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Audit Report

Animal and Plant Health Inspection Service
Oversight of Avian Influenza

Report No. 33099-11-Hy
June 2006

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

June 12, 2006

REPLY TO
ATTN OF: 33099-11-Hy

TO: W. Ron DeHaven
Administrator
Animal and Plant Health Inspection Service

ATTN: William J. Hudnall
Deputy Administrator
Marketing and Regulatory Programs – Business Services

FROM: Robert W. Young /s/
Assistant Inspector General
for Audit

SUBJECT: Oversight of Avian Influenza

This report presents the results of our audit of the Animal and Plant Health Inspection Service Oversight of Avian Influenza. Your response to the official draft, dated June 1, 2006, is included as exhibit B. Excerpts of your response and the Office of Inspector General's position are incorporated into the Findings and Recommendations section of the report. Based on your response, we were able to reach management decision on the report's eight recommendations. Please follow your internal agency procedures for reporting final action to the Office of the Chief Financial Officer.

Please note that Departmental Regulation 1720-1 requires final action to be completed within 12 months of management decision.

We appreciate the courtesies and cooperation extended to us by members of your staff during this audit.

Executive Summary

Animal and Plant Health Inspection Service Oversight of Avian Influenza (Audit Report No. 33099-11-Hy)

Results in Brief

This report presents the results of the Office of Inspector General's (OIG) audit of the Animal and Plant Health Inspection Service (APHIS) oversight of Avian Influenza (AI). We assessed the adequacy of APHIS' procedures to identify the occurrence of AI in the United States and to limit the impact on the general public and poultry industry. We concluded that APHIS has made commendable progress in developing plans and establishing the networks necessary to prepare for, and respond to, outbreaks of AI. However, APHIS has not yet developed a comprehensive approach for surveillance and monitoring of AI in domestic poultry.

APHIS relies on a variety of voluntary State and commercial programs to monitor and test domestic poultry and wild birds. Because these programs are voluntary and there is no mechanism for reporting activity to APHIS, it does not know the extent of surveillance activity in place; and APHIS is not gathering consistent data to enable it to draw conclusions, to permit the detection of changes in epidemiological parameters (e.g., subtype of AI or rate of prevalence), or to report incidents of AI in accordance with new international trade requirements.

In response to the President's National Strategy for Pandemic Influenza (Strategy),[1] APHIS has developed the National AI Preparedness and Response Plan (Response Plan) to address the threat of AI. Characterized by its authors as a "living document" and subject to revision, it establishes a comprehensive approach to the management of an outbreak of highly pathogenic AI (HPAI) on a large commercial poultry operation. It incorporates best practices and procedures from incident management disciplines—homeland security, emergency management, law enforcement, firefighting, public works, public health, responder and recovery worker health and safety, emergency medical services, and the private sector—and integrates them into a unified structure. It forms the basis for how the Federal Government coordinates with State, local, and Tribal Governments, and the private sector once an incident occurs.

To date, APHIS' resources have been primarily directed toward responding to a potential HPAI pandemic. APHIS is coordinating and establishing networks with other Federal, State, and private entities. The agency is working with Federal and State cooperators in developing strategies for monitoring

[1] National Strategy for Pandemic Influenza, Homeland Security Council, dated November 1, 2005.

migratory birds, as well as working internationally to provide education, outreach, and technical assistance.

Worldwide, there are many strains of the AI virus that can cause varying degrees of clinical illness in poultry. AI viruses can infect chickens, turkeys, pheasants, quail, ducks, geese, and guinea fowl, as well as a wide variety of other birds, including migratory waterfowl. This virus changes rapidly in nature by mixing its genetic components to form different virus subtypes. AI is caused by many slightly different viruses. There are 144 different characterizations of the AI virus based on two groups of proteins found on the surface of the virus. One group is composed of hemagglutinin proteins (H), of which there are 16 different types (H1-H16); the other group is composed of neuraminidase proteins (N), of which there are 9 different types (N1-N9).

AI viruses can be further classified into low pathogenicity and high pathogenicity forms based on the severity of illness they cause in poultry. Most AI strains are classified as low pathogenic AI (LPAI) and cause mild or asymptomatic infections in birds. In contrast, HPAI causes a severe and extremely contagious illness and death among infected birds. Mortality rates for birds affected by an HPAI outbreak can be as high as 90 to 100 percent, and any surviving birds are usually in poor condition. While LPAI infections are typically mild, some low pathogenic subtypes–the H5 and H7 strains-have the capacity to mutate into highly pathogenic strains. These types of infections, as well as HPAI, are referred to as notifiable AI (NAI).[2] LPAI poses no known serious threat to human health. However, some strains of HPAI viruses can be infectious to people.

APHIS officials stated that the agency had only recently received adequate funding and that its approach had been to bolster surveillance and control in the most important areas first while identifying additional surveillance needs. On December 12, 2005, we issued a management alert to APHIS which outlined concerns with current AI surveillance activities. In its response, APHIS described a number of initiatives planned and in-process to address our concerns. For example, the National Surveillance Unit is currently developing standards for the design of surveillance systems within Veterinary Services and plans to publish these standards in early 2006. Following these standards, a National AI Surveillance System (to include Federal and non-Federal surveillance components) will be designed as a component of comprehensive poultry disease surveillance. The project completion date is October 31, 2006.

In regard to its Response Plan, APHIS needs to provide additional guidance on preparing for and responding to HPAI or NAI outbreaks in live bird

[2] Notifiable AI refers to the Terrestrial Animal Health Code requirements that require all member countries, including the United States, to report to the World Organization for Animal Health any infections of commercial poultry from influenza A viruses of the H5 and H7 subtypes as well as any AI subtypes meeting the established pathogenicity (mortality) standard.

markets or other "off–farm" environments, clarify actions that employees should take in obtaining and administering necessary vaccines and anti-virals in the event that a culling operation for HPAI occurs, and finalize interagency coordination on the process and procedures for notifying owners of susceptible animals of the current infectivity risks, and the necessary protective actions they should take when an outbreak of AI occurs.

Recommendations In Brief

In our management alert, we recommended that APHIS develop and implement a comprehensive AI surveillance plan and perform and document an analysis that identifies any gaps in sampling surveillance and assesses risk as a basis for determining the need for additional sampling. In response, APHIS provided a strategy for developing a comprehensive plan. APHIS should update its response to include details of how the inventory of current surveillance systems will be developed and revised timeframes for project completion.

We recommend that APHIS revise the Response Plan to include detailed instructions for (1) handling HPAI occurrences in live bird market systems and other "off-farm" environments and (2) obtaining and administering vaccines and anti-virals to people in the event of a culling operation. Also, APHIS needs to coordinate with the Farm Service Agency and the States to develop and formalize producer notification and action procedures when an outbreak of AI occurs, to include identification of the roles and responsibilities of personnel involved, specific timeframes for action, and linkage to the Standard Operating Procedures set forth in the Response Plan.

Agency Response

APHIS agreed with the reports recommendations stating it believed the audit presented an accurate and realistic picture of APHIS' capabilities at the time of the review. APHIS noted that the audit was performed prior to the receipt AI supplemental funding allocated by Congress to APHIS in fiscal year 2006. APHIS stated the supplemental funding is currently being used to enhance its surveillance and diagnostics, preparedness, and response, and wild bird surveillance programs. Additionally, a portion of this funding is also being used to fund international efforts designed to help prevent the spread of HPAI into the United States.

We have incorporated excerpts from APHIS' response in the Findings and Recommendations section of this report along with the OIG position. APHIS' response is included as Exhibit B. We did not include the attachments APHIS provided to its response because of the sensitive nature of the information and size of the attachments.

OIG Position

We concur with the agency's response and have reached management decision for all eight recommendations within this report.

Table of Contents

Abbreviations Used in This Report

AHPA	Animal Health Protection Act
AI	Avian Influenza
APHIS	Animal and Plant Health Inspection Service
EMRS	Emergency Management Response System
FAD	Foreign Animal Disease
FSA	Farm Service Agency
HHS	Department of Health and Human Services
HPAI	Highly Pathogenic Avian Influenza
LBM	Live Bird Market(s)
LBMS	Live Bird Marketing System
LPAI	Low Pathogenic Avian Influenza
NAI	Notifiable Avian Influenza
NPIP	National Poultry Improvement Plan
NSU	National Surveillance Unit
NVSL	National Veterinary Services Laboratory
OIE	World Organization for Animal Health
OIG	Office of Inspector General
Response Plan	National Avian Influenza Preparedness and Response Plan
Secretary	Secretary of Agriculture
Strategy	National Strategy for Pandemic Influenza
USDA	U.S. Department of Agriculture
VS	Veterinary Services

Background and Objectives

Background

Avian Influenza (AI) is an infectious disease of birds caused by type A influenza viruses. All birds are thought to be susceptible to AI, though some species are more resistant to infection than others. Wild waterfowl, shorebirds, and gulls serve as a natural host and reservoir for AI viruses.

AI viruses are classified in accordance with the specific combination of two protein groups (H and N) they carry. At present, 16 H type proteins have been recognized (H1-H16) and 9 N (N1-N9) types. The H protein can theoretically be partnered with any one of the N proteins. Thus, there are potentially nine different forms of each virus subtype (for example, the nine forms of subtype H5 would be notated as H5N1, H5N2, H5N3, etc., through H5N9).

Influenza A viruses can also be divided on the basis of their pathogenicity (ability to cause disease). The very virulent viruses cause highly pathogenic AI (HPAI) with up to 100 percent rates of mortality in poultry. Other AI viruses cause low pathogenic AI (LPAI), a much milder disease. Clinical signs for LPAI are much less evident or even absent and mortality is much lower or nonexistent. Only viruses of the H5 and H7 subtypes are known to cause HPAI. However, not all H5 and H7 viruses are highly pathogenic.

In recent years, concern about HPAI infection in humans has increased after the discovery that some of these viruses have acquired the capacity to infect humans. Since 2003, a number of Asian countries have reported outbreaks of HPAI (subtype H5N1) which has been responsible for either the death or destruction of millions of birds and caused at least 100 human deaths. Recently, HPAI (subtype H5N1) has been found in Africa and Europe.

The widespread persistence of H5N1 in poultry poses risks to human health. The current pandemic threat stems from an unprecedented outbreak of AI in Asia and Europe, caused by the H5N1 strain of the influenza A virus.[3] There are two potential routes for human infection. The first route is direct infection, whereby the virus passes from poultry to humans, resulting in severe disease. A second route, of potentially greater concern, occurs if the virus changes (mutates) into a form that is highly infectious to humans and spreads easily from person to person. Currently, the virus has not mutated into a form that can be transmitted easily from human to human.

Direct contact with infected poultry or objects contaminated by their feces is thought to be the main way humans are currently infected. At present, most human cases occur in areas where small poultry flocks exist. In many cases, the poultry roam free, sometimes entering living quarters or areas where

[3] National Strategy for Pandemic Influenza (Strategy), Homeland Security Council, dated November 1, 2005.

children play. As infected birds shed virus in their feces, the opportunities for exposure to infected feces or to a contaminated environment increase.

The President of the United States has recognized the public health threat of AI. In November 2005, he issued the National Strategy for Pandemic Influenza (Strategy).[4] This document outlines a strategy for preparation, detection, and response to a pandemic. It recognizes roles for all segments of society, including Federal, State, local and Tribal Governments, private industry, international trade partners, and individual citizens.

The United States is the world's largest producer and exporter of poultry meat and the second-largest egg producer. Total U.S. poultry production was valued at over $28.8 billion in 2004. Broiler production was valued at $20.4 billion, followed by eggs at $5.3 billion and turkeys at $3.1 billion. Also, the United States is the world's largest exporter of broilers and turkeys. In 2004, U.S. chicken exports were valued at $1.6 billion and turkey exports at $248 million. Any outbreak of HPAI, regardless of the strain, could have very serious economic and health impacts on the U.S. poultry industry. An HPAI outbreak could result in significant poultry production losses in affected areas due to quarantine and bird depopulation activities. It is possible that foreign trading partners would impose a ban on all U.S. exports of poultry and poultry products. In the past our foreign trading partners have occasionally imposed partial bans on U.S. exports when LPAI was identified.

The World Organization for Animal Health (OIE) guidelines in the Terrestrial Animal Health Code are recognized by the World Trade Organization as international recommendations for animal disease control. The OIE has revised its Terrestrial Animal Health Code guidelines regarding AI. Effective January 1, 2006, the guidelines require all member countries, including the United States, to report to the OIE any infections of commercial poultry from influenza A viruses of the H5 and H7 subtypes as well as any AI subtypes meeting the established pathogenicity (mortality) standard. Infections meeting these definitions are referred to as notifiable AI (NAI).

The Animal Health Protection Act (AHPA), Public Law 107-171, dated May 13, 2002, consolidated and revised the authority of the Secretary of Agriculture (Secretary) related to protection of animal health. The AHPA enables the Secretary to prevent, detect, control, and eradicate diseases and pests of animals, such as AI, in order to protect animal health, the health and welfare of people, economic interests of livestock and related industries, the environment, and interstate and foreign commerce in animals and other articles. The AHPA gives the Secretary a broad range of authorities to use in the event of an outbreak of AI in the United States and to prevent the introduction of such a disease into the United States. The Secretary is

[4] National Strategy for Pandemic Influenza, Homeland Security Council, dated November 1, 2005.

specifically authorized to carry out operations and measures to detect, control, or eradicate any pest or disease of livestock, which includes poultry, and to promulgate regulations and issue orders to carry out the AHPA. The Secretary may also prohibit or restrict the importation, entry, or interstate movement of any animal, article, or means of conveyance to prevent the introduction into or dissemination within the United States of any pest or disease of livestock. Under certain specified circumstances, the Secretary may declare an extraordinary emergency to regulate intrastate activities or commerce. The Secretary also has authority to cooperate with other Federal agencies, States or political subdivisions of States, national or local Governments of foreign countries, domestic or international organizations or associations, Indian tribes and other persons to prevent, detect, control, or eradicate AI.

The Animal and Plant Health Inspection Service (APHIS) protects and promotes agriculture in the United States by keeping agricultural pests and diseases from entering the country, facilitating agricultural exports, and ensuring science-based standards in agricultural trade. Within APHIS, Veterinary Services (VS) protects and improves the health, quality, and marketability of our nation's animals and animal products by (1) preventing, controlling, and/or eliminating animal diseases and (2) monitoring and promoting animal health and productivity.

HPAI is considered to be a foreign animal disease (FAD), and subject to certain types of APHIS monitoring and review. Historically, LPAI was considered to be a responsibility of the States, and thus not subject to intense APHIS attention.

Although a more comprehensive plan is being developed, APHIS notes that current surveillance activities occur in four broad areas. These are the National Poultry Improvement Plan (NPIP), the live bird marketing system (LBMS), State and independent commercial sampling, and wild bird surveillance. Additionally, APHIS has developed a backyard biosecurity campaign that does not include a testing component but provides education for owners of backyard flocks.

NPIP is a cooperative Federal-State-industry program for controlling certain poultry diseases, including AI. The NPIP consists of a variety of programs intended to prevent and control egg and hatchery disseminated poultry diseases. Flocks are ruled "AI Clean" if a specified number of birds test negative for AI over a specified period. Diagnostic testing is done by State and industry laboratories; the National VS Laboratories (NVSL) in Ames, Iowa, confirm positive results. Participation in the program is voluntary and currently only applies to breeding flocks. APHIS has drafted regulations, which will extend the program to broiler, turkey, and egg laying operations. APHIS reports that many operations and flocks have already begun

implementation of the regulations in advance of their issuance. While APHIS does not have reliable information about the proportion of commercial poultry that is monitored for AI under the NPIP, officials agree that a significant segment of poultry operations is not covered, predominantly commercial poultry operations that produce birds for domestic production and do not export to foreign countries.

Live bird markets (LBM) are facilities that sell live poultry, which is often slaughtered onsite. It is estimated that over 70 percent of the LBM in the United States are located in major cities in the northeast. Other poultry markets include poultry auctions and botanicas, which are shops that sell live birds for ritual slaughter. The LBMS includes the markets, and their production and distribution systems. APHIS, in consultation with State and industry representatives, has developed uniform standards for the Prevention and Control of H5 and H7 LPAI in the Live Bird Market System. The standards include testing requirements for the production, distribution, transportation, and retail segments of the LBMS. Adoption of the standards is voluntary.

States and the commercial poultry industry perform some AI monitoring. For example, a Texas poultry industry group established an effort for an active serological surveillance for AI following the identification of H5N2 in a single flock of broilers. Pennsylvania has established its own AI monitoring program in cooperation with industry. North Carolina has AI monitoring efforts beyond the requirements of NPIP, such as testing a portion of blood samples submitted to State laboratories every month.

Wild birds, in particular certain species of waterfowl and shorebirds, are natural reservoirs for AI. Migratory birds represent one potential route for the spread of HPAI into the United States. The ability to effectively prevent or limit the spread of HPAI into domestic poultry operations is greatly enhanced by early detection. Based on a request by the Department of Homeland Security, the U.S. Department of Agriculture (USDA) and the Department of the Interior developed a coordinated plan for the early detection of HPAI in wild birds. The surveillance activities will include a large increase in the number of samples taken from live wild birds and hunter-taken birds. Initial focus will be on the Alaska and Pacific flyways as these are the most likely routes of introduction during the spring of 2006, when birds migrate back to the United States from Asia.

For backyard activities, APHIS has developed a “Biosecurity for the Birds” campaign. APHIS provides information regarding the risk and signs of disease, encourages good biosecurity practices, and reporting of sickness. This program does not include a testing component; it depends upon the public to report to authorities the sickness or the death of birds.

Objectives

The objective of this audit was to assess the adequacy of APHIS' activities to identify the occurrence of AI and limit its impact upon the public health and poultry industry.

To accomplish our objective, we performed fieldwork at APHIS Headquarters, APHIS Regional offices, APHIS' National Center for Animal Health Surveillance, and five State Departments of Agriculture. We also interviewed personnel and obtained data from APHIS' NVSL.

APHIS has not yet developed a comprehensive approach to surveil and monitor for AI. APHIS relies on a variety of voluntary State and commercial programs to monitor and test domestic poultry and wild birds. If a State, producer, or private/referring veterinarian reports a suspect FAD (e.g., HPAI), APHIS guidance requires that a diagnostic specimen be sent to the NVSL in Ames, Iowa, and that an investigation be conducted.[5] The investigation and its resolution are to be recorded in the Emergency Management Response System (EMRS), a system that enables veterinarians, epidemiologists, and outbreak personnel to more quickly respond during an outbreak. APHIS has long-range plans to develop a comprehensive approach to poultry health surveillance, of which AI surveillance is one part.

The emergence of HPAI as a potential pandemic has rapidly changed the environment in which APHIS operates. The issuance of the President's Strategy on November 1, 2005, accelerated APHIS' actions in dealing with AI. The President's Strategy is based on the principles of (1) preparedness and communication, (2) surveillance and detection, and (3) response and containment.

On December 12, 2005, the Office of Inspector General (OIG) issued a management alert which identified concerns with APHIS' AI surveillance activities. OIG reported that APHIS does not have a comprehensive surveillance system; did not know the extent of surveillance activities in place; and was not gathering consistent data to enable it to draw conclusions, to permit the detection of changes in epidemiological parameters (e.g., subtype of AI or rate of prevalence), or to report incidents of AI in accordance with new international requirements.[6] Further, APHIS was not updating EMRS to reflect resolution of avian disease investigations.

Due to these developments, as well as increased domestic and international concern, APHIS expanded its efforts to address AI in all its forms. To date, APHIS resources have been primarily directed toward HPAI and developing a National AI Preparedness and Response Plan (Response Plan). APHIS is also coordinating and establishing networks with other Federal, State, and private entities and working with Federal and State cooperators on developing strategies for monitoring migratory birds, as well as working internationally to provide education, outreach, and technical assistance. Additional planned actions include enhancing surveillance efforts, obtaining more detailed

[5] VS Memorandum 580.4, Procedures for Investigating a Suspected FAD Emerging Disease Incident, March 30, 2004.
[6] Effective January 2006, the OIE expanded its requirements for reporting AI to include all commercial instances of H5/H7 regardless of pathogenicity (ability to cause disease).

information about State surveillance and monitoring activity, aggregating and analyzing test results, developing a probability surveillance approach,[7] and expanding diagnostic laboratories' network capabilities.

Finding 1 Developing a Comprehensive Surveillance Plan for Domestic Poultry

APHIS is in the early stages of developing a national AI surveillance program for domestic poultry. The agency defines surveillance as the systematic collection, collation, analysis, and interpretation of related events occurring in animal populations. This process is to be followed by timely dissemination of results to those involved in planning, implementing, and evaluating of prevention and control measures so that action may be taken. Monitoring is defined as the routine collection of information for a disease condition, characteristic, or state with the purpose of detecting changes in the epidemiological parameters affecting the population.[8]

Agency officials established a committee to develop a National Surveillance Plan for Poultry Diseases which initially met in January 2005. This committee confirmed the need for a plan to protect the public health, the poultry industry, and trade relations. The committee planned to evaluate current surveillance systems, identify surveillance gaps, and develop corrective actions. While the committee did not have a leader for much of 2005, and little progress was made during that time, a newly hired staff veterinarian has now been assigned as committee chairman and a followup meeting was held in January 2006. A review of existing AI surveillance and surveillance gaps was performed; however, the resulting analysis was limited in scope because aggregated data were not available to the reviewers. The analysis noted that concentrated efforts to integrate data and fill gaps are underway.

APHIS officials note that the agency has recently begun developing comprehensive and integrated surveillance components. According to APHIS, the National Animal Health Surveillance System will be a comprehensive, coordinated, and integrated surveillance network of alliances and partnerships among multiple Government agencies and private entities. Its purposes will include protecting animal health, veterinary public health, and food security associated with animal populations. However, plans for this system are still under development and timelines for implementation and other documentation have yet to be established.

We identified the following areas that should be considered as APHIS develops its comprehensive surveillance plan.

[7] Probability surveillance determines the probability of introduction based on risk analysis, pathway analysis, and threat analysis.
[8] APHIS VS webpage (http://aphis.usda.gov/vs/nahps/surveillance)

Determining how much United States poultry is not subject to surveillance or monitoring. To date, APHIS has not performed a documented risk assessment to identify the volume and distribution of poultry that is not addressed through one or more of the segments, to include the NPIP,[9] the LBMS, and commercial or State monitoring activities. Without this information, APHIS has reduced assurance that risks are being appropriately mitigated or that scarce dollars and resources are being targeted to the areas of greatest concern. The recent analysis of surveillance by APHIS cites the absence of data on "potential spatial…gaps" (the States or geographic areas where data is not available) and "potential temporal gaps," (seasons or months when sampling may not occur).

Collating and comprehensively analyzing the surveillance data that has been generated through AI testing. While there has been some analysis of various segments (e.g., State level and LBMS results), the data from the disparate sources has not been aggregated to allow APHIS to draw conclusions about AI in United States bird populations or to permit the detection of changes in epidemiological parameters (e.g., subtype of AI or rate of prevalence). Thus, it is difficult or impossible to reach valid conclusions based on the data. A senior APHIS official agreed that the AI surveillance data currently obtained does not support overall conclusions about the prevalence of AI or changes in epidemiological parameters. In response to our management alert, the Administrator acknowledged "the inability to aggregate and compile surveillance data for AI viruses…[which] inhibits the valuable flow of information to animal decision makers at all levels."

An APHIS survey of State agencies showed disparities in AI surveillance activities. For example, one State reported that it performed full diagnostic testing on eggs, broilers, and turkeys, while another limited tests to NPIP participants. Many States with a large poultry industry sector report major testing efforts. However, the extent of testing remains unclear, when considered on a nationwide basis, and APHIS officials have not collected comprehensive data on the topic.

APHIS relies heavily on State participation in the NPIP for AI testing. State participation in the NPIP does not guarantee that large commercial breeders actually participate in this voluntary program. An official of a State with significant poultry operations informed us that 3 of 14 parent breeder flocks for meat-type chickens (comprising about 4.2 million or 10 percent of State hatching capacity)[10] did not participate in the AI component of the NPIP program nor did the State officials know whether these companies tested for AI at levels comparable to the NPIP provisions. For another major poultry

[9] NPIP is a voluntary program for testing poultry diseases in the breeding stock for commercial poultry growers, including egg and meat-type chickens, turkeys, and exhibition birds.

[10] Hatching capacity is defined as the number of eggs a facility can hatch at any given time.

producing State, none of the seven parent breeder flocks for meat-type chickens (hatching capacity of 11.6 million) participate in the AI component of the NPIP program, instead relying on a State sponsored AI program.

Establishing a system to collect AI surveillance data at the National level. Trading partners routinely ask for AI testing data. In response, APHIS provides information about various surveillance efforts (NPIP, LBMS, and State or industry surveillance). APHIS employees advised us of three particular concerns expressed to them by trading partners during trade negotiations. Specifically, trading partners did not understand why APHIS could not (1) provide actual numbers by State, (2) advise whether all commercial bird species are tested, or (3) advise whether backyard flocks are tested.

Recent changes in OIE guidelines increase the urgency of the need for comprehensive and reliable systems to sample for, and report on, AI. Effective January 1, 2006, the Terrestrial Animal Health Code guidelines require all member countries, including the United States, to report to the OIE any infections of commercial poultry from influenza A viruses of the H5 and H7 subtypes, as well as any AI subtypes meeting the established pathogenicity standard. Based on our review, APHIS currently does not have reasonable assurance that it can accurately or timely detect all the instances of NAI. As a result all instances of NAI may not be reported to OIE as required.

AI surveillance in the United States is performed at different levels, including activity by the poultry industry, the States, and APHIS. APHIS managers have historically not considered the threat of LPAI to warrant the same types of monitoring and surveillance as the diseases that traditionally represent more of a threat to United States interests (e.g., bovine tuberculosis). Resource constraints and competing priorities were cited as reasons that the development of the surveillance plan for poultry diseases had been put on hold. However, after we discussed the results of our review with agency officials on October 21, 2005, agency management developed a timeline for reviewing AI surveillance and identifying gaps in its surveillance efforts.

On December 12, 2005, we issued a management alert to APHIS which outlined the issues identified in this finding. APHIS provided a written response dated December 21, 2005 (see Exhibit A). In its response, APHIS provided a tentative strategy and described a number of initiatives planned and in process to address our concerns.

According to APHIS, the National Surveillance Unit (NSU) is developing standards for the design of surveillance systems within VS and will publish these standards in early 2006. Following these standards, a National AI Surveillance System (to include Federal and non-Federal surveillance

components) will be designed as a component of comprehensive poultry disease surveillance. The project completion date is October 31, 2006.

Further, APHIS responded that the NSU maintains an inventory of current surveillance system initiatives and programs throughout the United States, including Federal and State level programs. The completeness of this inventory will be reviewed and evaluated, and, where necessary, additional poultry health surveillance components will be added.

Recommendation 1

Develop and implement a comprehensive AI surveillance plan to include goals and objectives, case definitions, data collection and analysis methodologies, reporting of surveillance results, and assessment of surveillance program.

Agency Response.

APHIS agreed with this recommendation and is working to achieve this goal. The NSU, which is part of APHIS' VS division, is drafting an AI surveillance plan that will include all of the components suggested in OIG's recommendation. APHIS intends to have a draft of this plan available by June 30, 2006.

OIG Position.

We concur with the agency response for this recommendation and have reached management decision.

Recommendation 2

Perform and document an analysis identifying gaps in sampling surveillance, and assessing risk as a basis for determining the need for additional sampling, or documenting the basis for any decision not to sample a portion of the population.

Agency Response.

APHIS agreed with this recommendation and stated it had recently conducted a gap analysis to better understand remaining issues and what actions need to occur. The agency provided documentation of gaps identified and actions being performed to obtain additional information for data gaps.

OIG Position.

We concur with the agency response for this recommendation and have reached management decision.

Finding 2 Documenting Resolution of Potential Instances of AI

APHIS did not always document in EMRS the resolution of potential instances of FAD when they were identified. APHIS personnel did not follow established procedures that require closure of investigations within a week of receiving final laboratory results, along with any "followup" information, that rules out a FAD.[11] At the time of our review, we identified 46 cases entered into EMRS where a potential diagnosis was avian FAD, and the investigation had not been recorded as completed. Forty-three of the unresolved cases were more than 6 months old, and 19 of the 43 cases had gone unresolved for more than a year. After we questioned the disposition of the aging cases, APHIS officials closed the cases, stating that the investigations had all been completed and closed appropriately throughout the year, but not entered into the EMRS until our inquiry.

EMRS is a web-based task management system designed to automate many of the tasks routinely associated with the disease outbreaks and animal emergencies. It is used for routine reporting of FAD investigations, State-specific disease outbreaks or control programs, classic national animal health emergency responses, or natural disasters involving animals. EMRS enables veterinarians, epidemiologists, and outbreak personnel to more quickly respond to patterns during the outbreak and deliver high-resolution, high quality maps to decision makers, Government institutions, and the public.[12]

A typical example of a case unresolved in EMRS follows. An investigation of a high death rate of guinea hens in a backyard flock in Virginia was opened as an emergency program case on January 25, 2005. This investigation was closed on October 3, 2005, via data entry. Since the most probable diagnosis listed by the area emergency coordinator who initiated the case was either “Avian Influenza, High Path” or “Avian Influenza, Low Path,” and other potential diseases including Exotic Newcastle Disease and various domestic poultry diseases, it is significant that the case was open for more than 8 months. It should be noted that we confirmed with NVSL that the samples submitted had been returned as negative for both AI and Exotic Newcastle Disease in January 2005. While the State employee who sampled the guinea hens knew that the sample was returned negative, users of EMRS would be led to believe that final laboratory results had not yet been returned. This is an

[11] VS Memorandum No. 580.4, Procedures for Investigating a Suspected FAD/Emerging Disease Incident, dated March 30, 2004.
[12] APHIS VS webpage (http://emrs.aphis.usda.gov/emrs_fact_sheet.pdf)

indication that EMRS was not being used routinely to identify cases where laboratory results had not been returned, and thus was not functioning as an effective internal control to ensure that all suspected cases were addressed promptly. It is imperative that APHIS strengthen its reporting and tracking of FADs to ensure that the agency will be able to act timely and effectively in the event of an HPAI outbreak.

On December 12, 2005, we issued a management alert to APHIS that outlined the issues identified in this finding. APHIS provided a written response dated December 21, 2005 (see Exhibit A). In its response, APHIS noted that all identified cases had been successfully resolved. The agency would focus on better education of all EMRS users. Further, they agreed to strengthen quality control by having regional offices regularly run and examine EMRS reports. These actions, if implemented effectively, will address our concerns.

Recommendation 3

Review the EMRS database and ensure resolution of all cases where a potential diagnosis of FAD has not been resolved within an appropriate period of time.

Agency Response.

VS continues to follow VS Memo 580.4, dated March 30, 2004, in resolving all potential FAD diagnoses within appropriate periods of time. The Western and Eastern Regional Emergency Managers each have identified regional epidemiologists responsible for reviewing all FAD investigations documented in the EMRS FAD investigation database for their regions. This ensures timely documentation of the resolution and closure of all the investigations includes all potential incidents of HPAI.

OIG Position.

We concur with the agency response for this recommendation and have reached management decision.

In response to the President's Strategy, APHIS developed a Response Plan in January 2006. APHIS has made commendable progress in developing and documenting the policies and practices to be implemented in the event of an outbreak of HPAI on a large commercial poultry operation. However, we identified additional areas where the Response Plan can be strengthened as APHIS and its partners prepare to react when HPAI or NAI is identified. APHIS needs to provide additional guidance on preparing and responding to HPAI or NAI outbreaks in LBM or other "off–farm" environments, clarify actions that employees should take in obtaining and administering necessary vaccines and anti-virals in the event that a culling operation for HPAI occurs, and finalize interagency coordination on the process and procedures for notifying owners of susceptible animals of the current infectivity risks when an outbreak of AI occurs.

Finding 3 Responding to AI in LBM, Botanicas, and "Off-Farm" Locations

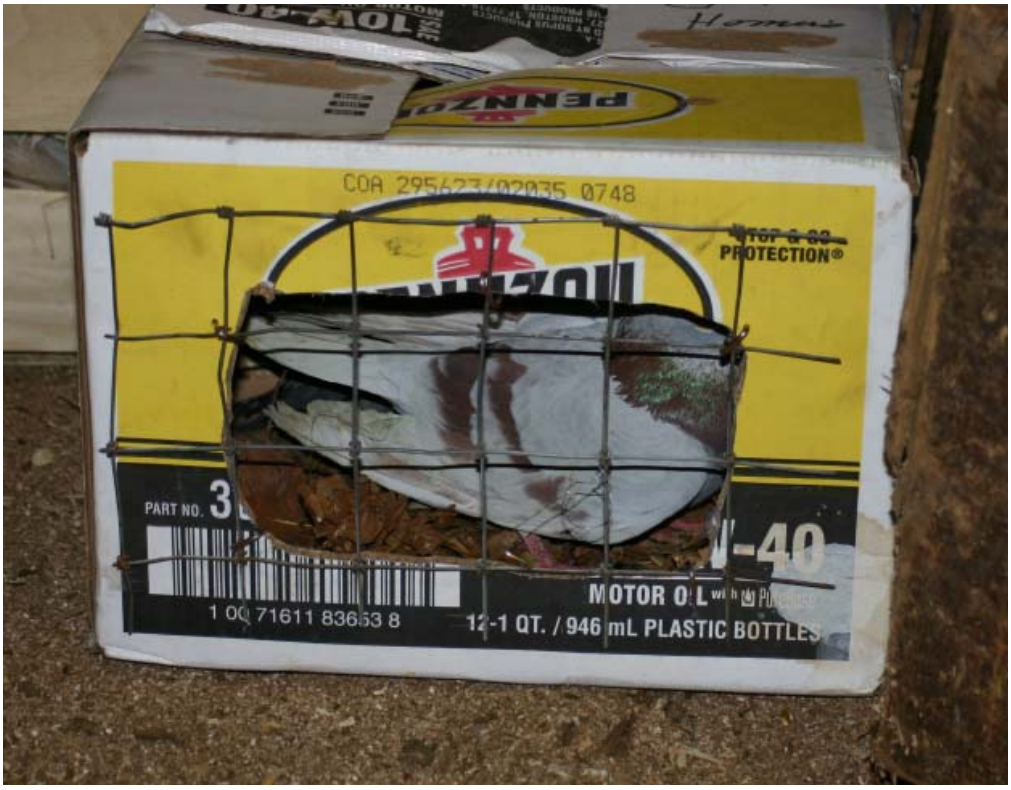
The Response Plan includes detailed operational guidance to be followed in the event that HPAI is identified on commercial poultry operations. However, the document lacks similar detailed guidance for dealing with HPAI in LBM, botanicas,[13] or other "off-farm" locations, such as those used for illegal gamecock fighting. According to APHIS officials, the Response Plan was assembled hastily and there was not adequate time to address all potential situations in which HPAI might be identified. Based on our discussion with APHIS officials, detailed instructions, similar to those developed for farms and large commercial operations, could help ensure a prompt and effective response if HPAI were identified in LBM, botanicas, or other locations where birds are bought and sold.

According to APHIS, LPAI H5 and H7 have been shown to possess the potential to mutate into HPAI. Historically, the H5 and H7 subtypes of LPAI have been repeatedly identified in the LBMS in the United States. Nearly all (approximately 99 percent) of the instances where H5 or H7 AI virus was confirmed in the United States during the period September 2004 through June 2005 occurred in samples from LBM. AI has also been identified in other "off-farm" locations, such as botanicas. Given that LBM and botanicas are frequently located in large metropolitan areas, the methods that would be effective in dealing with an instance of HPAI at those locations would likely vary from the methods to be used in a farm or large commercial poultry operation.

[13] Botanicas, which primarily are located in southern Florida, sell live birds for ritual slaughter.

Cleaning and Disinfection. According to the Response Plan, cleaning and disinfection are procedures used to impede the spread of pathogenic microorganisms, to include HPAI. The Response Plan includes specific guidance on cleaning poultry premises, to include breeder houses and broiler houses, but does not provide details of how to ensure proper cleaning and disinfection in a LBM. Based on our observations, cleaning and disinfecting a LBM location could present special challenges due to the non-standard nature of the containers in which the birds are kept (e.g., cardboard boxes and gunny sacks) and the proximity of poultry from various vendors.

The Response Plan should be augmented to include guidance for cleaning and disinfecting LBM and other non-traditional locations.



Pigeon, for sale at a livestock auction, is contained in a 'disposable box' that has been made reusable.

View of livestock auction – cages of ducks and chickens surrounded by cardboard boxes containing live birds.

Quarantine and Movement Control. The Response Plan explains that, during an outbreak of a highly contagious FAD such as HPAI, quarantine measures are put into place to prevent or mitigate the spread of disease pathogens. Movement control refers to activities regulating the movement of people, animals, animal products, vehicles, and equipment. It also includes keeping records on these movements as an important tool in the management of a disease outbreak. While the Response Plan includes detailed information about issues, such as declaring a premise to be infected and implementing a permit system to allow movement, the Response Plan is geared toward a farm or rural environment. It does not specifically address the unique challenges that could occur if HPAI were identified in a LBM, to include the high level of foot traffic, potential language difficulties due to the ethnicity of vendors and customers, and the presence of other businesses in the zone of concern. The Response Plan should be augmented to address the potential need for movement control in a metropolitan area, such as at a LBM.

Euthanasia. According to the Response Plan, during an HPAI outbreak euthanasia measures would be implemented to prevent or mitigate pathogen spread. Both carbon dioxide and electrocution are cited as preferred methods for large numbers of birds. However, the instructions for these methods do not seem appropriate to an open urban setting, such as a LBM. Other methods are mentioned, to include injectable euthanasia agents and cervical dislocation, but they are noted to be appropriate only for very small numbers

of birds. The Response Plan should be augmented to address the potential need for euthanasia operations at a LBM or in another populated setting.

Recommendation 4

Prepare and distribute detailed instructions for handling HPAI occurrences in LBM, botanicas, and other "off-farm" environments.

Agency Response.

APHIS is working with its partners in the LBM Working Group, which is comprised of State and industry representatives, to develop further response plans. These plans will address all aspects of response, including cleaning and disinfection, humane euthanasia, quarantine and movement control, and other response areas as needed. Although these efforts rely heavily on State participation, APHIS anticipates that response plans will be in place by December 31, 2006.

On April 27, 2006, APHIS participated in a meeting with poultry industry representatives and a number of States. One outcome from this meeting was a sub-working group that will focus on response efforts in the event of a positive finding of AI. APHIS intends to work closely with this group to address gaps in our response plan and efforts. APHIS is well aware of the need to include non-commercial poultry stakeholders, such as LBMs or botanicas. APHIS' next step includes the establishment of an agreement with the University of Minnesota to continue the work begun at the industry meeting. APHIS anticipates having this agreement in place by June 30, 2006.

OIG Position.

We concur with the agency response for this recommendation and have reached management decision.

Finding 4 Protecting Personnel Involved in HPAI Control and Eradication

According to APHIS VS Memorandum No. 580.18,[14] exposure to infected poultry, feces, respiratory secretions, and contact with contaminated surfaces are thought to result in transmission of HPAI virus to humans and subsequent infection; however, this is a rare occurrence. The Response Plan appropriately established guidance for protecting workers against HPAI. Requirements include receipt of the current season's influenza vaccine (to reduce the possibility of dual infection with HPAI and human influenza) and a daily

[14] VS Memorandum No. 580.18, Policy to Ensure the Protection of Personnel Involved in Highly Pathogenic Avian Influenza Control and Eradication Activities, June 13, 2005.

prophylactic dose of an anti-viral drug. However, APHIS is still developing its understanding of how to ensure worker safety, and the Response Plan does not include details of how workers will obtain the vaccines and anti-virals, where the vaccines are to be stored, how APHIS will get the medications to the worksite, or a point of contact for additional information.

Based on our discussions with APHIS officials, it is anticipated that the Department of Health and Human Services (HHS) will take responsibility for providing, storing, and shipping the necessary vaccines and anti-virals in the event that a culling operation for HPAI takes place. Given the detailed nature of other information included in the Response Plan and the likelihood that medications would be needed quickly, it would be appropriate to include specific information about HHS involvement in the plan and points of contact. Also, APHIS needs to provide detailed procedures for the use of vaccines and anti-virals for workers involved in the culling, transporting, or disposal of HPAI-infected poultry, or an explanation of how and where the medicines will be obtained from HHS.

Recommendation 5

Develop and implement procedures for obtaining and administering the necessary vaccines and anti-virals in the event that a culling operation for HPAI occurs.

Agency Response.

APHIS is seeking collaboration/cooperation with the HHS to have APHIS response personnel included in the Center for Disease Control and Prevention's Strategic National Stockpile response plans as "first responders." The APHIS Occupational Medical Monitoring Program is managed by the Safety, Health, and Employee Wellness Branch, and is administered through an interagency agreement with Federal Occupational Health, an agency of HHS. Within this interagency agreement are provisions for prescribing and distributing the anti-viral medication Tamiflu to APHIS employees as dictated by accepted documentation of a potential or actual exposure to HPAI.

APHIS issued its own internal guidance on protecting employees involved in AI activities. The guidance, APHIS Directive 6800.1, titled "Ensuring The Protection of Employees Involved In Highly Pathogenic Avian Influenza Control and Eradication Activities," dated May 10, 2006, was recently issued on May 16, 2006. On April 14, 2006, APHIS issued preliminary guidance to potential first responders called the "Interim Personal Protective Equipment Plan." This provided field employees with the information they needed to safely respond to HPAI. This guidance included information regarding personal protective equipment, the use of anti-virals medications, and the Agency's plans to provide appropriate equipment in the event of an incident.

OIG Position.

We concur with the agency response for this recommendation and have reached management decision.

Finding 5 Informing the States, Media, and Industry

The Response Plan is based on a response strategy with specific goals and guidelines. The goals and guidelines are generally supplemented by companion documents (also included as part of the Response Plan) that provide specific operational direction. The goal to implement biosecurity procedures within 24 hours of the identification of the index case references a companion document, "Biosecurity." While the overall companion document includes valuable information for a response to an HPAI outbreak, it does not include the detailed information necessary to implement the 24 hour notification guideline established in the response strategy.

The APHIS response strategy provides for each State to set up a notification procedure that informs owners of susceptible animals of the current risk of being infected. Arrangements are to be made with the Farm Service Agency, (FSA) which, according to the strategy, has mailing lists of all producers in the county. However, we confirmed that FSA has not yet designated a person or established a set plan or procedures. The agency understands that if an HPAI outbreak occurs, arrangements will be made, but no work has been done so far. Given the goal to implement biosecurity procedures within 24 hours of an indication of an index case, APHIS should establish procedures before an outbreak occurs.

The "Biosecurity" document in the Response Plan does not identify the roles and responsibilities of the personnel involved in the notification process, specify timeframes for action, or link to the standard operating procedures as set forth in the APHIS AI Response Plan.

APHIS should coordinate with FSA to develop and formalize producer notification procedures, and the protective actions they should take, within 24 hours of the identification of the index case. Additionally, APHIS should ensure that the notification process is clearly linked to the Standard Operating Procedures set forth in the Response Plan.

Recommendation 6

Coordinate with FSA to ensure the availability of updated mailing lists for use in the event of HPAI outbreak.

Agency Response.

APHIS concurs with this recommendation, and agrees to collaborate with the FSA to establish a mechanism to quickly obtain information on producers of susceptible animals in the event of a HPAI outbreak, and to alert them to the current risk of being infected. This notification will also give USDA the opportunity to describe appropriate biosecurity procedures and standards. We anticipate that this mechanism will be in place by the end of the calendar year.

OIG Position.

We concur with the agency response for this recommendation and have reached management decision.

Recommendation 7

Develop and distribute instructions for obtaining notification information from FSA.

Agency Response.

We anticipate sharing this information with Area-Veterinarians-in-Charge, and with Area Emergency Coordinators, once we have worked out the procedures as outlined in Recommendation 6. Thus, in the event on an outbreak, these individuals will be in the best position possible to work with a designated Incident Commander as outlined in the National Animal Health Emergency Management System guidelines and in accordance with the draft HPAI Response Plan Summary published on May 2, 2006.

OIG Position.

We concur with the agency response for this recommendation and have reached management decision.

Recommendation 8

Augment the Response Plan with details of the notification process for States, media, and industry, to include identification of the roles and responsibilities of personnel involved, specific timeframes for action, and linkage to the Standard Operating Procedures set forth in the AI Response Plan.

Agency Response.

APHIS has refined the Interim HPAI Response Plan since the date of this audit report. As part of the revision, dated April 28, 2006, APHIS has included supplemental information in Appendix C that outlines in some detail the process by which USDA will communicate with States, media, and others regarding the establishment of an Incident Command System structure, and Joint Information Centers. This information helps frame the roles and responsibilities of State, local, and Federal entities.

As a result of the April 27, 2006, industry meeting, a specific working group was established to deal with risk communication. APHIS will be continuing to work with the University of Minnesota and poultry industry stakeholders to refine AI-related information sharing, transparency, and processes. We anticipate having an agreement in place with the University of Minnesota by June 30, 2006.

OIG Position.

We concur with the agency response for this recommendation and have reached management decision.

Scope and Methodology

Our review was performed to assess the adequacy of APHIS' procedures to identify the occurrence of AI in domestic poultry in the United States and to limit the impact on the general public and poultry industry. Our review covered APHIS initiatives to address AI in fiscal years 2005, and 2006, and activity from prior years as needed.

To accomplish our audit objectives, we:

- Interviewed APHIS officials at the APHIS Headquarters in Washington, D.C., and Riverdale, Maryland, eastern and western regional offices, and area offices in North Carolina, Pennsylvania, and New York. Additionally, we interviewed an official of APHIS' National Center for Animal Health Surveillance in Fort Collins, Colorado, and interviewed personnel of the APHIS' NVSL in Ames, Iowa.

- Reviewed AI background information, standards, and disease status reports from other subject matter experts such as the World Health Organization, the OIE, and the Agricultural Research Service.

- Visited State Departments of Agriculture in North Carolina, Pennsylvania, and New York, and contacted State officials in Wisconsin and Nebraska by phone to obtain information on State AI surveillance operations, State statutes, regulations, and policies. We judgmentally selected States and respective area offices based on significant poultry production and LBM activity.

- Visited a live bird auction in Maryland.

- Analyzed laws, policies and regulations and data obtained from APHIS and the States regarding AI surveillance, testing, and outbreak responses.

- Assessed industry, State, and APHIS actions when potential disease occurrences were identified during AI testing.

- Attended the LBM Working Group meeting.

- Obtained and analyzed AI testing results from NVSL.

- Analyzed APHIS Review of Existing AI Surveillance and Surveillance Gaps.

Audit fieldwork was performed from April 2005 through March 2006. The audit was conducted in accordance with Generally Accepted Government Auditing Standards.

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Washington, DC 20250

TO: Robert W. Young
Assistant Inspector General for Audit

FROM: W. Ron DeHaven
Administrator

DEC 2 1 2005

SUBJECT: Animal and Plant Health Inspection Service (APHIS)
Response to the Office of Inspector General's Management Alert, APHIS' Oversight of Avian Influenza (33099-11-Hy(1))

APHIS has reviewed the above Management Alert on Avian Influenza (AI), and appreciates this review conducted by Office of the Inspector General (OIG). APHIS accepts the three recommendations listed in the Management Alert. In fact, these are actions which APHIS has intended to complete and that are currently in process. Before discussing our corrective actions taken or planned in response to the three recommendations, we would like to provide a brief overview of the substantial efforts APHIS has already devoted to AI surveillance.

The low pathogenicity AI (LPAI) programs and the National Animal Health Surveillance System (NAHSS) are under development and were only recently funded. During the past 18 months, APHIS has:

1. Hired personnel to begin these programs at headquarters and in the field (to date, we have hired 4 Veterinary Medical Officers, 10 Animal Health Technicians, 1 Investigative and Enforcement Services specialist, and 1 administrative assistant).
2. Partnered with States and the poultry industry through cooperative agreements which fund expansion of their AI surveillance activities;
3. Implemented a Steering Committee that has developed a general NAHSS approach for all species;
4. Obtained industry and state approval and support for and drafted regulations to implement commercial poultry AI surveillance; and
5. Published and implemented uniform state standards for AI surveillance and control in live bird marketing systems, resulting in a significant reduction in the prevalence of LPAI in the Northeast live bird marketing system.

In short, our approach has been to bolster AI surveillance and control in the most important areas first, in accordance with the direction received with our funding, and then to identify additional surveillance needs. Therefore, we believe that OIG's characterization of our approach to surveillance as "not comprehensive" with "fragmented sampling" misrepresents our efforts to date. APHIS recognizes, and OIG acknowledges, that APHIS alone does not maintain or have access to all AI surveillance

data, nor are we the only organization with authority to conduct AI surveillance. Thus, it will take significant developmental efforts and multi-jurisdictional cooperation to establish a comprehensive, integrated system of AI surveillance for the United States. We are working to achieve this vision as rapidly as funding allows. While APHIS is working diligently to establish a more comprehensive system, we are also thoroughly evaluating the current system to target areas for improvement. With the additional funding outlined in the President's supplemental AI package, APHIS will continue to enhance the current system and will work quickly and effectively toward the comprehensive approach that is needed.

We agree with OIG's conclusion that APHIS has not always documented in the Emergency Management Response System (EMRS) resolution of potential instances of foreign animal disease. It is important to recognize that EMRS was implemented only a year ago in 2004; and since then, we have made significant progress in optimizing the system's use. Through Veterinary Services' (VS) established policy Memorandum 580.4, which establishes EMRS case reporting and closing procedures, APHIS will continue to ensure EMRS is consistently used. We are continuing to develop and implement further quality control mechanisms.

APHIS provides the following responses to the recommendations:

Recommendations 1 and 2: (1) Develop and implement a comprehensive AI surveillance plan to include goals and objectives, case definitions, data collection, and analysis methodologies, reporting of surveillance results, and assessment of surveillance program, and (2) Perform and document an analysis identifying gaps in sampling surveillance, and assessing risk as a basis for determining the need for additional sampling, or documenting the basis for any decision not to sample a portion of the population.

Extensive surveillance for AI viruses continues in the United States within multiple federal, state and industry led programs. However, coordination among programs is not optimal. This is reflected in the inability to aggregate and compile surveillance data for AI viruses and other poultry diseases (this, in turn, inhibits the flow of valuable information to animal health decision makers at all levels). The National Animal Health Surveillance Strategic plan states that:

> *The transition from current surveillance activities to a comprehensive, coordinated and integrated NAHSS will require institutional and cultural changes in both Veterinary Services and the animal health community. Movement must be made from conducting compartmentalized surveillance efforts surrounding one disease, to viewing animal disease surveillance as an overall system. This complex undertaking will require development and integration of many activities and partnerships. New methods and approaches need to be designed, evaluated and implemented.*

VS has established a planning committee for the development of a national plan for poultry disease surveillance. This planning committee includes representatives from industry, laboratories, and state and federal animal health officials. AI surveillance will be a key

component of this plan but will not stand alone. A tentative strategy for developing the comprehensive plan including a timeline for completion is discussed below.

Inventory of current surveillance systems

The National Surveillance Unit maintains an inventory of current surveillance initiatives and programs throughout the United States including federal and state level programs. The completeness of this inventory relative to poultry health surveillance will be reviewed and evaluated; and where necessary, additional poultry health surveillance components will be added. The projected completion of this is January 31, 2006.

Identification of gaps in current systems

Review of the inventory evaluation findings will be discussed by the planning team in January 2006 at the International Poultry Exposition. At this meeting, specific objectives for comprehensive poultry disease surveillance will be established. In addition, surveillance and data integration gaps will also be discussed. Gaps may be geographic, by commodity sector or by disease. This process will include a prioritization of the surveillance objectives identified. The projected completed date is March 31, 2006.

Evaluation of Avian Influenza component of Comprehensive Poultry Surveillance System

Surveillance system evaluation is the systematic collection and review of information about a surveillance system undertaken for the purpose of assessing the extent to which the system fulfills its stated objectives and meets accepted surveillance standards. The evaluation process identifies program strengths and areas for improvement, and the evaluation findings are intended to facilitate the system's development, to better integrate the system into a coordinated and integrated NAHSS, and to understand the system's contributions relative to the VS Strategic Plan. As part of the surveillance planning process, an evaluation of current poultry surveillance components will be conducted. The projected completion date is July 31, 2006.

First draft surveillance plan – Avian Influenza component

The National Surveillance Unit is developing standards for the design of surveillance systems within Veterinary Services and will publish these standards early in 2006. Standards and guidelines for the construction and operation of a surveillance system will assist surveillance planners and managers in considering specific objectives, design strategies, reporting systems, implementation methods, and long-term maintenance of the system. These guidelines ensure that consideration is given to the collection, organization, and analysis of data before the surveillance is implemented and that the objectives of the system are predefined. Further, they allow for review and evaluation of the surveillance to assure that it is providing the type and quality of information it was designed to achieve. Following these standards, a National Avian Influenza Surveillance System (to include Federal and non-federal surveillance components) will be designed as a component of comprehensive poultry disease surveillance. The projected completion date is October 31, 2006.

AI Data Management

Surveillance systems of the twenty-first century are increasingly dependent on the storage of massive quantities of information with a need for quick and efficient accessibility of the information. Utilization of data is complicated by its storage in multiple databases, which may be administered by groups spanning Federal and State governments as well as industry and other non-government organizations. A web-based data management system is currently under development for the National Poultry Improvement Plan. This system, in conjunction with other systems under development, will result in an overall Avian Health Data Management system. This system will be a component of an integrated, comprehensive data warehouse/factory facilitating all surveillance streams to be centralized for data analysis and reporting. The projected completion completion date is December 31, 2006 for the NPIP system, and June 30, 2007 for the overall system.

Recommendations 3: Review the EMRS database and ensure resolution of all cases where a potential diagnosis of a foreign animal disease has not been resolved within an appropriate amount of time.

Again, APHIS agrees with, and is already working to implement, this recommendation. EMRS has only been fully implemented since 2004; since then, we have made steady improvements in its use and our ability to document and track cases of potential foreign animal disease. OIG noted that 46 potential avian foreign animal diseases cases were unresolved. All of those cases have been successfully resolved. Further, 19 of the 46 unresolved cases were entered into EMRS prior to the system's full implementation. Additionally, through our own trouble-shooting and quality control research, we determined that an additional 24 of those 46 cases were directly attributable to problems in just one of our more than 40 Area offices. Since this discovery, management has implemented the use of EMRS in that Area office, and the Area office has demonstrated compliance.

Since 2005, the VS Regions, the Center for Epidemiology and Animal Health, and the Emergency Management staff have collaborated closely to share reports on documentation issues that need improvement. Our focus is on better education of all EMRS users, and careful and thorough resolution of all FY05 EMRS documentation deficiencies.

Our quality control is further strengthened by the fact that the Regional offices regularly run and examine EMRS reports. Both offices are committed to preventing mistakes. Finally, VS Memorandum 580.4 functions as standing policy that provides uniform direction to all EMRS users. Emergency Management Staff, in conjunction with Regional management, will continue to ensure that the procedures in that memorandum are followed. We expect that close management, training, and quality control will continue to improve EMRS.

USDA

United States Department of Agriculture

Animal and Plant Health Inspection Service

Washington, DC 20250

MEMORANDUM

TO: Robert W. Young
Assistant Inspector General for Audit
Office of the Inspector General

FROM: W. Ron DeHaven
Administrator
Kevin Shea for JUN 0 1 2006

SUBJECT: APHIS Response to OIG Report, Oversight of Avian Influenza (33009-11-HY)

The Animal and Plant Health Inspection Service (APHIS) would like to thank you for the opportunity to provide comments on this report. Overall, APHIS believes this audit, which began on April 18, 2005, presents an accurate and realistic picture of APHIS' capabilities at the time the review was being conducted. This audit was performed prior to the avian influenza (AI) supplemental funding allocated by Congress to APHIS in fiscal year 2006. This supplemental funding is currently being used to enhance three domestic APHIS programs: surveillance and diagnostics, preparedness and response, and wild bird surveillance. A portion of this funding is also being used to fund international efforts which would ultimately help prevent the spread of HPAI into the United States.

Recommendation 1: Develop and implement a comprehensive AI surveillance plan to include goals and objectives, case definitions, data collection and analysis methodologies, reporting of surveillance results, and assessment of surveillance program.

APHIS agrees with this recommendation and is working to achieve this goal. The AI supplemental funding is being used to promote collaboration between our State and industry partners in order to rapidly detect and respond to disease. Specific examples of such cooperation and outreach include:

- The National Surveillance Unit (NSU), which is part of APHIS' Veterinary Services (VS) division, is drafting an AI surveillance plan that will include all of the components suggested in OIG's recommendation. The first version of the prospective surveillance standards is now completed and under review. The final version of these standards will be used to complete the comprehensive surveillance plan. APHIS intends to have a draft of this plan available by June 30, 2006.

- Any State, university, or industry laboratory that receives a positive result on an AI screening test, whether through the National Poultry Improvement Plan (NPIP)

program, the various State surveillance programs, or through passive surveillance, must submit samples to the National Veterinary Services Laboratories (NVSL) for confirmation and additional tests to determine subtype and pathogenicity. The NVSL is the only AI confirmatory laboratory in the United States. As a result, all notifiable AI positive samples come under Federal control and are then reported to the World Organization for Animal Health (OIE).

- APHIS has developed new regulations to enhance the NPIP that incorporate existing State and industry testing programs for AI. The interim rule has been submitted for clearance as required under the Administrative Procedures Act and is progressing through the U.S. Department of Agriculture (USDA) clearance process. APHIS expects this rule to be cleared and published in the Federal Register by September 1, 2006.

- APHIS is engaged in efforts to augment surveillance of live bird markets (LBMs) and backyard flocks. APHIS also plans to survey upland game and waterfowl birds raised for release and enhance existing surveillance of auctions, sales, swap meets, flea markets, and public exhibitions. Funds will be used to create new cooperative agreements with additional States in both the eastern and western regions that have significant live bird marketing systems (LBMS) and other non-commercial poultry activities, and State laboratories participating in the NPIP low pathogenic AI (LPAI) program. We anticipate that the cooperative agreements for surveillance will be in place by September 30, 2006. NVSL will provide support to approved laboratories for the processing of samples submitted from the wildlife, commercial, and LBM segments of the HPAI surveillance program.

- APHIS has been expanding its "Biosecurity for the Birds" educational outreach program to promote best practices in both the LBMS and backyard flock owners. New veterinary medical officers (VMOs) have been trained to recognize AI and to promote biosecurity practices in LBMs, auctions, wholesalers, distributors, dealers, and producer facilities. These practices have been in progress since September 2005 and will continue as new VMOs and Animal Health Technicians are hired.

Recommendation 2: Perform and document an analysis identifying gaps in sampling surveillance, and assessing risk as a basis for determining the need for additional sampling, or documenting the basis for any decision not to sample a portion of the population.

APHIS agrees with this recommendation and is working to achieve this goal. APHIS recently conducted a gap analysis to better understand remaining issues and what actions need to occur. The surveillance standards that are currently under development by the NSU will address these issues. These standards are currently under review and we anticipate a draft by June 30, 2006. This activity links to APHIS' actions regarding Recommendation #1 regarding the surveillance plan. We have enclosed documents related to the gap analysis:

Review of Existing Avian Influenza Surveillance, and Active Sentinel Flock Surveillance for the Early Detection of Asian H5N1 HPAI Guidelines for Developing Surveillance Plans.

Recommendation 3: Review the Emergency Management Reporting System (EMRS) database and ensure resolution of all cases where a potential diagnosis of a foreign animal disease (FAD) has not been resolved within an appropriate period of time.

As presented in our December 21, 2005 response to OIG, VS continues to follow VS Memo 580.4, dated March 30, 2004, in resolving all potential FAD diagnoses within appropriate periods of time. The Western and Eastern Regional Emergency Managers each have identified regional epidemiologists responsible for reviewing all FAD investigations documented in the EMRS FAD investigation database for their Regions. This ensures timely documentation of the resolution and closure of all the investigations, includes all potential incidents of HPAI.

Recommendation 4: Prepare and distribute detailed instructions for handling HPAI occurrences in LBMs, botanicas, and other "off-farm" environments.

APHIS has undertaken several internal and external actions to inform entities on the handling of HPAI occurrences. As previously mentioned, APHIS has a public information and educational outreach campaign called "Biosecurity for the Birds." This campaign educates bird owners about biosecurity and provides tips on how to recognize certain diseases (in particular AI). A key component of this campaign involves biosecurity tips, such as six ways to prevent poultry disease. The campaign, currently available via the Internet, instructs persons to report sick or dead birds through a toll-free number. USDA works closely with the State departments of agriculture, USDA's Cooperative Extension Service, and private veterinarians to educate animal owners about biosecurity practices. While this campaign is currently directed at backyard flock owners APHIS also directs it to related 'non-farm' environments.

APHIS is also working closely with the American Zoo and Aquarium Association (AZA) to develop guidelines to handle HPAI occurrences in non-farm environments such as zoos and other 'specialty' bird raising facilities.

APHIS continues to enhance guidance and reporting mechanisms for both its LPAI and HPAI programs, due to the increased interest in H5/H7 findings regardless of pathogenicity. With regard to LBMs, guidelines for handling H5 or H7 confirmed positives have been developed and distributed through the LPAI program. These guidelines include provisions for bioscecurity practices, testing, and notification and reporting guidelines.

APHIS is working with its partners in the LBM Working Group, which is comprised of State and industry representatives, to develop further response plans. These plans will address all aspects of response, including cleaning and disinfection, humane euthanasia, quarantine and movement control, and other response areas as needed. Although these efforts rely heavily

on State participation, APHIS anticipates that response plans will be in place by December 31, 2006.

On April 27, 2006, APHIS participated in a meeting with poultry industry representatives and a number of States. One outcome from this meeting was a sub-working group that will focus on response efforts in the event of a positive finding of AI. APHIS intends to work closely with this group to address gaps in our response plan and efforts. APHIS is well aware of the need to include non-commercial poultry stakeholders, such as LBMs or botanicas. Our next step includes the establishment of an agreement with the University of Minnesota to continue the work begun at the industry meeting. APHIS anticipates having this agreement in place by June 30, 2006.

Recommendation 5: Develop and implement procedures for obtaining and administering the necessary vaccines and anti-virals in the event that a culling operation for HPAI occurs.

APHIS is seeking collaboration/cooperation with the U.S. Department of Health and Human Services (HHS) to have APHIS response personnel included in the Center for Disease Control and Prevention's (CDC) Strategic National Stockpile response plans as "first responders." The APHIS Occupational Medical Monitoring Program is managed by the Safety, Health, and Employee Wellness Branch, and is administered through an interagency agreement with Federal Occupational Health (FOH), an agency of HHS. Within this interagency agreement are provisions for prescribing and distributing the anti-viral medication Tamiflu to APHIS employees as dictated by accepted documentation of a potential or actual exposure to HPAI. In addition, we have recently received U.S. Department of Labor Occupational Safety and Health Organization (OSHA) guidance updates titled "Protecting Workers from Avian Flu (Avian Influenza) Viruses," and at the request of the Office of Management and Budget, APHIS provided comment on the guidance.

APHIS issued its own internal guidance on protecting employees involved in AI activities. The guidance, APHIS Directive 6800.1, titled "Ensuring The Protection of Employees Involved In Highly Pathogenic Avian Influenza Control and Eradication Activities," dated May 10, 2006, was recently issued on May 16, 2006. This directive, which was developed based on CDC and OSHA guidance, is available on the APHIS website. On April 14, 2006, APHIS issued preliminary guidance to potential first responders called the "Interim Personal Protective Equipment Plan." This provided field employees with the information they needed to safely respond to HPAI. This guidance included information regarding personal protective equipment, the use of anti-virals medications, and the Agency's plans to provide appropriate equipment in the event of an incident. We have enclosed the May 10, 2006 and April 14, 2006 guidelines for your review.

Recommendation 6: Coordinate with FSA to ensure the availability of updated mailing lists for use in the event of an HPAI outbreak.

APHIS concurs with this recommendation, and agrees to collaborate with the Farm Service Agency (FSA) to establish a mechanism to quickly obtain information on producers of susceptible animals in the event of an HPAI outbreak, and to alert them to the current risk of being infected. This notification will also give USDA the opportunity to describe appropriate biosecurity procedures and standards. APHIS has made preliminary contact with FSA, and the two agencies will continue substantive discussions to ensure that there is a collective understanding of how both can best work together in the event of an outbreak. We anticipate that this mechanism will be in place by the end of the calendar year.

Recommendation 7: Develop and distribute instructions for obtaining notification information from FSA.

We anticipate sharing this information with Area-Veterinarians-in-Charge, and with Area Emergency Coordinators, once we have worked out the procedures as outlined in Recommendation 6. Thus, in the event on an outbreak, these individuals will be in the best position possible to work with a designated Incident Commander as outlined in the National Animal Health Emergency Management System guidelines and in accordance with the draft HPAI Response Plan Summary published on May 2, 2006. This will be a very important component of the Incident Command System (ICS) structure and responsibility, and FSA information will play a vital role.

Recommendation 8: Augment the AI Response Plan with details of the notification process for States, media, and industry to include identification of the roles and responsibilities of personnel involved, specific time frames for action, and the linkages to the standard operating procedures set forth in the AI Response Plan.

APHIS has refined the Interim HPAI Response Plan since the date of this audit report. As part of the revision, dated April 28, 2006, APHIS has included supplemental information in Appendix C that outlines in some detail the process by which USDA will communicate with States, media, and others regarding the establishment of an ICS structure, and Joint Information Centers. This information helps frame the roles and responsibilities of State, local, and Federal entities.

As a result of the April 27, 2006, industry meeting, a specific working group was established to deal with risk communication. APHIS will be continuing to work with the University of Minnesota and poultry industry stakeholders to refine AI-related information sharing, transparency, and processes. We anticipate having an agreement in place with the University of Minnesota by June 30, 2006.