

Report to Congressional Committees

June 2007

AVIAN INFLUENZA

USDA Has Taken Important Steps to Prepare for Outbreaks, but Better Planning Could Improve Response





Highlights of GAO-07-652, a report to congressional committees

Why GAO Did This Study

A highly pathogenic strain of avian influenza (AI) has spread to nearly 60 countries over the past few years, killing millions of birds and more than 170 humans. Controlling the virus in poultry is key to reducing the risk of a human pandemic. The Department of Agriculture (USDA) is responsible for planning for AI outbreaks in poultry, with states' assistance. The Department of Homeland Security (DHS) is responsible for coordinating the federal response for certain emergencies and developing policy documents that serve as a basis for national emergency planning. GAO described the steps USDA is taking to prepare for highly pathogenic AI and identified key challenges. GAO reviewed response plans, statutes, and regulations; visited poultry operations; interviewed federal, state, and industry officials in five states that experienced outbreaks; and reviewed 19 state plans.

What GAO Recommends

GAO recommends that USDA and DHS develop a memorandum of understanding to clarify their roles during certain emergencies, and USDA should take several steps to improve its planning and that of the states. USDA agreed with all recommendations except for the use of a memorandum of understanding to clarify roles. DHS agreed further clarification of roles is needed.

www.gao.gov/cgi-bin/getrpt?GAO-07-652.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Daniel Bertoni at (202) 512-3841 or bertonid@gao.gov.

AVIAN INFLUENZA

USDA Has Taken Important Steps to Prepare for Outbreaks, but Better Planning Could Improve Response

What GAO Found

USDA is taking important steps to prepare for highly pathogenic AI. For example, the department has established mechanisms to prevent infected poultry (see photo) and products from being imported and has developed several surveillance programs to detect AI. In addition, USDA is developing response plans specific to highly pathogenic AI and has begun conducting exercises to test these plans. Moreover, USDA is building a National Veterinary Stockpile to maintain critical supplies, including equipment to protect responders. Finally, USDA has launched various AI research projects, including one to explore why the virus causes disease and death in some domestic poultry and wild birds but not in others.

While USDA has made important strides, incomplete planning at the federal and state levels, as well as several unresolved issues, could slow response. First, USDA is not planning for the lead coordinating role that DHS would assume if an outbreak among poultry occurred that is sufficient in scope to warrant various federal disaster declarations. GAO's prior work has shown that roles and responsibilities must be clearly defined and understood to facilitate rapid and effective decision making. Moreover, USDA response plans do not identify the capabilities needed to carry out the critical tasks associated with an outbreak scenario—that is, the entities responsible for carrying them out, the resources needed, and the provider of those resources. Furthermore, some state plans lack important components that could facilitate rapid AI containment, which is problematic because states typically lead initial response efforts. Finally, there are several unresolved issues that, absent advance consideration, could hinder response. For example, controlling an outbreak among birds raised in backyards, such as for hobby, remains particularly difficult because federal and state officials generally do not know the numbers and locations of these birds. In addition, USDA has not estimated the amount of antiviral medication that it would need during an outbreak or resolved how to provide such supplies in a timely manner. According to federal guidance, poultry workers responding to an outbreak of highly pathogenic AI should take antiviral medication to protect them from infection.

A Chicken Infected with Avian Influenza



Source: USDA.

Contents

Letter		Results in Brief Background USDA Is Implementing Important Measures to Help the Nation Prepare for Outbreaks of Highly Pathogenic Avian Influenza Federal and State Response Plans Are Incomplete, and Several Issues Are Unresolved Conclusions Recommendations for Executive Action Agency Comments and Our Evaluation		
Appendixes				
	Appendix I:	Scope and Methodology	46	
	Appendix II:	Comments from the Department of Agriculture GAO Comments	48 53	
	Appendix III:	Comments from the Department of Homeland Security	54	
	Appendix IV:	GAO Contact and Staff Acknowledgments		
Tables		Table 1: States That Have Experienced Outbreaks of Avian Influenza in Commercial Poultry Since 2002 Table 2: Gaps Identified in State Plans	11 29	
Figures		Figure 1: Common Types of Commercial Poultry Operations Figure 2: Percentages of Poultry Types Produced in the United States, 2005	8	
		Figure 3: Value of Poultry Products in the United States, 2005	9	
		Figure 4: How Disease Spreads Among Commercial Poultry Figure 5: Identifying Capabilities Needed for Highly Pathogenic	10	
		AI Figure 6: Methods of Poultry Disposal	27 36	

Contents

Abbreviations

AI avian influenza

APHIS Animal and Plant Health Inspection Service

DHS Department of Homeland Security

USDA Department of Agriculture

HHS Department of Health and Human Services

This is a work of the U.S. government and is not subject to copyright protection in the United States. It may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.



United States Government Accountability Office Washington, D.C. 20548

June 11, 2007

Congressional Committees:

A highly pathogenic strain of H5N1 avian influenza has, over the past few years, spread to nearly 60 countries, resulting in the death and destruction of millions of wild and domestic birds throughout Asia, Europe, Africa, and the Middle East. Serious concerns exist that it could reach North America at any time via migrating birds or smuggled imports of diseased birds and bird products. Although primarily an avian disease, this virus has also infected 291 humans—most of whom had close contact with infected poultry—and more than half of them have died. Health experts are concerned that should highly pathogenic H5N1 (or another subtype), to which humans have no immunity, develop the capacity to spread easily from person to person, a pandemic could occur. According to the World Health Organization, controlling the virus in poultry is the principal way to reduce opportunities for human infection and, therefore, reduce opportunities for a pandemic to emerge.

Avian influenza (AI) 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. Most AI viruses are low pathogenic and usually result in mild or asymptomatic infections in birds. In the United States, these viruses are common in wild waterfowl and shorebirds. Highly pathogenic AI viruses are associated with high morbidity and mortality in poultry and are considered foreign animal diseases because they rarely occur in the United States. Despite the relative mildness of low pathogenic AI, some of these strains are worrisome because they have the potential to mutate into highly pathogenic AI. This happened most recently in 2004 in British Columbia, Canada, resulting in the death of 17 million birds.

The Department of Agriculture (USDA) is responsible for acting to prevent, control, and eradicate foreign animal diseases in domestic livestock and poultry, in coordination with a number of other entities. For example, 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. If humans become infected, the Department of Health and Human Services (HHS) leads the federal medical

¹These numbers are based on statistics reported by the World Health Organization as of April 11, 2007.

response. In the event of an outbreak serious enough for the President to declare an emergency² or major disaster³ or for the Secretary of Homeland Security to declare an Incident of National Significance,⁴ the Secretary of Homeland Security assumes responsibility for coordinating the federal response. In addition, the Department of Homeland Security (DHS) has been charged with developing policy documents that provide the foundation for emergency planning for all levels of government.

A well-planned, coordinated emergency response is essential when dealing with highly pathogenic AI in order to mitigate financial losses to the \$28 billion U.S. poultry industry. The United States is the world's largest producer and second largest exporter of poultry meat, accounting for nearly 35 percent of global trade valued at more than \$2 billion annually. Once certain strains of low pathogenic AI or any strain of highly pathogenic AI are found in domestic poultry in the United States, trading partners are notified, and exports of poultry and poultry products from within the affected area are halted. To control the spread of the disease and to ultimately resume trade, USDA, often with assistance from states and the poultry industry, typically destroys—depopulates—exposed and infected birds, including those raised in commercial operations and in backyards. ⁵

The Robert T. Stafford Disaster Relief and Emergency Assistance Act, Pub. L. No. 93-288, 88 Stat. 143 (1974) (codified as amended at 42 U.S.C. §§ 5121 et seq.), defines an emergency as "any occasion or instance for which, in the determination of the President, Federal assistance is needed to supplement State and local efforts and capabilities to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe in any part of the United States." 42 U.S.C. §5122(1).

³The Stafford Act defines a major disaster as "any natural catastrophe (including any hurricane, tornado, storm, high water, winddriven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm or drought), or, regardless of cause, any fire, flood, or explosion, in any part of the United States, which in the determination of the President causes damage of sufficient severity and magnitude to warrant major disaster assistance under [the Act] to supplement the efforts and available resources of States, local governments, and disaster relief organizations in alleviating the damage, loss, hardship, or suffering caused thereby." 42 U.S.C. §5122(2).

⁴According to the National Response Plan, an Incident of National Significance is "an actual or potential high-impact event that requires a coordinated and effective response by an appropriate combination of Federal, State, local, tribal, nongovernmental, and/or private-sector entities in order to save lives and minimize damage, and provide the basis for long-term community recovery and mitigation activities."

⁵Backyard birds are those raised, for example, for cockfighting or personal consumption.

USDA provides compensation to owners—indemnifies them—for losses incurred when USDA depopulates birds.⁶

USDA has had some experience working with states and the poultry industry to eradicate highly pathogenic AI. For example, USDA worked with Pennsylvania to control an outbreak of highly pathogenic AI in 1983, leading to the depopulation of 17 million birds. However, the agency has never confronted the challenge of an AI strain with the unique characteristics of highly pathogenic H5N1: the unprecedented speed with which it has spread, its human health implications, and the extensive scrutiny it has received as a result of coverage in the world media. Moreover, the possibility exists that terrorists could introduce highly pathogenic AI at multiple locations, instilling fear in the public about the safety of the food supply and disrupting the economy.

Given the intense global concern about highly pathogenic AI, we (1) described the steps USDA has taken to prepare for highly pathogenic AI in domestic poultry and (2) identified any challenges that could affect USDA's ability to prepare for highly pathogenic AI. A list of congressional committees that requested this report appears on the last page of this letter.

To describe the steps USDA has taken to prepare for outbreaks of highly pathogenic AI in domestic poultry, we reviewed presidential directives and national emergency planning documents, relevant statutes and regulations, and USDA documents and programs related to AI. To identify any challenges that could affect USDA's ability to prepare for outbreaks of highly pathogenic AI, we conducted structured interviews with federal, state, and industry officials in California, Delaware, Maryland, Texas, and Virginia. We selected these states because they have experience responding to an outbreak of AI or another highly infectious avian disease in the past 5 years and because of their varying poultry demographics. We also interviewed USDA emergency management and industry officials, including those personnel specifically charged with helping states develop AI response plans, to identify strengths and weaknesses in state plans and to characterize their state's level of readiness for an outbreak. In addition, we performed our own review and assessment of 19 state plans to corroborate identified strengths and weaknesses from the interviews. Furthermore, we attended a USDA and state AI training exercise and

 $^{{}^{\}overline{6}}$ In addition, USDA may, under certain circumstances, indemnify owners when states and industry depopulate birds.

visited live bird markets and numerous types of poultry operations. Finally, we interviewed DHS officials to discuss emergency planning and DHS' role in outbreaks of AI. Additional details about our scope and methodology are presented in appendix I. We conducted our review between May 2006 and June 2007 in accordance with generally accepted government auditing standards.

Results in Brief

USDA is taking many important measures to help the nation prepare for outbreaks of highly pathogenic AI. For example, USDA has put mechanisms in place to prevent the importation of poultry and poultry products contaminated with highly pathogenic AI. It also has developed several surveillance programs to detect AI, including a long-standing voluntary program that systematically tests samples of birds from participating poultry operators' flocks for the virus. In addition, USDA is developing response plans specific to highly pathogenic AI, and the department has begun preliminary exercises with other federal agencies, states, and industry to test preparedness. Moreover, USDA has begun creating a National Veterinary Stockpile containing, among other things, personal protective equipment such as goggles and respirators to protect responders against foreign animal diseases. Furthermore, USDA recently expanded its indemnification regulations and has developed communication strategies to inform the public and instill confidence that USDA is taking steps to quickly address any potential AI outbreak. Finally, USDA has critical AI research under way. For example, it is conducting experiments to better understand how the virus causes disease and death in some domestic poultry and wild birds but not in others.

While USDA has made important strides, incomplete planning at the federal and state levels, as well as several unresolved issues, could slow response and delay recovery from an outbreak. First, USDA is not planning for DHS to assume the lead coordinating role if an outbreak among poultry occurs that is sufficient in scope to warrant a presidential declaration of an emergency or major disaster, or a DHS declaration of an Incident of National Significance. USDA officials told us that DHS involvement would likely be unnecessary unless there are multiple outbreaks, an agroterrorism event is suspected, or the virus causes a human pandemic. Moreover, in the view of USDA officials, it is not clear that a presidential declaration of an emergency or major disaster would even apply to a highly pathogenic AI outbreak. However, the decision to involve DHS is not USDA's to make. It is the President who declares an emergency or major disaster when he determines that an outbreak is sufficient in scope to warrant federal

assistance. Furthermore, DHS officials told us that it is possible that an Incident of National Significance would be declared by the Secretary of Homeland Security depending on the severity, magnitude, or complexity of the outbreak. In the event of a presidential declaration of an emergency or major disaster, or a declaration of an Incident of National Significance, the Secretary of Homeland Security assumes responsibility for directing the federal response. DHS officials told us they should be involved in planning for such an event. Our prior work has shown that roles and responsibilities for those responding to major incidents must be clearly defined and understood to facilitate rapid and effective decision making. Because this DHS/USDA coordination is absent from USDA planning, the federal response may be slowed as these agencies resolve their roles and responsibilities following the onset of a significant outbreak. Second, USDA response plans do not identify the capabilities needed to carry out the tasks associated with an outbreak scenario—that is, the entities responsible for carrying them out, the resources needed, and the source of those resources. Planning of this nature is essential for an effective emergency response.

Furthermore, 14 of 19 state plans that we reviewed lack important components that could facilitate rapid containment of the virus. For example, some lack time frames for accomplishing response activities that would enable the states to determine the extent to which they were being successful in controlling the outbreak. USDA and state officials told us that state-level plans are incomplete for several reasons, including the lack of established federal criteria for what a response plan for highly pathogenic AI should include. In the absence of such criteria, USDA and state officials we interviewed told us they are relying, among other things, on experience from previous outbreaks. These planning gaps are particularly problematic because states typically lead initial response efforts, when rapid action is essential to limiting the spread of disease.

Finally, several unresolved issues could affect response. For example, federal and state officials generally do not know the numbers and locations of backyard birds so controlling an outbreak among these birds remains particularly difficult. A recent California outbreak of exotic Newcastle disease—a highly infectious foreign animal disease in birds—illustrates this point. This virus originated in backyard flocks in California and spread to two neighboring states. Controlling the disease was impeded because responders had to go door-to-door to locate potentially infected birds. A second issue is that the disposal of carcasses and materials infected with AI may be more problematic than in the past. State officials told us that in

light of highly pathogenic H5N1, operators of landfills have become reluctant to accept materials infected with even low pathogenic AI because of the perceived human health risk. Furthermore, USDA has not estimated the amount of antiviral medication that it would need in the event of an outbreak or resolved how to provide such supplies within the first 24 hours of an outbreak. According to federal guidance, workers responding to an outbreak of highly pathogenic AI should take antiviral medication daily at the site of an outbreak and each day for 7 days after leaving the site to protect them from infection.

To increase the likelihood that an outbreak of highly pathogenic AI is rapidly contained so efforts can focus on recovery, we are making several recommendations. For example, we are recommending that the Secretaries of Agriculture and Homeland Security develop a memorandum of understanding that describes how USDA and DHS will work together in the event of a declared presidential emergency or major disaster, or an Incident of National Significance, and test the effectiveness of this coordination during exercises. In addition, we are recommending that the Secretary of Agriculture identify and test the capabilities necessary to respond to a probable outbreak scenario(s); develop standard criteria for the components of state response plans; focus additional work with states on how to overcome potential problems associated with unresolved issues; and address concerns about antiviral medication.

In commenting on a draft of this report, USDA agreed with all but one of our recommendations. USDA stated that it does not believe a memorandum of understanding is the best vehicle for clarifying and defining the roles of USDA and DHS in the event of a declared presidential emergency or major disaster, or an Incident of National Significance. Nevertheless, USDA accepted the need to clarify the roles during such an event and further supported the need to test this coordination in formal exercises. DHS agreed that USDA and DHS roles need further clarification and suggested that a concept of operation plan could be used to define this relationship. DHS further supported the need to test this coordination through exercises.

Background

In November 2005, the President of the United States released the Homeland Security Council's *National Strategy for Pandemic Influenza* to guide the country's overall effort to address the threat that highly pathogenic AI could create a human pandemic influenza. The strategy identified four lead agencies, each responsible for developing a plan to

implement a component of the strategy: USDA is responsible for the veterinary response, HHS is responsible for the medical response, the Department of State is responsible for international activities, and DHS is responsible for overall domestic incident management and federal coordination. In May 2006, the *Implementation Plan for the National Strategy for Pandemic Influenza* was issued to describe how the strategy would be implemented. Specifically, this implementation plan describes more than 300 critical actions that the appropriate federal agencies must carry out to address the threat of pandemic influenza. The department has responsibility for nearly 100 of these critical actions.⁷

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 facility. The most common types of poultry raised commercially are chickens for consumption (called broilers) and chickens that lay eggs (called layers), as well as turkeys (see fig. 1). Broilers represent 93 percent of poultry produced in the United States (see fig. 2) and almost three-quarters of poultry and poultry products by value sold to consumers (see fig. 3). There are also commercial birds that are genetic breeding stock whose main function is to produce offspring that facilitate mass production and are economical to raise. 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 highly pathogenic AI, hundreds of thousands of birds can be exposed and need to be depopulated.

 $^{^{\}overline{7}}$ According to USDA, the department is responsible for leading 57 of these critical actions and supporting 41 more.

Figure 1: Common Types of Commercial Poultry Operations

Broilers

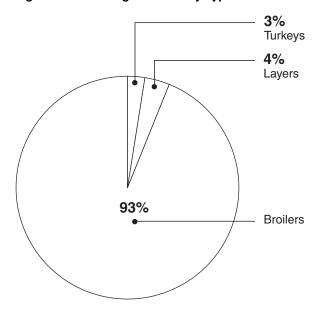




Layers

Source: GAO.

Figure 2: Percentages of Poultry Types Produced in the United States, 2005



Source: GAO presentation of USDA data.

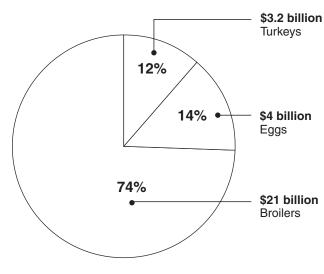


Figure 3: Value of Poultry Products in the United States, 2005

Source: GAO presentation of USDA data

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

When poultry become infected with AI, it may be spread by the movement of contaminated people and equipment to and from a site where the infected birds are located (see fig. 4). For example, a poultry worker enters one bird house containing birds infected with AI but does not disinfect boots or change clothing before entering another house, carrying the virus and causing the disease to spread. As a precaution, commercial producers often implement biosecurity measures. For example, the number of people entering a bird house is restricted, and these people must dress in special, sometimes disposable, clothing. Moreover, vehicles arriving at a farm are usually required to be disinfected upon entry and exit. The workers' boots and hands are also disinfected. For highly valuable birds, such as genetic

breeding stock, biosecurity may be higher—for example, visitors may be required to shower before entering and leaving the facility.

Farm 1 People
• Boots
• Clothing Vehicles Handling Farm 4 Farm 2 Poultry equipment • Filler flats Hauling crates/coops
 Feeder, waterers Vehicle/equipment Manure spreader Tractor Bird-to-bird • Trucks Front end loader Carcasses Farm 3 Manure • Litter/debris Feathers Livestock and Bird Market Grocery Live Chickens

Figure 4: How Disease Spreads Among Commercial Poultry

Source: USDA and GAO.

Despite biosecurity measures, outbreaks among commercial poultry have recently occurred (see table 1). For example, in 2002, Virginia experienced an outbreak of low pathogenic AI that resulted in the depopulation of nearly 5 million birds in order to control the disease. In 2003, Connecticut had an outbreak of low pathogenic AI that affected more than 3 million commercial laying hens. While low pathogenic AI is detected from time to time in domestic poultry, highly pathogenic AI is known to have occurred only three times in the United States: in 1924, 1983, and 2004. It is believed that all three of these highly pathogenic outbreaks originated in live bird markets. The Pennsylvania outbreak in 1983 began as a low pathogenic AI virus but mutated into a highly pathogenic strain, leading to the depopulation of 17 million birds. Although diagnostic testing confirmed that a virus in Texas in 2004 was technically highly pathogenic, the virus did not cause high mortality in the infected birds, as would be typical with highly pathogenic AI.

Table 1: States That Have Experienced Outbreaks of Avian Influenza in Commercial Poultry Since 2002

State	Avian disease	Year of outbreak	Origin	Number/type of birds depopulated	Time taken to eradicate
Virginia/North Carolina/West Virginia	Low pathogenic Al	2002	Unconfirmed; live bird market suspected	4.7 million birds	4 months
Connecticut	Low pathogenic AI	2003	Unconfirmed; wildfowl suspected	100,000 laying hens; millions more vaccinated	Over 1 year
Delaware/Maryland	Low pathogenic Al	2004	Live bird market	More than 400,000 commercial broilers	2 months
Texas	Highly pathogenic Al	2004	Live bird market	6,600 commercial broilers	Less than 2 months
West Virginia ^a	Low pathogenic Al suspected	2007	Unknown at this time	25,000 turkeys (unconfirmed)	Unknown at this time

Source: GAO

^aOn March 31, 2007, USDA confirmed the presence of an H5N2 AI virus in turkeys located on a farm in West Virginia. USDA reported that this virus is consistent with low pathogenic strains of AI. The turkeys showed no signs of illness, and there was no mortality. USDA plans to run sequencing and pathogenicity tests to further identify the virus.

⁸Poultry in North Carolina and West Virginia were also affected.

⁹In this instance, vaccines were used in conjunction with depopulation to control the outbreak.

Biosecurity Measures on the Farm



To prevent the introduction of highly pathogenic Al into flocks, USDA recommends that poultry producers strengthen biosecurity practices. For

- · Protect poultry flocks from coming into contact with wild or migratory birds and any source of water that may have been contaminated by wild birds.
- · Permit only essential workers and vehicles to enter the farm.
- · Thoroughly clean and disinfect equipment and vehicles entering and leaving the farm.
- · Do not loan equipment or vehicles to, or borrow from, other farms
- · Avoid visiting other poultry farms. If you do visit another farm or live bird market, change footwear and clothing before working with your own flock.
- · Do not bring birds from slaughter channels, especially live bird markets, back to the farm.



Source: GAO

An outbreak of AI can have serious trade repercussions. The World Organization for Animal Health is an international animal health group with 167 member countries, including the United States. Members agree to notify the organization of outbreaks in domestic poultry of all highly pathogenic AI and some low pathogenic strains—those with H5 and H7 proteins—because they have the capacity to mutate into highly pathogenic Al. 10 Consequently, when a country's poultry tests positive for "notifiable" AI, its international trading partners are likely to restrict trade with that country until the partners believe the virus is eradicated—an outcome that can take many months to achieve. For example, when a single farm in Texas was infected with highly pathogenic AI in 2004, more than 50 countries instituted complete or partial bans on U.S. poultry; Mexico has yet to lift its ban. Therefore, when a flock is infected with AI, the goal becomes controlling and eradicating the disease as rapidly as possible in order to prevent the spread of the disease and to regain the confidence of U.S. trading partners that any future imports will be disease free. This is accomplished by acting 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 disease is eradicated, USDA, states, and the poultry industry continue to test birds to monitor for AI.

USDA derives its authority to carry out operations and measures to prevent, detect, control, and eradicate AI from the Animal Health Protection Act. 11 The act authorizes the Secretary of Agriculture to hold, seize, treat, destroy, or dispose of any animal, vehicle, or object that can harbor the disease, or to restrict their movement in interstate commerce. The act also authorizes the Secretary to transfer 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 addition, the act authorizes the Secretary to declare an "extraordinary emergency" when it has been determined that a state's actions are inadequate to control or eradicate a livestock disease that threatens domestic livestock. Under this declaration, the Secretary's

¹⁰The World Organization for Animal Health defines notifiable AI as an infection of poultry caused by any influenza A virus of the H5 or H7 subtypes or by any AI virus with an intravenous pathogenicity index greater than 1.2, or with at least 75 percent mortality.

¹¹7 U.S.C. §§ 8301-8321.

authority to regulate includes any animal, vehicle, or object that can harbor the disease in intrastate, as well as interstate commerce.

Within USDA, a number of agencies have responsibility for protecting U.S. poultry from AI. The Animal and Plant Health Inspection Service (APHIS) operates the National Veterinary Services Laboratories, the only laboratory in the United States recognized by the World Organization for Animal Health to perform confirmatory testing for AI. Also, APHIS' Smuggling, Interdiction, and Trade Compliance unit conducts activities to prevent smuggled and prohibited agricultural goods from entering and being distributed throughout the country. In addition, the Agricultural Research Service conducts research on endemic and exotic poultry diseases, including highly pathogenic AI; the Food Safety and Inspection Service works to ensure that the nation's commercial supply of meat, poultry, and egg products is safe for human consumption; the Office of Communications coordinates public information from USDA program agencies.

In the past few years, USDA's total obligations for AI preparedness efforts have increased from approximately \$3.2 million in fiscal year 2004 to \$74.1 million in fiscal year 2006. In 2005, USDA received \$91.35 million from the 2-year Emergency Supplemental Appropriation to Address Pandemic Influenza. The bulk of USDA's supplemental funding (\$80.3 million) was allocated to APHIS, which in turn obligated \$43 million for AI surveillance of domestic wildlife, commercial poultry, and live bird markets in fiscal year 2006. In addition, USDA obligated portions of the remaining emergency supplemental funding to areas such as AI research and public communications. According to USDA officials, the department is requesting \$82 million for fiscal year 2008 to support its ongoing AI programs.

While USDA has for many years been responsible for protecting livestock and poultry from foreign animal diseases, it now does so under new authorities and has additional roles and responsibilities. Following the terrorist attacks of 2001, the Congress passed the Homeland Security Act of

¹²Pub. L. No. 109-148, div. B. tit. II. 119 Stat. 2782 (2005).

¹³The \$80.3 million allocated to APHIS consisted of \$71.5 million from the 2-year emergency supplemental and, according to USDA officials, \$8.8 million from supplemental funds appropriated to the Office of the Secretary.

2002, ¹⁴ establishing DHS as the chief coordinating agency for efforts to protect the United States from terrorist acts and disasters, including those that affect the agriculture sector. As such, DHS undertook major policy initiatives to promote emergency preparedness, including developing the National Incident Management System, the National Response Plan, and the National Preparedness Goal.

The National Incident Management System is intended to provide a consistent framework for incident management at all jurisdictional levels regardless of cause, size, or complexity of the situation and to define the roles and responsibilities of federal, state, and local governments during an emergency event. A key component of this system is the Incident Command System, designed to coordinate the communications, personnel, and procedures of different agencies and levels of government within a common organizational structure during an emergency.

The National Response Plan is an all-hazards plan built on the template of the National Incident Management System. It established a single, comprehensive approach to domestic incident management to prevent, prepare for, respond to, and recover from terrorist attacks, major disasters, and other emergencies. The National Response Plan is stated to always be in effect. Under the National Response Plan, resources are grouped into Emergency Support Functions that would most likely be needed during a domestic incident. Under Emergency Support Function #11, which addresses the protection of agriculture, APHIS is responsible for implementing an integrated federal, state, tribal, and local response to an outbreak of a highly contagious or economically devastating animal disease, such as highly pathogenic AI. A fundamental principle of the National Response Plan is that incidents are first handled at the lowest possible level of government. If an incident overwhelms local and state capabilities, a state may request resources from other states through mutual aid agreements, or may request federal assistance. The Robert T. Stafford Disaster Relief and Emergency Assistance Act 15 established the process for states to request supplemental resources from the federal government when state and local resources have been or will be overwhelmed. The President invokes a federal response under the Stafford Act by declaring an "emergency" or a "major disaster."

¹⁴Homeland Security Act of 2002, Pub. L. No. 107-296, 116 Stat. 2135.

¹⁵Pub. L. No. 93-288, 88 Stat. 143 (1974) (codified as amended at 42 U.S.C. §§ 5121 et seq.).

Homeland Security Presidential Directive 8 required the Secretary of Homeland Security to coordinate the development of a national domestic all-hazards preparedness goal to establish measurable readiness priorities and targets that appropriately balance the potential threat and magnitude of terrorist attacks and major disasters with the resources required to prevent, respond to, and recover from them. The goal was to include standards for preparedness assessments and strategies and a system for assessing the nation's overall preparedness to respond to major events. To implement this directive, DHS developed the National Preparedness Goal using 15 emergency event scenarios¹⁶ whose purpose was to form the basis for identifying the capabilities needed to respond to a wide range of emergency events.¹⁷ One of the defined scenarios was an outbreak of a foreign animal disease.

Finally, Homeland Security Presidential Directive 9 established a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies. Specifically, it directs the Secretary of Agriculture, in coordination with the Secretary of Homeland Security, and in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, to work with state and local governments and the private sector to develop a National Veterinary Stockpile containing sufficient amounts of animal vaccine, antiviral, or therapeutic products to appropriately respond to the most damaging animal diseases affecting human health and the economy within 24 hours of an outbreak.

¹⁶The 15 scenarios are (1) improvised nuclear device attack, (2) aerosol anthrax attack, (3) pandemic influenza, (4) biological attack with plague, (5) chemical attack with blister agent, (6) chemical attack with toxic chemical agent, (7) chemical attack with nerve agent, (8) chemical attack resulting in chlorine tank explosion, (9) major earthquake, (10) major hurricane, (11) radiological attack with dispersal device, (12) improvised explosive device attack, (13) biological attack with food contamination, (14) biological attack with foreign animal disease, and (15) cyber attack.

¹⁷Capabilities—the ability to carry out specific tasks under particular conditions with desired results—are built upon the appropriate combination of people, skills, processes, and assets.

 $^{^{18}\!\}text{The}$ mission of the Environmental Protection Agency is to protect human health and the environment.

USDA Is Implementing Important Measures to Help the Nation Prepare for Outbreaks of Highly Pathogenic Avian Influenza USDA has taken important steps to prepare for highly pathogenic AI. For example, the department has put mechanisms in place to prevent the importation of infected poultry and poultry products. In addition, it has developed several surveillance programs to detect AI. Moreover, in the event outbreaks do occur, USDA is developing written response plans and has begun preliminary exercises to test aspects of these plans with federal, state, local, and industry partners. USDA has also begun creating a National Veterinary Stockpile to augment state and local resources during outbreaks. Finally, the department has recently expanded its indemnification coverage for AI, developed public service messages to provide accurate information during outbreaks, and has undertaken critical AI research.

Import and Smuggling Control

Trade in live poultry and its products and the smuggling of birds and bird products have played a large role in the spread of highly pathogenic H5N1. To counteract these threats, USDA has mechanisms in place to prevent the importation of infected poultry and poultry products. For example, APHIS maintains trade restrictions on the importation of poultry and its products originating from regions where highly pathogenic AI has been detected. APHIS also requires that all live birds imported into the United States, with the exception of those from Canada, spend 30 days at a USDA quarantine facility where they are tested for AI. If found positive for the virus, the bird is destroyed.

In addition, APHIS' Smuggling, Interdiction, and Trade Compliance unit has increased its monitoring for smuggled poultry and products through an antismuggling program in coordination with DHS. ²⁰ Specifically, during fiscal year 2006 and the first 2 months of 2007, it conducted a total of 54 special AI operations. For example, at the Port of Los Angeles/Long Beach, this unit conducted an operation that targeted poultry and associated products that were being brought into the United States for the Asian New

¹⁹Report of the Second FAO/OIE Regional Meeting on Avian Influenza Control in Asia, in collaboration with: Government of Viet Nam (Ministry of Agriculture and Rural Development) and World Health Organization, February 23-25, 2005.

²⁰Coordination with DHS is necessary because the Homeland Security Act of 2002, Pub. L. No. 107-296, 116 Stat. 2135, transferred most of USDA's responsibility for conducting agricultural import inspections to DHS. (See GAO, *Homeland Security: Much Is Being Done to Protect Agriculture from a Terrorist Attack, but Important Challenges Remain*, GAO-05-214 (Washington D.C.: Mar. 8, 2005).

Year, when Asian imports typically increase. A total of 15 cargo inspections were conducted, and 4,324 kilograms of prohibited poultry products (including products from China and Japan, which were experiencing outbreaks of highly pathogenic H5N1 at the time of this report) were discovered. USDA has recently hired more than 20 field officers and eight analysts that specialize in AI to enhance surveillance and target potential AI shipments. Furthermore, in the spring of 2007, USDA officials told us that it will launch a national public awareness campaign to raise awareness among importers, distributors, wholesalers, and other key stakeholders about the threat of AI in smuggled poultry.

Surveillance

Highly Pathogenic AI Clinical Signs



Source: USDA's APHIS.

Highly pathogenic AI is an extremely infectious and fatal form of the disease for chickens. The virus can strike poultry quickly without any infection warning signs. Once established, the disease can spread rapidly from flock to flock. Clinical signs include sudden death; lack of energy and appetite; decreased egg production; soft–shelled or misshapen eggs; swelling of the head, eyelids, comb, wattles, and hocks; purple discoloration of the wattles, combs, and legs; nasal discharge; coughing and sneezing; lack of coordination; and discrete.



Source: USDA's APHIS.

USDA has several surveillance programs intended to rapidly detect and prevent the spread of AI. These programs augment USDA's veterinary infrastructure—an infrastructure that provides the foundation for USDA foreign animal disease monitoring. For example, APHIS' long-standing voluntary program, the National Poultry Improvement Plan, tests participating commercial poultry flocks to ensure they are free from diseases, including AI. If flocks test negative for AI, USDA provides certification that the flock is free of the disease, 21 thereby assisting with interstate and international trade, which provides an incentive for commercial industry participation. Forty-eight states participate in this program. In addition, APHIS' Biosecurity for the Birds program encourages, among other things, 22 surveillance of backyard birds. APHIS works closely with state departments of agriculture, USDA's Cooperative Extension Service, and private veterinarians to make information available to backyard bird owners on the risks and signs of disease and good biosecurity practices. While this program does not include a testing component, APHIS offers the public a toll-free number to notify authorities when backyard birds become sick and die. USDA is also expanding its surveillance programs as required in the Implementation Plan for the National Strategy for Pandemic Influenza. For example, among other efforts, APHIS is working with the Department of the Interior, ²³ state wildlife agencies, and others to increase surveillance of wild birds in Alaska and the 48 continental states. Moreover, USDA is working with states and industry to conduct surveillance of birds at auctions, swap meets, flea markets, and public exhibitions. Furthermore, in 2002, USDA established the National Animal Health Laboratory Network as part of a national strategy to coordinate and link the testing capacities of the federal veterinary diagnostic laboratories with the extensive infrastructure of state and university capabilities. This network now includes 51 approved

²¹The certification USDA provides indicates that breeder flocks are "AI clean" and that production flocks are "AI monitored."

²²For example, this educational program also encourages good biosecurity practices among backyard bird owners.

²³The Department of Interior is responsible for managing healthy wildlife populations.

laboratories that partner to conduct enhanced AI surveillance efforts. ²⁴ Finally, APHIS recently formed the National Avian Influenza Surveillance System, designed to link existing AI surveillance data from USDA, other federal and state agencies, and industry.

Response Plans

APHIS is currently drafting response plans for highly pathogenic AI.²⁵ For example, its draft Summary of the National Highly Pathogenic Avian Influenza Response Plan describes the activities that are necessary to respond to an outbreak.²⁶ In addition, USDA is working with the White House Homeland Security Council and other key federal agencies to produce an "interagency playbook"²⁷ intended to clarify how primary federal responders would initially interact to respond to six scenarios: detection of highly pathogenic H5N1 (1) in wild birds, (2) in a commercial poultry flock, (3) in multiple commercial poultry flocks within the United States, (4) in a live bird market, (5) along a contiguous border, and (6) involving a single case of poultry-to-human infection. According to the interagency playbook, although USDA is the federal department primarily responsible for controlling the disease in poultry (or other livestock), it would work with other federal partners. For example, HHS would ensure that systems were in place to detect and monitor infection in humans. In addition, the Environmental Protection Agency would provide expertise on disinfecting and disposing of materials; the Department of Labor, ²⁸ in

²⁴For more information on the National Animal Health Laboratory Network, see GAO, Homeland Security: Much Is Being Done to Protect Agriculture from a Terrorist Attack, but Important Challenges Remain, GAO-05-214 (Washington D.C.: Mar. 8, 2005).

²⁵According to USDA, these draft AI documents have undergone intense development and would be used as a basis for activities that the department would undertake in the event of an outbreak of highly pathogenic AI.

²⁶This plan summarizes APHIS' *National Highly Pathogenic Avian Influenza Preparedness and Response Plan*, which the agency describes as a strategic plan for rapidly detecting and responding to highly pathogenic AI. The summary and the original plan are based on APHIS' National Animal Health Emergency Management System, which provides guidance on mitigating, preparing for, responding to, and recovering from major animal health emergencies. Among other things, the system contains guidance for responding to highly contagious foreign animal diseases and uses foot-and-mouth disease as its example.

²⁷The playbook is entitled the *Interagency Playbook for Domestic Response to a Detection* of Highly Pathogenic Avian Influenza H5N1 in Birds.

²⁸Within the Department of Labor, the Occupational Safety and Health Administration assures the safety and health of America's employees.

conjunction with HHS, would provide guidance on how to protect workers, including the use of personal protective equipment; and DHS would monitor outbreak and intelligence information to determine if an outbreak was bioterrorism-related.

Exercising Response Plans

USDA has begun conducting preliminary tabletop exercises²⁹ on aspects of response plans with other federal agencies, as well as states and private industry, to gain a greater understanding of preparedness for highly pathogenic AI. For example, APHIS conducted tabletop exercises with two large poultry producing states to help identify the type and level of personal protective equipment necessary to respond to an outbreak. Industry officials were also present at these exercises, since the selected scenarios identified outbreaks in commercial operations in both states. In addition, USDA's Food Safety Inspection Service conducted five tabletop exercises with state and local public health and emergency response officials to test the operability and efficacy of its response procedures against deliberate contamination of the food supply, as well as against an AI outbreak. Moreover, the Food Safety Inspection Service and APHIS conducted a joint tabletop exercise that simulated an outbreak of highly pathogenic H5N1 in commercial poultry, backyard flocks, live bird markets, and wild bird populations. Other participants included officials from DHS and HHS; officials from four states; representatives from the National Association of County and City Health Officials, 30 the National Association of State Departments of Agriculture, 31 and the Association of State and Territorial Health Officials³²; representatives of consumer groups and industry officials; and representatives from the Canadian Food Inspection Agency.

²⁹A tabletop exercise is a group discussion guided by a scenario-based, simulated disaster.

 $^{^{30}\!\}text{The National Association of County and City Health Officials is the national organization representing local health departments.$

³¹The National Association of State Departments of Agriculture's mission is to represent the state departments of agriculture in the development, implementation, and communication of sound public policy and programs that support and promote the American agricultural industry, while protecting consumers and the environment.

³²The Association of State and Territorial Health Officials is a national nonprofit organization representing the state and territorial public health agencies of the United States, the U.S. territories, and the District of Columbia.

Moving forward, APHIS is contracting with the Center for Naval Analysis to develop and implement up to 60 additional tabletop exercises of state response plans in the coming year. Once these exercises are conducted, the agency intends to analyze the outcomes and identify areas that need further improvement.

National Veterinary Stockpile

In coordination with DHS and others, APHIS has begun creating a National Veterinary Stockpile. This stockpile is intended to be the nation's repository of animal vaccines, personal protective equipment, and other critical veterinary products to respond to the most dangerous foreign animal diseases. The National Veterinary Stockpile's goal is to acquire countermeasures against the 10 animal diseases that pose the greatest threat, including highly pathogenic AI, within 5 years, and against an additional 7 of these diseases within 10 years. 33 To accomplish this task, National Veterinary Stockpile officials have begun building an infrastructure to identify, acquire, store, maintain, manage, and deploy this critical inventory within 24 hours of a foreign animal disease outbreak, as required by the directive.³⁴ The stockpile currently owns material sufficient to produce 140 million doses³⁵ of H5 and H7 AI vaccine to protect older birds. ³⁶ According to USDA officials, the current inventory also includes 31 "push packs"—that is, ready-to-ship containers stocked with a variety of personal protective equipment and veterinary supplies, such as disinfectants; protective clothing (e.g., respirators, face masks, and protective body suits); and ancillary supplies (e.g., decontamination fluid for responders to clean their boots). Each push pack contains enough

³³The 17 critical animal diseases were selected based on the following factors: whether or not the disease-causing organism is highly contagious; the extent of its ability to rapidly spread and infect many species; the extent of its ability to cause disease in humans; and its economic impact both domestically and on trade.

³⁴Homeland Security Presidential Directive 9, at § 18.

 $^{^{35}\!\}text{This}$ exceeds the target in the Implementation Plan for the National Strategy for Pandemic Influenza.

³⁶Stockpile officials evaluated the feasibility of acquiring ready-to-use vaccine(s); costs of purchasing them; and other life-cycle costs, such as storage, expiration, replacement, and disposal. As a result, the National Veterinary Stockpile has adopted a strategy of maintaining a limited supply of vaccine on hand but has purchased guaranteed access to larger amounts. For example, the stockpile also has access to 500 million doses of vaccine to protect younger chickens 1 to 7 days old. The stockpile has guaranteed access to 25 million doses within 24 hours, with the remainder to follow, if necessary.

materials to support 10 outbreak responders for 10 days.³⁷ According to USDA officials, the National Veterinary Stockpile successfully tested its capability to deploy its critical inventory by sending push packs to West Virginia for the suspected low pathogenic AI outbreak that occurred in March of 2007.

Indemnification

USDA recently decided to provide compensation for losses incurred as a result of low pathogenic strains of H5 and H7 because of their potential to mutate to highly pathogenic AI. Indemnification is provided, in part, to encourage the early reporting of outbreaks and participation in response efforts. For many years, USDA provided compensation for losses incurred when birds were destroyed because of AI only when they were infected with or exposed to a highly pathogenic strain. Under the new indemnity regulations for H5/H7 low pathogenic AI, along commercial poultry facilities must participate in USDA's National Poultry Improvement Plan's AI surveillance program, through a cooperating state agency, in order to be eligible to receive 100 percent indemnity for destroyed birds. Large commercial facilities that do not participate in the surveillance program

³⁷This acquisition of push packs was based, in part, on available funds, rather than a calculation based on outbreak scenarios. The National Veterinary Stockpile is in the process of acquiring additional personal protective equipment (enough to support 1,500 responders changing five times per day for 40 days).

³⁸Foot-and-Mouth Disease, Pleuropneumonia, Rinderpest, and Certain Other Communicable Diseases of Livestock or Poultry, 9 C.F.R. pt. 53. Indemnification has been provided under these regulations when the affected states had entered into cooperative agreements with USDA. Although these regulations do not generally provide indemnity for low pathogenic strains, on two occasions, USDA did so by amending the regulations.

³⁹For complete low pathogenic AI indemnity rules and regulations, see Low Pathogenic Avian Influenza; Voluntary Control Program and Payment of Indemnity, 71 Fed. Reg. 56,302 (Sept. 26, 2006) (codified at 9 C.F.R. pt. 56).

⁴⁰In addition, the states in which the facilities participate must conduct passive surveillance and have an initial state response and containment plan.

⁴¹For commercial poultry, a participating flock or slaughter plant is required to participate in the active surveillance program only if they are larger than a certain size standard. For table-egg layer flocks, the standard is 75,000 birds. For meat-type chicken slaughter plants, the standard is slaughtering 200,000 meat-type chickens in an operating week, while for meat-type turkey slaughter plants, the standard is slaughtering 2 million meat-type turkeys in a 12-month period.

may receive only 25 percent indemnity. ⁴² These new regulations also explicitly allow greater flexibility than the regulations for highly pathogenic AI, which, for example, state that a USDA official must appraise the value of destroyed poultry. ⁴³ Under the new regulations, this requirement may be waived in order to expedite response to large outbreaks when USDA appraisers may be in short supply. Under these circumstances, USDA may allow USDA-authorized state appraisers, in addition to USDA appraisers, to conduct appraisals. ⁴⁴ In addition, USDA has included revised and very broad indemnity guidelines within its draft summary response plan to allow for a more flexible indemnification process during a highly pathogenic AI outbreak.

Communications

USDA's Office of Communications has developed risk communication messages about highly pathogenic AI. ⁴⁵ According to USDA officials, the goal of these messages is to provide accurate, timely, and consistent information during an outbreak; minimize public panic and fear; and instill public confidence in the government's ability to respond to an outbreak. Specifically, USDA, in partnership with HHS, the Department of the Interior, and DHS, developed three scenarios for the detection of highly pathogenic AI in the United States: (1) a highly pathogenic AI detection in the United States other than H5N1, (2) highly pathogenic H5N1 in wild birds, and (3) highly pathogenic H5N1 in commercial poultry. Each of these scenarios contains a series of key questions and answers about animal health and guidance for the public, as well as a summary of the actions

⁴²Backyard birds are eligible for 100 percent indemnification without participating in the National Poultry Improvement Plan surveillance program because, according to USDA officials, participation would be too burdensome; it is more important that there be an incentive for these owners to report sick birds.

⁴³9 C.F.R. § 53.3.

⁴⁴Officials at USDA's Office of General Counsel told us that the Secretary of Agriculture, under the authority of the Animal Health Protection Act, also retains this flexibility for indemnification procedures for highly pathogenic AI. Under the Animal Health Protection Act, the Secretary may authorize the destruction or disposal of certain animals he has reason to believe may carry, have carried, have been affected, or have been exposed to an animal disease. 7 U.S.C. § 8306(a), (b). The Secretary is further authorized to compensate the owner for any animals that he requires to be destroyed. 7 U.S.C. § 8306(d).

⁴⁵These messages were created in response to the *Implementation Plan for the National Strategy for Pandemic Influenza*, which identified their development as a critical action item.

USDA would take. USDA has placed these messages, as well as key fact sheets on its Web site for public viewing. The agency has also developed public service announcements for television and radio and, according to USDA, these messages have reached 175 markets and have been broadcast over 1,100 times.

Research

USDA is concentrating its AI research efforts on areas it considers critical to prepare for outbreaks of highly pathogenic AI. ⁴⁶ For example, the Agricultural Research Service is testing currently available poultry AI vaccines to determine if they are protective against highly pathogenic H5N1; developing new vaccines to protect against AI viruses that can be efficiently administered to large number of birds at once, such as through aerosol; enhancing diagnostic tools⁴⁷ to allow for rapid testing of wild bird samples; sequencing the genomes—a complete set of hereditary factors—of 1,000 AI viruses in order to better understand the epidemiology, or causes, of the diseases; and conducting experiments in birds to better understand how the virus causes disease and death in some domestic poultry and wild birds but not in others.

In addition, the Agricultural Research Service is collaborating with several other federal agencies on AI research. For example, it worked with USDA's Food Safety and Inspection Service to develop a test to determine the presence of highly pathogenic AI in poultry meat. It has also been working with the Environmental Protection Agency to research the ability of residual chlorine in drinking water to deactivate the highly pathogenic H5N1 virus. In addition, the Agricultural Research Service has been assisting HHS with the development of a vaccine for use during a human outbreak.

USDA's AI research efforts also focus on swine. For example, the Agricultural Research Service is supporting DHS in determining how highly pathogenic H5N1 viruses transmit to poultry and mammalian models. This is important because, although highly pathogenic H5N1 is predominantly a disease in poultry and wild birds, dogs, cats, and swine have also become

⁴⁶Many of these items are tasks identified in the *Implementation Plan for the National Strategy of Pandemic Influenza*.

⁴⁷These are reverse transcription polymerase chain reaction diagnostic tests.

infected. 48 Swine are particularly worrisome because they can become infected with not only swine influenza viruses but also human and avian influenza viruses as well. The World Health Organization cautions that pigs could play a role in the potential emergence of a pandemic virus.

Federal and State Response Plans Are Incomplete, and Several Issues Are Unresolved

Despite actions taken by USDA, incomplete plans and unresolved issues could slow outbreak response. Currently, USDA is not planning for the lead coordinating role that DHS would assume in certain outbreak emergencies. In addition, USDA's response plans do not identify the capabilities needed to carry out critical tasks for controlling highly pathogenic AI outbreaks. Furthermore, state plans are lacking key components for facilitating a rapid response. Finally, several unresolved issues could further delay response.

USDA Has Not Planned for DHS' Lead Coordination Role

USDA is not planning for DHS to assume the lead coordinating role if an outbreak among poultry occurs that warrants a presidential declaration of an emergency or major disaster, or a DHS declaration of an Incident of National Significance. USDA officials told us that DHS will not likely be needed to perform this coordinating role unless there are multiple outbreaks, an agroterrorism event is suspected, or the virus causes a human pandemic. However, USDA's draft interagency playbook includes a scenario involving multiple outbreaks without addressing this DHS coordinating role. USDA officials also cite years of experience eradicating foreign animal diseases as the reason for not needing DHS involvement. Moreover, some officials told us that many within the agency are concerned that DHS officials at the operational level of response would not limit DHS involvement to that detailed in the National Response Plan but would instead take over the veterinary response as well. Our prior work⁴⁹ has shown that roles and responsibilities at all levels of government must be clearly defined, effectively communicated, and well understood to facilitate rapid and effective decision making during an emergency. If this is

⁴⁸According to the Food and Agriculture Organization of the United Nations, all carnivores could become infected through eating infected poultry or infected wild birds.

⁴⁹GAO, Catastrophic Disasters: Enhanced Leadership, Capabilities, and Accountability Controls Will Improve the Effectiveness of the Nation's Preparedness, Response, and Recovery System, GAO-06-618 (Washington, D.C.: Sept. 6, 2006).

not the case, problems such as those that plagued response during past disasters could result.

Although USDA believes the need for DHS coordination is unlikely, the decision to involve DHS is not USDA's to make. Specifically, a presidential declaration of an emergency or major disaster is made by the President of the United States at the request of state governors via the Stafford Act, and such declarations require the Secretary of Homeland Security to assume responsibility for directing the federal response. State officials told us that their governors would consider making such a request. For example, in 2000, a presidential declaration of emergency was declared for the West Nile virus outbreak in New York state. ⁵⁰ DHS lawyers are in the process of determining the applicability of a declaration to an outbreak of highly pathogenic AI; therefore, this possibility should not be disregarded.

Moreover, the Secretary of Homeland Security has the discretion to declare an Incident of National Significance. The National Response Plan states that the Secretary of Homeland Security, in consultation with other departments and agencies, and the White House, as appropriate, may make such a declaration on the basis of criteria noted in Homeland Security Presidential Directive 5, ⁵¹ including in the event of a presidential declaration under the Stafford Act. However, the Secretary is not limited to these criteria and may consider other factors when making this decision. The determining factor is whether the incident is of such severity, magnitude, or complexity that it requires the Secretary of Homeland Security to manage the federal response. DHS officials told us that if highly pathogenic H5N1 arrived in the United States, the Secretary of Homeland Security would, in consultation with the White House and cabinet members, consider declaring an Incident of National Significance if its

⁵⁰West Nile virus is usually spread by the bite of an infected mosquito. Mosquitoes become infected when they feed on infected birds. Infected mosquitoes can then spread the virus to humans and other animals. The presidential declaration of emergency declared for West Nile virus authorized funding so that local governments could be reimbursed for the cost of fighting the disease.

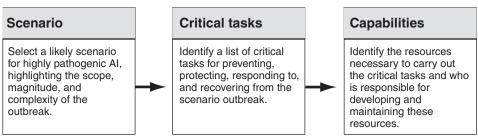
⁵¹The criteria set out in Homeland Security Presidential Directive 5 are (1) a federal department or agency acting under its own authority has requested the assistance of the Secretary of Homeland Security; (2) the resources of state and local authorities are overwhelmed and federal assistance has been requested by the appropriate state and local authorities, for example, under the Stafford Act; (3) more than one federal department or agency has become substantially involved in responding to an incident; or (4) the Secretary of Homeland Security has been directed by the President to assume responsibility for managing a domestic incident.

impact warranted one. DHS officials further noted that the economic impact to the agriculture industry would be huge if the virus spread across multiple states, making it imperative to prevent this from happening. DHS officials told us that they hope that USDA will have the ability to contain the disease if an outbreak occurs. Nevertheless, DHS officials told us that this does not obviate the need to plan for such an event. Moreover, past experience has demonstrated that, despite USDA efforts, quickly controlling a disease has not always been possible. The exotic Newcastle disease outbreak that originated in California in 2002 is a case in point: it spread to two neighboring states over the course of a year despite vigorous USDA and state efforts. ⁵²

USDA Has Not Identified Response Capabilities for Highly Pathogenic AI

DHS and state officials have expressed concern that USDA's plans for highly pathogenic AI do not identify the capabilities needed to carry out the tasks associated with an outbreak scenario—that is, the entities responsible for carrying out the tasks, the specific resources needed, and the source of those resources (as described in fig. 5). Although USDA's draft summary response plan identifies various tasks, such as mass depopulation, it does not address the capabilities needed to carry out the tasks under a particular scenario.

Figure 5: Identifying Capabilities Needed for Highly Pathogenic Al



Source: GAO.

⁵²This highly contagious and fatal poultry disease cost the states and federal government more than \$170 million to eradicate, and it cost an unknown number of bird owners their livelihoods and, in some cases, their pets.

While we recognize that identifying capabilities is complex because it involves input from all responding entities and the capabilities required will change according to the outbreak scenario, it is important to provide a benchmark for planning purposes, particularly in the face of uncertainty. Moreover, Homeland Security Presidential Directive 8 calls for a national preparedness goal that uses capabilities-based planning. According to DHS, such planning helps determine how prepared we are as a nation, how prepared we need to be, and how to prioritize efforts to effectively respond to an emergency. ⁵³

In response to this directive, USDA has, with assistance from other federal agencies and entities, begun identifying capabilities in advance for an outbreak of foot-and-mouth disease. Although some of the capabilities associated with foot-and-mouth disease could translate to responding to an outbreak of highly pathogenic AI, there are differences between addressing disease outbreaks in livestock and in poultry. In addition, unlike foot-and-mouth disease, highly pathogenic AI can infect humans, so capabilities must be identified in advance for protecting human health. USDA has also started planning for various scenarios with its draft interagency playbook. However, this playbook does not identify the capabilities for the various tasks, and it excludes key players, including state and industry officials. Moreover, USDA officials told us that the playbook was never intended to be shared with states.

According to DHS officials, once capabilities are identified, they should be incorporated into a response plan that can be used to track progress. Such a plan—known as a concept of operation plan—is central to emergency management. The plan should list the critical tasks for responding to the selected outbreak scenario and, for each task, the responsible entities and the location of resources needed. In addition, the plan should specify time frames and completion status for each critical task. DHS officials told us that a plan of this nature is essential to identify gaps in capabilities. As we reported in 2006, ⁵⁴ emergency preparedness and response should be

⁵³On December 17, 2003, the President issued Homeland Security Presidential Directive 8 to establish policies to strengthen the preparedness of the United States to prevent and respond to threatened or actual domestic terrorist attacks, major disasters, and other emergencies by requiring national domestic all-hazards preparedness "Goal." The Goal utilizes a capabilities-based planning approach.

⁵⁴GAO, Emergency Preparedness and Response: Some Issues and Challenges Associated with Major Emergency Incidents, GAO-06-467T (Washington D.C.: Feb. 23, 2006).

characterized by measurable goals and effective efforts to identify key gaps between those goals and current capabilities, with a clear plan for closing those gaps. However, a plan alone is not sufficient to ensure effective response. Conducting exercises is critical for developing skills and identifying what works well and what needs further improvement.

Incomplete State Plans Could Slow Response

USDA officials told us, and our own review corroborated, that some state plans for addressing outbreaks of highly pathogenic AI are lacking important components that could facilitate rapid containment of the virus (see table 2). Our review of 19 state plans⁵⁵ found that 5 plans at least partially addressed all of the AI planning components that we identified as important in managing an AI outbreak. However, 14 plans did not address one or more critical planning components. The states reviewed account for 51 percent of total U.S. poultry production and 7 of the top 10 poultry producing states.⁵⁶

Table 2: Gaps Identified in State Plans

7 of 19
7 01 19
4 of 19
4 of 19
2 of 19
3 of 19
1 of 19
4 of 19
5 of 19

Source: GAO.

⁵⁵USDA officials responsible for helping states develop response plans provided us with 19 plans, which the states made available to them during the course of our review.

⁵⁶These numbers are based on USDA's 2002 Census of Agriculture.

The following discussion details some of the gaps we identified:

- Incident Command System. The Incident Command System is critical to ensure that responses to any type of incident are effectively managed, yet 7 of the 19 state plans we reviewed—including 3 of the top 10 poultry producing states—had no discussions about incident command or its importance in AI response. Moreover, all levels of government are required to adopt the Incident Command System into their response plans.
- *Time frames*. To help contain an outbreak, USDA recommends several critical actions for the affected state in the early stages of response, such as initiating laboratory confirmation procedures and issuing quarantine notices; however, 4 of the 19 plans had no discussions about initial critical actions. Incident Command System training documents⁵⁷ and USDA's highly pathogenic AI response plan,⁵⁸ respectively, recommend establishing immediate response priorities and creating a detailed plan for the first 24 hours of response to an incident.
- Depopulation. Four of the 19 plans did not address depopulation. Depopulating birds is the fundamental strategy USDA and states employ for controlling outbreaks, as identified in USDA's highly pathogenic AI response plan.
- *Disposal*. Two of the 19 plans did not address the disposal of AI infected poultry and materials. USDA's highly pathogenic AI response plan states that effective disposal is a key component of highly pathogenic AI response and includes issues such as disposal options and the biosecure transportation of infected materials.
- Response among backyard birds. Three of the 19 plans did not include a
 discussion about response activities for backyard birds. USDA officials
 told us that the development of some state plans was heavily influenced
 by the poultry industry, which may be the reason this response
 component was omitted. This is troublesome because an outbreak must

⁵⁷⁴Incident Command System Review Materials" from the Federal Emergency Management Agency's ICS Resource Center Contents Web site, http://training.fema.gov/EMIWeb/IS/ICSResource/index.htm.

⁵⁸The response plan we refer to is APHIS' National Highly Pathogenic Avian Influenza Response Plan.

be contained among backyard birds, as well as in commercial operations. In addition, a recent USDA survey estimates that about 40 percent of backyard birds are located within 1 mile of at least four commercial poultry facilities. ⁵⁹ This close proximity could allow the virus, if not quickly contained, to spread from backyard birds to commercial operations—as has occurred in previous poultry disease outbreaks.

- *Biosecurity*. We found that one state plan had no discussion about biosecurity. USDA recommends implementing biosecurity measures to keep flocks free from disease during an outbreak. ⁶⁰ In addition, our site visits to commercial and backyard facilities found varying levels of biosecurity—from very stringent to very lax. Further, a recent USDA survey found that backyard bird owners do not always implement basic biosecurity measures. For example, 89 percent do not require visitors to wash their hands before handling birds, and only 40 percent require hand washing after handling birds.
- Public communications. Four of 19 state plans did not address public communications. Federal and state officials told us that clear public communications are essential during an outbreak to manage the media, avoid public confusion, and disseminate a clear public health message. In addition, the required Incident Command System calls for a Joint Information Center and a Public Information Officer (who is responsible for media outreach) to ensure clear and accurate public information, none of which were mentioned in these four plans.
- Public health. Five of the 19 plans did not address the role of local, state, or federal public health authorities during an outbreak. USDA's draft summary plan recommends that public health authorities initiate appropriate health measures (e.g., identify those potentially exposed and in need of antiviral medication) and help ensure accurate public communications.

USDA and state officials told us there are several reasons why planning at the state level is not more complete. First, although USDA officials review

⁵⁰Poultry '04 Part I: Reference of Health and Management of Backyard/Small Production Flocks in the United States, 2004; USDA, August 2005.

⁶⁰For specifics, see USDA's National Animal Health Emergency Management System.

state response plans, the agency does not have the authority to do more than offer comments and recommendations. It is up to the state to make any changes that USDA recommends. Second, USDA and state officials told us that there are no established federal criteria for what a state response plan for highly pathogenic AI should include, which has made developing and assessing the plans more difficult. In the absence of such criteria, USDA and state officials we interviewed told us they are relying on experience from past outbreaks or applying criteria from other programs. Third, state officials said that state emergency planning resources are limited. Despite recognizing the need for such planning, officials said they do not have the resources and staff to devote to such a planning effort. Similarly, these same officials told us that because APHIS officials who assist in planning cover several states simultaneously, their resources are also spread too thin to meet each state's AI planning needs. State officials told us that because of these resource limitations and other considerations, some states have formed cooperatives in order to pool limited planning resources and work together regionally to integrate AI and other foreign animal disease emergency planning.

Unresolved Issues Could Delay Response

We have identified several unresolved issues that, if not addressed, could hinder response efforts. Moreover, some could pose a particular challenge for states that have never encountered an outbreak. These unresolved issues are as follows:

• The location and number of backyard birds. According to USDA, state, and industry officials from all five states that we visited, containing an outbreak among backyard birds remains a challenge because their numbers and location are still unknown. For example, a 2002 outbreak of exotic Newcastle disease in California took almost a year to contain because the disease spread as responders spent valuable time trying to locate potentially infected birds in urban areas. State and USDA officials told us they were surprised by and unprepared for the large number of backyard birds that existed in such areas. This difficulty was exacerbated by the heavy automobile traffic, slowing responders' ability to reach each potential bird owner's home. Further complicating matters, many of these birds were expensive game fowl bred for illegal cockfighting and, as a result, owners sometimes moved the birds into hiding to avoid authorities and prevent the birds from being depopulated. This contributed to the spread of the disease.

Biosecurity Measures at Live Bird Markets



Source: GAO

To prevent a possible outbreak of highly pathogenic AI, USDA recommends that poultry producers and dealers use biosecurity precautions at live bird markets. Live bird markets operate in many major cities. AI can be introduced into these markets if they receive infected birds or contaminated crates and trucks. Once the virus is established in the market, the movement of birds, crates, or trucks from a contaminated market can spread the virus to other farms and markets. Therefore, USDA recommends the following protective measures should be taken at live bird markets to prevent the possible spread of disease:

- Use plastic instead of wooden crates for easier cleaning.
- Keep scales and floors clean of manure, feathers, and other debris.
- Clean and disinfect all equipment, crates, and vehicles before returning them to the farm.
- Keep incoming poultry separate from unsold birds, especially if birds are from different lots.
- Clean and disinfect the marketplace after every day of sale.
- Do not return unsold birds to the farm.



Source: GAO

While the numbers and locations of backyard birds within the state may never be definitively known, state officials told us there are steps that can be taken to help mitigate this problem. California formed a group of state and USDA officials whose goal is to minimize the risk of disease spread through local outreach and education. In addition, the group performs regular testing and voluntary surveillance of backyard premises, live bird markets, feed stores, pet stores, auction yards, and swap meets.

Other states that have experienced outbreaks are similarly concerned because when an outbreak occurs, typical response involves conducting an epidemiological investigation—a careful tracking of all animals, people, and equipment that are within a certain distance of the infected premises. Because it is not known where backyard bird owners are located, epidemiological teams must go door-to-door to survey surrounding residences. To help overcome this tracking problem, Delaware and Maryland—both with dense commercial poultry operations—have introduced mandatory registration for all poultry owners, including those with backyard flocks. Further, some state officials, such as those in Texas, are working with USDA to do extensive outreach to game fowl owners. A recent USDA survey shows that game fowl represent the third largest population of birds raised in backyard environments. Texas officials told us that game fowl are particularly prevalent in the state because of its proximity to Mexico. Louisiana, and New Mexico. Cockfighting is legal in Louisiana and had been legal in New Mexico until March of 2007. Consequently, state officials are trying to locate these bird owners to brief them about the importance of reporting birds that die or appear diseased with highly pathogenic AI. Officials have also briefed these owners on the risks highly pathogenic AI poses to game fowl handlers.⁶¹

• *Diagnostic laboratory response*. Officials from all five states we visited cautioned that diagnostic laboratory capacity could be quickly overwhelmed during an outbreak. In particular, the large number of samples that would need to be tested and the limited number of laboratory personnel available remain problematic. These tests are

⁶¹State officials familiar with cockfighting told us that handlers resuscitate down birds in the middle of a fight by using their mouth to clear congestion in the beak. According to the Occupational Safety and Health Administration, exposure of the conjunctival membranes of the eyes and/or nasal mucosa to secretions from AI infected birds is the predominant route of transmission of these viruses to humans.

necessary to identify the extent of the disease spread, as well as to track the success of eradication efforts and prove to trading partners that poultry products are safe for export. Laboratory officials told us that within days of an outbreak—sometimes even hours—their diagnostic laboratories were running at capacity, with exhausted employees working overtime, usually for several months, to meet the testing needs during the outbreak. To accommodate the increased volume of samples, laboratory officials in two states told us they relied on support from USDA's National Veterinary Services Laboratories or neighboring laboratories. However, these same laboratory officials told us that while USDA was very generous with its support, they are concerned that the agency may not be able to provide such support in the event of multiple outbreaks. Officials in another state overcame this problem by accepting volunteers from various agencies to run samples but noted that, because these volunteers were unskilled in laboratory procedures. valuable time was lost in training them.

Another problem encountered during past outbreaks was transporting samples to the laboratory in a timely manner, especially in large states. For example, in one state, the laboratory running the diagnostic AI tests was located 3 hours from the site of the outbreak. Laboratory officials told us it was resource-intensive for personnel to drive 3 hours each way to collect samples. Moreover, because samples were collected and delivered to the laboratory at the end of the day, a bottleneck developed, requiring laboratory technicians to work overtime to complete tests. The laboratory has since put in place a "pony express" system, in which samples will be delivered to and collected from a dropoff point midway between the infected premises and the laboratory. Laboratory officials in California that dealt with these challenges throughout the yearlong exotic Newcastle disease outbreak advocate developing an advance emergency response plan specifically for diagnostic laboratory operations that covers, for example, rotating work schedules for laboratory workers, protocols for receiving samples, and an Incident Command System specific to a laboratory setting to facilitate emergency response.

• *Depopulation*. Mass depopulation of infected birds is a continuing challenge because of the number of workers needed to depopulate a commercial poultry house, the time required to do so, and the risk to human health as a result of workers' direct exposure to the virus. State and industry officials estimate that it takes 20 to 30 workers to depopulate a single commercial broiler house using a common method

of mass depopulation, carbon dioxide gas. Because of the large number of birds involved—tens of thousands in a commercial broiler house—this process can take several hours. This method, therefore, puts workers' health at risk by exposing them for prolonged periods of time to potentially high concentrations of the virus within a confined space.

Recently, USDA conditionally approved the use of a new water-based foam method for mass depopulation that requires only two or three workers to administer, thereby minimizing the number of workers exposed to the virus. Despite the availability of this new method, there are still two issues of concern related to its use. First, USDA's approval of this method is conditional. For example, it cannot be used to depopulate many types of poultry, such as ducks, geese, and quail, because the necessary testing to prove that the birds are not suffering during the depopulation process has yet to be conducted. USDA officials told us that they have begun working with the University of Delaware and the North Carolina Department of Agriculture and Consumer Services to investigate the effects of using foam to depopulate these populations. Second, this method cannot be applied in all environments, such as in houses where birds are raised in cages, which is the most challenging commercial environment to depopulate. USDA, state, and industry officials told us that depopulating layers raised in cages is a particularly time-consuming process because a commercial layer house can contain hundreds of thousands of birds, and each bird must be removed from its cage before it can be killed.

• *Disposal*. State officials told us that disposal remains a problem for three reasons. First, although there are several disposal options—such as burial on-site or in a landfill, and incineration (see fig. 6)—the feasibility of each option is largely dependent on environmental conditions within that state. For example, officials in one state told us that while burial is allowed under state law, the existence of shallow bedrock in some parts of the state renders that option physically impossible.

Figure 6: Methods of Poultry Disposal

Composting



Landfill



Incineration



Source: Virginia Department of Environmental Quality.

Second, disposal requires coordination among various state agencies, including animal health, environment, and transportation to identify acceptable locations and methods. For example, during one state outbreak, response stood still for several weeks while the state animal health agency negotiated with the state environmental quality agency on permissible disposal sites. Animal health officials in the state told us that they had customarily used on-site burial for disposal, but that during the outbreak, the environmental agency prohibited that option because residents worried about water contamination. For nearly a month, the animal health agency worked to identify major municipal landfills that would accept the birds and establish protocols for transporting the carcasses there. During this time, they could not dispose of any birds, and 40 more flocks became infected, overwhelming state and industry resources.

Third, given the heightened public awareness and concerns about highly pathogenic H5N1, disposal options may be limited. Officials in one state told us that landfill owners who once accepted AI-infected poultry and material are now refusing to accept poultry carcasses infected with either low pathogenic or highly pathogenic AI because of public fears about the human health risks. ⁶² Officials in another state are beginning to experience the same problem. State and USDA officials told us that on-site composting is a preferred method because it kills the virus

 $^{^{\}overline{62}}$ State officials told us that the general public does not understand the difference between low and highly pathogenic AI.

without moving the infected material off the infected premises. But this option is not always available because, for example, some poultry houses are too small to accommodate the equipment needed to compost. State and industry officials also told us that ensuring the infected materials are completely composted requires careful attention and maintenance. Failure to dispose of infected carcasses in a timely manner increases the risk of disease spread and allows the virus to remain in the environment.

Movement of birds through the mail. DHS and some state officials remain concerned that birds shipped through the mail or on commercial airlines do not all have health certificates to ensure they are free from disease. As a result, birds infected with highly pathogenic AI could be delivered to unsuspecting owners, causing the disease to spread long distances to once healthy flocks. For example, poultry are often moved through the U.S. Postal Service for distribution and breeding purposes. Most states require that birds brought into the state be health-certified via USDA's National Poultry Improvement Plan⁶³ or accompanied by a veterinary health certificate issued in the state of origin. However, concerned state officials told us that the U.S. Postal Service does not always check for the state-required documentation, and they are concerned that many birds are entering states undocumented, illegally, and potentially diseased. In 2003, agriculture officials in North Carolina tracked shipments of birds at three postal facilities for 9 days. Of the 5,113 birds entering the state via the U.S. Postal Service, 72 percent, or 3,127 birds did not have the necessary health documentation certifying they were free from disease. In addition, birds without health certification were collocated in the same room as birds with health clearances, possibly spreading disease from infected to certified healthy birds.

DHS and state officials told us that this problem could affect commercial airlines as well. Birds are transported on commercial aircraft, but, according to state officials, airlines do not consistently check for health certification. In light of this concern, state officials in North Carolina interviewed airline representatives and found that airline policies for accepting birds varied widely. While some airlines required health documentation, others did not. These officials told us

⁶³States generally require USDA's National Poultry Improvement Plan certification for salmonella, pullorum, and typhoid.

they do not know the extent of this problem because they were restricted from entering airline cargo holding areas.

Personal protective equipment. State and industry officials who have used personal protective equipment in past outbreaks caution that, although necessary, equipment to protect workers remains problematic and, under various conditions, could encumber and delay response. In 2006, the Department of Labor's Occupational Safety and Health Administration released updated guidance for protecting poultry workers in the event of a suspected or confirmed AI outbreak at a poultry facility. ⁶⁴ Specifically, it recommends that animal health responders wear protective clothing, such as an impermeable apron or surgical gown with long, cuffed sleeves; disposable protective shoe covers or rubber or polyurethane boots that can be cleaned and disinfected; safety goggles to protect the mucous membranes of the eyes; and, at a minimum, disposable, particulate respirators (e.g., N95). Responders who cannot wear a disposable, particulate respirator, because of facial hair or other limitations, should wear a loose-fitting (i.e., helmeted or hooded) powered air purifying respirator equipped with high-efficiency filters.

State officials told us that in poultry houses that have been sealed to prevent the virus from spreading, temperatures can become extreme in hot weather, slowing down responders wearing this type of equipment. In addition, state officials told us goggles can become fogged, making it impossible to see. Moreover, the minimum required disposable particulate respirator is difficult to breathe through, yet it is commonly used because of its low cost. For these reasons, workers have, at times, removed the protective equipment while carrying out their duties. Furthermore, officials told us it is difficult and dangerous for

⁶⁴The guidance takes into consideration HHS' Centers for Disease Control and Prevention Interim Guidance for Protection of Persons Involved in U.S. Avian Influenza Outbreak Disease Control and Eradication Activities. The recommendations are based on precautions that are considered best practices for protecting individuals involved in the response to an AI outbreak.

⁶⁵The disposable particulate respirator costs about \$1 each, depending on the model.

⁶⁶According to updated guidance from the Occupational Safety and Health Administration for protecting employees from AI viruses, in the event of an outbreak, a safety and medical adviser should be identified to ensure compliance with procedures. However, according to USDA officials, these advisers need not be at the site of the outbreak.

responders to attempt to climb ladders to reach birds in cages several stories high wearing heavy boots, thick gloves, and hooded respirators.

Finally, federal, state, and industry officials told us that respirators pose other challenges. Specifically, the Occupational Safety and Health Administration's standards require that respirators be used in the context of a complete respiratory protection program. This program involves, among other things, selecting an appropriate respirator, conducting medical evaluations to determine an employee's ability to use a respirator, providing training, and checking to ensure that respirators fit properly. To be effective, tight-fitting respirators must have a proper sealing surface on the wearer's face. USDA officials told us that, although they are diligently working to medically evaluate and fit responders with respirators at this time, it is expected that some of this will still need to occur at the time of an outbreak, slowing down the response process. Another concern involves the use of powered air purifying respirators. Some state officials told us they are expensive and impractical.⁶⁷ It takes many hours to depopulate a house, but the batteries to operate this kind of respirator last only for specified periods of time, potentially delaying response. ⁶⁸ These respirators are also heavy. One state official told us that, as an alternative, the state department of agriculture is planning to use a full-face respirator for a variety of reasons. A full-face respirator is lighter and less expensive⁶⁹ than a powered respirator and, because it does not require batteries, there is no time limit for use. Also, it has an advantage over goggles because it is less prone to fogging. According to Occupational Safety and Health Administration guidelines, all respirators have pros and cons.

Antiviral medication. USDA has not estimated the amount of antiviral
medication that it would need in the event of an outbreak of highly
pathogenic AI or resolved how to provide such supplies within the first
24 hours of an outbreak. According to Occupational Safety and Health
Administration guidelines, poultry workers responding to an outbreak

⁶⁷Powered air purifying respirators cost about \$1,500 each, but price can vary depending on model and type of batteries used.

⁶⁸The length of time depends on the battery.

 $^{^{69}\}mathrm{A}$ full-face respirator costs about \$130 each, but the price can vary depending on the model.

of highly pathogenic AI should take antiviral medication daily while working at the site of an outbreak and each day for 7 days after leaving the site. Further, the National Veterinary Stockpile is required to contain sufficient amount of antiviral medication to respond to the most damaging animal diseases that affect human health and the economy, and it must be capable of deployment within 24 hours of an outbreak.⁷⁰

Despite these requirements, stockpile officials have not estimated how much antiviral medication would be needed during a particular outbreak scenario. In addition, the National Veterinary Stockpile has not yet obtained any antiviral medication for highly pathogenic AI. Stockpile officials cite several reasons for this. First, since the National Veterinary Stockpile is responsible for many animal diseases, not just highly pathogenic AI, it faces competing priorities. According to these officials, the first priority is to build the infrastructure to acquire, maintain, and deliver veterinary supplies for critical animal diseases, including highly pathogenic AI. Second, although this infrastructure could be used to deliver antiviral medication for highly pathogenic AI, stockpile officials told us that, to prevent duplication of efforts and limit costs, 71 the best strategy would be to gain access to HHS' Strategic National Stockpile of 16 million doses of the same antiviral. 72 Presidential Directive 9 emphasizes that the National Veterinary Stockpile should leverage, where appropriate, the mechanisms and infrastructure that have been developed for the management, storage, and distribution of the Strategic National Stockpile. However, HHS officials told National Veterinary Stockpile officials that the antiviral medication in the Strategic National Stockpile is reserved for use during a human pandemic and is not to be used to protect responders to an outbreak of AI among poultry. Third, as an alternative, National Veterinary Stockpile officials told us they are in the process of contracting with a manufacturer of antiviral medication to provide, within 24 hours of an

⁷⁰Homeland Security Presidential Directive 9 § 18(a).

 $^{^{71}\}mbox{According}$ to DHS and National Veterinary Stockpile officials we interviewed, the stockpile is underfunded.

 $^{^{72}}$ The Strategic National Stockpile's goal is to have 26 million doses of antiviral medication on hand by the end of 2006 and a total of 50 million by the end of 2008.

outbreak, antiviral medication for 3,000 responders for 6 weeks.⁷³ However, according to stockpile officials, this contract is not yet in place.

Although the National Veterinary Stockpile does not yet have antiviral medication on hand, another unit within APHIS—the Safety, Health, and Employee Wellness Branch—currently has 34,800 doses and has been working to secure more. In fact, the branch recently entered into an agreement with HHS' Federal Occupational Health agency to, among other things, provide medical professionals at the site of an outbreak who would supply and distribute antiviral medication to responders, as well as monitor their health.⁷⁴ However, the agreement does not specify how many doses will be provided or when they will be delivered. According to branch officials, delivery can be guaranteed only if APHIS purchases a set amount of antiviral medication in advance of an outbreak. Given the current situation, Federal Occupational Health will supply whatever amount of antiviral medication it has in stock at the time of an outbreak, which may or may not be sufficient, and then pursue additional doses. In the meantime, according to branch officials, the branch will provide responders the 34,800 doses it currently has on hand. However, this supply is set to expire at the end of 2007, and the branch has no funds to replace it. Branch officials told us they are working to extend the shelf life of the antiviral medication, but this process can take up to 6 months.⁷⁵

Conclusions

The rapid spread of highly pathogenic H5N1 has heightened worldwide awareness of the potential damage AI can inflict on the poultry industry and the serious implications it has for human health. Considerable effort is being made by USDA and other federal agencies, the states, and the poultry industry to ensure a swift and effective response to highly pathogenic AI.

⁷³National Veterinary Stockpile officials told us that this number reflects, in part, the total number of individuals involved during the height of the exotic Newcastle disease outbreak in California in 2002. It does not reflect a calculated estimate of those exposed to the virus and in need of antiviral medication.

⁷⁴Branch officials told us they selected Federal Occupational Health for this purpose because it has frequently worked with DHS' Federal Emergency Management Agency to ensure worker protection during emergencies.

 $^{^{75}}$ Branch officials told us that the process they are using is similar to HHS' process called the Shelf Life Extension Program.

While much has been accomplished already, opportunities remain to identify and close gaps and to address shortcomings in the preparations that have been made thus far.

First, unless USDA and DHS work diligently together to ensure roles and responsibilities are clearly defined, effectively communicated, and well understood in advance of a significant outbreak, delay could occur at the federal level as the two agencies attempt to work out their relationship during a time of crisis. Second, unless USDA identifies capabilities for a defined outbreak scenario, creates a response plan based on this information with the appropriate performance measures, and then tests this plan, USDA and its response partners will not be well-informed on their level of readiness. Third, until USDA develops a standard set of criteria that state response plans should contain, state-level plans will continue to have shortcomings that could impede efforts to contain future outbreaks. Fourth, unless USDA provides additional assistance to states to address unresolved issues, USDA and the states will face real-time challenges as an outbreak unfolds; a potentially devastating scenario. Similarly, until USDA resolves uncertainties regarding antiviral medication, the health risks associated with highly pathogenic AI may prevent or delay responders from carrying out their duties within a critical and limited window of opportunity.

Recommendations for Executive Action

To address challenges that limit the nation's ability to quickly and effectively respond to highly pathogenic AI, we recommend that the Secretaries of Agriculture and Homeland Security develop a memorandum of understanding that describes how USDA and DHS will work together in the event of a declared presidential emergency or major disaster, or an Incident of National Significance, and test the effectiveness of this coordination during exercises.

In addition, we recommend that the Secretary of Agriculture take the following seven actions:

• In consultation with other federal agencies, states, and the poultry industry, (1) identify the capabilities necessary to respond to a probable scenario(s) for an outbreak of highly pathogenic AI; (2) use this information to develop a response plan that identifies the critical tasks for responding to the selected outbreak scenario and, for each task, identifies the responsible entities, the location of resources needed,

time frames, and completion status; and (3) test these capabilities in ongoing exercises to identify gaps and ways to overcome those gaps.

- Develop standard criteria for the components of state response plans for highly pathogenic AI, enabling states to develop more complete plans and enabling USDA officials to more effectively review them.
- Focus additional work with states on how to overcome potential problems associated with unresolved issues, such as the difficulty in locating backyard birds and disposing of carcasses and materials.
- Determine (1) the amount of antiviral medication that USDA would need in order to protect animal health responders, given various highly pathogenic AI scenarios, and (2) how to obtain and provide supplies within 24 hours of an outbreak.

Agency Comments and Our Evaluation

We provided a draft of this report to USDA and DHS for their review and comment. Also, both departments provided technical comments that we incorporated as appropriate.

USDA agreed with all but one of our recommendations. USDA stated that it does not believe a memorandum of understanding is the best vehicle for clarifying and defining the roles of DHS and USDA in the event of a declared presidential emergency or major disaster, or an Incident of National Significance. Nevertheless, USDA accepted the need to clarify roles during such an event and further supported the need to test this coordination in formal exercises. USDA also stated that it will work with DHS, states, and other agencies to identify the best interagency mechanism to accomplish this planning. GAO believes that written clarification is important and that a memorandum of understanding is an appropriate mechanism to accomplish this goal. In fact, the National Response Plan anticipates the use of such documents to further clarify agency roles.

USDA also stated that the report is a comprehensive look at USDA's efforts to prepare for highly pathogenic AI. However, the department noted that the report does not highlight several critical components of successful foreign animal disease planning, such as USDA's robust veterinary infrastructure and the National Animal Health Laboratory Network. GAO recognizes that USDA has important preparations in place to respond to foreign animal diseases in general that are also relevant for AI. However, it is not possible to include all planning measures. Our report focuses on

USDA preparations for highly pathogenic AI specifically. USDA's written comments and our evaluation appear in appendix II.

DHS agreed that further coordination between USDA and DHS is needed in the event of a declared presidential emergency or major disaster, or an Incident of National Significance. In addition, the department supported the need to test the effectiveness of this coordination through exercises. DHS also suggested that coordination could occur through an interagency concept of operation plan. DHS' written comments appear in appendix III.

As we agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 15 days from the date of this report. At that time, we will send copies of this report to the appropriate congressional committees, the Secretaries of Agriculture and Homeland Security, and other interested parties. We will also make copies available upon request. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staff has any comments or questions about this report, please contact me at (202) 512-3841 or bertonid@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.

Daniel Bertoni

Director, Natural Resources and Environment

James Butrie

List of Committees

The Honorable Tom Harkin Chairman The Honorable Saxby Chambliss Ranking Member Committee on Agriculture, Nutrition and Forestry United States Senate

The Honorable Joseph Lieberman Chairman The Honorable Susan M. Collins Ranking Member Committee on Homeland Security and Government Affairs United States Senate

The Honorable Edward M. Kennedy Chairman Committee on Health, Education, Labor, and Pensions United States Senate

The Honorable Arlen Specter
Ranking Member
Subcommittee on Labor, Health and Human Services,
Education, and Related Agencies
Committee on Appropriations
United States Senate

The Honorable Daniel K. Akaka
Chairman
Subcommittee on Oversight of Government Management,
the Federal Workforce, and the District of Columbia
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Richard Burr Ranking Member Subcommittee on Retirement and Aging Committee on Health, Education, Labor and Pensions United States Senate

Scope and Methodology

To describe the steps that the Department of Agriculture (USDA) has taken to prepare for outbreaks of highly pathogenic avian influenza (AI) in domestic poultry, we reviewed statutes, regulations, directives, and national planning documents that broadly define USDA's role in an animal health or other national emergency. Specifically, we reviewed the Animal Health Protection Act; the Stafford Act; regulations for indemnification applicable to highly pathogenic AI, Part 53 of Title 9 of the Code of Federal Regulations, and those for low pathogenic AI, Part 56 of Title 9 of the Code of Federal Regulations; Homeland Security Presidential Directives 5, 8, and 9, which respectively address management of domestic incidents, national preparedness, and the defense of agriculture and food; the National Response Plan with revisions issued in May 2006; and recently developed presidential documents, including the National Strategy for Pandemic Influenza and the Implementation Plan for the National Strategy for Pandemic Influenza. We also reviewed USDA's National Poultry Improvement Plan, documents in the National Animal Health Emergency Management System, as well as those being drafted for highly pathogenic AI specifically. Furthermore, we interviewed USDA officials from the Animal Plant Health Inspection Service (APHIS), the Agricultural Research Service, the Food Safety and Inspection Service, as well as officials from the offices of the Executive Secretariat, Communications, Budget and Program Analysis, and General Counsel. We also interviewed Department of Homeland Security (DHS) officials from the Office of the Chief Medical Officer, the Federal Emergency Management Agency, and the Preparedness Directorate. Moreover, we interviewed officials from the National Association of State Departments of Agriculture, the American Veterinary Medical Association, the National Turkey Foundation, the National Chicken Council, the U.S. Poultry and Egg Association, and the Food and Water Watch. We also attended a Highly Pathogenic Avian Influenza Workshop that was jointly sponsored by the U.S. Poultry and Egg Association and USDA, with attendees from academia, the poultry industry, state governments, and the federal government. Finally, we attended a 3day AI tabletop exercise involving representatives from USDA, industry, and the state of Georgia.

To identify any challenges that could affect USDA's ability to protect domestic poultry from highly pathogenic AI, in addition to the activities described above for objective one, we conducted structured interviews in person and via telephone with officials from five states that have experienced and responded to an outbreak of AI or a comparable highly infectious avian disease in the past 5 years. These states also represent varying poultry demographics. Specifically, we interviewed state animal

Appendix I Scope and Methodology

health and APHIS officials; poultry industry representatives; and animal health diagnostic laboratory personnel in California, Delaware, Maryland, Texas, and Virginia. We also visited several commercial and one backyard poultry operation, as well as live bird markets that kept animals indoors in cages, as well as those markets with animals housed in outdoor pens. We also interviewed avian health specialists whom we selected for their technical expertise on avian health and emergency avian disease response. In particular, we sought to obtain their comments on the virology and epidemiology of highly pathogenic AI, including H5N1, as well as current research in mass poultry depopulation and disposal methods.

To better understand challenges associated with planning at the state level, we interviewed the officials noted above as well as, at the recommendation of DHS, officials from the North Carolina Department of Agriculture and Consumer Services and officials representing 21 states from the Multi-State Partnership for Security in Agriculture and the Southern Agriculture and Animal Disaster Response Alliance. We also conducted structured interviews with APHIS' Regional Directors and Area Emergency Coordinators who are responsible for working directly with the states. Among other things, we asked the Area Emergency Coordinators, who are specifically charged with helping states develop AI response plans, to identify strengths and weaknesses in their state plans and to characterize their state's level of readiness for an outbreak. We also performed our own review and assessment of 19 state plans to corroborate identified strengths and weaknesses from the interviews. Although we requested that USDA's coordinators provide us with AI plans from the 44 states with which they work, they provided us with the 19 plans they had available.

Finally, within GAO, we coordinated our review with GAO teams examining the role of federal agencies involved in pandemic influenza preparedness, including DHS, the Department of Health and Human Services, the Department of State, and the Department of Defense.

We conducted our review from May 2006 to June 2007 in accordance with generally accepted government auditing standards.

 $^{{}^{\}bar{1}}\!\mathrm{At}$ the time of our review, there were 16 Area Emergency Coordinators representing 44 states.

Comments from the Department of Agriculture

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



United States Department of Agriculture

Office of the Secretary



MAY 2 1 2007

Mr. Daniel Bertoni Director Natural Resources and Environment United States Government Accountability Office 441 G Street, NW Washington, DC 20548

Dear Mr. Bertoni:

The Department of Agriculture (USDA) has reviewed the U.S. Government Accountability Office's (GAO) draft report, "AVIAN INFLUENZA: USDA Has Taken Important Steps to Prepare for Outbreaks, but Better Planning Could Improve Response" (07-652). We are appreciative that the GAO found that USDA has taken many important and vital steps to prepare for the possibility of a highly pathogenic avian influenza (HPAI) outbreak. USDA has devoted significant resources to this effort and has taken the lead on many important initiatives. The report is a comprehensive look at our HPAI efforts, but it does not take into account several aspects that we believe are critical components of successful foreign animal disease planning efforts that are the result of our extensive experience with animal disease eradication over the course of many decades.

USDA has a robust veterinary infrastructure and key relationships with its emergency management response partners in place to deal with many types and kinds of animal health events, including foreign animal diseases such as HPAI. USDA recognizes the importance of the combined resources of State, local, and tribal entities, along with support from Department of Homeland Security (DHS) and other Federal agencies, to help us respond effectively to disease outbreaks. This ongoing collaboration and partnership between USDA and its State veterinary counterparts will be the foundation for disease response. Further, USDA is the lead or co-lead on 57 of the action items and a support agency on another 41 action items listed in the National Strategy for Pandemic Influenza (NSPI) Implementation Plan, giving USDA responsibility in nearly 100 action items.

USDA believes the GAO did not emphasize one of the most important aspects of avian influenza (AI) surveillance—the veterinary infrastructure that is the foundation of USDA's foreign animal disease monitoring. Appropriate procedures are embedded in USDA policies and requirements to protect the industry and minimize losses due to international and interstate restrictions. The first precaution concerns USDA "front line" defense. When a veterinary foreign animal disease diagnostician is deployed to investigate a possible situation, that diagnostician has authority from

An Equal Opportunity Employer

See comment 1.

See comment 2.

Mr. Daniel Bertoni Page 2

the State to act immediately upon his or her findings. The surveillance also provides an indication whether the import restrictions that safeguard U.S. agriculture and natural resources are effective in preventing the disease from entering the United States.

USDA accepts the need identified in the Recommendation for Executive Action to develop additional clarity and definition around the coordination roles of DHS and USDA in the event of a declared presidential emergency or major disaster, or an incident of national significance. USDA supports the idea of testing this coordination by using planned, formal exercises and by engaging interagency participation during smaller incidents. However, the Department believes a memorandum of understanding (MOU) is not the best vehicle to accomplish this task. USDA will work with DHS, States, and other agencies to identify the best interagency mechanism to accomplish this within the context of the National Response Plan (NRP).

In addition, USDA and DHS continue to come together to articulate how the two organizations will work together in the event of a foreign animal disease through the Foreign Animal Disease Threat Subcommittee and General Coordinating Council and its associated Sector Specific Council. USDA and DHS are in agreement on the core principles of the National Incident Management System and the Incident Command System. All emergencies are dealt with as local incidents, and Federal support is brought in when State and local resources are not adequate to address the emergency.

USDA concurs with the additional Recommendations for the Secretary of Agriculture, but believes the GAO Report failed to properly recognize important planning and preparation for AI. In 2002, the USDA Homeland Security Office established the National Animal Health Laboratory Network (NAHLN) as part of a national strategy to coordinate and link the testing capacities of the Federal veterinary diagnostic laboratories with the extensive infrastructure of State and university capabilities. The USDA's National Veterinary Services Laboratories serve as a national reference laboratory and provide training and proficiency tests to 51 approved NAHLN laboratories who partner to conduct enhanced AI surveillance efforts.

Funds have been used to double the testing capacity of NAHLN laboratories by distributing high-throughput equipment to 31 NAHLN laboratories located in the highest risk States. A NAHLN Activation Plan is currently being finalized. This Activation Plan sets the stage to move NAHLN to a state of readiness by outlining commitments to perform diagnostic tests up to the capacity of the laboratory as required by Federal and State officials to provide diagnostic services during a disease event. This is but one example of USDA's efforts to define a common operating picture and to define response capabilities.

The GAO characterizes USDA's response efforts as being in the draft stage, particularly regarding the Summary of the National Highly Pathogenic Avian Influenza Response Plan and the Interagency Playbook for Domestic Response to a Detection of Highly Pathogenic Avian Influenza H5N1 in Birds (also known as the Interagency Playbook). Each of these documents has undergone intense development and scrutiny, and is ready to be used as a basis for the

See comment 3.

See comment 4.

See comment 5.

Mr. Daniel Bertoni Page 3

activities that USDA would undertake in the event of an HPAI outbreak. The *National Highly Pathogenic Avian Influenza Preparedness and Response Plan* was designed to be a resource for State and local entities as they considered how to plan for a potential HPAI outbreak. It has been invaluable to USDA as we continue to talk with States and industry representatives regarding their plans for potential HPAI occurrences.

Likewise, USDA has worked extensively with the White House Homeland Security Council and with other Federal departments and agencies, including DHS, to develop the *Interagency Playbook*. This document was not intended to document Federal, State, and local interaction and collaboration in responding to the detection of H5N1 HPAI in birds. Its intent, from the beginning, was to outline how Federal departments and agencies would work collaboratively to respond to such an event. This document will continue to evolve as we develop the roles that each organization will play in the event of an HPAI outbreak in birds.

USDA established the National Veterinary Stockpile (NVS) in 2004 in response to the call for such an asset in Homeland Security Presidential Directive 9. The NVS has established a steering committee that provides recommendations regarding the most serious disease threats facing our Nation. These recommendations form the basis for the priorities the NVS has used to acquire countermeasures. HPAI was deemed a high priority for acquisition of veterinary countermeasures, so a great deal of effort and time has been spent setting up the logistics and acquiring appropriate capabilities to fight HPAI should it be found in the United States. The capability of the NVS to respond to AI was tested in March 2007 when turkeys in West Virginia were found infected with low pathogenic avian influenza (LPAI). USDA used the NVS to provide needed equipment to the site within 25 hours of the call for activation.

The GAO has indicated that USDA response plans do not identify the capabilities needed to carry out the tasks associated with an outbreak scenario, including specifying the entities responsible for carrying them out, the resources needed, and the source of these resources. The GAO is also concerned that USDA does not have a response plan that will help USDA track progress and establish a concept of operation. USDA has several resources in place to fill the gaps the GAO identified—the National Animal Health Emergency Management System guidelines that provide a foundation for coordinated national, regional, State, and local activities in an emergency situation, and the AI Response Coordination Team Concept of Operations document.

USDA has focused on the review and approval of the State plans as a method to control LPAI, some forms of which could otherwise become the more serious HPAI. Many States also have HPAI response plans. USDA agrees with the GAO's assessment regarding the need to more closely review HPAI plans and ensure that they prescribe an appropriate response should there be an HPAI outbreak. The new H5/H7 LPAI regulation requires States to develop Initial State and Response Containment Plans for H5/H7 LPAI and authorizes USDA's Animal and Plant Health Inspection Service (APHIS) to review and approve those plans.

Mr. Daniel Bertoni Page 4

The GAO raised concerns that Federal and State officials do not know the numbers and locations of backyard birds, which would make disease control difficult. USDA shares the concerns raised by State officials and by the GAO. Backyard flocks do pose risks, but USDA believes that to collect and maintain information on backyard flocks would be prohibitively expensive and rapidly outdated. Efforts to do so may be better managed at the State level as evidenced by examples described by the GAO in the States of Delaware and Maryland, although it may be more difficult to achieve in larger States. The challenges of locating backyard flocks led USDA to begin its "Biosecurity for Birds" campaign—to reach an audience that might otherwise be missed in our traditional outreach to States and industry partners and to encourage testing of sick birds. USDA has also begun limited active observational surveillance of backyard poultry in some States under HPAI Supplemental Funding cooperative agreements. Through these agreements, USDA provided \$11.4 million to States in fiscal year 2006 to address issues related to HPAI surveillance and response.

USDA continues its work to identify better methods of mass depopulation, including methods for other types of poultry and egg laying operations. Water based foam was used successfully in the mass depopulation of turkeys in West Virginia in March 2007. The depopulation of thousands of very large birds was completed in a more timely fashion and with fewer resources, including personnel, than would have been possible with more traditional technology. Regarding disposal, USDA agrees that disposal options are limited by the environmental conditions within a particular State. USDA has been working with its State counterparts to encourage the development of a carcass disposal plan within each State, and has encouraged State veterinary officials to collaborate with State environmental agencies to assess and determine the options available, and to develop plans in the event that carcass disposal becomes necessary.

The GAO indicates that DHS and State officials remained concerned that birds shipped through the mail or on commercial airlines do not all have health certificates to ensure they are free from disease, and that this might be a potential pathway for the spread of HPAI to unsuspecting owners. In December 2005, USDA conducted a study titled, "Assessment of the Risk of Transmission of H5N1 Avian Influenza via Adult Chickens and Adult Fowl Transported Domestically in the U.S. by the U.S. Postal Service (USPS)." The study concluded that should H5N1

be present in chicken or fowl in the United States, some risk may be posed by such movements. Following this risk assessment, USDA contacted the USPS to determine how we could best work together in implementing National Poultry Improvement Plan labeling requirements for AI certification of poultry moving interstate. USDA will continue to work with the USPS in resolving this issue.

Another concern raised is that USDA has not estimated the amount of antiviral medication that it would need in the event of an outbreak or resolved how to provide such supplies within the first 24 hours of an outbreak. USDA has estimated the amount of antiviral medication that would be needed, based on our experience with exotic Newcastle disease, and the total number of individuals who responded during the lifetime of the event (3,000). The NVS has systems

See comment 6.

Mr. Daniel Bertoni Page 5

in place that will provide 24-hour delivery of antiviral medications for 3,000 responders for 6 weeks. The NVS has made considerable progress towards ensuring responders will have the antiviral they need to deal with an HPAI outbreak. The NVS has confirmed that the manufacturer has sufficient commercial supplies available to support responders. The NVS has capitalized on contracts held by the Strategic National Stockpile to obtain antiviral at a cost effective price. The NVS has coordinated deployment planning to ship antiviral supplies held by APHIS to the site of an outbreak within 24 hours, thereby providing adequate supplies until additional stock arrives from the manufacturer. And lastly, the NVS has worked with agency partners and the Department of Defense to extend the shelf life of its current antiviral supplies.

In summary, USDA is committed to keeping HPAI from becoming established in the U.S. poultry population by fully using our scientific expertise on AI viruses and our real world experience in planning for and responding to incursions of significant animal diseases into the United States.

Sincerely,

Mike Johanns Secretary

The following are GAO's comments on the Department of Agriculture's letter dated May 21, 2007.

GAO Comments

- 1. USDA commented that our report does not take into account several critical components of successful foreign animal disease planning efforts. GAO recognizes that USDA has important preparations in place to respond to foreign animal diseases in general that are also relevant for AI. For example, USDA calls attention to its veterinary infrastructure and its National Animal Health Laboratory Network. We agree that these are important for responding to multiple types of disease outbreaks. However, it is not possible to include all planning measures. The focus of our report is on steps USDA has taken to prepare for highly pathogenic AI specifically.
- 2. We modified our report to include a statement about the importance of veterinary infrastructure to AI surveillance.
- 3. The National Response Plan anticipates the use of interagency agreements, such as memorandums of understanding, to further clarify agency roles. The intent of the recommendation is to further formalize how the two departments will coordinate during such an event.
- 4. We modified our report to include a statement about USDA's National Animal Health Laboratory Network.
- 5. During the course of our work, USDA officials specifically requested that we refer to these reports as "drafts." In addition, the summary AI response plan is published on USDA's Web site as a draft document. Nevertheless, we modified our report to state that these documents would be used in the event of an outbreak.
- 6. Our report acknowledges that USDA has a preliminary estimate regarding the amount of antiviral medication needed based on the exotic Newcastle disease outbreak. However, as our report also states, this number does not reflect a calculated estimate of those exposed to the virus in need of medication. Furthermore, our report acknowledges that National Veterinary Stockpile officials are in the process of contracting with a manufacturer of antiviral medication to provide, within 24 hours of an outbreak, antiviral medication for 3,000 responders for 6 weeks. However, as our report also states, this contract to supply antiviral medication is not yet in place.

Comments from the Department of Homeland Security

U.S. Department of Homeland Security Washington, DC 20528

US GAO

2007 MAY 17 PH 1: 06



May 16, 2007

Mr. Daniel Bertoni Director National Resources and Environment U.S. Government Accountability Office 441 G Street, NW Washington, DC 20548

Dear Mr. Bertoni:

Thank you for the opportunity to review and comment on the Government Accountability Office's (GAO's) draft report GAO-07-652 entitled AVIAN FLU: USDA Has Taken Important Steps to Prepare for Outbreaks, but Better Planning Could Improve Response.

We concur with the recommendation that further coordination between the Department of Homeland Security (DHS) and the Department of Agriculture (USDA) is needed in the event of a declared presidential emergency or major disaster, or an Incident of National Significance. We support the need for additional clarification for how DHS, USDA, the Department of Health and Human Services (HHS), and other agencies will coordinate during incidents as listed in the report. DHS also supports the need to test this coordination through exercises and during incidents such as the current food contamination event. DHS understands that GAO is not de-emphasizing the role of the National Response Plan (NRP) by recommending a Memorandum of Understanding as the mechanism for furthering coordination between the departments. However, DHS suggests coordination could occur through an interagency Concept of Operations (CONOPs) that would specify how the NRP would be used.

Thank you again for the opportunity to comment on this draft report and we look forward to working with you on future homeland security issues.

Sincerely

Steven J. Pecinovsky

Director

Departmental GAO/OIG Liaison Office

sewer & fecurousty

www.dhs.gov

GAO Contact and Staff Acknowledgments

GAO Contact

Daniel Bertoni, (202) 512-3841, or bertonid@gao.gov

Staff Acknowledgments

In addition to the individual named above, Charles Adams, Assistant Director; Kevin Bray; Nancy Crothers; Mary Denigan-Macauley; Jeff Jensen; Christopher Lyons; Terry Richardson; and Margaret Vo made key contributions to this report.

Don Cowan, Joyce Evans, Lynn Musser, Katherine Raheb, Jeremy Sebest, Daniel Semick, and Cynthia Taylor also made contributions.

(360700) Page 55 GAO-07-652 Avian Influenza

GAO's Mission	The Government Accountability Office, the audit, evaluation and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.
Obtaining Copies of GAO Reports and Testimony	The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's Web site (www.gao.gov). Each weekday, GAO posts newly released reports, testimony, and correspondence on its Web site. To have GAO e-mail you a list of newly posted products every afternoon, go to www.gao.gov and select "Subscribe to Updates."
Order by Mail or Phone	The first copy of each printed report is free. Additional copies are \$2 each. A check or money order should be made out to the Superintendent of Documents. GAO also accepts VISA and Mastercard. Orders for 100 or more copies mailed to a single address are discounted 25 percent. Orders should be sent to:
	U.S. Government Accountability Office 441 G Street NW, Room LM Washington, D.C. 20548
	To order by Phone: Voice: (202) 512-6000 TDD: (202) 512-2537 Fax: (202) 512-6061
To Report Fraud, Waste, and Abuse in Federal Programs	Contact:
	Web site: www.gao.gov/fraudnet/fraudnet.htm E-mail: fraudnet@gao.gov Automated answering system: (800) 424-5454 or (202) 512-7470
Congressional Relations	Gloria Jarmon, Managing Director, JarmonG@gao.gov (202) 512-4400 U.S. Government Accountability Office, 441 G Street NW, Room 7125 Washington, D.C. 20548
Public Affairs	Paul Anderson, Managing Director, AndersonP1@gao.gov (202) 512-4800 U.S. Government Accountability Office, 441 G Street NW, Room 7149 Washington, D.C. 20548