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Northeast Region

Audit Report

USDA'S Implementation of the National Strategy for Pandemic Influenza

Report No.33701-01-Hy
January 2008



UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

January 15, 2008

REPLY TO

ATTN OF: 33701-01-HY

TO: Cindy J. Smith
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: U. S. Department of Agriculture's (USDA) Implementation of the National Strategy for Pandemic Influenza

This report presents the results of our audit concerning USDA's implementation of the National Strategy for Pandemic Influenza. Your response to the official draft, dated December 20, 2007, is included as Exhibit D. Excerpts of your response and the Office of Inspector General's (OIG) position are incorporated into the Findings and Recommendations section of the report. Based on your response, we were able to reach management decision on 8 of the report's 10 recommendations. Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer. Management decision for Recommendations 4 and 10 can be reached once you have provided us with the additional information outlined in the report section, OIG Position.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the planned corrective action and timeframe for implementing Recommendations 4 and 10. Please note that the regulation requires management decision to be reached on all findings and recommendations within 6 months of report issuance.

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

Executive Summary

USDA's Implementation of the National Strategy for Pandemic Influenza (Audit Report No. 33701-01-Hy)

Results in Brief

On November 1, 2005, the President of the United States announced the National Strategy for Pandemic Influenza (Strategy), a comprehensive approach to addressing the threat of pandemic influenza.¹ Building upon the Strategy, the Homeland Security Council (HSC), advisors to the President, released the Implementation Plan of the National Strategy for Pandemic Influenza (Plan) in May 2006. The Plan included over 300 tasks that were designed to ensure that the Federal Government, along with State and local partners, continue to prepare for a possible outbreak in the United States. It assigned the Department of Agriculture (USDA) the responsibility for completing 98 of these tasks.

The Secretary of Agriculture assigned the Under Secretary for Marketing and Regulatory Programs the responsibility for ensuring tasks were effectively performed. The Under Secretary appointed a facilitator to compile and convey the status of USDA's progress to HSC. Each task was given a measure of performance that was to be completed by a specific date. The measures of performance required USDA to implement and/or revise procedures and coordinate with other Federal agencies to prepare for a possible pandemic.

The 98 tasks were divided into 57 lead² and 41 support³ tasks. The support tasks necessitate periodically collaborating with other Federal agencies and addressing what is requested by the lead agency. Of the 98 tasks, we reviewed 55 that were to be completed by February 2007, which included 26 lead tasks and 29 support tasks. We examined whether USDA had adequately implemented the actions (lead and support tasks) required by the Plan. We also followed up on the status of corrective actions to recommendations made in our previous audit, Oversight of Avian Influenza (Audit Report No. 33099-11-Hy), issued in June 2006.

We found that USDA has made significant progress in developing or revising policies and procedures to detect, contain, and eradicate highly pathogenic avian influenza (HPAI). For example:

- The Animal and Plant Health Inspection Service (APHIS) helped to develop an interagency response playbook⁴ that detailed step-by-step

¹ A pandemic is a global disease outbreak.

² The lead agencies are responsible for coordinating with the supporting agencies and implementing the tasks according to the measures of performance specific to each lead task.

³ Support agencies are not responsible for ensuring that the support tasks are completed but are to coordinate and collaborate with the lead agency.

⁴ The Interagency Playbook for Domestic Response to a Detection of HPAI H5N1 in Birds, dated August 2006.

actions that Federal agencies should take in response to an HPAI outbreak.

- APHIS revised the Summary of the National HPAI Response Plan to help Federal, State, local, and private entities respond rapidly.
- APHIS implemented a “Biosecurity for the Birds” program to provide, among other things, surveillance of backyard birds.
- USDA’s Office of Communications developed and distributed pre-scripted risk communication messages about HPAI.
- APHIS expanded its avian influenza indemnification regulation to include compensation for losses incurred due to infections of low pathogenic strains of H5 and H7 because of their potential to mutate to HPAI.
- USDA has collaborated with other Federal agencies and the private sector to prepare for, detect, and respond to a pandemic.

According to the HSC, USDA met the measures of performance for all the tasks completed through May 2007. We found that USDA took action on each lead task we reviewed; however, it did not institute adequate management controls to ensure readiness in the event of an outbreak. Also, USDA did not correctly report the status of two major APHIS functions to the HSC.

- APHIS has not yet implemented its ePermit system, a web-based system that would allow it to rapidly issue, track, and verify the validity of import permits for live avian species or products. Currently, only a manual import permit process exists. APHIS inaccurately reported to the HSC that permits for high risk importers can be withdrawn electronically. According to an APHIS official, permits can be timely withdrawn with the manual system; however, this has not been tested.
- APHIS also inaccurately reported the status of its actions to stockpile emergency response protective equipment. APHIS reported that it stockpiled enough personal protective equipment in strategic locations to protect workers. However, the equipment has been stockpiled at one location, not in multiple locations, as reported to the HSC.

These reporting errors occurred because USDA did not implement adequate management controls, such as second-party reviews of lead tasks. In addition, 4 of the 29 support tasks were not assigned to the correct APHIS official who could ensure the tasks were properly completed or who had the authority to commit resources. This occurred because USDA did not monitor the

responsiveness to the support tasks. As a result, there is reduced assurance that USDA can respond at the time of an outbreak, to the extent reported to the HSC.

We also found that USDA did not test newly developed procedures or assess and evaluate the revised procedures to ensure they worked as designed. USDA reported that it had completed all 26 lead tasks that were due through February 2007 (see Exhibit A). However, we determined that the processes and procedures related to 14 of the 26 tasks had not been tested. Of these 14 tasks, 10 related to APHIS procedures; 2 were associated with the Office of Communications; and 1 each related to Agricultural Research Service and Food Safety and Inspection Service procedures.

For example, APHIS did not update its website to notify stakeholders within 24 hours of a confirmed outbreak, which highlights the potential gap between reported accomplishments and actual achievements for the untested tasks. The Plan did not require USDA to test the measures of performance to ensure they worked as designed; thus, USDA did not require agencies (i.e., APHIS) to test their procedures. However, APHIS' own guidelines require testing of its policies and procedures by participating in realistic exercises. Because this testing was not done, USDA lacks assurance that policies, procedures, and plans developed or revised in response to the Plan will work as designed in the event of an outbreak.

In addition, APHIS did not fully implement two of the eight recommendations from our prior report, Oversight of Avian Influenza (Audit Report No. 33099-11-Hy, issued June 2006), as of September 2007. The recommendations were intended to strengthen APHIS' ability to respond to an avian influenza outbreak. APHIS agreed to implement the corrective actions no later than December 2006. Our recommendations addressed such matters as coordinating with States and obtaining their response plans, and revising APHIS' Response Plan (see Exhibit C). Although APHIS has taken strides to implement the corrective actions, it has not been able to finalize their Response Plan or agreements with State level authorities. This occurred because APHIS did not assign a program official with the responsibility to finalize corrective actions addressed in our prior report. As a result, APHIS has reduced assurance that it will be able to timely and effectively respond in the event of an outbreak.

According to USDA officials and information reported from the HSC, 90 percent of over 300 actions in the Plan have been completed. The remaining actions are in progress and are expected to be completed by the 18-month mark.

**Recommendations
In Brief**

In order to ensure USDA's readiness to respond to a pandemic, USDA should establish a control mechanism to accurately report information on assigned tasks, provide HSC with corrected information for the inaccurately reported tasks, and monitor support tasks and coordinate with HSC. In addition, USDA needs to develop plans for testing the tasks that have not been tested and formalize procedures to update its notification website. Further, APHIS needs to immediately assign responsibility to finalize corrective actions set forth in our prior report.

Agency Response

APHIS agreed with the recommendations in the report. We have incorporated APHIS' response into the Findings and Recommendation section of the report. The response to the draft report, dated December 20, 2007, is included as Exhibit D (we did not include the attachment APHIS included with its response because it contained phone numbers and email addresses).

OIG Position

Based on APHIS' response, we were able to reach management decision on 8 of the report's 10 recommendations. We were not able to reach management decision on recommendations 4 and 10. APHIS will need to provide the additional information outlined in the OIG position section of the report, in order to reach management decision on these recommendations.

Abbreviations Used in This Report

APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
DHS	Department of Homeland Security
DOI	Department of Interior
END	Exotic Newcastle Disease
FAD	Foreign Animal Disease
FAS	Foreign Agricultural Service
FSA	Farm Service Agency
FSIS	Food Safety and Inspection Service
GAO	Government Accountability Office
HPAI	Highly Pathogenic Avian Influenza
HHS	Department of Health and Human Services
HSC	Homeland Security Council
LBM	Live-bird Market
LPAI	Low Pathogenic Avian Influenza
NVS	National Veterinary Stockpile
OC	Office of Communications
OCFO	Office of the Chief Financial Officer
OIG	Office of Inspector General
Plan	Homeland Security Council's Implementation Plan for the National Strategy for Pandemic Influenza
PPE	Personal Protective Equipment
Secretary	Secretary of Agriculture
Strategy	National Strategy for Pandemic Influenza
Under Secretary	Under Secretary for Marketing and Regulatory Programs
U.S.	United States
USDA	U.S. Department of Agriculture
VS	Veterinary Services
WHO	World Health Organization

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Background and Objectives

Background

The previous three pandemics of the influenza virus killed approximately 43 million people worldwide. The current pandemic threat stems from an unprecedented outbreak of avian influenza in Asia and Europe, caused by the H5N1⁵ strain of the influenza A virus.⁶ There are two potential routes for human infection. The first route is direct infection, whereby the virus passes from poultry to humans. Since 2003, highly pathogenic avian influenza (HPAI) has infected 328 people in 12 countries, resulting in 200 deaths.⁷ A second route, of even greater concern, occurs if the virus changes (mutates) into a form that is highly infectious to humans and spreads easily from human to human. Currently, the virus has not mutated into this form.

In response to the growing threat, the President issued the National Strategy for Pandemic Influenza (Strategy) on November 1, 2005. The Strategy outlined the following pillars to address the threat of a pandemic influenza: (1) preparedness and communication; (2) surveillance and detection; and (3) response and containment. The Strategy assigns responsibility across all levels of government and all segments of the public. The Strategy identified four departments that would lead this assignment:

- Department of Homeland Security (DHS), for the overall domestic incident management and Federal coordination;
- Department of Agriculture (USDA) for veterinary response;⁸
- Department of Health and Human Services for medical response; and
- Department of State for international activities.

Each Federal agency is responsible for coordinating all efforts within its authorized mission area and developing plans to implement this Strategy.

In October 2001, the Homeland Security Presidential Directive-1 was issued to communicate Presidential decisions about homeland security policies in the United States. The Homeland Security Council (HSC) is responsible for advising and assisting the President with respect to all aspects of homeland

⁵ According to World Health Organization (WHO), only viruses of the H5 and H7 subtypes are known to cause HPAI. However, not all H5 and H7 viruses are highly pathogenic.

⁶ According to WHO, influenza viruses are grouped into three types, designated A, B, and C. Influenza A and B viruses are of concern for human health. Only influenza A viruses can cause pandemics.

⁷ WHO data as of September 10, 2007.

⁸ The Animal Health Protection Act authorizes the Secretary to prevent, protect, control, and eradicate diseases and pests of animals such as animal influenza in order to protect animal health, the health and welfare of people, and the Nation's economic interests.

security and coordinating activities among executive departments and agencies.

To implement the Strategy, the HSC released the Implementation Plan for the National Strategy for Pandemic Influenza (Plan) on May 3, 2006. It provides the principles and objectives for pandemic preparedness. The Plan further translates the Strategy into more than 300 critical tasks along with measures of performance to ensure that the Federal Government, along with State and local partners, continues to prepare for an outbreak and a possible human influenza pandemic. These tasks were to be implemented by specific dates ranging from August 1, 2006 through May 1, 2009.

The Secretary of Agriculture (Secretary) is responsible for coordinating the veterinary response to a domestic animal outbreak of a pandemic virus and ongoing surveillance in domestic animals and animal products as outlined in the Plan. HSC assigned 98 tasks⁹ (57 lead tasks and 41 support tasks) in the Plan to USDA. The lead agencies are responsible for coordinating with the supporting agencies and implementing the tasks according to the performance measures specific to each lead task. Support agencies are not responsible for ensuring that the support tasks are completed but are to coordinate and collaborate with the lead agency.

The Secretary assigned the Under Secretary for Marketing and Regulatory Programs (Under Secretary) the responsibility of ensuring that all 98 tasks were effectively performed. The Under Secretary appointed a facilitator to compile and convey the status of USDA's progress to the HSC. The Animal Plant and Health Inspection Service (APHIS) is the primary USDA agency that protects the Nation's animal health from disease; therefore, it was assigned the majority of the tasks. Other USDA agencies involved in this effort included:

- Foreign Agricultural Service (FAS),
- Agricultural Research Service (ARS),
- Food Safety and Inspection Service (FSIS), and
- Office of Communications (OC).

As the agency officials completed and summarized their work, they explained how their efforts addressed the performance measures defined in the Plan for each task. This information is captured in QuickPlace, a central, web-based repository that is accessible by authorized users. USDA's facilitator then

⁹ Throughout, we refer to the Plan's requirements for USDA as lead and support agency as tasks rather than actions in order to avoid confusion between what APHIS was asked to do (task) and what APHIS did (action).

forwarded updates to HSC. HSC reviewed the information to determine if the tasks were timely completed and if the tasks addressed the performance measures.

In June 2006, we issued an audit report on the Oversight of Avian Influenza (Audit Report No. 33099-11-Hy). The objective of the prior audit was to assess the adequacy of APHIS' activities to identify the occurrence of avian influenza and limit its impact on public health and the poultry industry. In this report, we concluded that APHIS had made commendable progress in developing plans and establishing the networks necessary to prepare for and respond to outbreaks of avian influenza.

We recommended that APHIS develop and implement a comprehensive avian influenza 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. We also recommended that APHIS revise the Response Plan to include detailed instructions for (1) handling HPAI occurrences in live-bird market (LBM) systems and other "off-farm" environments, (2) obtaining and administering vaccines and antivirals to people in the event of a culling operation, and (3) coordinating with the Farm Service Agency (FSA) and the States to develop and formalize producer notification and action procedures if an outbreak of avian influenza occurs.

During the course of this audit, we coordinated with the Government Accountability Office (GAO) because it was also conducting a review related to the Plan. GAO notified us that it would be conducting several audits in this area involving USDA. GAO further specified it would be assessing USDA's efforts in addressing 12 of the 98 tasks assigned to USDA (see Exhibit B). Therefore, we eliminated these tasks from the scope of our review to avoid duplication. In June 2007, GAO reported that USDA has taken important steps to prepare for outbreaks, but better planning could improve response. GAO recommended that USDA and DHS develop a memorandum of understanding to clarify their roles during certain emergencies, and that USDA take several steps to improve its planning and that of the States.¹⁰

Objectives

Our overall objective was to examine whether APHIS had adequately implemented the actions (lead and support tasks) required by the Plan. Specifically, we determined whether APHIS took the necessary steps to fulfill its roles and responsibilities and implemented these tasks within the prescribed timeframe. We also followed up on corrective actions to recommendations in our previous audit, Oversight of Avian Influenza (Audit Report No. 33099-11-Hy), issued in June 2006.

¹⁰ Avian Influenza – USDA Has Taken Important Steps to Prepare for Outbreaks but Better Planning Could Improve Response (GAO-07-652).

Findings and Recommendations

Section 1 Management Controls to Ensure Readiness

The Strategy outlined how Federal agencies should prepare for and respond to a potential pandemic. USDA is responsible for coordinating all efforts within its authorized mission and developing plans to implement this Strategy for veterinary response issues. The Plan identified the critical steps that must be taken immediately and over the coming months and years to address the threat of an influenza pandemic.

USDA developed or revised policies and procedures to detect, contain, and eradicate HPAI in carrying out its part of the Plan. For example, APHIS helped to develop the interagency response playbook that detailed step-by-step actions that Federal agencies should take in response to an outbreak. In addition, APHIS revised its Summary of the HPAI National Response Plan to help Federal, State, local, and private entities respond rapidly should an outbreak occur in the United States. APHIS revised its guidance on protecting backyard flocks and preventing poultry infection. According to the HSC, USDA met the measures of performance for all tasks completed through May 2007, based on the information USDA reported.

We reviewed 55 tasks that were scheduled to be completed by February 2007. This included 26 tasks led by USDA (see Exhibit A) and 29 tasks in which USDA had a supporting role. The information USDA reported to HSC on these tasks in February 2007, was the same as the information reported in May 2007.

USDA took action on each lead task we reviewed; however, it did not institute adequate management controls to ensure readiness in the event of an outbreak. Specifically, USDA reported progress on lead tasks to HSC without verifying that the descriptions were accurate and assigned support tasks without maintaining oversight. USDA had not instituted an adequate tracking system for the 29 support tasks. In addition, USDA had no plans to test 14 of the 26 lead tasks (see Exhibit A) to verify that they worked as designed because, according to USDA officials, the Plan did not require the tasks to be tested. As a result, APHIS has reduced assurance of its readiness to respond to an outbreak.

An outbreak of HPAI could have serious economic and health impacts. The United States is one of the world's largest producers of eggs and poultry meat, valued at \$4.39 and \$22.45 billion, respectively. The U. S. exports approximately 10 percent of the poultry meat that is produced. Foreign trading partners could impose a ban on U.S. exports of poultry products if an

outbreak occurred. In addition, an outbreak increases the opportunity for a disease to spread and possibly mutate into a pandemic.

Finding 1**USDA Did Not Implement Adequate Management Controls**

USDA needs to verify the accuracy of the responses to the HSC. USDA did not accurately report the progress for two of the major functions within APHIS to the HSC. For example, APHIS inaccurately reported how it was able to identify high risk importers and withdraw their Federally-issued permits for importing live birds. In addition, USDA did not assign 4 of 29 support tasks to the correct official who could ensure the tasks were properly completed or had the authority to commit resources. This occurred because USDA did not implement adequate management controls, such as providing a second-party review of lead tasks or monitoring responsiveness to the support tasks. As a result, there is reduced assurance that USDA can respond at the time of an outbreak, to the extent reported, to the HSC.

Inaccurately Reported Progress on Lead Tasks

- Animal Importation Permits

Task 5.2.5.2 of the Plan directed USDA to review the process for withdrawing permits for the importation of live avian species or products to identify ways to increase the timeliness, improve detection of high-risk importers, and increase outreach to importers and their distributors. The measures of performance for this task required USDA to revise the process for withdrawing permits of high-risk importers. USDA assigned this task to APHIS.

The permit process serves as one of the Nation's first lines of defense against animal diseases because permits establish control over the importation and movement of animals. Withdrawing permits in a timely manner is also vital for preventing diseases from entering the United States.

APHIS' procedures require that all imported birds be accompanied by a permit. These permits allow the importation of live poultry,¹¹ commercial birds,¹² and pet birds. During 2006, APHIS issued 287 live-bird permits which allowed 63,589 live-birds into the Country. The permit process allows multiple live-birds to enter under a single approved permit.

¹¹ USDA defines poultry to include chickens, doves, ducks, geese, grouse, guinea fowl, partridges, pea fowl, pheasants, pigeons, quail, swans, and turkeys (including eggs for hatching).

¹² USDA defines commercial birds as birds that are imported for resale, breeding, public display, or any other purpose, except pet birds, zoological birds, research birds, or performing or theatrical birds.

APHIS is currently using a manual system to monitor the live-bird permits. However, APHIS reported to HSC that it was using the ePermit system, a web-based system that allows APHIS to rapidly issue, track, and verify the validity of import permits, thus reducing data-entry, processing, delivery time, and expense. An APHIS official mistakenly reported that the agency was using the ePermit system for tracking live-bird permits as of July 2006, when according to the same Official, the expected implementation date was July 2007.¹³ This occurred because APHIS did not conduct a second-party review to verify the information before forwarding it to the HSC.

The inaccurately reported implementation date is significant because live-bird permits cannot be withdrawn electronically as reported to HSC. According to an APHIS official, permits can be withdrawn timely with the manual system; however, this has not been tested.

- Stockpiling Emergency Equipment

Task 7.1.4.2 of the Plan charged USDA with stockpiling emergency response protective equipment (e.g., non-permeable protection suit, decontaminant, boot covers, gloves, first aid kit, 20 gallon sprayer, soap, Gatorade, and a pressurized air-flow device) to be used in the event of responding to an actual outbreak. This would ensure that the materials were pre-positioned for rapid delivery to infected areas. USDA assigned this task to APHIS.

These stockpiles are the Nation's repository of vaccines, personal protective equipment, and other critical veterinary products to help augment State and local resources to contain and eradicate an outbreak that could potentially devastate American agriculture. To fulfill this task, APHIS reported in February 2007 that "it holds in strategic locations push packs¹⁴ containing enough personal protective equipment and other materials to protect workers." An APHIS official informed us, though, that emergency equipment was stockpiled at one location, not multiple locations, as reported to the HSC. This occurred because APHIS did not conduct a second party review of the information reported. As of May 2007, APHIS had not finalized the procurement activities to acquire additional response material and storage locations. As of October 2007, APHIS had not updated us on whether this procurement was finalized. Although pre-positioning the materials at a single location addressed the task, APHIS' reported progress did not match its response.

¹³ In an interview in May 2007, APHIS informed us that it had encountered software configuration issues between the ePermit system and the portal used to access the system. The July 2007 date was not met, and as of October 2007, APHIS had not provided us with an updated implementation date. According to APHIS' response to this report, the ePermit System was available for internal APHIS users as of April 2007 for animals.

¹⁴ Push packs are ready to ship containers stocked with a variety of necessary personal protective equipment and veterinary supplies.

Misassigned Support Tasks

Of the 29 support tasks we reviewed, 4 were assigned to an official who had not been informed that he was responsible for them. USDA needs to ensure that the support tasks are properly assigned and monitored in order to be able to play its part fully when called upon by the lead agency. USDA did not develop a tracking system to maintain oversight of the supporting tasks. These tasks are as follows:

- Implement response or screening protocols at domestic airports and other transport modes based on disease characteristics and availability of rapid detection methods and equipment (Task 5.3.1.6). According to APHIS officials, this task was inappropriately assigned to USDA because USDA does not have the authority to regulate interstate transportation of agricultural products. As of May 2007, this issue had not been resolved. USDA needs to coordinate with the HSC to reassign the task identified to be outside of USDA's authority.
- Implement screening protocols at U.S. ports of entry based on disease characteristics and availability of rapid detection methods and equipment (Task 5.3.1.5). As a result of our audit, this task was reassigned to the appropriate APHIS official.
- Implement and enforce cargo restrictions for export or import of potentially contaminated cargo, including embargo of live birds, and notify international partners and shippers (Task 5.3.2.3). As a result of our audit, this task was reassigned to the appropriate APHIS official.
- Consult with the domestic and international travel industry (e.g., carriers, hospitality industry, and travel agents) and freight transportation partners to discuss travel and border options (Task 5.3.4.4). As a result of our audit, this task was reassigned to the appropriate APHIS official.

Although only 2 of 26 lead tasks were inaccurately reported to the HSC, USDA lacks a control mechanism to verify that it reports its progress accurately for any of the tasks reported on to date and future tasks. In addition, USDA did not ensure that support tasks were fully addressed and communicated to responsible officials. Given the potential economic and health impact of an HPAI outbreak, USDA should not risk discovering that its response procedures have been inaccurately reported or unassigned.

Accordingly, USDA should institute a management control mechanism capable of ensuring that progress is reported accurately to the HSC. Also, a tracking system should be developed to monitor supporting tasks, and tasks identified to be outside of USDA's authority should be coordinated with HSC.

Recommendation 1

Establish a control mechanism to ensure the accuracy of information reported to HSC on assigned tasks.

Agency Response.

APHIS reported to the HSC the status of 57 tasks for which it is the lead agency seven times over a 12 month period, resulting in 97 percent accuracy using the control mechanisms questioned. All future submissions will require first line supervisor clearance prior to submission.

OIG Position.

We accept APHIS' management decision.

Recommendation 2

Provide the HSC with corrected information for the inaccurately reported tasks.

Agency Response.

APHIS's response clarified its use of the e-Permitting System for review and cancellation of "high risk" permits to the HSC. With the implementation of USDA's new e-Permitting system, APHIS' efficiency in withdrawing permits has increased. The system is available to Customs and Border Patrol, and APHIS' Veterinary Services (VS) program area users as of July 2006 for animal products and available for internal users (VS) as of April 2007 for animals.

APHIS has corrected a planned future state of being rather than the current situation on a task status: with respect to Stockpiling of Emergency Equipment, APHIS corrected the record that, as of February 2007, there were multiple locations in which emergency veterinary supplies were stored, but only one location where Personal Protective Equipment (PPE) was warehoused for delivery to an incident site within 24 hours. The final response to the HSC corrects *locations* to *location*. A contract for additional PPE was awarded in June 2007. Currently, the National Veterinary Stockpile (NVS) also holds, in a separate location from the PPE, antivirals to protect 3,000 responders for six weeks.

OIG Position.

We accept APHIS' management decision.

Recommendation 3

Develop a tracking system or expand the existing one to monitor support tasks.

Agency Response.

APHIS understands that the role of a support agency is to collaborate with the lead agency in an appropriate manner. As such, APHIS believes the current tracking system is sufficient to manage support activities appropriately assigned to APHIS. However, APHIS has proposed to the HSC and they have accepted to use Quick Place to track all future action items for all Departments. This will allow them to monitor their lead action items and the actions they are responsible for as a support agency. The HSC will make this a voluntary system initially. APHIS will request completed action items for which they are support to ensure USDA's interests are considered appropriately.

OIG Position.

We accept APHIS' management decision.

Recommendation 4

Coordinate with the HSC to reassign the task identified to be outside of USDA's authority (i.e., Task 5.3.1.6).

Agency Response.

APHIS agrees that the task referenced requires resolution. In the response, APHIS stated it would collaborate with DHS, the lead agency, to determine scope and suggest any reassignments to the HSC. This action item might require USDA involvement on trucking, rail, passenger car, or other kind of "response of screening protocols" that might be needed domestically. It could apply to any animals or animal products that might spread the virus domestically and for which USDA might need to help determine/write/implement a response or screening protocol.

OIG Position.

Although we agree with APHIS' proposed corrective action for management decision, APHIS needs to provide a date when the collaboration with DHS will take place on the details regarding the assignment of task 5.3.1.6.

Finding 2

Response Procedures Need to be Tested

USDA reported that it had completed all 26 lead tasks that were due through February 2007, because it had implemented and/or revised procedures, and coordinated with the appropriate Federal agencies as required by the Plan. However, the processes and procedures that related to 14 of the 26 tasks had not been tested to ensure that they addressed the threat of an influenza pandemic because the Plan did not specifically require testing. We found that

APHIS did not update its website to notify stakeholders within 24 hours of a confirmed outbreak, highlighting the potential gap between reported accomplishments and actual achievements. As a result, USDA lacks assurance that policies, procedures, and plans developed or revised in response to the Plan will work as designed. Thus, USDA could not ensure the effectiveness of procedures in the event of an outbreak.

APHIS performed limited testing on 4 of the 18 testable lead tasks;¹⁵ however, the testing was not done as part of a systematic process that verifies the effectiveness of completed tasks. Specifically, APHIS conducted tabletop exercises with two States that also involved local government and private organizations.¹⁶ APHIS initiated the tests before the Plan was released in May 2006. In part, the tabletop exercises addressed 3 of the 18 testable lead tasks that involve APHIS' procedures to produce, deploy, and distribute emergency response supplies such as vaccine and protective equipment. However, since the exercises are group discussions that identify the needs and possible responses of participants, they do not test the actual procedures used during a simulated outbreak.

For the fourth task, APHIS tested laboratories' capabilities to handle the increase or surge in samples (e.g., water, throat, etc.) that will follow an outbreak.¹⁷ Officials stated the agency has no plans to test the remaining 14 lead tasks because the Plan did not require that they be tested. However, we found a breakdown in APHIS' notification and response procedures, which demonstrates the need to verify and test the remaining procedures to ensure their effectiveness. Specifically, we identified that the notification website was not timely updated, response activity procedures were not updated, and other processes and procedures have not been tested according to APHIS guidelines. In addition, APHIS has no plans to test the remaining 31 tasks scheduled for completion after February 2007.

Website Notification

Through the Plan, HSC required USDA to review existing transportation and border notification protocols to ensure that timely information is shared in case of quarantinable disease. USDA reported, as part of its completion of Task 5.2.1.1, that existing procedures would report a foreign outbreak within 24 hours—in part, by updating APHIS' notification website. In February 2007, such an outbreak occurred in England.¹⁸ APHIS did not update its website for over 48 hours after confirmation of the outbreak because its notification procedures did not specify contacting the information

¹⁵ There were 26 total lead tasks but we determined that 8 were not testable. For example, many of the steps required APHIS to coordinate with international organizations such as the United Nations Food and Agricultural Organization. APHIS provided us documentation supporting that it had met these requirements (see Exhibit A).

¹⁶ A tabletop exercise is a group discussion guided by a scenario-based, simulated disaster.

¹⁷ Task 7.1.2.2 (see Exhibit A).

¹⁸ The outbreak occurred on two poultry farms in Suffolk and Norfolk counties on February 3, 2007.

technology staff to post information on the website. Early warning of an outbreak in other countries is critical to APHIS to allow it time to implement the screening protocols at United States border points (land, air, and sea). APHIS officials stated that they use other means of communication to notify the necessary individuals or groups at the time the outbreak is declared. However, these means are reliant on having correct and current contacts and addresses.

Within APHIS, the National Center for Import and Export (NCIE) is responsible for notifying field offices of an outbreak through alerts. Once a country declares an outbreak, NCIE must report the information on APHIS' notification website. A delay could allow agents to let infected birds into the United States to contaminate domestic flocks and the food supply.

APHIS officials agreed that the notification website was not updated according to the protocol reported to the HSC. APHIS stated it would resolve the problem by formalizing the website procedures. However, APHIS did not provide a definite timeframe for doing so.

Breakdown in Response Procedures

APHIS contained and eradicated an outbreak of Exotic Newcastle Disease (END), a highly infectious foreign animal disease (FAD) in birds, in 2002-2003. However, a study funded by the agency, the "Analysis of Response Operations to Eradicate END in 2002-2003: Response Management," issued in December 2004, identified management response breakdowns. For example, APHIS had procedures in place to address management response across multiple States and regions; however, the study questioned APHIS' ability to effectively respond to a widespread outbreak. Some of the key recommendations were as follows:

- USDA should carefully consider where to assign critical personnel with specialized experience in the context of large FAD outbreak scenarios.
- USDA should continue to train essential personnel in Incident Command System¹⁹ procedures.
- USDA should examine State-Federal coordination issues in the context of FAD scenarios or exercises to determine whether incident command structures can accommodate larger, multi-state outbreaks.
- USDA should refine its written delegation of authority and response plans to facilitate a more rapid deployment of personnel, clarify financial

¹⁹ A standardized onsite emergency management system made up of facilities, equipment, personnel, procedures, and communications designed to aid in the management of resources during incidents.

responsibility and oversight for eradication activities, and be more specific about decisions that can be made independently versus those that require an agency administrator's approval.

Although APHIS spent \$471,000 to fund the study, the agency has neither incorporated its recommendations nor tracked responses to them. According to APHIS officials, competing demands and priorities have prevented APHIS from implementing these recommendations. Although specific outbreak situations vary, APHIS' National Animal Health Management System provides the response requirements to detect, control, and eradicate any highly contagious FAD, including HPAI. Therefore, the recommendations present APHIS with an opportunity to strengthen its END and HPAI response procedures.

Processes and Procedures Warranting Testing

We found 14 of the 26 lead tasks, due as of February 2007, had not been tested. Also, USDA did not test newly developed procedures or assess and evaluate the revised procedures to ensure they worked as designed. The 14 untested lead tasks constitute an important part of the Nation's pandemic influenza defense. Of these tasks, 10 related to APHIS procedures; 2 were associated with OC; and 1 each related to ARS and FSIS procedures. For example, the untested APHIS tasks include, but are not limited to, the following:

- USDA, in coordination with DHS, shall review the protocols, procedures, and capacity at animal quarantine centers to meet the requirements outlined in Part 93 of Title 9 of the Code of Federal Regulations, within 4 months (Task 5.2.5.4).
- USDA, in coordination with DHS, the Department of Justice, and the Department of Interior (DOI), shall enhance risk management and anti-smuggling activities to prevent the unlawful entry of prohibited animals, animal products, wildlife, and agricultural commodities that may harbor influenza viruses with pandemic potential, and expand efforts to investigate illegal commodities, block illegal importers, and increase scrutiny of shipments from known offenders, within 9 months (Task 5.2.5.5).
- USDA shall coordinate with DHS and other Federal, State, local, and tribal officials, animal industry, and other affected stakeholders during an outbreak in commercial or other domestic birds and animals to apply and enforce appropriate movement controls on animals and animal products to limit or prevent spread of influenza virus (Task 7.3.1.2).

- USDA, in coordination with DHS, DOI, and Health and Human Services, shall review the process for withdrawing permits for importation of live avian species or products and identify ways to increase timeliness, improve detection of high-risk importers, and increase outreach to importers and their distributors, within 6 months (Task 5.2.5.2).

APHIS' guidelines²⁰ require participation in realistic exercises that focus on practical activities that place the participants in a simulated situation requiring them to function in the capacity that would be expected of them in a real event. The purpose is to promote preparedness by testing policies and plans and training personnel. APHIS guidelines contain a number of training exercises to test their policies and procedures in real live situations such as:

- **Tabletop exercises** - a facilitated analysis of an emergency situation in an informal, stress-free environment.
- **Functional exercise** - a fully simulated interactive exercise that tests the capability of an organization to respond to a simulated event.
- **Full-scale exercise** - simulates a real event as closely as possible.

The Plan did not require testing; however, USDA can strengthen its policies and procedures and heighten its assurance of USDA's readiness by using the exercises outlined in APHIS' guidelines. The exercises will also emphasize the need for participants to develop and maintain strong collaborative relationships with other Federal agencies and counterparts in the emergency management community. As part of this testing, USDA should determine the need to test the tasks scheduled for completion after February 2007.

USDA's Communication Strategy

USDA has not evaluated the effectiveness of its public communication strategy, and information may not reach as wide an audience as intended during an outbreak. USDA has several lead tasks that relate to informing the public about issues, activities, and its responsibilities regarding HPAI through various types of media (e.g., internet, fliers, television, etc.). The OC has developed and distributed pre-scripted risk communication messages about HPAI, and according to the HSC, met the measures of performance for these tasks completed through May 2007.

USDA has produced certain educational brochures in English, Spanish, and Vietnamese. In addition, USDA's Avian Influenza website is currently available in English and Spanish. However, USDA still risks missing large segments of the affected population. Depending on the outbreak scenario,

²⁰ APHIS' National Animal Health Emergency Management System.

USDA may need to release its communications in other languages, such as Cantonese, Arabic, and Hindi.

Given the potential economic and health impact of an outbreak, USDA cannot risk discovering that its processes and procedures are not effectively implemented or communicated during an outbreak. By testing to ensure that its reported accomplishments match actual achievements, USDA can heighten its readiness to respond in the event of an outbreak.

Recommendation 5

Test actual procedures during a simulated outbreak to supplement tabletop exercises.

Agency Response.

APHIS agrees that testing is essential to assess readiness. APHIS has previously offered to provide information that demonstrates their testing and preparedness activities. Actual responses allow APHIS to refine procedures as well as or better than, test scenarios do. In addition, APHIS has tested certain functions that are not part of their routine work, such as:

- Actual incidents of low pathogenic avian influenza (LPAI) test communications, logistics, operations, planning, and finance and administrative capabilities. LPAI incidents that require movement control and depopulation most closely resemble the response that would be carried out in the case of an HPAI outbreak. In fiscal year 2007 APHIS personnel responded to four such incidents in commercial operations in West Virginia, Virginia, and South Dakota (two incidents), and one in a live-bird market production unit in New York.
- NVS was notified to deploy personal protective equipment and disinfectant needed for a State response to the West Virginia outbreak referenced immediately above. The NVS deployed the requested supplies of personal protective equipment and disinfectants within 24 hours of notification. The majority of items were in stock, but one emergency purchase was made. Thereafter, the NVS coordinated the simultaneous arrival of shipments from Wisconsin and Missouri into West Virginia. NVS also deployed contractors to conduct depopulation, decontamination, and disposal functions in Virginia and New York incidents.
- The NVS conducted a physical deployment exercise in Fall 2007 in which it shipped various products types in Iowa. Push packs of PPE and other materials were delivered via semi-truck from one location, and vaccine and antiviral delivery was simulated from two other locations to test cold-chain delivery. The State successfully tested its ability to request, receive, store, stage, manage, process, and deliver supplier before returning the materials

to NVS for use in other exercises. Additional exercises are planned with California (March 2008) and South Carolina (December 2008).

OIG Position.

We accept APHIS' management decision. APHIS officials were given the opportunity to provide information that demonstrates their testing and preparedness activities throughout the conduct of the audit. APHIS did not provide us with evidence of the tests of actual procedures during a simulated HPAI outbreak that would supplement tabletop exercises.

Recommendation 6

Formalize procedures to update APHIS' notification website within 24 hours of a confirmed outbreak.

Agency Response.

At the time an outbreak occurs, APHIS' VS will notify, first and directly, other APHIS components, and DHS, Customs and Border Patrol to ensure that screening protocols at borders can be implemented timely. The process for updating the website has been formalized, as described in the revised Standard Operating Procedure, titled "National Center for Import and Export/Import Alert Notification," dated December 6, 2007. APHIS provided a copy of this procedure.

OIG Position.

We accept APHIS' management decision.

Recommendation 7

Incorporate the recommendations from the "Analysis of Response Operations to Eradicate Exotic Newcastle Disease in 2002-2003: Response Management" into APHIS' HPAI response plan.

Agency Response.

APHIS continues to assess its state of readiness and is devoting considerable effort toward the recommendations described in the referenced report. The agency-wide Emergency Management Leadership Council leads the planning of APHIS' emergency response with respect to resources and personnel. The status of APHIS' activities are tracked and internal reports generated at regular intervals. At present, the Council is overseeing:

- The review of Mobilization Guide, drafted using Forest Service's style;
- The cataloguing of personnel capabilities and assigning availability of

dispatch into the Resource Ordering and Status System;

- The training of executives and staff officers in Incident Command System (ICS) procedures; and
- The development of a formal, auditable certification process for all Animal Health, Plant Health, ICS, Advisory/Support and All Hazard positions.

APHIS' HPAI Response Plan is in the process of being updated to include greater detail about the response process and roles of those involved. In addition, National Animal Health Emergency Management System guidelines are currently being revised. APHIS anticipates completion of these documents by October 31, 2008.

OIG Position.

We accept APHIS' management decision.

Recommendation 8

Develop a timetable for testing the 14 tasks that have not been tested. Also, perform an assessment to determine the need to test the remaining 31 tasks scheduled for completion after February 2007.

Agency Response.

APHIS agrees with a number of recommendations in the report, particularly the necessity of ensuring response capabilities for those the Agency is assigned a lead role. APHIS' response provided information on how 11 of the 14 tasks are being tested. For actions 1, 11, and 12 (see Exhibit A) and the remaining 31 tasks scheduled for completion after February 2007 – APHIS will develop an assessment to determine the need for testing by February 28, 2008.

OIG Position.

We accept APHIS' management decision.

Recommendation 9

Determine the languages that will maximize public outreach relating to HPAI and produce and disseminate the communications accordingly.

Agency Response.

For the "Biosecurity for Birds" program, APHIS polled the States on which populations were important to reach in order to maximize public outreach relating to avian disease prevention. APHIS received requests for specific languages and is willing to translate more languages if requested.

APHIS will apply the findings from the consumer research done in the development of the “Biosecurity for Birds” program to maximize public outreach to an HPAI campaign.

OIG Position.

We accept APHIS’ management decision.

Finding 3

APHIS has not fully implemented two of the eight recommendations from our prior report, which were intended to strengthen its ability to respond to an outbreak. This occurred because APHIS did not assign a program official with the responsibility to finalize corrective actions addressed in our prior report. These recommendations addressed such matters as coordinating with States to obtain their response plans and revising APHIS' Response Plan (see Exhibit C).

Although APHIS has taken strides to implement the corrective actions, it has not finalized its Response Plan or officially executed the agreements with State level authorities. Throughout our fieldwork, we attempted to obtain reasons why the prior recommendations had not been addressed. APHIS did not provide us with supporting documentation or justification for why corrective actions were not implemented in accordance with the agreed upon dates. Because the corrective actions have not been implemented, APHIS has reduced assurance that it will be able to timely and effectively respond in the event of an outbreak. APHIS should take immediate action and assign responsibility to finalize corrective actions to address these two recommendations.

- APHIS Has Not Provided State Response Plans

We disclosed in our prior audit that APHIS did not include detailed operational guidance in its Response Plan when dealing with HPAI in LBM, botanicas,²¹ or other “off-farm” environments.

We recommended that APHIS prepare and distribute detailed instructions for handling HPAI occurrences in the LBMs, botanicas, and other “off-farm” environments. APHIS agreed with our recommendation and indicated that it would work closely with its partners in the LBM Working Group, comprised of State and industry representatives, to develop further response plans and require State plans to be submitted to APHIS for certification (Recommendation 4). These plans are necessary to address gaps in the response plan, including cleaning and disinfection, humane euthanasia, quarantine, movement control, and other response areas as needed. Although APHIS recognized that this corrective action relied heavily on State participation, corrective action was agreed to and expected by December 2006. As of October 2007, APHIS had not provided the State response plans and evidence of acceptance or justification as to why corrective action was not implemented in accordance with the agreed upon date.

²¹ Botanicas, which primarily are located in southern Florida, sell live-birds for ritual slaughter.

- Response Plan

In the prior audit, we found that APHIS did not have notification procedures in place to inform owners of animals with the risk of being infected during an outbreak.

We recommended that APHIS 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 (Recommendation 8). As of May 2007, APHIS had revised the Response Plan but had not finalized it. As of October 2007, APHIS had not provided the final document or justification as to why corrective action was not implemented in accordance with the agreed upon date. As noted in APHIS' response to recommendations in this report, the requirements were met and final action is pending with the Office of the Chief Financial Officer (OFCO).

Recommendation 10

Immediately assign responsibility to finalize corrective actions set forth in Audit Report No. 33099-11-Hy and provide the timeframes for implementing the corrective actions.

Agency Response.

APHIS' response stated that Recommendation 8 of Audit Report No. 33099-11-Hy is currently pending closure at OCFO. Recommendation 4 is the only outstanding recommendation. With regards to this recommendation, APHIS provides standards and criteria in the form of the HPAI National Response Plan. APHIS recognizes that States, industry, and stakeholders have requested another level of detail. APHIS expects to provide additional guidance in the form of procedures and checklists with the next major revision of the HPAI National Response Plan in 2008. The current program for State plans is limited to LPAI Initial State Response and Containment Plans as outlined under the National Poultry Improvement Program. While the focus of these plans, as defined in the regulations, is LPAI, it must be noted that many of the actions and responses are equally applicable to HPAI situations and the States may use part or all of the plans in a HPAI outbreak situation. At this time, APHIS has no plans in place to initiate or implement a State HPAI certification program.

OIG Position.

For management decision, APHIS needs to request a change in management decision for Recommendation 4 of Audit Report No. 33099-11-Hy that explains why the agency is not requiring State plans to be submitted to APHIS for certification.

Scope and Methodology

The Plan assigned 98 tasks to USDA, of which 12 were reviewed by GAO (See Exhibit B). Of the remaining 86, we reviewed 55 tasks that were due to be completed by February 2007 (26 lead and 29 support tasks). Our audit focused on evaluating whether USDA adequately implemented the tasks within the prescribed timeframes required by the Plan. We assessed the progress reported by USDA, noting whether policies and procedures were developed or revised. We also determined if APHIS took steps to test if the policies and procedures would work as designed and be effective.

We primarily reviewed the status submissions to HSC and obtained supporting documentation. To do this we obtained read-only access to “QuickPlace” and were able to review USDA’s status updates and the supporting documentation submitted to HSC. We interviewed 26 APHIS employees, including the Deputy Administrator and Associate Deputy Administrator for VS, as well as the Directors and staff of the VS offices: (1) National Center for Animal Health Emergency Management, (2) National Veterinary Services Laboratories, (3) National Center for Animal Health Programs, (4) National Center for Import and Export, and 5) National Animal Health Policy and Programs. Because certain tasks in the Plan were the responsibility of other agencies within USDA, we also interviewed officials from FAS, ARS, FSIS, and OC. We obtained an understanding of the roles and responsibilities of APHIS as they relate to implementing the tasks addressed in the Plan and associated supporting documentation.

In addition, we followed-up on the actions taken to implement the recommendations provided to APHIS in a prior report, Oversight of Avian Influenza, Audit Report No. 33099-11-Hy, issued June 2006.

We conducted our audit from October 2006 to May 2007, in accordance with generally accepted *Government Auditing Standards*. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. We updated the status of our audit results through July 2007, and subsequently in September and October 2007.

Exhibit A – 26 Lead Tasks

Action No.	Need to Test	APHIS Tested	Can Not Test	TASK#	TASK REQUIREMENTS	Measure of Performance
1	X			5.2.1.1	Review existing transportation and border notification protocols to ensure timely information sharing in cases of quarantinable disease.	Coordinated, clear interagency notification protocols disseminated and available for transportation and border stakeholders.
2	X			7.3.5.1	Develop, clear and coordinated pre-scripted public messages that can later be tailored to the specifics of a given outbreak.	Appropriate informational and risk mitigation messages developed prior to an outbreak, then shared with the public within 24 hours of an outbreak.
3	X			7.1.3.4	Develop guidelines to reduce the risk of transmission between domestic animals and wildlife during an animal influenza outbreak.	Guidelines for various outbreak scenarios produced, disseminated and incorporated by partners.
4	X			7.1.5.5	Identify any deficiencies relative to needs for Federal animal research facility capacity, including appropriate biosafety level.	Deficiencies in capacity of Federal animal research facilities identified and plans developed for addressing those needs.
5	X			7.2.1.2	Develop and distribute information to State and tribal entities on the detection, identification, and reporting of influenza viruses in wild bird populations.	Information distributed and a report available describing the type, amount, and audiences for the information.
6	X			7.3.5.2	Develop guidelines to assure the public of the safety of the food supply during an outbreak of influenza in animals.	Guidelines for various outbreak scenarios produced and shared with partners; within first 24 hours of an outbreak, appropriately updated guidelines on food safety shared with the public.
7	X			7.3.3.1	Partner with appropriate officials to reduce the barriers that inhibit veterinary personnel from crossing State or national boundaries to work in an animal influenza outbreak response.	Agreements or other arrangements in place to facilitate movement of veterinary practitioners across jurisdictional boundaries.
8	X			5.3.3.1	Develop emergency notifications of probable or confirmed cases and/or outbreaks to key stakeholders within 24 hours of an outbreak.	Emergency notifications occur within 24 hours or less of events of probable or confirmed cases or outbreaks.
9	X			7.3.1.1	Develop procedures to use during an outbreak relating to eradicating any influenza outbreak, and safely disposing of animal carcasses, within 24 hours of an outbreak.	At least one incident management team from USDA on site within 24 hours of detection of such an outbreak.
10	X			7.3.5.3	Develop procedures and/or guidelines to use when updating and distributing information to the public during an outbreak, within the first 24 hours of an outbreak.	Guidelines updated and shared with the public within first 24 hours of an outbreak.
11	X			5.2.5.4	Reviewed and revised protocols, procedures, and capacity at animal quarantine centers to meet requirements outlined in Part 93, Title 9 of the Code of Federal Regulations.	Procedures in place to respond effectively and efficiently to the arrival of potentially infected avian species, including provisions for adequate quarantine surge capacity.

Exhibit A – 26 Lead Tasks

Action No.	Need to Test	APHIS Tested	Can Not Test	TASK#	TASK REQUIREMENTS	Measure of Performance
12	X			5.2.5.5	Develop plans to decrease smuggling and further distribution of prohibited agricultural products with influenza risk.	Plan developed to decrease smuggling and further distribution of prohibited agricultural commodities and products with influenza risk.
13	X			7.3.1.2	Develop procedures to enforce appropriate movement controls on animals to limit or prevent the spread of the virus, within 24 hours of an outbreak.	Initial movement controls in place within 24 hours of detection of an outbreak.
14	X			5.2.5.2	Ensure the process for withdrawing permits for importation is done more timely and comprehensively. Also determine if APHIS has increased their outreach to importers and their distributors.	Revised process for withdrawing permits of high-risk importers.
15		X		7.1.4.1	Increase the vaccine stockpile of avian influenza to 110 million doses.	Avian influenza vaccine stockpiles increased to 110 million doses.
16		X		7.1.4.2	Stockpile diagnostic reagents, PPE, antiviral medication for protection of response personnel, and other response materiel.	Materiel pre-positioned for rapid delivery to areas where poultry or other animals are believed to be at highest risk for an introduction of an influenza virus with human pandemic potential.
17		X		7.3.2.1	Develop plans to distribute veterinary medical countermeasures and material from the NVS to Federal, State, local and tribal influenza outbreak responders within 24 hours of confirmed outbreak.	National Veterinary Stockpile materiel distributed within 24 hours of confirmation of an outbreak.
18		X		7.1.2.2	Partner with States and tribal entities to ensure sufficient veterinary diagnostic laboratory surge capacity for response to an outbreak.	Plans and necessary agreements to meet laboratory capacity needs for a worst case scenario influenza outbreak in animals validated by utilization in exercises.
19			X	4.1.73	Develop and provide best practice guidelines and technical expertise to countries that express interest in obtaining aid in the implementation of a national animal vaccination program.	Interested countries receive guidelines and other assistance within 3 months of their request.
20			X	4.1.5.4	Provide technical expertise, information, and guidelines for stockpiling and use of animal vaccines to affected and high risk countries.	All priority countries and relevant international organizations have received information on animal vaccines' efficacy and application strategies to guide country-specific decisions about preparedness options.
21			X	4.2.1.7	Expand the scope, accuracy, and transparency of human and animal surveillance systems and to streamline and strengthen official protocols for reporting avian influenza cases.	75 percent of priority countries have established early warning networks, international case definitions, and standards for laboratory diagnostics of human and animal samples.

Exhibit A – 26 Lead Tasks

Action No.	Need to Test	APHIS Tested	Can Not Test	TASK#	TASK REQUIREMENTS	Measure of Performance
22			X	4.1.2.3	Support FAO and OIE in implementing an instrument to assess priority countries' veterinary infrastructure for prevention, surveillance, and control of animal influenza and increase veterinary rapid response.	Per the OIE's Performance, Vision and Strategy Instrument, assessment tools exercised and results communicated to the Partnership, and priority countries are developing, or have in place, an infrastructure capable of supporting their national prevention and response plans for avian or other animal influenza.
23			X	4.3.1.5	Support operational deployment of rapid response teams and provide technical expertise and technology to support avian influenza assessment and response teams in priority countries.	All priority countries have rapid access to avian influenza assessment and response teams; deployment assistance provided in each instance and documented in a log of technical assistance rendered.
24			X	4.1.6.3	Generate new information on avian vaccine efficacy and production technologies and disseminate to international organizations, animal vaccine manufacturers, and countries at highest risk.	Information disseminated to priority countries.
25			X	4.2.2.2	Increase support of scientists tracking potential emergent influenza strains through disease and virologic surveillance in susceptible animal species in priority countries.	Surveillance for emergent influenza strains expanded in priority countries.
26			X	4.3.6.3	Ensure that clear and coordinated messages are provided to international trading partners regarding animal disease outbreak.	Within 24 hours of an outbreak, appropriate messages will be shared with key animal/animal product partners.

Exhibit B – GAO Tasks

Action #	TASK REQUIREMENTS	Measure of Performance	Lead (L) Support (S)	Due Date
5.2.5.3	Enhance protocols at air, land, & sea ports of entry to identify and contain animals, animal products, and/or cargo that may harbor viruses with pandemic potential and review procedures to quickly impose restrictions.	Risk based protocols established and in use.	L	Nov-06
7.1.1.1	Establish and exercise animal influenza response plans.	Plans in place at specified Federal agencies and exercised in collaboration with States believed to be at a highest risk for an introduction into animals of an influenza virus with human pandemic potential.	L	Nov-06
7.1.3.1	Develop, disseminate, and encourage adoption of best practices and recommendations for maintaining the biosecurity of animals, especially poultry and swine, against infection and spread of influenza viruses and for reporting suspected cases of influenza with human pandemic potential in animals to State or Federal authorities.	Incorporation of best practices by industry.	L	Sep-06
7.1.3.2	Partner with State and tribal entities, and industry groups representing poultry and swine producers and processors, and other stakeholders, to define and exercise response roles and capabilities.	Exercises involving State or tribal entities, at least one poultry industry group, and one swine industry group, conducted and after action reports produced.	L	Feb-07
7.1.3.3	Work with the poultry and swine industries to provide information regarding strategies to prevent avian and swine influenza infection among animal workers and producers.	Develop and disseminate guidelines to poultry and swine industries.	S	Nov-06
7.1.5.1	Perform research to understand better how avian influenza viruses circulate and are transmitted in nature, in order to improve information on biosecurity distributed to local animal owners, producers, processors, markets, auctions, wholesalers, distributors, retailers, and dealers, as well as wildlife management agencies, rehabilitators, and zoos.	Complete research studies provide new information, or validate current information, on the most useful biosecurity measures to be taken to effectively prevent introduction, and limit or prevent spread, of avian influenza viruses in domestic and captive animal populations.	L	Nov-07
7.1.5.4	Perform research to improve vaccines and mass immunization techniques for use against influenza in domestic birds.	An effective avian influenza vaccine that can be delivered simultaneously to multiple birds ready for commercial development.	L	May-09
7.1.5.6	Partner with State and tribal authorities to refine disease mitigation strategies for avian influenza in poultry or other animals through outbreak simulation modeling.	Simulation models produced and reports issued on the results of influenza outbreak scenario modeling.	L	Nov-06

Exhibit B – GAO Tasks

Exhibit B – Page 2 of 2

Action #	TASK REQUIREMENTS	Measure of Performance	Lead (L) Support (S)	Due Date
7.2.1.3	Work with State and tribal entities, and industry groups, to perform surveys of game birds and waterfowl raised in captivity, and implement surveillance of birds at auctions, swap meets, flea markets, and public exhibitions.	Samples collected at 50 percent of the largest auctions, swap meets, flea markets, and public exhibitions held in at least five States or tribal entities believed to be at highest risk for an avian influenza introduction.	L	May-07
7.2.1.4	Work with State and tribal entities to provide additional personnel in additional locations to increase the number of facilities inspected and number of samples collected for avian influenza number of facilities inspected & number of samples collected for AI testing within LBMS.	Number of facilities inspected and sampled increased by 50 percent compared to previous year.	L	May-07
7.3.1.3	Prepare to provide near real-time technical information and policy guidance for State and tribal entities, animal industries, and individuals, on best practices to prevent the spread of avian influenza in commercial and other domestic birds and animals during an outbreak.	Information and guidance distributed within 72 hours of confirmed outbreak and report available describing type and amount of information, and audiences to whom delivered.	L	Sep-06
7.3.4.1	Assess the outbreak response surge capacity activities that other Federal partners, including the DOD, may be able to support during an outbreak of influenza in animals and ensure that mechanisms are in place to request such support.	Written assessment completed and all necessary activation mechanisms in place.	L	Nov-06

Exhibit C – Followup on OIG’s 8 Prior Recommendations

Exhibit C – Page 1 of 1

Rec. No.	Prior Recommendations Addressed by Audit Report 33099-11-Hy	Management Decision Yes/No	Final Action Yes/No	Status
1	Develop and implement a comprehensive avian influenza surveillance plan to include goals and objectives, case definitions, data collection and analysis methodologies, reporting of surveillance results, and assessment of surveillance program.	Yes	Yes	
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.	Yes	Yes	
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.	Yes	Yes	
4	Prepare and distribute detailed instructions for handling HPAI occurrences in LBM, botanicas, and other “off-farm” environments. In addition, provide approved State plans along with certifications that all States have an approved plan.	Yes	No	Nothing yet submitted to OCFO for final action. APHIS has not received or approved the States’ plans.
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.	Yes	Yes	
6	Coordinate with FSA to ensure the availability of updated mailing lists for use in the event of HPAI outbreak.	Yes	Yes	The requirements were met and final action is pending with OCFO.
7	Develop and distribute instructions for obtaining notification information from FSA.	Yes	Yes	The requirements were met and final action is pending with OCFO.
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 Avian Influenza Response Plan.	Yes	Yes	The requirements were met and final action is pending with OCFO.

Exhibit D – Agency Response

Exhibit D – Page 1 of 7



United States
Department of
Agriculture

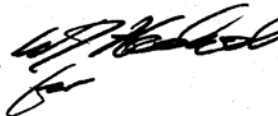
Animal and Plant
Health Inspection
Service

Washington, DC
20250

MEMORANDUM

TO: Robert W. Young
Assistant Inspector General
for Audit

FROM: Cindy J. Smith
Administrator

 DEC 20 2007

SUBJECT: APHIS Response to OIG Report, "USDA's Implementation of the National Strategy for Pandemic Influenza" (33701-01-HY)

Thank you for the opportunity for the Animal and Plant Health Inspection Service (APHIS) to respond to the above titled report. APHIS appreciates the Office of Inspector General's (OIG) recognition of USDA's significant progress in developing or revising policies and procedures to detect, contain, and eradicate highly pathogenic avian influenza. APHIS also appreciates OIG's recognition that the Homeland Security Council (HSC) approved all of USDA's submissions as having met the measures of performance. Further, we recognize that planning and preparedness is an ongoing continual improvement process. It is with this commitment to continual improvement that we respond to the OIG Recommendations.

Before addressing each Recommendation, we like to reiterate some of the overarching concepts used in the Audit Report and Executive Summary with clarifying language.

- The National Strategy for Pandemic Influenza is intended to address both an outbreak of avian influenza in birds (caused by a virus with the potential to infect humans) and a human influenza pandemic that may be associated with an avian outbreak.
- The Office of the Secretary assigned the Office of the Under Secretary for Marketing and Regulatory Programs with ensuring the 98 tasks assigned to USDA were effectively addressed.
- For tasks required to be completed by February 2007, and which were reviewed in the audit, APHIS undertook a number of initiatives, including implementation of a "Biosecurity for Birds" program (this title was recently modified from "Biosecurity for the Birds").



Safeguarding American Agriculture

APHIS is an agency of USDA's Marketing and Regulatory Programs
An Equal Opportunity Provider and Employer

Federal Relay Service
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Recommendation 1: Establish a control mechanism to ensure the accuracy of information reported to HSC on assigned tasks.

APHIS Response: APHIS reported to the HSC the status of 57 tasks for which it is the lead agency seven times over a 12 month period, resulting in 97 percent accuracy using the control mechanisms questioned. All future submissions will require first line supervisor clearance prior to submission.

Recommendation 2: Provide the HSC with corrected information for the inaccurately reported tasks.

APHIS Response: On December 20, 2007, we submitted a response to the HSC that clarifies our use of the e-Permitting System for review and cancellation of “high risk” permits. With the implementation of USDA’s new e-Permitting system, APHIS’ efficiency in withdrawing permits has increased. The system is available to Customs and Border Patrol, and APHIS’ Veterinary Services (VS) program area users as of July 2006 for animal products, and available for internal users (VS) as of April 2007 for animals.

We have corrected, with HSC, the one and only occasion on which APHIS reported a planned future state of being rather than the current situation on a task status: with respect to Stockpiling of Emergency Equipment, APHIS has corrected the record that, as of February 2007, there were multiple locations in which emergency veterinary supplies were stored, but only one location where Personal Protective Equipment (PPE) was warehoused for delivery to an incident site within 24 hours. The final response to the HSC, below, corrects *locations* to *location*. A contract for additional PPE was awarded in June 2007. Currently, the National Veterinary Stockpile (NVS) also holds, in a separate location from the PPE, antivirals to protect 3000 responders for six weeks.

USDA has contracts with distributors and manufacturers of PPE, diagnostic reagent commercial entities, and other veterinary suppliers for just in time delivery to an incident site. These contracts include processes for call and delivery within 24 hours to the incident site. In addition, USDA holds in a strategic *location* push packs containing enough PPE and other materials to protect workers to support 310 people for 10 days. These push pack are held on pallets, reducing the time needed to pack and push out to contracted shipping. USDA has completed this objective.

Recommendation 3: Develop a tracking system or expand the existing one to monitor support tasks.

APHIS Response: APHIS understands that the role of a support agency is to collaborate with the lead agency, as required and requested, to make sure that any agriculture related issues that are part of the action have been, or will, be addressed in an appropriate manner. As such, we believe the current tracking system is

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sufficient to manage support activities appropriately assigned to APHIS. However, we have proposed to the HSC the use of Quick Place to track all future action items for all Departments. They have accepted this proposal and we have developed this site for HSC use. This will allow us to not only monitor our lead action items but all action items we are support on. The HSC will make this a voluntary system initially. We will be requested completed action items for which we are support to ensure our interests are considered appropriately.

Recommendation 4: Coordinate with the HSC to reassign the task identified to be outside of USDA’s authority. (i.e., Task 5.3.1.6)

APHIS Response: We agree that the task referenced requires resolution. The intent of the task, as written, is unclear as to its scope (i.e., whether human or animal disease, or both). We will collaborate with DHS, the lead agency, at their request, to determine scope and suggest any reassignments to HSC. This action item might require USDA involvement on trucking, rail, passenger car, or other kind of “response or screening protocols” that might be needed domestically. It could apply to any animals or animal product that might spread the virus domestically and for which USDA might need to help determine/write/implement a response or screening protocol.

Recommendation 5: Test actual procedures during a simulated outbreak to supplement tabletop exercises.

APHIS Response: We agree that testing is essential to assess readiness. We have previously offered to provide information that demonstrates our testing and preparedness activities. Actual responses allow us to refine procedures as well as, or better than, test scenarios do. In addition, we have tested certain functions that are not part of our routine work.

- Our responses to actual incidents of low pathogenic avian influenza (LPAI) test communications, logistics, operations, planning, and finance and administrative capabilities. Responses to LPAI incidents that require movement control and depopulation most closely resemble the response that would be carried out in the case of an HPAI outbreak. In fiscal year 2007 APHIS personnel responded to four such incidents in commercial operations in West Virginia, Virginia, and South Dakota (two incidents), and one in a live bird market production unit in New York.
- NVS was notified to deploy personal protective equipment and disinfectant needed for a State response to the West Virginia outbreak referenced immediately above. The NVS deployed the requested supplies of personal protective equipment and disinfectants within 24 hours of notification. The majority of items were in stock, but one emergency purchase was made. Thereafter, the NVS coordinated the simultaneous arrival of shipments from Wisconsin and Missouri into West Virginia. NVS also deployed contractors to

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conduct depopulation, decontamination, and disposal functions in Virginia and New York incidents.

- The NVS conducted a physical deployment exercise in Fall 2007 in which it shipped various product types to Iowa. Push packs of PPE and other materials were delivered via semi-truck from one location, and vaccine and antiviral delivery was simulated from two other locations to test cold-chain delivery. The State successfully tested its ability to request, receive, store, stage, manage, process, and deliver supplies before returning the materials to NVS for use in other exercises. Additional exercises are planned with California (March 2008) and South Carolina (December 2008).

Recommendation 6: Formalize procedures to update APHIS' notification website within 24 hours of a confirmed outbreak.

APHIS Response: At the time an outbreak occurs, APHIS' Veterinary Services will notify, first and directly, other APHIS components, and the Department of Homeland Security, Customs and Border Patrol, to ensure that screening protocols at borders can be implemented timely. The process for updating the website has been formalized, as described in the revised Standard Operating Procedure (SOP), titled "National Center for Import and Export/Import Alert Notification," dated December 6, 2007. We have attached a copy of this SOP.

Recommendation 7: Incorporate the recommendations from the "Analysis of Response Operations to Eradicate Exotic Newcastle Disease in 2002-2003" into APHIS' HPAI response plan.

APHIS Response: APHIS continues to assess its state of readiness and is devoting considerable effort toward the recommendations described in the referenced report. The agency-wide Emergency Management Leadership Council leads the planning of APHIS' emergency response with respect to resources and personnel. The status of its activities is tracked and internal reports generated at regular intervals. At present, the Council is overseeing:

- the review of Mobilization Guide, drafted using Forest Service style;
- the cataloguing of personnel capabilities and assigning availability of dispatch into the Resource Ordering and Status System;
- the training of executives and staff officers in Incident Command System (ICS) procedures; and
- the development of a formal, auditable certification process for all Animal Health, Plant Health, ICS, Advisory/Support and All Hazard positions.

APHIS' HPAI Response Plan is in the process of being updated to include greater detail about the response process and roles of those involved. In addition, National Animal Health Emergency Management System guidelines are currently being revised. We anticipate completion of these documents by October 31, 2008.

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Recommendation 8: Develop a timetable for testing the 14 tasks that have not been tested. Also, perform an assessment to determine the need to test the remaining 31 tasks scheduled for completion after February 2007.

APHIS Response: We agree with a number of recommendations in the report, particularly the necessity of ensuring response capabilities for those the Agency is assigned a lead role. Many of the tasks listed designated “not tested” in Exhibit A of the Audit Report are, in fact, tested through daily operations of the agency or have been through some other practical assessment.

- Actions #2, #6, and #10 – APHIS’ VS, and Legislative and Public Affairs (LPA) developed messaging with the Communications Officers of the State Departments of Agriculture (COSDA), as well as various response plans, in 2006. LPA participated in a table-top exercise in October 2007 with COSDA in which several scenarios were presented and messaging was customized to each situation. APHIS communications protocols include providing content to state or local partners who can further disseminate our messages to their partners. Information was publicized timely via our website in the Virginia and West Virginia LPAI incidents as referenced in our response to Recommendation 5. APHIS developed its public messages, emphasizing food safety, based on testing those messages with a focus group.
- Actions #3 and #5 – USDA helps to facilitate the distribution of AI information to State and tribal entities on the detection, identification, and reporting of avian influenza viruses in wild bird populations. As part of its comprehensive wildlife monitoring and surveillance activities, APHIS communicates directly with state wildlife agencies, agricultural departments, and tribal entities and posts information on the National Biological Information Infrastructure from its highly pathogenic avian influenza surveillance efforts. APHIS also has cooperative agreements with non-governmental organizations to educate public hunting communities and other wildlife enthusiasts. This includes advertisements in popular magazines, pocket cards for distribution to the general public, and trifold informational packets. In addition, a public service announcement was made available to radio stations across the country directed to those same audiences. Initial reaction to the PSA has been positive and resulted in additional media coverage.
- Action #4 -- Current facilities at National Veterinary Services Laboratories (NVSL) allow laboratory and animal work in the study of avian, swine and equine influenza. This work can be conducted in BSL 2 facilities except for HPAI work which is conducted in enhanced BSL3 facilities. NVSL is currently registered to work with H5N1 strains in the laboratory and in vivaria containing animal isolator caging. NVSL will be able to work with loose housed animals infected with HPAI in its newly constructed BSL3Ag facility.

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- Action #7 – Federal veterinary personnel, including those dispatched through the National Animal Health Emergency Reserve Corps, would be able to cross state lines to work in an animal influenza outbreak response. Internationally, APHIS VS signed a Memorandum of Understanding in 2004 with Australia, Canada, Ireland, New Zealand, and the United Kingdom to form the International Animal Health Emergency Reserve (IAHER) which is able to provide skilled and competent personnel, such as veterinarians, in an animal health emergency. It has been exercised with a simulation, and by table-top in 2007 in New Zealand.
- Action #8 – APHIS electronically provided an Import Alert to Customs and Border Patrol and key stakeholders on August 8, 2007, within 24 hours of notification of a foot-and-mouth disease finding in the United Kingdom. APHIS distributed a notice and updated notice to state veterinarians and other key stakeholders within 24 hours of notification of a possible foot-and-mouth disease investigation in Denmark.
- Actions #9 and #13 -- See our response to Recommendation 5.
- Actions #1, #11, and #12 and the remaining 31 tasks scheduled for completion after February 2007 – APHIS will develop an assessment to determine the need to test the untested items and remaining 31 tasks by February 28, 2008.

Recommendation 9: Determine the languages that will maximize public outreach relating to HPAI and produce and disseminate the communications accordingly.

APHIS Response: For the “Biosecurity for Birds” program, APHIS polled the states on which populations were important to reach in order to maximize public outreach relating to avian disease prevention. We received requests for specific languages and are willing to translate into more should we receive the request. Currently, the following information about avian influenza is available in the languages indicated:

- Traditional Chinese - factsheets, live bird market posters
- Tagalog - factsheets, live bird market posters
- Arabic - live bird market posters
- Spanish - all of the materials
- Hmong - factsheets, live bird market posters, DVD. (Minnesota and North Carolina have translated additional APHIS materials into Hmong due to each state’s concentration of Hmong speakers at plants and farms in those states).

APHIS will apply the findings from the consumer research done in the development of the “Biosecurity for Birds” program to maximize public outreach to an HPAI campaign.

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Recommendation 10: Immediately assign responsibility to finalize corrective actions set forth in Audit Report No. 33099-11-Hy and provide the timeframes for implementing the corrective actions.

- Recommendations #1-3 and #5 were officially closed by the Office of the Chief Financial Officer (OCFO) between September 15, 2006 and August 3, 2007. No further information or documentation is needed for these recommendations.
- Recommendations #6-8 are currently pending closure at OCFO, with documentation being submitted between August 18, 2006 and October 16, 2007.
- Recommendation #4 remains the only outstanding. With regards to this Recommendation, APHIS provides standards and criteria in the form of the HPAI National Response Plan. We recognize that States, industry, and stakeholders have requested another level of detail. We expect to provide additional guidance in the form of procedures and checklists with the next major revision of the HPAI National Response Plan in 2008. The current program for state plans is limited to LPAI Initial State Response and Containment Plans as outlined under the National Poultry Improvement Program. While the focus of these plans as defined in the regulations is LPAI, it must be noted that many of the actions and responses are equally applicable to HPAI situations and the States may use part or all of the plans in a HPAI outbreak situation. At this time, APHIS has no plans in place to initiate or implement a State HPAI certification program.

Attachment