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Animal and Plant Health Inspection Service's Control Over the Bovine Tuberculosis Eradication Program

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REPLY TO

ATTN OF: 50601-0009-CH

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

Dr. Barbara Masters
Administrator
Food Safety and Inspection Service

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

William C. Smith
Assistant Administrator
Office of Program Evaluation, Enforcement and Review

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

SUBJECT: Animal and Plant Health Inspection Service's Control Over
the Bovine Tuberculosis Eradication Program

This report presents the results of our audit of the Animal and Plant Health Inspection Service's control over the Bovine Tuberculosis Eradication Program. Your response to the draft report is included in its entirety as exhibit G, with excerpts and the Office of Inspector General's position incorporated into the Findings and Recommendations section of the report.

Based on the response, we agree with your management decision for all Recommendations. Please follow your agency's internal procedures in forwarding final action to the Office of the Chief Financial Officer.

We appreciate the cooperation and assistance provided by your staff during this audit.

Executive Summary

APHIS' Control over the Bovine Tuberculosis Eradication Program Audit Report No. 50601-0009-Ch

Results in Brief

The Animal and Plant Health Inspection Service (APHIS) is responsible for the Bovine Tuberculosis Eradication Program (BTEP). The BTEP was established in 1917 to eliminate bovine tuberculosis (TB) in the United States (U.S.). The objective of our audit was to evaluate APHIS' controls to ensure that TB surveillance was adequate to timely detect TB outbreaks for eradication. We concluded that while APHIS has made improvements in recent years, weaknesses with the program's oversight and controls make it difficult for APHIS to timely detect and eradicate the disease.

In recent years APHIS has initiated efforts to improve the BTEP, particularly in response to a TB Declaration of Emergency issued by the Secretary of Agriculture in October 2000. In response to the emergency APHIS initiated actions to address weaknesses in TB detection at slaughter facilities, wildlife infecting cattle with TB in Michigan, and TB problems in herds along the Mexico border in the El Paso, Texas area. APHIS has also continued to work with its counterparts in Mexico to address their TB problem, and made some rule changes intended to improve our domestic program. Although we determined that there are weaknesses with the BTEP, the program has sufficiently operated in that no widespread outbreaks have occurred, and the incidence of known TB in the country is low (less than one percent) in relation to the domestic cattle population as a whole. However, because TB is contagious to most mammals, and there is no vaccination or cure for animals, it requires immediate attention when detected.

We determined that in order for APHIS to get closer to realizing its goal of eradicating TB the following areas need improvement: program oversight, the status classification system and TB surveillance.

Program Oversight

APHIS' was not using its oversight tools timely or effectively. The reporting tools we reviewed consisted of State annual and monthly reports which contain valuable information on the status of TB activities in each State, and on-site program reviews. Our review of fiscal year (FY) 2004 annual reports noted that the reports were not submitted, reviewed or approved in a timely manner. We found that the monthly reports were not being reviewed by the national or regional offices. In addition, program reviews were not being consistently used as an oversight tool, as 16 of 23 States in APHIS' western region had not had a program review since 1999.

Prior to the latest outbreak of TB in Minnesota, the State's annual and monthly reports indicated weaknesses with slaughter surveillance and on-farm testing results. However, since APHIS was not extensively using these reports, it may have missed an opportunity to detect the disease earlier. This outbreak has found 5 affected herds and led to testing at over 100 farms in 8 States.

Status Classification System

In managing the BTEP, APHIS employs a status system to classify each State according to its TB prevalence level. This system is important because it dictates the extent of Federal testing and movement controls for cattle in each State or zone. APHIS has also worked with Mexico to establish the same status system controls for cattle imported into the United States. Status is based on the number of affected cattle herds assessed to a specific State or zone.

We determined that APHIS' status system did not provide an accurate representation of TB in the United States because it did not capture most TB cases. APHIS' key TB detection activity is surveillance conducted at slaughter facilities. Over the last 5 years 272 TB cases were detected by slaughter surveillance, but 260 (or 96 percent) of these cases were not reflected by the status system. In a related audit we reported how nearly 500 TB cases (over an 8-year period) in the wildlife of 1 State were omitted from the status system.¹ These cases were not included because the status system is based only on affected cattle herds, and in practice, APHIS requires that an additional infected animal be found at the source herd before it will be considered affected. This practice differs from what Federal regulations and APHIS' operating procedures define as necessary to declare a herd affected, and in some instances led to the exclusion of herds with strong evidence of TB. For example, four separate TB cases were traced back to one herd, but because testing did not find a current infected animal at the premises, the herd was not declared affected.

We also determined that APHIS' could have taken more prompt action to reduce Minnesota's status in response to that FY 2005 TB outbreak. APHIS delayed reducing Minnesota's status for four months after criteria in Federal regulations was met in order to allow the investigation to finish. This also delayed the implementation of testing and movement requirements. As a result, some States put their own criteria into effect, while one other State continued to receive cattle from Minnesota. After additional cases of TB were found in December 2005, APHIS reduced Minnesota's status.

¹ National Cooperative State-Federal Tuberculosis Eradication Program in Michigan, Audit No. 33099-0005-Ch. APHIS is already working to address this condition.

Between FY's 2001 and 2005, 75 percent of the TB-infected cattle detected by slaughter surveillance originated in Mexico. These infected animals were identified in 12 different States. Our analysis of FY 2004 TB cases found that animals of Mexican origin spent up to 14 months at U.S. farms before going to slaughter, with each case potentially spreading the disease. APHIS has worked with Mexico to improve its TB eradication program; however APHIS' efforts are undermined by the disease's 3 to 12 month incubation period. Cattle may test negative for the disease prior to export, and develop the disease after crossing the border. APHIS has not developed controls to restrict the movement of cattle, or required additional testing to compensate for the incubation period.

TB Surveillance

There are three main phases to APHIS' key surveillance system: disease detection at slaughter facilities, an epidemiologic investigation of detected TB cases, and the eradication process when an investigation finds the source of the disease. Since the Secretary's TB Emergency Declaration in October 2000, APHIS and the Food Safety and Inspection Service (FSIS) have collaborated to significantly improve detection of TB at slaughter. However, significant improvements are still needed to the investigation phase, as APHIS struggles to timely and successfully investigate TB cases.

As noted above, significant improvements have occurred in the detection of TB at slaughter facilities across the country. However, FSIS interprets the standard number of tissue samples needed under an agreement with APHIS to be applied as a national average, and not at each slaughter facility. Under this interpretation, the standard was met on a national basis in both FY's 2004 and 2005 even though 21 and 5 of the top 40 slaughter facilities, respectively, did not meet the standard. The standard was met nationally because some facilities submitted more than the standard amount, while others submitted less. For example, in FY 2005 one facility submitted no tissue samples for TB testing while another submitted almost 16 times the required number.

APHIS' investigations of FY 2004 TB cases were neither timely nor effective at finding TB for eradication. We reviewed all 36 FY 2004 TB investigations and determined that 33 were not timely and not a single case resulted in the identification of an affected domestic herd. There have been only 12 successful investigations (out of 272 cases) in the last 5 years. APHIS' FY 2004 investigations took an average of 300 days to complete, far more than the standard of 90 days which APHIS' established in January 2005. When investigations did lead to questionable but not infected herds, these herds were not routinely added to high-risk herd listings for subsequent testing. As a result, the majority of TB cases did not lead to eradication, additional testing or other controls.

We determined that the TB investigations were hampered by the lack of information, mainly identification for a particular animal, but also documentation kept by owners, dealers or brokers. APHIS anticipates the implementation of an animal identification system in 2009. In addition APHIS implemented new requirements to improve other aspects of the investigation process, but it did not follow-up with training or other assessments to ensure that the new requirements effectively addressed targeted weaknesses. The timely success of these investigations is critical to eradicating the disease.

While APHIS has made improvements in recent years, weaknesses with the program's oversight and controls make it difficult for APHIS to timely detect and eradicate the disease.

**Recommendations
In Brief**

We recommend that APHIS perform a risk assessment using existing management reports to determine where its highest risks are located, and work to minimize those risks. Oversight can also be improved by more timely and effective use of management reports and periodic reviews of local program operations. We also recommend changes to two key control functions of the BTEP, the status classification system and the slaughter surveillance system. Adjustments are also needed to cattle import controls for Mexico. APHIS and FSIS can further solidify recent improvements to detect TB with a change to their existing agreement. Although an animal identification system is expected to enhance disease investigations, it is not forecasted to be in place until 2009. Therefore, we recommend better use of high-risk herd provisions, additional oversight of TB investigations, and that APHIS assess if new regulations and operating procedures were effective, or determine if further improvements are needed.

Agency Response

In their response dated September 28, 2006, APHIS and FSIS officials agreed with our recommendations. We have incorporated applicable portions of their response, along with our position in the Findings and Recommendations section of the report. The response is incorporated in its entirety as exhibit G of the report.

OIG Position

We agree with APHIS' and FSIS' proposed actions and have reached management decision for all recommendations.

Abbreviations Used in This Report

APHIS	Animal and Plant Health Inspection Service
BTEP	Bovine Tuberculosis Eradication Program
CFR	Code of Federal Regulations
FSIS	Food Safety and Inspection Service
FY	Fiscal Year
MOU	Memorandum of Understanding
NAIS	National Animal Identification System
OCFO	Office of the Chief Financial Officer
OIG	Office of Inspector General
TB	Bovine Tuberculosis
UM&R	Uniform Methods and Rules - Bovine Tuberculosis Eradication
U.S.	United States
USDA	United States Department of Agriculture
VS	APHIS' Veterinary Services

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Background and Objective

Background

Bovine Tuberculosis (TB) caused more deaths among farm animals in the United States (U.S.) in the early 20th century than all other infectious diseases combined. Bovine TB is contagious to most mammals, including humans. Whereas the disease is treatable in humans, there is no treatment for animals. The transmission of bovine TB² from animal to human is unlikely because adequate cooking of meat and pasteurizing milk kills the TB bacteria. The disease can spread between animals through the air or consumption of contaminated water, feed, or milk. The most effective means of controlling the disease is by destroying infected or exposed animals.

Begun in 1917, the Bovine Tuberculosis Eradication Program (BTEP) has sought to eliminate the disease. In October 2000, when USDA's Animal and Plant Health Inspection Service (APHIS) discovered warning signs that the disease might spread through the animal population again, the Secretary of Agriculture signed a Declaration of Emergency which authorized \$44 million for a multi-year effort to expand the BTEP. In each of the last few fiscal years (2004-2006), APHIS allocated \$14 to \$15 million for the BTEP.

APHIS administers the Cooperative State/Federal BTEP through 2 regional offices and 41 area offices, which work cooperatively with the 50 States, Washington D.C., Puerto Rico and the Virgin Islands. States must follow both APHIS' operating procedures and Federal regulations.³ Regulations note that a State must have the legal and financial resources to implement and enforce a TB eradication program, and that a State or zone must maintain clinical and epidemiologic surveillance of animal species at risk of TB.

For the first time since January 1999, APHIS updated its operating procedures, the Uniform Methods and Rules (UM&R) in January 2005 (herein referred to as operating procedures). This update incorporated changes to the program including: (1) New performance measures for slaughter and on-farm TB surveillance, (2) Establishment of timeframes for epidemiologic investigations, which search for the source of the detected disease, and (3) Incremental increases to the length of time dealers/brokers need to retain animal records (from 2 to 5 years) progressively through 2008.

Slaughter Surveillance

APHIS detects TB primarily through inspections at slaughter facilities conducted by USDA's Food Safety and Inspection Service (FSIS). APHIS focuses its attention on the carcass inspections and surveillance rates at the

² Additional forms of tuberculosis exist, including avian and human tuberculosis. However, this report solely discusses *Mycobacterium bovis* (bovine tuberculosis) and will use "TB" to mean bovine tuberculosis throughout the report.

³ Bovine Tuberculosis Eradication, Uniform Methods and Rules (UM&R) (January 2005) and Title 9, Code of Federal Regulations (CFR), Part 77.

largest 40 slaughter facilities because these facilities account for over 90 percent of the cattle slaughtered in the United States. Slaughter inspections are performed according to a memorandum of understanding between APHIS and FSIS. Under the terms of this agreement, FSIS inspectors (or the State meat inspectors whom they oversee) will examine carcasses for suspicious lesions and collect 1 lesion per 2,000 adult cattle slaughtered. The inspectors will then submit the suspect lesions to the National Veterinary Services Laboratory or to other APHIS-approved laboratories for testing. The carcass is retained at the slaughter facility until the lab results are received. When a sample is found TB-positive, FSIS condemns the carcass if the lesions are generalized, but may condemn only a portion of the carcass if the lesions are localized. Unaffected portions of the carcass may be released for cooking. The laboratory forwards the test results to the appropriate APHIS area office for further investigation.

On-Farm TB Testing

APHIS supplements the slaughter surveillance discussed above with TB testing on farms. The most common reasons for on-farm testing are as follows: (1) Epidemiologic investigations of infected animals found at slaughter; (2) Area testing in zones with low TB classifications; (3) Interstate movement testing requirements (for States/zones with TB problems); (4) Annual testing for accredited herds;⁴ and (5) Testing of high-risk herds.

The caudal fold test is the primary on-farm test. Responder animals are subjected to secondary tests, unless they are sent directly to slaughter.⁵ APHIS published performance standards in its 2005 rules that chart expected test results. These results are predicated on the assumption that 1 percent of non-affected cattle will falsely test positive for the disease.⁶ Animals that test positive upon secondary testing are slaughtered for post-mortem testing with tissue samples submitted for laboratory examination.

Epidemiologic Investigations

When an APHIS area office receives positive test results from a laboratory they will work with the infected animal's State veterinarian organization to conduct an epidemiologic investigation.⁷ APHIS' investigations attempt to locate and test the herd(s) that the infected animal belonged to or that it may have exposed to the disease. Veterinarians use identification tags (if available), dealer and broker records, and discussions with herd owners to identify the source of the infection. The herd(s) of origin or potential source herds are required to be quarantined and tested.⁸ If the herd of origin or

⁴ An accredited herd has successfully passed two consecutive TB tests in a 9 to 15 month period, and annual/biennial herd testing in subsequent years.

⁵ Responder animals have had a positive reaction to a TB test. For APHIS' technical definition see UM&R Part I "Definitions," (January 2005).

⁶ For APHIS' Performance Standards for Caudal Fold Tuberculin Testing, see UM&R Appendix C (January 2005).

⁷ The procedures for performing tracebacks are outlined in VS Memorandum No. 552.2, Part V.D.

⁸ UM&R Part I (January 2005) states a herd of origin may be the herd of birth or where the animal resided for a minimum of 4 months prior to movement.

infected herd is not found, APHIS requires that all consignors to that particular lot are to be added to the high-risk herd list for subsequent testing.⁹

Beginning in January 2005, APHIS requires that all investigations be completed within 90 days of initiation. APHIS area offices report the results of their investigations to their regional office, which is responsible for verifying all actions taken and then closing the case. If TB is confirmed in a herd through on-farm testing and subsequent laboratory analysis, APHIS declares the herd “affected”¹⁰ and initiates eradication procedures.

Eradication

APHIS’ goal is to eradicate the disease. When a herd has been determined to be affected, APHIS recommends depopulating (i.e., destroying) the entire herd. If the owner elects not to depopulate the herd, the herd shall remain under quarantine until all the requirements of an individual herd (test and remove) plan have been completed.¹¹ APHIS also recommends that all cattle sold from known affected herds be depopulated. If not depopulated, these animals must remain under quarantine and be retested under the rules for high-risk herds.¹²

TB Status Classification System

APHIS has established a hierarchy of TB statuses for States and zones, based on the number (or percentage) of affected herds found in that area.¹³ A State’s status determines the TB testing requirements that must be met before animals can be moved out of the affected area. Testing and movement restrictions increase with each lower classification (see appendices A and B in UM&R). The five TB status classifications are as follows:

1. Accredited-Free. No TB problem has been identified, or a defined low prevalence level has been reached. Livestock movement is unrestricted.
2. Modified Accredited Advanced. TB found in less than 0.01 percent of the herds. Negative TB test required prior to interstate movement for breeding animals.

⁹ High-risk herds are those which have had a history of lesions suggestive of TB (but not confirmed), premises where a TB affected herd has been depopulated, or herds that contain exposed animals sold from known affected herds. VS Memorandum 552.2 states that when a slaughter traceback does not identify the herd of origin or infected herd, all consignors must be added to the high-risk herd list.

¹⁰ UM&R Part I (January 2005) defines an affected herd as a herd of livestock in which there is strong substantial evidence that *Mycobacterium bovis* (bovine TB) exists. This can include epidemiologic evidence such as contact with known sources of infection.

¹¹ Under a test and remove plan animals in an affected herd remain under quarantine, are subject to periodic testing, and must be removed for post-mortem examination if they respond to a primary test. For more detail, see UM&R Part III.J.3 (January 2005).

¹² UM&R, Part III.K.3 (January 2005).

¹³ A zone is a bounded land area (e.g., geological, political, man made, etc.) which, for the purposes of BTEP, can be defined as having its own mechanisms of disease spread, epidemiologic characteristics, and ability to control movement of animals across its boundaries. This definition allows APHIS to apply its control mechanisms more precisely to areas within States. A State can have multiple TB zones, i.e., Michigan has three zones.

3. Modified Accredited. TB found in less than 0.10 percent of the herds. Negative TB test required for entire herd of origin (e.g., herd from which animal infected with TB originated) before moving breeding and non-breeding animals.

4. Accreditation Preparatory. TB found in less than 0.5 percent of the herds. This status requires significant restrictions and prohibitions on cattle movements.

5. Non-Accredited. TB found in 0.5 percent or more herds. This status prohibits movement of cattle for feeding or breeding purposes.

As of June 2006, there were 46 States in the highest classification, accredited-free, while the rest of the States and zones were distributed among the next two lower classifications, modified accredited advanced and modified accredited.

Mexico

The United States imports over 1 million cattle from Mexico every year, and because Mexico has a higher prevalence of TB than the United States, it continues to be the main source of positive TB cases found by APHIS' slaughter surveillance. For example, in 2004 Mexico reported over 2,000 TB-infected herds compared to only 10 reported by the United States.

Through cooperative efforts, APHIS and its counterparts in Mexico's government have been working together to improve Mexico's TB situation. As part of this effort they established testing requirements for cattle imported from Mexico based upon APHIS' TB status classification system. The lower status Mexican States or zones have stricter controls. Based upon this system almost all of the United States is accredited-free (the highest classification); but APHIS only considers one zone in Mexico to have a status higher than modified accredited (see exhibit D). Because of the low statuses in Mexico, virtually all cattle are tested prior to export to the United States.

Although there are no additional test requirements for cattle after being imported from Mexico, all require official identification in the form of a blue ear tag or "M" or "MX" brand; a certificate of origin with the animals Mexican State of birth; and an international export health certificate. Each certificate is authenticated by APHIS' counterparts in Mexico's government.

Objective

The objective of the audit was to evaluate APHIS' controls to ensure that TB surveillance is adequate to timely detect TB outbreaks for eradication efforts.

Findings and Recommendations

Section 1: Control and Oversight of the BTEP

Overall, APHIS' management of the BTEP has been sufficient in that no widespread outbreaks have occurred and TB continues to have a low incidence of occurrence in the United States, in relation to the cattle population as a whole. In recent years APHIS has also made progress on addressing the issues that prompted the Secretary of Agriculture to declare a TB emergency in October 2000. These improvements include a significant increase in the number of lesions and tissue samples submitted by slaughter facilities for TB analysis, and progress with APHIS' cooperative efforts to address the TB problems in specific zones in the States of Michigan and Texas. Although these achievements are notable, we did identify areas where additional improvements are needed to help APHIS achieve its goal of eradicating TB.

We determined that the agency can improve its oversight by making more effective use of the management resources at its disposal. In particular, APHIS can increase its control over States' execution of the BTEP by timely reviewing and responding to the annual and monthly summaries of program results that States submit to the agency, and by periodically reviewing States for program compliance. This is important as illustrated by the TB outbreak detected in July 2005 in Minnesota, which has resulted in quarantines and testing at over 100 cattle herds in 8 States. Timely analyses and clearer operating procedures could have enabled APHIS to recognize and address the program weaknesses in Minnesota in a timelier fashion.

APHIS can also enhance its control over the program by adjusting how it determines States' TB statuses—which dictate the controls necessary to eradicate the disease—by incorporating all known cases of TB into its status system and by requiring timely status reductions in response to an outbreak. Under the current status system, only 12 of 272 TB cases detected by slaughter surveillance in the last 5 years resulted in additional controls or eradication efforts. APHIS also delayed reducing Minnesota's TB status for 4 months while they continued to investigate the outbreak. As a result, animals continued to leave the State without testing or restriction.

Finding 1**Areas APHIS Can Improve Its Oversight of the BTEP**

Three of the tools that APHIS uses to assess States' BTEP performance are their annual and monthly reports and program reviews.¹⁴ APHIS, however, has not used these tools as timely or effectively as it could to maintain oversight and control. Given limited staff resources, responding to the Secretary's Emergency Declaration in October 2000, and priorities that emerged from other animal diseases (e.g., Bovine Spongiform Encephalopathy and Exotic Newcastle Disease), APHIS has not consistently emphasized the use of these tools. In addition, APHIS' operating procedures were not clear on when or how to use these reports, and it did not specify how often program reviews should occur. As a result, APHIS may have missed an opportunity for early detection of a recent outbreak of the disease, and they have reduced assurance that States are effectively detecting and eradicating the disease.

Although APHIS is taking steps to improve its program oversight – hiring additional national staff, establishing performance standards for slaughter surveillance and for individuals performing on-farm tests, and new timeframes for completing TB investigations – it needs to enact measures to make better use of its oversight tools. For example, during FY 2005 Minnesota had an outbreak of TB detected by slaughter surveillance in Wisconsin, which has resulted in quarantines and TB testing of over 100 cattle herds in 8 States. Our analysis of FY 2004 and FY 2005 annual and monthly reports showed that Minnesota and Wisconsin slaughter surveillance, and Minnesota's on-farm testing just prior to the outbreak were well below current standards. Had standards been met in previous years, it is possible that this increased surveillance could have detected the disease at an earlier stage.

Annual Reports

According to its operating procedures, APHIS requires each State to submit an annual report by November 30 every year. These reports inform APHIS about the prevalence of TB in that State, its management of infected and high-risk herds, and the overall results of its slaughter surveillance and on-farm testing. APHIS' Administrator must review and approve each report in order for the State or zone to maintain the higher statuses of TB classification (accredited-free or modified accredited advanced).

¹⁴ States' annual reports provide APHIS' management an overview of States' BTEP activities and results for the year while their monthly reports indicate the number and results of on-farm TB tests conducted for that month. APHIS' program reviews determine whether or not States are conducting BTEP in accordance with agency guidance and Federal regulation.

As of September 2005, however, APHIS had not reviewed 15 of the 50 FY 2004 annual reports and an additional 14 (for a total of 29) had not been approved. We separately determined that 34 reports were submitted to APHIS late (after the November 30, 2004, due date). APHIS officials¹⁵ stated that the agency had delayed its reviews for the preceding 2 years because management resources had been diverted to address other emergency animal diseases (e.g., Bovine Spongiform Encephalopathy and Exotic Newcastle Disease) and because the agency had been understaffed. An APHIS official stated one position had been filled in FY 2005, and that they are in the process of filling three additional positions in order to increase their oversight and monitoring capabilities.

In April 2005, over 4 months past the filing deadline, we selected a sample of nine States' FY 2004 annual reports for review, including each of the four TB-affected States (Michigan, Texas, California, and New Mexico) at that time. One of the nine selected States, Tennessee, had not submitted a report. We also found that APHIS had not reviewed any of the other eight reports and five of these reports did not include all of the required data, or contained questionable data. For example, Minnesota did not report its on-farm testing results or the number of adult cattle slaughtered. Both Minnesota and Wisconsin reported slaughter surveillance results well below current standards (see Finding 5). We also found that all four TB-affected States (at that time) were deficient in reporting activities related to high-risk herds (see Finding 6).

Without timely analysis of the annual reports to identify and respond to issues or assess compliance with their rules, APHIS has limited assurance that it has correctly determined the State's TB status and, therefore, limited assurance that the disease is being effectively detected and eradicated. During the course of our audit, APHIS added an additional staff member who initiated reviews of the annual reports, but they had been unable to include areas such as analyzing reports for trends or proper disclosure and treatment of high-risk herds.

Monthly Reports

Every month, each State is required to post its on-farm test results to a database which is accessible for review by APHIS' national and regional offices. The effectiveness of on-farm testing is important because it is the only means by which APHIS will declare an affected herd or adjust a State's status (see Finding 2). If the tests results are not accurate, then APHIS may have miscalculated the prevalence of the disease in some States and consequently not applied the appropriate testing and movement restrictions.

¹⁵ Throughout this report any reference to APHIS officials means national officials unless otherwise noted.

During our review of internal controls and the procedures related to monthly reports, we found APHIS did not have procedures in place to review monthly reports at the national or regional offices. In the absence of guidance, the national office and the western regional office each believed that the other was reviewing the reports when neither was. Without such oversight, the agency has reduced assurance that individuals are administering on-farm testing according to standards.

We also determined that even though APHIS established a TB performance standard for individual veterinarians in January 2005, it has not utilized the monthly reports to assess the effectiveness of each State's on-farm testing.¹⁶ We applied APHIS' individual performance standard principle (that at least 1 percent of all cattle are expected to falsely test positive),¹⁷ to nine State's monthly reports for the period October 2003 to January 2005. We found that 4 States reported significantly less than the expected number of responders for the 16 months reviewed. For example, while testing almost 22,000 animals Minnesota reported only 3 responders for the entire period. Based on APHIS' standard, we calculated that Minnesota should have reported 220 responders. In response to this concern, an APHIS official stated that they intend to increase monitoring of on-farm test results at the national level, and clarify the region's responsibilities to review the reports.

Program Reviews

APHIS area offices are responsible for ensuring that all BTEP requirements are accomplished cooperatively with a State. APHIS' operating procedures require each State to have an effective veterinary organization and infrastructure so that it can carry out BTEP in accordance with program regulations.¹⁸ APHIS' reviews measure the area office's and State's ability to comply with program provisions.¹⁹

While APHIS does have criteria for area office reviews, these standards did not ensure that States were being reviewed.²⁰ Two of the criteria listed in APHIS standards to consider for conducting a review are administrative or program concerns, and the length of time since the last review. However, a specific length of time is not specified. We examined the western region's program review reports from August 1999 to March 2005, and determined that 16 of the region's 23 States had not been reviewed for BTEP compliance. As a result, APHIS lacks the extra assurance these reviews

¹⁶ APHIS' UM&R Appendix C (January 2005) contains "Performance Standards for Caudal Fold TB Testing."

¹⁷ APHIS' performance standards in UM&R Appendix C (January 2005) are based on the premise that at least 1 percent of animals will test positive, but not have the disease. This is commonly referred to as a false positive result. Animals testing positive are retested at a later date.

¹⁸ UM&R Part V.A.4 (January 2005)

¹⁹ According to VS Memorandum 515.1 (April 18, 2003), there are two types of reviews that APHIS conducts at its area offices: "program" reviews and "station" reviews. Program reviews focus on BTEP, while station reviews check various administrative and program activities.

²⁰ VS Memorandum 515.1 (April 18, 2003).

could provide, that its area offices and State counterparts are adequately executing the program.

We recognize that APHIS has faced challenges with allocating its resources to effectively manage emerging animal diseases. In response to these areas, an APHIS official noted that they have been attempting to fill several vacancies that they intend to use to enhance their ability to oversee BTEP, including improvements to the annual and monthly reporting processes. Because other priorities and resource issues have adversely impacted APHIS' attention to BTEP data in recent years, other weaknesses or vulnerabilities similar to Minnesota may exist; where both on-farm testing and slaughter surveillance results were below standards. Therefore, we believe that APHIS needs to perform a risk assessment using available information to identify weaknesses or program vulnerabilities, and then prioritize its resources to take actions to address highest risk areas. In order to enhance its control over the program on a more consistent basis, APHIS needs to implement procedures that define actions to timely and effectively use its management reports, and to perform program reviews on a more consistent basis.

Recommendation 1

Perform a risk assessment using information in annual, monthly or other reports, to identify weak conditions or higher risk factors. Utilizing this information, develop and implement an action plan to address the highest risk areas.

Agency Response

APHIS officials have analyzed the 2006 annual reports and will conduct risk assessments using the information in the annual, monthly and other reports to identify weaknesses in program delivery at the State level. Based on these risk assessments, they will prioritize resources and identify States to be reviewed by the regional tuberculosis epidemiologist. APHIS officials also agreed to outline this process in a set of standard operating procedures to be completed by December 31, 2006, which will define guidelines and timeframes for reviewing the reports at the national and regional levels.

OIG Position

We accept APHIS' management decision.

Recommendation 2

Establish standard operating procedures including timeframes for the review and approval of States' annual and monthly reports, and for taking actions on delinquent, errant or incomplete report submissions.

Agency Response

APHIS officials agreed to establish standard operating procedures for reviewing annual and monthly reports. These procedures will also detail actions to be taken on errant and incomplete reports. They plan to implement the new procedures by December 31, 2006.

OIG Position

We accept APHIS' management decision.

Recommendation 3

Perform program reviews each year to evaluate whether State TB surveillance and eradication activities are in compliance with regulations and agency procedures.

Agency Response

The response stated that beginning in FY 2007, APHIS officials will conduct annual program reviews on at least 10 percent of the State programs. They will select States each year after analyzing the States' annual reports, and base these selections on compliance with program requirements, surveillance efforts and the length of time since a previous review was conducted. The FY 2007 selections will be prepared and ready for APHIS' management approval by November 1, 2006.

OIG Position

We accept APHIS' management decision.

Finding 2

APHIS Needs to Improve Its TB Status Classification System

In a control central to its management of the BTEP, APHIS classifies States according to a status system under which lower rankings translate into more restrictive control measures. We concluded that this system does not accurately reflect the status of TB in the country because it is based solely on the number of affected cattle herds, and APHIS applies a narrow definition for what it considers to be an affected herd. We determined that APHIS' practice for declaring affected herds and assessing slaughter cases to source States differs from Federal regulations and APHIS' operating procedures. As a result, only 4 percent (12 of 272) of the TB cases found by slaughter surveillance in the last 5 years were reflected in the status system. In a related audit report, because the status system is based solely on cattle, nearly 500 wildlife cases in one State over an 8-year period were also excluded.²¹ Without including the majority of known TB cases in its status determinations, APHIS is not implementing its controls over TB as effectively as it could be, thereby weakening its ability to contain and eradicate the disease.

APHIS' internet website notes that TB has been nearly eradicated from the Nation's livestock population, and demonstrates this with a chart of the TB statuses for all 50 States. As of June 2006, the website illustrates that 46 States are classified as accredited-free, which essentially means that these States have no TB problems. We determined that APHIS based its status decisions for FY 2001 through FY 2005 on 36 affected herds identified by slaughter surveillance and/or on-farm testing (see exhibit A).²² As noted in the following pages, we determined that a significant number of TB cases were not being included in the status system nor were they reflected on APHIS' website.

The status system is based on the number of TB-affected herds found in a State or zone. Federal regulations define an affected herd as one in which TB has been disclosed in any cattle or bison by an official TB test or by post mortem examination.²³ APHIS' operating procedures define an affected herd as one in which strong and substantial evidence of TB exists; this evidence should include, but is not limited to histopathology, bacterial isolation, testing data or epidemiologic evidence such as contact with known sources of infection.²⁴ However, in practice APHIS will only declare a herd affected if it has the evidence mentioned in the official definitions, plus an additional infected animal is found during the investigation to identify the animal's herd(s) of origin. This practice is used because of the difficulty APHIS experiences while trying to

²¹ National Cooperative State-Federal Bovine Tuberculosis Eradication Program in Michigan, Audit Report No. 33099-0005-Ch (April 2005).

²² From FY 2001 through FY 2005, APHIS declared 38 affected herds, of which 2 were later reversed.

²³ 9 CFR 77.5.

²⁴ UM& R Part I.

identify where an animal originated and where the animal became infected with the disease.

TB Cases Identified by Slaughter Surveillance

For the period of FY 2001 through FY 2005, APHIS' slaughter surveillance program identified 272 TB-infected cattle which traced to 22 States (see exhibit B), yet only 12 of these cases (4 percent) were included for purposes of determining State status. This occurred because APHIS' practice for declaring an affected herd differs from the official definitions, and it does not apply an existing operating procedure for State status determinations that specifies what the State of origin should be for an infected animal. As a result, no additional controls in the form of testing and movement restrictions were put into place for a majority of TB cases detected in the past 5 years. Furthermore, these cases are not reflected on APHIS' website, so although the BTEP is a cooperative program with States, the States do not have the benefit of this additional information.

In practice, APHIS will only declare a herd affected for status purposes if its investigation identifies a source herd, and APHIS is able to find another infected animal at that source herd with on-farm testing. We determined that this practice does not agree with the definitions of an affected herd in Federal regulations or APHIS' own operating procedures, and it reduces the number of herds declared affected. As noted in Finding 6, if APHIS' investigation finds a herd of origin, by that point in time the composition of the herd may have changed, which can limit the effectiveness of testing. For example, our review of FY 2004 investigations found that 12 of the 20 herds of origin experienced turnover and no longer had any animals remaining on the farm to test. An APHIS official explained that their practice for declaring an affected herd applies a narrow interpretation of the definitions. He further explained they follow this practice because of the difficulties they experience in identifying where an animal originated, and in determining where the animal became infected with the disease.

We also questioned an APHIS official about why a procedure specific to assessing slaughter cases to a particular State was not being used for status purposes. This procedure states "Tuberculosis found during slaughter inspection or otherwise in any livestock will be considered to have originated in the State where the animal was slaughtered or the disease was disclosed unless successful traceback procedures identify another State as the original source."²⁵ In response, an APHIS official explained that they do not apply the State of origin rule in determining State status, but these cases are assessed against the appropriate States. However, this assessment does not result in additional controls or requirements. This official also did not

²⁵ APHIS' UM&R Part III.

feel it was appropriate to apply the rule for status purposes, because it would penalize States with larger slaughter facilities and feedlot operations, particularly those that deal with cattle imported from Mexico.

Herds with Strong Evidence of TB

Our analysis of APHIS epidemiologic investigations found that APHIS did not always declare a herd affected when there was strong evidence of TB. We identified three herds that were not declared affected even though each met the definition of an affected herd by APHIS' regulations and operating procedures. These herds had strong evidence of TB, which was disclosed through either on-farm TB testing and/or post mortem examination. One of the cases would have adversely impacted State status, while another would have expanded the existing affected zone.

In separate investigations, four TB-infected cattle were traced to a single herd in New Mexico that was not declared affected. This herd was originally reported affected in APHIS' publications, but APHIS later reversed its decision.²⁶ We concluded that four infected cattle constituted strong evidence of infection. However, an APHIS official stated that they only considered the herd exposed, not affected, because they were unable to confirm the infection at the premises with successful on-farm tests.²⁷ New Mexico has an affected zone consisting of two counties. This case was in an adjacent county, so it could have expanded the affected zone had it been declared an affected herd.

In a related situation, one TB-infected animal was found by on-farm testing in an Arizona herd prior to interstate transportation. Similar to the New Mexico herd in the previous paragraph, APHIS originally reported this herd as affected in its publications, but subsequently reversed the decision. An APHIS official stated this herd was only classified as an exposed herd because the animal originated from the aforementioned New Mexico herd. This animal was found by on-farm testing, and since it resided at that premises for more than 4 months, by another APHIS definition, it qualified as a herd of origin. Had this herd been declared affected, Arizona's status would have qualified for reduction when another affected herd was found in FY 2005.

Our third example involves an animal that was born, raised and slaughtered in the same State (Nebraska). This case was detected via slaughter surveillance, and it was determined that the animal lived at only two locations in its lifetime, both in the same State. The animal in question proceeded directly from its second residence to slaughter. This case was not

²⁶ APHIS reported the New Mexico and Arizona cases as affected herds in its FY 2004 United States Animal Health Report, its FY 2004 report to the Office of International Epizootics, and in its Status of State/Federal Cooperative Bovine TB Eradication Program, FY 2004.

²⁷ APHIS UM&R defines an exposed animal as any livestock exposed to TB by associating with other livestock in which TB has been diagnosed.

assessed against the State because APHIS was unable to find an additional infected animal during on-farm testing of the two herds of origin. Had an affected herd been assessed against the State, it would not have impacted State status, as it takes 2 cases within a 48-month period to adversely impact status.²⁸

Wildlife Infect Livestock with TB

In a related audit report, we found that APHIS excluded wildlife TB cases from the status system, and as a result, did not include close to 500 TB cases in deer and other animals in Michigan (from FYs 1995 to 2002).²⁹ Wildlife was infecting livestock in Michigan, such that the Secretary included it as one of the main reasons for a TB Declaration of Emergency in October 2000. In response to our previous audit, APHIS agreed to revise its status classification standards for Michigan's infected zone to include measurements of TB in the wildlife population as a status-determining factor. APHIS is still in the process of implementing corrective actions to that audit. Because TB cases have since been found in Minnesota wildlife, and continue to be found in Michigan, we asked an APHIS official whether they planned to make earlier corrective actions specific to Michigan, or nationwide. This official responded that the corrective actions would be nationwide. As a result, we will not make an additional recommendation in this report.

We concluded that APHIS needs to improve the TB status classification system to better reflect the current status of TB in the United States. By incorporating these results into the status system, APHIS could better target its controls and testing to States/zones with more TB cases, thereby enhancing the eradication program. Although TB incidence in the United States is at a low level, the status system and APHIS website do not clearly illustrate TB in the country, or ensure controls are put in place when it is detected. With a more accurate representation, States may choose to implement additional controls, similar to when APHIS delayed downgrading Minnesota's status during the latest TB outbreak, when a number of States imposed their own restrictions upon Minnesota cattle. Because the status system is outlined in both APHIS regulations and rules, adjustments would be needed to both to better address these issues.

While APHIS officials provided explanations for why their practice for declaring an affected herd differs from the official definitions, and why they do not apply the State of origin rule for status purposes, they do agree improvements are needed, and they continue to explore ways to improve the program. APHIS' website notes that in 2009, the National Animal Identification System (NAIS) will trace infected animals to their herd(s) of origin within

²⁸ 9 CFR 77.7 (c).

²⁹ National Cooperative State-Federal Bovine Tuberculosis Eradication Program in Michigan, Audit Report No. 33099-0005-Ch April 2005.

48 hours. Our recommendations can help improve current practices and serve as a precursor to the animal identification system, as it will assess all of these cases to the appropriate States when it is implemented.

Recommendation 4

Expand TB status classification guidelines to include all bovine TB-infections, including animals identified by slaughter surveillance, to be status-determining factors for State TB-status classifications.

Agency Response

APHIS officials stated that they need to do more to account for each case of TB, while not inappropriately penalizing States that have the majority of slaughtering and feedlot facilities where these cases are found. They are carefully examining modifying TB status classification guidelines and developing a proposed rule to be published in the Federal Register by April 2007. The proposal will require herds be placed on a high-risk herd list for further testing, and be tested whenever another epidemiological trace identifies them as a possible source. In addition, the agency's response to Recommendation 5 explains that it will also expand the classification guidelines to include use of DNA technology to confirm the source of slaughter samples.

OIG Position

We accept APHIS' management decision.

Recommendation 5

Revise the current practice of declaring a herd affected only if it is confirmed by on-farm testing to conform to the existing regulatory and operating procedure definition(s) of an affected herd.

Agency Response

In the response, APHIS officials noted that their goal is to find every infected herd in the Nation, but to accomplish that goal additional animal identification is needed on most animals. Prior to this year, DNA technology had not been available to help confirm the source of slaughter samples. That technology is now available; therefore, APHIS will propose (in the new regulations), expansion of the status classification guidelines to include bovine infections that can be traced back to herds of origin, without finding infected animals in the herd, based on DNA confirmation of the source animal for the positive slaughter sample, and where the epidemiology clearly shows the animal most likely had the infection while it was a member of the herd. APHIS will publish the proposed rule by April 2007.

OIG Position

We accept APHIS' management decision.

Recommendation 6

On a current and historical basis (for the preceding 5 years), publish all TB cases (slaughter or otherwise identified) on APHIS' website.

Agency Response

APHIS officials stated they have initiated the process to publish all positive M.bovis cases on their website. They plan to complete this process by October 30, 2006.

OIG Position

We accept APHIS' management decision.

Finding 3

Controls Were Not Implemented Timely in Response to an Outbreak

We determined that APHIS could have taken more timely action to lower Minnesota's TB status after an outbreak was detected. Despite meeting the regulatory criteria for having its TB status lowered in September 2005 (2 or more affected herds in a 48-month period), APHIS decided to delay this action until they could complete the epidemiologic investigations. APHIS lowered Minnesota's status on January 30, 2006, after two additional herds were declared affected (but before the investigation was completed). The delay in lowering Minnesota's TB-status was permitted by APHIS' operating procedures³⁰ but contradicted Federal regulations.³¹ As a result, Minnesota continued to export cattle for 4 months before being subjected to mandatory testing. In addition, while APHIS delayed its action, several States imposed their own controls and protections with regards to Minnesota cattle.

Federal regulations state that when one affected herd is detected in an accredited-free (disease free) State, the State may retain its accredited-free status if the herd is depopulated, and the epidemiologic investigation is completed within 90 days of the detection with no evidence of the spread of TB.³² The regulations further state that if 2 or more TB-affected herds are detected in an

³⁰ UM&R Part V.D.1.b and c (January 2005).

³¹ 9 CFR 77.7 (c).

³² 9 CFR 77.7 (c).

accredited-free State in a 48-month period, the State will be reclassified as modified accredited advanced.

APHIS' operating procedures differed from regulations. These procedures describe how a State's status can remain accredited-free if an epidemiologic investigation of the initial affected herd is completed within 90 days, and investigation of subsequent affected herds is completed within an additional 120 days, with no evidence of spread of the disease.³³ The procedures also state that if 2 epidemiologically unrelated bovine TB-affected herds are detected in a TB-free State within a 24-month period ... the Administrator will determine whether or not to lower the status.

In February 2005, a TB-infected animal was detected at a Wisconsin slaughter facility, and traced to a Minnesota herd. Testing on this herd disclosed an additional 18 infected animals. APHIS completed the testing and declared the herd affected in July 2005, and began tracing prior animal movements in and out of this herd and also conducted testing of neighboring herds.

Additional testing based upon the tracing of animal movements in and out of the affected herd, and testing of neighboring herds identified two other affected herds in September 2005, at which time Federal regulations indicate Minnesota's status should have been lowered to modified accredited advanced. By December 2005, a total of five affected herds and one infected deer were reported in Minnesota.³⁴ However the State was still classified as accredited-free so no testing or movement restrictions were put into effect by APHIS. When APHIS delayed lowering Minnesota's status, several States imposed their own restrictions. On January 30, 2006, 4 months after meeting the regulatory criteria for downgrade, APHIS lowered Minnesota's TB-status to modified accredited advanced. An APHIS official explained that they decided to delay lowering the status until the investigation was completed, but finally proceeded with the reduction after the fifth affected herd was found. As of June 2006, the investigation was still in process and has impacted over 100 other herds in 8 States.

We concluded that APHIS needs to revise its operating procedures regarding an outbreak of TB to include prompt actions to lower a State's TB status when it becomes known the disease is not isolated to one herd. When APHIS revised them in January 2005, the results deviated from regulations. We discussed this difference and others that resulted from the update with an APHIS official, who indicated that they plan to modify both the procedures and regulations where needed.

³³ UM&R Part V.D.1.b and c (January 2005).

³⁴ A second infected deer was reported in January 2006.

Recommendation 7

Revise the UM&R to be in accordance with 9 CFR 77.7(c), by requiring that an accredited-free State's status be immediately lowered once an outbreak (of 2 or more affected herds in a 48-month period) is detected.

Agency Response

The response stated that the UM&R has been revised in accordance with 9 CFR 77.7(c). This was completed on March 14, 2006. APHIS officials will also clarify the regulations to make the process of lowering a State's status more immediate. These changes will be completed by April 2007.

OIG Position

We accept APHIS' management decision.

Finding 4 Controls Over Cattle from Mexico Need to be Improved

Between FYs 2001 and 2005, 75 percent (205 of 272) of the TB cases detected through slaughter surveillance were determined by APHIS to have originated from Mexico. In response, APHIS has worked with Mexico to improve their TB eradication program; however, these efforts are undermined by the disease's 3 to 12 month incubation period. Cattle may test negative for the disease prior to export, but develop TB and infect U.S. cattle after import. Although the majority of TB-infected cattle found by slaughter surveillance in the United States are from Mexico, APHIS has not developed controls to restrict the movement of cattle, or require additional testing to compensate for the disease's incubation period. Until additional controls are added, APHIS cannot reasonably expect to achieve its goal and eradicate TB when it is being imported into the United States each year.

Each year, Mexico exports approximately 1 million cattle to the United States. Because of a higher prevalence of the disease in Mexico, cattle are more likely to be infected with TB. As of September 2005, the United States had 47 States classified as accredited-free,³⁵ while APHIS indicates Mexico had no accredited-free States (see exhibit D). In addition, Mexico reported over 2,000 TB-infected cattle herds in 2004 compared to just 10 positive herds reported by the United States.³⁶

Controls for the import of animals from Mexico are covered in Federal regulations and by APHIS' operating procedures.³⁷ APHIS publishes updates to import controls in VS Notices. The VS Notices describe specific status rankings of each Mexico State/zone, and the import requirements for that status.

We analyzed APHIS' slaughter surveillance results and the TB cases detected between FYs 2001 through 2005 and determined that 75 percent (205 of 272) of the cattle identified as TB-positive originated in Mexico. In our analysis of FY 2004 investigations of TB-infected cattle found at slaughter, we found that the Mexican-origin cattle spent 5 to 14 months at U.S. farms and feedlots prior to arriving at slaughter facilities. At these premises, the Mexican-origin cattle may be commingled with domestic cattle without restriction. In general over 99 percent of the cattle imported from Mexico spend time on U.S. premises prior to slaughter.

³⁵ As of June 2006, the United States had 46 accredited-free States due to the January 2006 lowering of Minnesota's status.

³⁶ Annual Report - Food and Agriculture Organization /Organization Internationale des Epizooties /World Health Organization Questionnaire - 2004.

³⁷ 9 CFR 93.427(c) and UM&R Part V.D. and Appendices A and B (January 2005).

Despite the higher prevalence of TB-infected cattle in Mexico, APHIS has not established additional import controls or requirements to test or restrict the movement of Mexican cattle after importation to the United States. Furthermore, even though animals are tested before being exported to the United States, according to APHIS, the disease can incubate for a period of 3 to 12 months,³⁸ and evade detection while it incubates. After being imported, these animals simply become part of U.S. herds and can be traded and transported throughout the country. As illustrated below, the lack of additional controls has resulted in infected cattle being detected in 12 States over the last 5 years.



TB Cases Traced to Mexico for FYs 2001-2005

Beginning in 1998, APHIS and its counterparts in Mexico have worked cooperatively to improve Mexico’s TB prevention and detection efforts. Specific import documentation and testing requirements were implemented based upon APHIS’ status classification system. When affected herds are found, stricter testing and movement controls go into effect before cattle can enter the United States from that Mexican State/zone. Because of APHIS’ assessment of low State/zone statuses that exist in Mexico, all cattle imported from Mexico are tested prior to import, except for steers and spayed heifers from Mexico’s only modified accredited advanced zone. These efforts have resulted in a reduction in the number of TB cases traced to Mexico. From FYs 2001 through 2005 APHIS’ slaughter surveillance identified 54, 75, 27, 22 and 27 Mexican origin TB cases, respectively.

Even though the above actions were taken, we concluded that additional actions are necessary to address the importation of cattle with TB from Mexico. Until additional controls are implemented, APHIS cannot reasonably expect to achieve its goal of eradicating TB from the United States, and this places the United States at risk for additional outbreaks of the disease. An APHIS official agreed that additional measures are needed to further curb the influx of disease from Mexico, and discussed an agency plan to strengthen restrictions on cattle movements with a change to the status classification system. This proposal

³⁸ Webster’s Dictionary defines “incubation” as the phase in the development of a disease between the infection and the first appearance of symptoms.

included restricting cattle movements from accredited preparatory States/zones to only pre-approved locations. APHIS determined that a higher ratio of infected animals originated from accredited preparatory States/zones in Mexico when compared to imports from modified accredited States/zones. However, accredited preparatory States/zones only account for approximately 20 percent of the cattle imported from Mexico. The majority (up to 80 percent) of cattle imported from Mexico come from modified accredited States/zones. So although modified accredited States/zones account for a lower ratio of TB cases, more TB cases originate from modified accredited areas. While APHIS' plan should help reduce the potential spread of the disease, it will not prevent the disease from being imported. In order to more completely address the incubation period, we believe that APHIS needs not only to implement its current proposal, but to develop and implement other measures to address modified accredited States/zones. However, at the time of our audit, APHIS did not have a plan or strategy to address the incubation period for cattle from modified accredited States/zones. Because the inflow of animals from modified accredited States/zones in Mexico is significant (approximately 800,000 annually), APHIS may need to incorporate the use of random sampling to select cattle for additional testing.

Recommendation 8

Implement the plan to strengthen movement and testing controls by adjusting the TB status classification system to restrict cattle movements from accredited preparatory States/zones to pre-approved locations. Develop a plan to implement additional actions to account for the TB incubation period for modified accredited States/zones.

Agency Response

APHIS' response stated they are in the process of amending and strengthening its regulations in a proposed rule to restrict the movement of cattle from TB accredited preparatory States/zones to pre-approved designated facilities only. This proposed rule will be published by April 2007. They are also in the process of developing a plan to implement additional actions to account for the TB incubation period for modified accredited States/zones. They plan to propose these additional actions to the States and industry for discussion this fall, and if general consensus is obtained incorporate the changes to the CFR through a proposed rule by April 2007.

OIG Position

We accept APHIS' management decision.

Section 3: Detection, Investigation and Eradication of Bovine TB

The goal of the BTEP is to eradicate the disease. APHIS accomplishes this through three phases: disease detection, an epidemiologic investigation, and then eradication. Detection is accomplished under an agreement between APHIS and FSIS, where FSIS inspects carcasses for the disease during slaughter. Once detected, APHIS initiates an investigation to find the source of the disease so it can be eradicated. Our audit determined that significant improvements have been made to detect the disease, but room for improvement still exists. We also determined that APHIS struggles to timely and successfully locate the source of the disease. When the investigation process is unsuccessful, eradication does not occur.

APHIS' inability to locate the source of the infection was caused by a lack of animal identification, recordkeeping weaknesses, herd commingling, timeliness, or a combination of these factors. APHIS has made procedural adjustments to address some of these areas, such as requiring investigations to be completed within 90 days, but it has not provided sufficient training or other resources to ensure these measures function as intended. For example, on average, FY 2004 investigations took 300 days to complete. While we agree that setting a timeframe is an appropriate measure, APHIS also needs to help with training and resources to help its investigators meet that new timeframe.

The NAIS initiative is expected to greatly assist with disease investigations, but it is not projected to be in place until 2009. Until that time APHIS needs to improve upon its ability to find the disease. One mechanism we believe APHIS was under utilizing was high risk herds. High risk herds provide APHIS a tool to target testing to questionable areas. When an investigation doesn't find the source of infection, all potential sources are to be added to a high risk herd list, and be monitored and tested in subsequent periods.

Finding 5

Detection Has Been Significantly Improved but More Work Is Needed

APHIS detects TB primarily through slaughter surveillance conducted by FSIS inspectors who submit suspicious lesions from carcasses to laboratories for testing. The APHIS standard for submission is 1 lesion per 2,000 slaughtered cattle at each facility. APHIS and FSIS have made significant improvements toward meeting this standard in recent years; however, since FSIS does not require each individual slaughter facility to meet this standard, submissions at a given facility may fall short of APHIS' standard for lesion submission. This has occurred because each agency has applied a different interpretation to language in their memorandum of understanding (MOU). As a result, APHIS cannot

ensure that individual slaughter facilities test for TB at the rate that the agency determined to be optimal for detecting the disease. This may in turn hamper its efforts to identify and eradicate localized outbreaks before they become widespread.

In October 2000, the Secretary of Agriculture issued an Emergency Declaration for TB which stated that the low levels of testing for tuberculosis (lesion submissions from slaughter) threaten to allow spread of the disease in the United States. Since that time, APHIS and FSIS have significantly improved detection activities by increasing lesion submissions for laboratory testing from 1,028 in FY 2000 to 9,439 in FY 2005.

In January 2005, APHIS adopted the standard that each slaughter facility would submit 1 lesion per 2,000 adult cattle slaughtered. (APHIS previously determined that this standard was the optimal TB surveillance rate but had set it as a goal in prior years rather than a requirement.)³⁹ However, an FSIS official noted that APHIS' standard does not have regulatory force for the FSIS inspectors who submit the samples. Instead, they are bound by a June 2005, MOU signed between APHIS and FSIS. This memorandum requires FSIS to submit "at least one lesion per 2,000 adult cattle" but does not specify whether FSIS inspectors must meet that rate at each slaughter facility, or as an average rate calculated from all the lesion submissions at all the slaughter facilities.

In an interview, an FSIS official pointed to the latter interpretation in order to explain why 5 of the top 40 facilities did not meet APHIS' optimal submission standard in FY 2005. Since the overall rate from all the facilities exceeded 1 in 2,000, FSIS determined that it had met the terms of the MOU. With this interpretation the submissions at a given facility may decline below the standard and be made up for by increased submissions at other facilities. In FY 2005, for example, one facility submitted no lesions while another submitted almost 16 times the required number. Furthermore, although 5 facilities falling below the standard represents a significant improvement over the 21 that fell below the standard in FY 2004, according to FSIS' interpretation of the memorandum, the standard was met each year.

Relying on the overall national average diminishes the effectiveness of APHIS' TB surveillance. Since FSIS inspectors at some facilities may submit no lesions for testing—a fact veiled by the overall submission rate—APHIS may miss the chance to timely detect and eradicate a TB outbreak. For example, although the 1 in 2,000 standard was met on a nationwide basis in FY 2004, 2 key slaughter States, Minnesota and Wisconsin, were well below the standard and did not detect the latest TB outbreak until improvements in their lesion submissions occurred in FY 2005.

³⁹ The standard was first derived from a 1969 APHIS study, based on statistical principles, in which APHIS determined that this rate would constitute the optimal surveillance rate and repeated in a 1994 report of the Committee on Bovine Tuberculosis Board on Agriculture National Research Council.

The current TB outbreak in Minnesota was detected by a Wisconsin slaughter facility in FY 2005. Minnesota and Wisconsin have 8 slaughter facilities ranking in the top 40 in the country, 7 of which did not meet the lesion submission standard in FY 2004. One facility in Minnesota reported submitting only 1 lesion for 193,000 slaughtered cattle, well below the expected figure of 96. In aggregate, Minnesota's 3 largest facilities averaged 0.09 submissions per 2,000 in FY 2004, while the 5 Wisconsin facilities averaged 0.56. In FY 2005, marked improvements occurred at all 8 facilities with 6 meeting or exceeding the standard. An APHIS official credited the improvements in lesion submissions in these States as being responsible for detecting this TB outbreak.

We concluded that APHIS and FSIS have made significant improvements in detecting TB at slaughter facilities, as demonstrated by the significant increase in lesions submitted over the 5-year span. However without requiring each facility to comply with the established submission standard, APHIS cannot accomplish optimal levels of surveillance that are representative of all geographical regions of the country. An APHIS official said that they had communicated their desire for this to be a plant-by-plant requirement to FSIS, and that they intended to pursue getting the requirement codified into Federal regulations. As it will take considerable time to propose and complete the regulatory process, we are recommending that the two agencies adjust their MOU to reflect the 1 in 2,000 standard as a requirement on an individual plant basis.

Recommendation 9

Revise the June 2005, MOU between APHIS and FSIS titled "Relative to Cooperation with Respect to Surveillance Programs," to reflect that the slaughter surveillance rate of 1 lesion submission per 2,000 adult cattle slaughtered is a requirement for each slaughter facility.

Agency Response

The response stated that APHIS and FSIS officials proposed an alternative corrective action to our recommendation. APHIS will continue to provide FSIS with a quarterly report on TB sample submissions for the top 40 cull cow slaughter plants. Further, FSIS officials will correlate with in-plant inspection personnel on an ongoing basis to ensure APHIS' sampling targets are met in these establishments. For other establishments, FSIS officials will update the appropriate TB directive to reflect the overall surveillance goal of 1 lesion submission per 2,000 adult cattle. They expect to have the relevant TB directives updated by December 2006.

Additionally, FSIS will update their public health veterinarian training to reflect the overall surveillance goal of 1 lesion per 2,000 adult cattle as well as the importance of collecting and submitting representative lesions from all

establishments. The updated training will be completed by December 2006. Finally FSIS will publish articles in "News and Notes" periodically during FY 2007. "News and Notes" is a weekly document that reaches the FSIS employees who collect TB samples. This document is a widely-read publication that covers current issues of importance to FSIS. FSIS management believes that this will keep TB sampling on the forefront for agency employees.

OIG Position

We accept APHIS' and FSIS' management decision.

Finding 6

BTEP Investigations Were Not Timely or Effective

After APHIS discovers a case of bovine TB, the agency initiates an epidemiologic investigation to find the disease's source, in order to eradicate the disease. Our audit determined that APHIS' investigations to find the source of TB were typically neither effective nor timely. Of 36 investigations initiated in FY 2004, not a single domestic source of TB was identified for eradication. The average time for an investigation was 300 days, far beyond the current standard of 90 days established by APHIS. We found that investigations were hampered by the lack of information, either on a particular animal, or in terms of documentation kept by owners, dealers or brokers. APHIS also implemented new requirements to improve certain aspects of the program; however, it did not follow-up with training or other assessments to determine the effectiveness of the new requirements. When the investigation process is unsuccessful, eradication does not occur. The timely success of these investigations is critical to APHIS' ability to contain and eradicate the disease.

If a laboratory confirms TB in an animal found at slaughter, it refers the case to the applicable APHIS area office for investigation. A case will generally trace from the slaughter establishment to a feedlot, where the animal may have spent considerable time and was commingled with animals from other locations. When the documentation trail fades, these investigations may proceed by word of mouth and considerable time may elapse before one or more source herds are located. When a source herd is found, APHIS tests the herd for the disease, and will only consider the herd affected if current stock has the disease. If the testing is negative, the farm should be added to the high-risk herd list for future monitoring and testing.⁴⁰

We reviewed all 36 FY 2004 TB slaughter surveillance initiated investigations and determined that all 36 were unsuccessful at finding a domestic source of the disease. The investigations were unable to locate the herds of origin for 16 of

⁴⁰ VS Memorandum 552.2 Part V.D.6.

36 TB-infected cattle (see exhibit F).⁴¹ In the remaining 20 investigations, APHIS identified herds of origin, but was unable to confirm those locations as the source of the disease (i.e. an affected herd). APHIS was able to determine that 22 of the 36 animals had been imported from Mexico, but since each of these animals spent time at U.S. farms or feedlots prior to slaughter, they could not be certain where the animal became infected, or may have spread the disease.

We determined that there were four main difficulties impeding APHIS' FY 2004 investigations: animal identification, recordkeeping, herd commingling, and timeliness of completing investigations. Some cases were impacted by a combination of these factors. An APHIS official noted the problems found and overall results of our analyses were typical for their investigations. As noted in Finding 2, from FYs 2001 through 2005, APHIS' investigations only found the source of the infection for 12 of 272 slaughter surveillance detected cases of TB.

Animal Identification

Under current Federal regulations, calves, steers, and spayed heifers are exempt from animal identification requirements.⁴² If one of these types of cattle tests positive for TB, the lack of identification can impede APHIS' investigation. Our analysis showed nine cases in which slaughtered steers tested positive for TB but their lack of identification hampered APHIS' attempts to trace them back to their herds of origin. APHIS acknowledged its overall difficulty with tracing younger cattle in a recent report on the status of the BTEP: "The potential for successfully concluding these investigations is hindered by our inability to trace younger unidentified cattle and account for their movements throughout their lifetimes."⁴³

APHIS' trace back efforts were also inhibited in five cases because feedlots removed cattle identification that could have helped trace animals found to be infected with TB at slaughter. As of November 2004, Federal regulations now prohibit the removal of official tags.⁴⁴

APHIS is in the process of working with the cattle industry to address weaknesses in animal identification and the ability to timely trace infected animals through a major initiative—the NAIS. The goal of NAIS is to be able to identify all animals and premises that have had contact with an infected animal within 48 hours from discovery. APHIS projects that the system will be in place by FY 2009.

⁴¹ A herd of origin may be the herd where the animal was born, or where it has resided for at least 4 months prior to movement, or part of a group of two or more herds maintained at different locations where there is movement between groups. A single animal, then, may have multiple herds of origin. For APHIS' definition of "herd of origin," see UM&R "Definitions," (January 2005).

⁴² 9 CFR 71.18.

⁴³ "FY 2005 Status of the State and Federal Cooperative Bovine Tuberculosis Eradication Program."

⁴⁴ 9 CFR 71.22.

Recordkeeping

Under current regulations, dealers and brokers, but not individual herd owners, are subject to recordkeeping requirements.⁴⁵ In three cases, we determined that APHIS was unable to continue its investigations since owners were not required to maintain documentation of cattle movement. In another instance a cattle dealer had no records of the origin of the infected animal but because the 2-year record retention period had passed, the dealer was no longer obligated to maintain records for this animal.

In its operating procedures, APHIS increased the recordkeeping requirement for dealers and brokers from 2 years in 2005 to 3 years as of January 1, 2006, 4 years as of January 1, 2007, and 5 years as of January 1, 2008.

Herd Commingling

When an investigation into the source for a TB infection leads to a lot (e.g., a slaughter lot or feedlot) where more than one owner has consigned animals, APHIS' policy emphasizes to "trace and test all possible sources until the infected herd is located." If the source of infection cannot be located, the policy also states that all consignors be added to the high-risk herd list.⁴⁶ We determined this rule was not followed for three FY 2004 investigations which were closed as untraceable. For two of these cases, APHIS concluded that since Mexican and domestic origin cattle were commingled into a lot, because the majority of the animals were from Mexico, the infected animal likely came from Mexico.

An APHIS regional official explained that these cases involved multiple potential source herds commingled into a lot without certainty as to the actual source herds. When this occurs he does not require all potential source herds to be tested. An official from the national office indicated that the regional official could best judge whether to conduct further testing. The national official also noted that they have not had the personnel to provide national oversight of investigations in recent years, but he planned to fill a current vacancy with a national epidemiologist, who would have this as an assigned duty.

By not testing all sources the region did not follow an existing national policy. APHIS has no means to ensure nationwide consistency if policies are not followed, or the national office doesn't periodically review cases. A mechanism for policy exceptions could be written into APHIS' guidance, requiring exceptions to receive written concurrence of other APHIS officials.

⁴⁵ UM&R Part II.K. (January 2005).

⁴⁶ VS Memorandum 552.2 Part V.D.5. (April 1, 2005).

Timeliness of Completing Investigations

The above difficulties with tracing the source of TB-infected cattle were compounded by APHIS' lack of timely investigations. For FY 2004, we determined that 33 of the 36 investigations were not completed timely—taking between 95 and 687 days (see exhibit E). APHIS spent an average of 300 days on FY 2004 investigations. This gives ample time for a herd to develop the disease and spread it to other herds as cattle are bought, sold, commingled, or transported throughout the country.

When a herd of origin is found APHIS will only declare that herd affected if the investigation finds a current case of the disease in the herd with an on-farm test. However, by the time an investigation finds a herd of origin, the composition of the herd may have changed. This limits the effectiveness of testing and the number of affected herds found. For 12 of the 20 FY 2004 cases where a herd of origin was located, there were no cattle at the premises to test, and testing was not successful at the other 8 locations.

In January 2005, APHIS began to require all investigations be completed within 90 days of initiation. (We derived our measure of timeliness for FY 2004 investigations from this requirement.) Although average cases were running well in excess of 90 days, APHIS did not support the implementation of this procedure with added resources or training to assist area offices in meeting the new timeframe. As a result, our analysis of FY 2005 cases opened after the rule went into effect but closed by November 2005 did not find noticeable improvement, as most cases (12 of 16) still exceeded 90 days. An APHIS official agreed that additional guidance and training were needed to improve the timeliness of investigations.

High-Risk Herds

Generally on-farm TB testing takes place because a State/zone has affected herds, it is part of a slaughter surveillance investigation, or it is being conducted for State-designated purposes. However, APHIS' operating procedures and memorandum contain high-risk herd provisions which present a means to administer follow-up testing at questionable locations, even though a herd was not declared affected.⁴⁷ High-risk herds are those which have had a history of lesions suggestive of TB (but not confirmed), premises where a TB-affected herd has been depopulated, or herds that contain exposed animals from known affected herds.⁴⁸ Most of the slaughter surveillance cases fall into the first category because APHIS' epidemiologic investigations rarely result in confirming TB (via testing) in a herd of origin.

⁴⁷ UM&R Part III.K.1 and VS Memorandum 552.2 Part V.D.6.

⁴⁸ VS Memorandum 552.2, Parts V.D.5 and V.D.6 (April 1, 2005) states that all possible sources are to be tested until the infected herd is located. If the herd of origin or infected herd is not found, all consignors to the affected slaughter lot are to be added to the high-risk herd list.

Generally, high-risk herds must be monitored and have two subsequent annual herd tests.

We determined that APHIS was not monitoring high-risk herds and the corresponding on-farm tests that are required. APHIS' annual report includes a section for States to report testing and activities for high-risk herds. We reviewed 9 States' annual reports, which covered 33 of the 36 FY 2004 slaughter cases, and did not find any herds (or potential herds) of origin reported as high-risk herds. For example, we observed that Texas identified 22 positive TB cases during slaughter surveillance, but did not report any of these cases as high-risk on their annual report. APHIS' instructions state that when the herd of origin or infected herd is not found, they should add all consignors to the affected lot to the high-risk herd list.⁴⁹ As a result, APHIS did not ensure that the required two subsequent annual herd tests were performed. An APHIS official agreed that they were not using high-risk herd provisions as much as they should.

We concluded that APHIS' efforts to trace the source of TB cases to their source were typically neither effective nor timely. We also determined that the high-risk herd testing could be a viable means of performing additional testing for questionable locations, but it is not being consistently used in this manner. Also, the policy to "trace and test all possible sources" needs to be evaluated against what is executed in the field and a determination made to either adjust the policy or adjust how it is executed during investigations.

We also recognize that APHIS has taken some steps to improve its investigations, but it must commit the necessary resources and conduct training to support the implementation of the new requirements, and assess the effectiveness of these measures. In addition, an APHIS official indicated that an existing vacant position will be filled by a national epidemiologist, who can assist and review investigative activities as well as high-risk herd management.

Recommendation 10

Initiate reviews of regional and area office activities relating to epidemiological investigations to identify to what extent high-risk herd monitoring and testing provisions are being utilized, and implement actions to ensure the consistent use of this tool to eradicate the disease; and determine whether exceptions are warranted to the VS Memorandum policy to "trace and test all possible herds."

Agency Response

The response stated that APHIS will implement actions to ensure the consistent use of high-risk herd monitoring and testing. In addition, APHIS officials will

⁴⁹ UM&R Part III.K.1.

re-evaluate their policy regarding tracing and testing of all possible sources and either adjust the policy or adjust how it is executed during investigations. This will be completed by April 2007.

OIG Position

We accept APHIS' management decision.

Recommendation 11

Assess whether the new rules which were aimed at improving the epidemiological investigations have been implemented and adhered to on a consistent basis. Identify additional areas for improvement, best practices, and any related resource needs. Based on these assessments, develop an action plan or plans in terms of training, guidance or providing additional resources in order to address weaknesses, or to further enhance the program.

Agency Response

In the response, APHIS officials stated that they updated the TB strategic plan and identified ways to improve investigations through increasing key positions that would have responsibility for closely monitoring epidemiological investigations, and identifying the training and resources needed to accomplish these tasks. They have requested additional funding based on the strategic plan, and subsequent action plans will be developed based on the funding received. These plans will be finalized and initial phases (except for hiring any new personnel) will be implemented by April 2007.

OIG Position

We accept APHIS' management decision.

Scope and Methodology

We performed our audit fieldwork from April 2005 through November 2005 at APHIS' national office in Riverdale, Maryland; FSIS' national office in Washington, D.C.; and APHIS' eastern and western regional offices. We also interviewed officials and evaluated information from six APHIS area offices. The audit covered FYs 2001 through 2005.

We initiated this audit because of concerns raised during our audit of the BTEP in Michigan. In that audit, we reported that APHIS' status classification system did not incorporate known cases of TB in Michigan's wildlife which were directly linked to outbreaks in cattle, and that APHIS needed to enhance its controls over the accountability and testing of animals within Michigan's infected zone.⁵⁰

At APHIS' national office, we reviewed the FY 2004 annual reports and the monthly reports for October 2003 through January 2005 for all four TB-affected States (as of April 2005) along with a judgmental sample of five TB-free States. The TB-free States (Kentucky, Tennessee, Wisconsin, Minnesota, and Kansas) were selected based on having both large cattle populations and low slaughter lesion submission rates. We also obtained TB case data through October 2005 to update our 2004 results and to perform some limited analysis on FY 2005 cases.

We selected the western region for review because three of the four TB-affected States (California, Texas and New Mexico) were in the region, and we had completed an audit of the fourth TB-affected State (Michigan) in 2005. Also, over 95 percent of the indemnity payments (over \$32 million) were disbursed to western region States from FY 2001 to 2004.

At APHIS' western regional office, we analyzed all available station (five) and BTEP review (three) reports that were completed from August 1999 to March 2005. We also examined final closing reports for all 36 epidemiologic investigations of TB-infected cattle identified at slaughter in FY 2004.

To accomplish our audit objectives we:

- Interviewed responsible program officials from APHIS' and FSIS national offices, APHIS' western region, and area veterinarians-in-charge from Texas, California, Kansas, and Iowa;
- Reviewed APHIS' and FSIS' rules, regulations, policies, procedures as well as correspondence between the two agencies related to the BTEP;

⁵⁰ National Cooperative State-Federal Bovine Tuberculosis Eradication Program in Michigan, Audit Report No. 33099-0005-Ch, (April 2005).

- Examined BTEP studies, evaluations, and reviews conducted since FY 1999 in order to assess implementation of recommendations for noted program deficiencies, and whether reviews assessed States' infrastructure;
- Analyzed APHIS' reports of TB slaughter surveillance submissions for FY 2001 through September 30, 2005, including data from the largest 40 cattle slaughter facilities in the United States, in order to determine whether each facility met the established standard of 1 lesion submission per 2,000 head of adult cattle slaughtered;
- Reviewed APHIS' annual reports (VS Form 6-38) for FYs 2003 and 2004, and monthly reports (VS Form 6-2) from October 2003 through January 2005, in order to assess timeliness in submission, managerial review of reports, and the effectiveness of reported program activities as related to established standards;
- Examined slaughter surveillance tracking logs, slaughter surveillance investigation closing reports (VS Form 6-35B) and supporting documentation in order to assess the timeliness and effectiveness of epidemiologic investigations of TB-infected cattle;
- Reviewed APHIS' import tracking system's report of animals imported from Mexico from FYs 2001 through 2005 in order to determine the quantity of cattle imported from Mexico; and
- Verified the accuracy of APHIS' reporting on Veterinary Services' performance measures.

The audit was conducted in accordance with *Generally Accepted Government Auditing Standards*.

Exhibit B — TB Cases Identified By Slaughter Surveillance

TB Cases Initiated As A Result of Slaughter Surveillance FY 2001 through FY 2005



NOTE

Slaughter surveillance identified 272 infected cattle from FYs 2001 to 2005. However, because the investigations determined that some of these cattle crossed State lines; additional cases were opened in other States, such that some individual cattle are represented more than once. This map reflects 320 TB cases that were opened in 22 States.

Exhibit C — TB Slaughter Cases Traced to Mexican Origin

Number of TB Slaughter Cases Traced to Mexican Origin Cattle FY 2001 through FY 2005

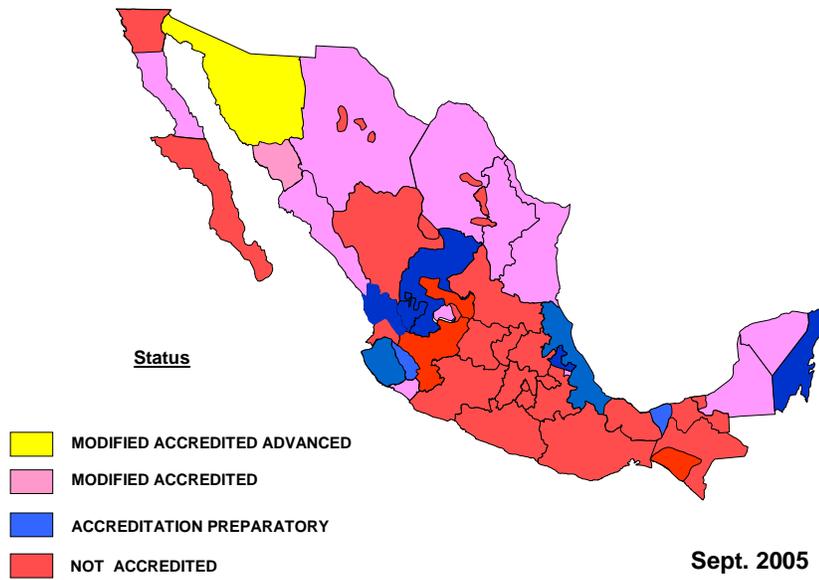


NOTE

This map reflects 226 TB cases in 12 States. These cases were the result of 205 TB-infected cattle found by slaughter surveillance. Some of the 205 infected cattle existed in multiple States, which gives rise to the difference between infected cattle found at slaughter and the number of cases opened in each State.

Exhibit D – USDA Status Classification of Mexican States and Zones

USDA CLASSIFICATION - MEXICAN STATES



NOTE

There were no accredited-free States or zones in Mexico as of September 2005.

Exhibit E — Elapsed Days for FY 2004 Investigations of TB-Infected Cattle

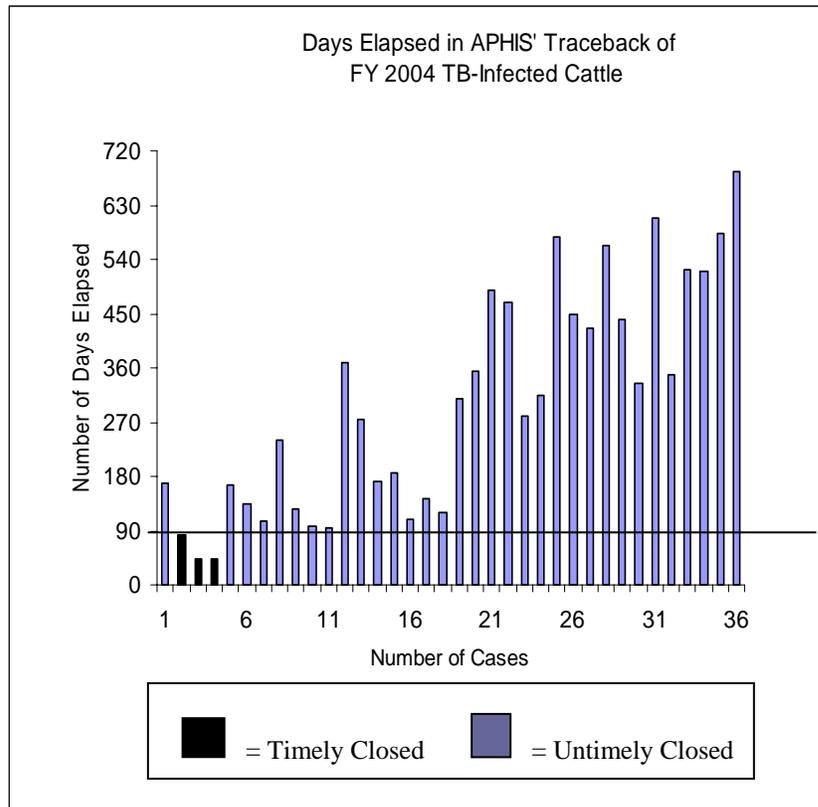


Exhibit F – Reasons for Closing FY 2004 Investigations as Untraceable

Reasons Why 16 of the FY 2004 Investigations Were Closed With an Outcome of “Untraceable”						
Case Number	IDENTIFICATION			RECORDKEEPING		TESTING
	No Tags on Animals (Tags Not Required)	Tags Not Collected	Feedlot Removed Tags	Owner Did Not Maintain Records (Because Not Required To Do So)	Dealer Records Not Retained Beyond 2-Year Retention Period	Commingled Herds Were Not Tested
331700	X			X		
294065	X					
310389	X					
330945	X					
335534		X				X
294866		X				
312796			X			
316874			X			
315182			X			
288738					X	
335940	X					
298019	X			X		X
317711			X			
317712			X			
312080	X					X
293599				X		

Exhibit G – Agency Response to the Draft Report

Exhibit G – Page 1 of 6



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: W. Ron DeHaven
Administrator

Kevin Shea

SEP 28 2006

Barbara J. Masters
Administrator
Food Safety and Inspection Service

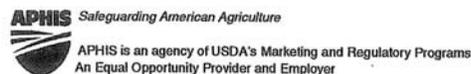
Wm C Smith for

SUBJECT: APHIS and FSIS Response to OIG Report, "Animal and Plant Health Inspection Services' Control Over the Bovine Tuberculosis Eradication Program" (50601-0009-CH)

The Animal and Plant Health Inspection Service (APHIS) and Food Safety and Inspection Service (FSIS) thank you for the opportunity to provide comments on this report. Our collective comments are detailed below.

Recommendation 1: Perform a risk assessment using information in annual, monthly, or other reports, to identify weak conditions or higher risk factors. Utilizing this information, develop and implement an action plan to address the highest risk areas.

Veterinary Services (VS) appreciates this recommendation. Already, VS' Ruminant Health Program staff has analyzed the 2006 annual reports. VS will conduct risk assessments using the information in annual, monthly, and other reports to identify weaknesses in program delivery at the State level. VS will outline this process in a set of standard operating procedures and revisions to VS memoranda (with examples), that will be developed and implemented by December 31, 2006. The process will include better defined guidelines and timelines on how the reports are reviewed by both the Tuberculosis Program staff and the regional tuberculosis epidemiologists. Based on the outcomes of these reviews, VS will prioritize its resources and identify those States that need reviewing. These State reviews will be conducted primarily by the regional tuberculosis epidemiologists, unless the risk assessment identifies a significant issue that needs to be resolved at a higher level.



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Recommendation 2: Establish standard operating procedures including timeframes for the review and approval of States' annual and monthly reports, and for taking actions on delinquents, errant, or incomplete report submissions.

VS understands this is a crucial step in ensuring accurate information and will establish standard operating procedures for reviewing annual and monthly reports. These procedures will detail actions to be taken on errant and incomplete reports. VS will implement the new procedures by December 31, 2006.

Recommendation 3: Perform program reviews each year to evaluate whether State TB surveillance and eradication activities are in compliance with Federal regulations and agency procedures.

VS regrets that this important activity has received less attention in recent years because of personnel shortages and animal disease emergencies. VS currently identifies States that have had significant program issues, and schedules reviews of those States based on other priorities, personnel availability, and funding. With renewed vigor, beginning in fiscal year 2007, VS personnel will conduct annual program reviews on at least 10 percent of the State programs. VS will select States to be reviewed after analyzing the previous year's annual reports, and will base selections on compliance with program requirements, surveillance efforts, and the length of time since a previous review was conducted. The list of States to be reviewed in Fiscal Year 2007 will be prepared for approval by the VS Management Team by November 1, 2006.

Recommendation 4: Expand TB status classification guidelines to include all bovine TB infections, including animals identified by slaughter surveillance, to be status-determining factors for State TB status classifications.

VS agrees that every case should be accounted for; simultaneously, we are working to ensure that we are not inappropriately penalizing those States that have the majority of slaughter and/or feedlot facilities where these cases are finally found. As such, VS agrees that more needs to be done, and will propose a requirement that herds be placed on a high-risk herd list for further testing, and be tested whenever another epidemiological trace identifies them as a possible source. This proposal must be published in the *Federal Register* and would be open for public comment before a decision could be made on inclusion in the program requirements. This process of notice and comment rulemaking is not entirely under APHIS control, but we will establish a goal to have this proposal published by April 2007.

For additional background, as OIG asserts, VS only declares a herd as affected for status purposes if the investigation identifies a source herd that contains infected animals. Title 9, Part 77.1 of the *Code of Federal Regulations* (CFR) defines an affected herd as "a herd of livestock in which there is strong and substantial evidence that *M. bovis* exists..."

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including epidemiological evidence.” Since there are numerous opportunities for mistakes to be made in tracing an animal back to the herd of origin, VS and the State cooperators agree that there should be strong and substantial evidence before declaring a herd as affected when no additional infected animals can be found in the herd.

In Fiscal Year 2005, there were 40 tuberculosis-positive animals detected at slaughter in the United States. Five cases (12.5 percent) were from adult animals, and were traced back to Arizona, Nebraska, South Dakota, Texas, and Minnesota. Five tuberculosis-affected herds were detected in Minnesota as a result of the traceback from the Minnesota slaughter facility. The other cases did not result in finding an affected herd. As a result, Minnesota lost its Tuberculosis Accredited Free status.

Thirty-one positive feeder animal cases originated from 14 feedlots in Texas. The remaining 4 feedlot cases originated in one from Arizona, one in Kansas, and 2 cases in Nebraska. These States are usually involved in the traceback of cases primarily because they are where the majority of large feedlots are located. Animals are brought to these facilities from almost every State in the country; however many are not identified back to their State of origin.

Again, VS is carefully examining modifying TB status classification guidelines and developing the proposed rule described above.

Recommendation 5: Revise the current practice of declaring a herd affected only if it is confirmed by on-farm testing to conform to the existing regulatory and operating procedure definition(s) of an affected herd.

VS’ goal is to find every infected herd in the Nation. In order to accomplish that, additional animal identification is needed on most animals. Prior to this year, DNA technology had not been available to VS to confirm the source of slaughter samples using DNA testing techniques. That technology is now available; therefore VS will propose (in the new regulations), expansion of the status classification guidelines to include bovine infections that can be traced back to herds of origin, without finding infected animals in the herd, based on DNA confirmation of the source animal for the positive slaughter sample, and where the epidemiology clearly shows the animal most likely had the infection while it was a member of the herd. The proposal would have to be published in the *Federal Register* and would be open for public comment before a decision could be made on inclusion in the program requirements. Our goal will be to publish this proposal by April 2007.

As background, in both the New Mexico and Arizona investigations discussed in OIG’s report, the “herds” involved were actually not herds according to the herd definition in the CFR, Part 77.1. Regrettably, the definition does not include livestock assembled at feedlots and livestock that have been maintained for less than 4 months on common

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ground. In New Mexico, the calves at this feedlot had not been together for 4 months. In Arizona, the animals were in a feedlot. Therefore, using the existing regulations, we could not declare these groups of animals as herds. In addition, we tested the remaining animals on those premises and could not find additional infected animals to verify infection. However, we are confident that the new regulation we are proposing will be instrumental in meeting OIG's recommendation.

Recommendation 6: On a current and historical basis (for the preceding 5 years), publish all TB cases (slaughter or otherwise identified) on APHIS website.

VS has initiated the process to publish all positive *M. bovis* cases on the APHIS website. This should be completed and available for review on or before October 30, 2006.

Recommendation 7: Revise the UM&R to be in accordance with Title 9 CFR 77.7 (c), by requiring that an accredited-free State's status be immediately lowered once an outbreak (of 2 or more affected herds in a 48-month period) is detected.

VS agrees with this recommendation and has made the revision of all Uniform Methods and Rules (UM&R's) a top priority. Specifically, VS personnel have already revised the UM&R to be in accordance with Title 9 CFR 77.1 (c). This process was completed prior to March 14, 2006. Language in the regulations will be altered to make the process of lowering a State's status more immediate. These changes will be completed by April 2007, assuming the new regulations are published as a proposal.

Recommendation 8: Implement the plan to strengthen movement and testing controls by adjusting the TB status classification system to restrict cattle movement from accredited preparatory States/zones to pre-approved locations. Develop a plan to implement additional actions to account for the TB incubation period for modified accredited States/zones.

VS agrees that strengthening movement and testing controls is crucial. As such, VS is in the process of amending and strengthening its regulations in a proposed rule (for April 2007) to restrict the movement of cattle from tuberculosis Accreditation Preparatory States and zones to pre-approved designated facilities only.

VS is also in the process of developing a plan to implement additional actions to account for the TB incubation period for Modified Accredited (MA) States and zones. This plan would be proposed to the States and industry for discussion this fall (and incorporated into the CFR changes being proposed in April 2007), if there is general consensus from the States and industry. The proposal for MA States and zones would include the following: Whenever 3 or more TB affected animals have been detected as a result of interstate movement from a MA, State, or zone, except for animals that have gone from the farm of origin direct to slaughter or through a market to slaughter, then all future

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interstate movement of cattle and bison will be restricted to pre-approved designated facilities (or to premises where these animals would be quarantined until retested between 90 to 120 days later), only until a review by VS determines that the risk of additional infection being from that MA State or zone has been adequately mitigated. Furthermore, these States or zones may have animal movement restricted even further (to slaughter only) if additional cases are found after movement has been restricted to approved facilities.

Recommendation 9: Revise the June 2005, MOU between APHIS and FSIS titled “Relative to Cooperation with Respect to Surveillance Programs,” to reflect that the slaughter surveillance rate of 1 lesion submission per 2,000 adult cattle slaughtered is a requirement for each slaughter facility.

Both APHIS and FSIS offer the following corrective action to address OIG's concern. FSIS proposes that for the top 40 cull cow slaughter plants (which comprise about 80-85 percent of this slaughter); APHIS will provide FSIS with a quarterly report on TB sample submissions, which APHIS currently does. These are the highest risk plants. Further, FSIS will correlate with in-plant inspection personnel on an ongoing basis to ensure APHIS sampling targets are met in these establishments. For other establishments, FSIS will update the appropriate TB directive to reflect the overall surveillance goal of 1 lesion submission per 2,000 adult cattle. FSIS expects to have the relevant TB directives updated by December 2006.

Additionally, FSIS will update the public health veterinarian training to reflect the overall surveillance goal of 1 lesion per 2,000 adult cattle as well as the importance of collecting and submitting representative lesions from all establishments. The updated training will be completed by December 2006. Finally, FSIS will publish articles in "News and Notes" periodically during FY2007. "News and Notes" is a weekly document that reaches the FSIS employees who collect TB samples. This document is a widely read publication that covers current issues of importance to FSIS. FSIS management believes that this will keep TB sampling on the forefront for Agency employees.

Recommendation 10: Initiate reviews of regional and area office activities relating to epidemiological investigations to identify to what extent high-risk herd monitoring and testing provisions are being utilized, and implement actions to ensure the consistent use of this tool to eradicate the disease, and determine whether exceptions are warranted to the VS Memorandum policy to “trace and test all possible herds.”

VS will implement actions to ensure the consistent use of high-risk herd monitoring and testing. In addition, VS will re-evaluate its policy regarding tracing and testing of all possible sources and either adjust the policy or adjust how it is executed during investigations. This will be completed by April 2007.

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Recommendation 11: Access whether the new rules, which were aimed at improving the epidemiological investigations, have been implemented and adhered to on a consistent basis. Identify additional areas for improvement, best practices, and any related resource needs. Based on these assessments, develop an action plan or plans in terms of training, guidance, or providing additional resources in order to address weaknesses, or to further enhance the program.

VS has updated its tuberculosis strategic plan and identified ways to improve investigations through increasing key positions that would have responsibility for closely monitoring epidemiological investigations, and identifying the training and resources needed to accomplish these tasks. VS has requested additional funding, based on the strategic plan, and will develop action plans based on the funding received. These plans will be finalized and initial phases (except for hiring any new personnel) will be implemented by April 2007.

Informational copies of this report have been distributed to:

Administrator, APHIS	(9)
Attn: Agency Liaison Officer	
Administrator, FSIS	(20)
Attn: Agency Liaison Officer	
Government Accountability Office	(1)
Office of Management and Budget	(1)
Office of the Chief Financial Officer	
Director, Planning and Accountability Division	(1)