disease threats. The National Wildlife Health Center works with department bureaus, as well as state, tribal, and other federal entities, on wildlife disease investigations, providing the best available science and technical support for issues related to wildlife health and disease.

Source: GAO, Interior, HHS, and USDA documents.| GAO-17-360

[a]The World Organisation for Animal Health, of which the United States is a member, is an intergovernmental organization responsible for improving animal health worldwide. It requires its 180 member countries to report certain diseases to the organization and other member countries.

[b]Pub. L. No. 109-417 § 401(c), 120 Stat. 2831, 2865 (codified as amended at 42 U.S.C. § 247d-7e(c)).

Appendix II: Results of Surveillance of Wild Birds for Avian Influenza, December 2014 through March 2017

In response to the outbreak of highly pathogenic avian influenza in December 2014, personnel from the U.S. Department of Agriculture (USDA) and the Department of the Interior re-convened the Interagency Wild Bird Avian Influenza Steering Committee in January 2015.[1] The steering committee developed a wild bird surveillance plan for avian influenzas that may pose a threat to human health or domestic poultry.[2] The plan encourages federal and state agencies and others to use a variety of sampling methods to test live and dead wild birds to detect both low pathogenic and highly pathogenic avian influenza. According to data recorded as of March 24, 2017, the surveillance program had collected test results from more than 88,000 wild birds since December 2014. The number of monthly highly pathogenic avian influenza detections was highest during the period from December 2014 through June 2015 before declining during the period from July 2015 through March 24, 2017, despite an increase in testing over this period of time. In total, the program detected highly pathogenic avian influenza in 102 birds, or 0.12 percent of those tested. (See table 8 for a summary of the monitoring data.) The surveillance program also detected low pathogenic influenza A virus in some wild birds; program data show that the percentage of wild duck samples that tested positive for low pathogenic influenza A virus in each month ranged from about 7 percent to about 30 percent in 2015 and 2016 (data not shown in table 8).[3] The state veterinarians we interviewed from six states (California, Indiana, Iowa, Minnesota, North Carolina, and Ohio) generally agreed with the need for wildlife surveillance. At the same time, while monitoring can serve as an early warning system to alert poultry owners and public health agencies, among others, of the presence of influenza A viruses in wild birds, it cannot eliminate wild birds as potential sources of the virus.

[1]According to its charter, the Interagency Wild Bird Avian Influenza Steering Committee is comprised of representatives from the USDA Animal and Plant Health Inspection Service; the U.S. Geological Survey; the U.S. Fish and Wildlife Service; the Centers for Disease Control and Prevention; the Association of Fish and Wildlife Agencies; the National Flyway Council; and other agencies or organizations, as mutually determined by the membership.

[2]*Early Detection and Monitoring for Avian Influenzas of Significance in Wild Birds: A U.S. Interagency Strategic Plan*, Interagency Wild Bird Avian Influenza Steering Committee (June 2015).

[3]Detections of Type A low pathogenic avian influenza virus include a range of subtypes. Detections of H5 and H7 subtypes, which are reportable to the World Organisation for Animal Health, in wild ducks have ranged from less than 1 percent to about 4 percent per month.

Table 8: Detections of Highly Pathogenic Avian Influenza in Wild Birds in the United States from December 2014 to March 2017

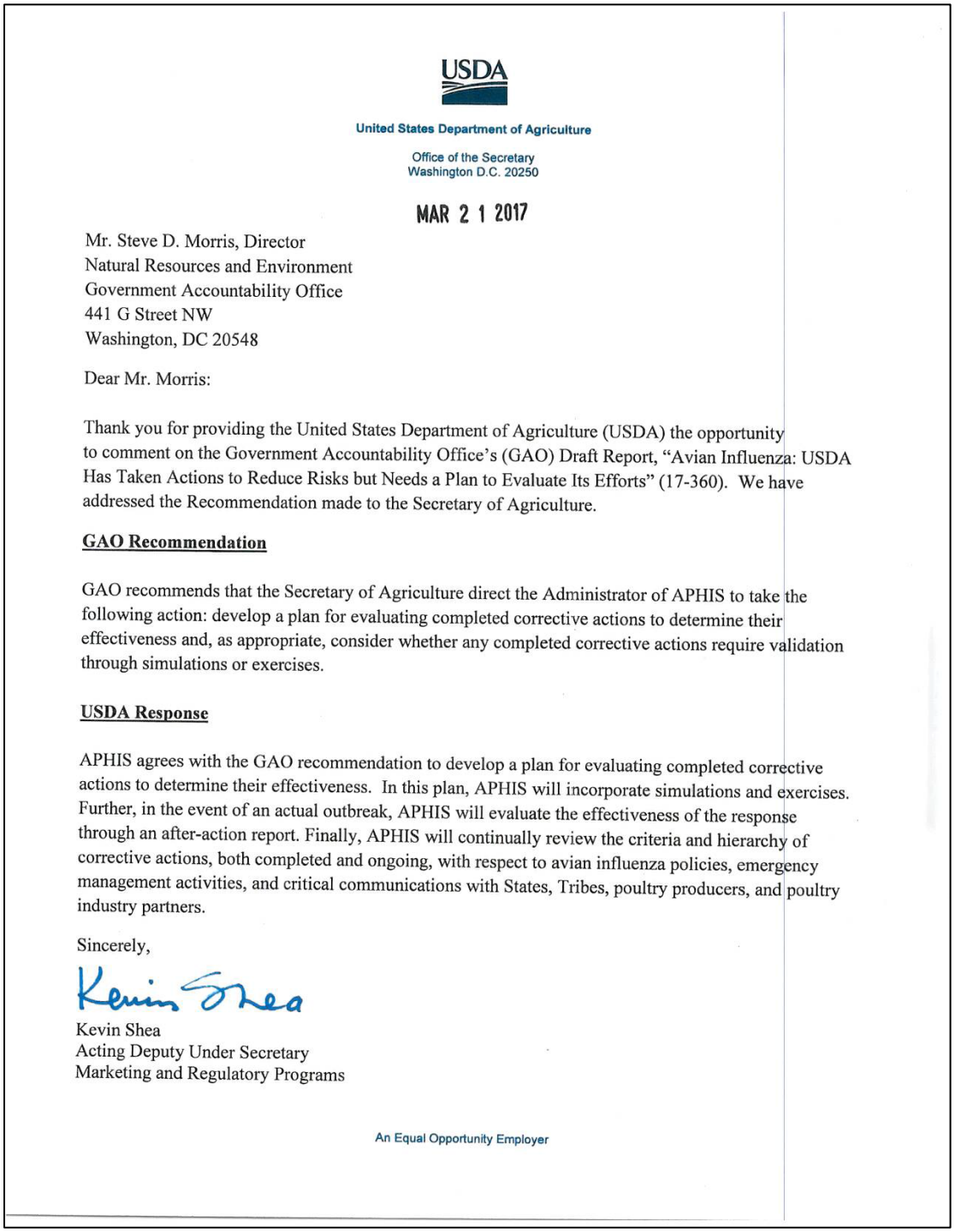
Period of testing (by year and month)	Total positive cases	Subtypes detected and number of cases (EA = Eurasian; AM=North American)
December 2014	19	• EA/AM H5N2 (9) • EA H5N8 (9) • EA/AM H5N1 (1)
January 2015	55	• EA/HM H5N2 (17) • EA H5N8 (14) • EA/AM H5N1 (2) • EA H5 (22)
February 2015	1	• EA H5 (1)
March 2015	7	• EA/HM H5N2 (6) • EA H5 (1)
April 2015	2	• EA/AM H5N2 (2)
May 2015	1	• EA H5 (1)
June 2015	13	• EA/AM H5N2 (5) • EA H5 (8)
July 2015	1	• EA H5 (1)
August 2015	0	N/A
September 2015	0	N/A
October 2015	0	N/A
November 2015	1	• EA H5 (1)
December 2015	0	N/A
January 2016	0	N/A
February 2016	0	N/A
March 2016	0	N/A
April 2016	0	N/A
May 2016	0	N/A
June 2016	0	N/A
July 2016	0	N/A
August 2016	1	• EA/AM H5N2 (1)
September 2016	0	N/A
October 2016	0	N/A
November 2016	0	N/A
December 2016	1	• EA/AM H5N2 (1)
January 2017	0	N/A

Period of testing (by year and month)	Total positive cases	Subtypes detected and number of cases (EA = Eurasian; AM=North American)
February 2017	0	N/A
March 2017	0	N/A
TOTAL BIRDS SAMPLED: 88,167	**102**	

Source: GAO analysis of National Wild Bird Avian Influenza Surveillance Program data. | GAO-17-360

Notes: Data are through March 24, 2017. Avian H5 influenza (H5N8) originating from Eurasia spread rapidly along wild bird migratory pathways during 2014. Introduction of this virus into the Pacific Flyway sometime during 2014 has allowed mixing with North American-origin viruses and generated new (novel) combinations with genes of both Eurasian and North American origin (or "reassortant" viruses). In some cases, testing did not identify the specific subtype of avian influenza. N/A = "not applicable" because no detections were made that month.

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



USDA

United States Department of Agriculture

Office of the Secretary
Washington D.C. 20250

MAR 2 1 2017

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

Dear Mr. Morris:

Thank you for providing the United States Department of Agriculture (USDA) the opportunity to comment on the Government Accountability Office's (GAO) Draft Report, "Avian Influenza: USDA Has Taken Actions to Reduce Risks but Needs a Plan to Evaluate Its Efforts" (17-360). We have addressed the Recommendation made to the Secretary of Agriculture.

GAO Recommendation

GAO recommends that the Secretary of Agriculture direct the Administrator of APHIS to take the following action: develop a plan for evaluating completed corrective actions to determine their effectiveness and, as appropriate, consider whether any completed corrective actions require validation through simulations or exercises.

USDA Response

APHIS agrees with the GAO recommendation to develop a plan for evaluating completed corrective actions to determine their effectiveness. In this plan, APHIS will incorporate simulations and exercises. Further, in the event of an actual outbreak, APHIS will evaluate the effectiveness of the response through an after-action report. Finally, APHIS will continually review the criteria and hierarchy of corrective actions, both completed and ongoing, with respect to avian influenza policies, emergency management activities, and critical communications with States, Tribes, poultry producers, and poultry industry partners.

Sincerely,

Kevin Shea

Kevin Shea
Acting Deputy Under Secretary
Marketing and Regulatory Programs

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Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Steve D. Morris, (202) 512-3841 or Morriss@gao.gov

Staff acknowledgments

In addition to the individual named above, Mary Denigan-Macauley (Assistant Director), Kevin Bray, Ross Campbell, Barbara El Osta, Kevin R. Fish, Katherine Killebrew, Erik Kjeldgaard, Cynthia Norris, and Amber Sinclair made key contributions to this report. Ashley Grant, Sara Sullivan, Kiki Theodoropoulos, and Rajneesh Kumar Verma also made important contributions to this report.

Related GAO Products

Biodefense: The Nation Faces Multiple Challenges in Building and Maintaining Biodefense and Biosurveillance. GAO-16-547T. Washington, D.C: April 14, 2016.

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

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