



U.S. Department of Agriculture



Office of Inspector General
Midwest Region

Audit Report

Animal and Plant Health Inspection Service National Cooperative State/Federal Bovine Tuberculosis Eradication Program

Report No. 33099-0005-Ch
APRIL 2005



UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL
Washington D.C. 20250



April 20, 2005

REPLY TO

ATTN OF: 33099-0005-Ch

SUBJECT: National Cooperative State/Federal Bovine Tuberculosis Eradication Program

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

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

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

This report presents the results of our audit of the National Cooperative State/Federal Bovine Tuberculosis Eradication Program in Michigan. Your response to the draft report, dated March 31, 2005, is included as Exhibit B, with excerpts and the Office of Inspector General's position incorporated into the related sections of the report.

We agree with your management decision for Recommendation 1. Please follow your agency's internal procedures in forwarding final action to the Office of the Chief Financial Officer. Management decisions for the remaining recommendations can be reached once you have provided the additional information outlined in the report sections OIG Position.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective action taken or planned and the timeframes for implementation for Recommendations 2, 3, and 4. Please note that the regulation requires a management decision to be reached on all findings and recommendations within a maximum of 6 months from report issuance.

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

Executive Summary

National Cooperative State/Federal Bovine Tuberculosis Eradication Program Audit Report No. 33099-0005-Ch

Results in Brief

This report presents the results of our audit of the National Cooperative State and Federal Bovine Tuberculosis Eradication Program (BTEP) in Michigan. The objectives of our audit were to identify and assess the Animal and Plant Health Inspection Service's (APHIS) internal controls related to the BTEP, and to determine whether the established protocols were followed. We selected Michigan because it had the highest prevalence of bovine tuberculosis (TB) in the United States. Our audit disclosed that the Michigan Department of Agriculture (MDA) generally followed established protocols and had made improvements to its controls over BTEP, particularly in the last two years. However we identified weaknesses in controls over accountability of animals within the infected zone. These weaknesses may negatively impact the effectiveness of Michigan's BTEP, and inhibit efforts to eradicate bovine TB.

Under APHIS' Cooperative State/Federal Tuberculosis Eradication Program, bovine TB has been nearly eradicated from much of the United States. However, scientific analysis has directly linked the spread of bovine TB from wildlife to cattle. To respond to this threat, the Secretary of Agriculture declared an emergency in October 2000, which authorized supplemental funding and resources to help address the problem.

Over the past few years, the BTEP in Michigan has progressively improved. For instance, APHIS and the MDA determined that the disease was contained in the northern half of Michigan's lower peninsula, which MDA identified as "the infected zone". This created a unique split-State situation, which helped maximize resources by focusing eradication efforts on the infected zone. Then, within this infected zone, they instituted more restrictive controls over animal movements and established annual whole-herd testing requirements of all herds. In addition, the remainder of the State is subjected to on-farm tuberculin testing based upon a statistical sampling plan.

These improvements were notable, however, we identified weaknesses in controls over the testing, as well as documenting the movement and depopulation of animals within the infected zone. We found that APHIS and MDA could not provide documentary evidence for 113 of 645 animals from four of eight sampled TB-infected herds that were required to be depopulated or remain on the farm under quarantine. In a separate analysis of MDA's annual testing of herds in the infected zone, we found that APHIS and MDA could not provide documentation to account for the disposition of 105 of 287 animals in four different herds. These animals were tested in one year, but were not available for testing in the subsequent year.

We also found that APHIS policy led MDA to release two infected herds from quarantine after preliminary lab test results, but before completing the final analyses, the lab culture. As a result, 22 animals were moved from an infected herd to a farm in Michigan's TB-free zone. These animals were subsequently depopulated.

In addition, we found that even though bovine TB in wildlife has been directly linked to outbreaks in livestock, APHIS' classification system for bovine TB State status does not incorporate the high levels of the disease in Michigan's wildlife.

Recommendations In Brief

We are recommending that APHIS enhance its procedures to include: (1) verifying that all animals in infected herds were either depopulated or remained on the farm under a herd plan; and (2) reconciling herd inventories to account for missing animals during annual testing in Michigan's infected zone. We are also recommending that APHIS revise its policy to maintain quarantines on herds in the infected zone that have positive responses to on-farm tuberculin tests, until the lab culture results are known. Finally, we are recommending that APHIS revise its bovine TB classification standards to include measurements of bovine TB in wildlife.

Agency Response

In its response dated March 31, 2005, APHIS agreed with each of our recommendations. We have incorporated applicable portions of APHIS' response along with our position, in the Findings and Recommendations section of the report. The agency's response is included in its entirety as Exhibit B of the report.

OIG Position

We agree with APHIS' proposed corrective actions and have reached management decision on Recommendation No. 1. To reach management decision for Recommendations Nos. 2 and 3, APHIS needs to provide us with timeframes to establish and implement procedures. To reach management decision for Recommendation No. 4, APHIS needs to provide us with its plan, including timeframes, for revising the classification standards for Michigan's infected zone to include bovine TB in wildlife as a status-determining factor.

Abbreviations Used in This Report

APHIS	Animal and Plant Health Inspection Service
BTEP	Bovine Tuberculosis Eradication Program
CFT	Caudal Fold Test
DTE	Designated Tuberculosis Epidemiologist
FAIR	Farm Animal Identification Record
FSIS	Food Safety and Inspection Service
ID	Identification
MDA	Michigan Department of Agriculture
MSU	Michigan State University
NVSL	National Veterinary Services Laboratory
OCFO	Office of the Chief Financial Officer
OIG	Office of Inspector General
TB	Tuberculosis
UM&R	Uniform Methods and Rules
USDA	United States Department of Agriculture
VS	APHIS Veterinary Services

Table of Contents

Executive Summary	i
Abbreviations Used in This Report	iii
Background and Objectives	1
Findings and Recommendations	5
Section 1: Controls Over Tuberculosis-Infected Zone	5
Finding 1 Controls Over the Disposition of Infected Herds Need Strengthening	5
Recommendation 1	8
Finding 2 All Animals Are Not Accounted for During the Annual Testing Process in the Infected Zone.....	8
Recommendation 2	10
Finding 3 Herd Quarantines Were Released Prior to Completing Lab Analysis	10
Recommendation 3	12
Section 2: Bovine Tuberculosis in Wildlife	13
Finding 4 Prevalence of Bovine Tuberculosis in Wildlife Is Not Incorporated in APHIS' Classification Standards	13
Recommendation 4	15
Scope and Methodology	16
Exhibit A – Infected (Modified Accredited) Zone, as of April 19, 2004	18
Exhibit B – Agency Response to the Draft Report	19

Background and Objectives

Background

Bovine tuberculosis (TB) is a contagious disease to animals and humans that has caused more deaths among United States farm animals in the early part of the 20th century than all other infectious diseases combined. Under APHIS' Cooperative State/Federal Tuberculosis Eradication Program (BTEP), bovine TB has been nearly eradicated from much of the United States. However, when scientific analysis identified significant TB threats that could lead to a spread of this disease, the Secretary of Agriculture signed a declaration of emergency in October 2000. This declaration authorized the transfer of \$44 million in as the initial payment of a multi-year effort to expand the TB eradication program in the United States.

APHIS-Veterinary Services (VS) is responsible for administering the BTEP, which it accomplishes by working cooperatively with States and by entering into a Memorandum of Understanding with each State. APHIS has established rules¹ and regulations² that must be followed by States. 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 tuberculosis.

Bovine TB surveillance is accomplished through slaughter monitoring and on-farm tuberculin testing. In the 46 TB-free States surveillance is primarily through slaughter monitoring, with only a limited amount of on-farm testing.

Slaughter Surveillance

Slaughter surveillance is performed through a Memorandum of Understanding between APHIS and the Food Safety and Inspection Service (FSIS). Under the agreement, FSIS inspectors at slaughter facilities inspect cattle carcasses, collect and submit suspected TB lesions, along with the required APHIS documentation, to the National Veterinary Services Laboratory in Ames, Iowa for testing. According to the National Staff Veterinarian responsible for the BTEP, the primary surveillance for TB in cattle depends on APHIS veterinarians and FSIS inspectors. When slaughter surveillance discovers the presence of bovine TB, APHIS' animal health personnel trace the animal to the herd of origin, restrict movement, and test the herd.

¹ Bovine Tuberculosis Eradication, Uniform Methods and Rules, effective January 1999.

² Title 9, Code of Federal Regulations (CFR), Part 77.

On-Farm Tuberculin Testing

APHIS supplements slaughter surveillance with on-farm tuberculin testing, on a limited basis in the TB-free States, and more significantly in TB-infected States. APHIS has established procedures³ for performing on-farm tuberculin testing. The herd is placed under quarantine during the entire testing process. The only movement of animals allowed while a herd is under quarantine is directly to a slaughter establishment, and under a permit issued by a State or Federal representative.⁴ The initial diagnostic test is the caudal-fold test (CFT), which involves injecting a tuberculin into the tail of the animal. Any animals with a response to the CFT test are classified as suspects. All suspects receive a supplemental test, such as a comparative cervical test, which consists of two tuberculin injections in the neck area. In Michigan, animals with a positive reaction to the supplemental test are sent to a laboratory at Michigan State University (MSU) for necropsy (animal autopsy) and histopathology test.

At the MSU lab, the necropsy looks for lesions as evidence of TB, and histopathology examines animal lesions/tissue for TB bacteria. If the necropsy and histopathology show no evidence of bovine TB, the herd is released from quarantine. As part of the examination process, MSU collects and submits suspected TB lesions and tissue samples to the National Veterinary Services Laboratory in Ames, Iowa, for the final and definitive test, a laboratory culture. The culture takes approximately 60 days to process. If the culture discloses that the herd is infected, the agency and the producer jointly decide to either depopulate the entire herd or develop an individual herd plan for test and removal. Infected animal(s) are also traced to the herds of origin, and testing is performed on those herds.

State TB Status

States submit annual reports to APHIS showing the results of on-farm testing and slaughter surveillance conducted. APHIS requires this surveillance to be done at a rate that allows detection of TB in the overall population of livestock at a 2-percent prevalence level with 95-percent confidence.⁵ Approval and maintenance of a State's status requires an annual review and approval by the APHIS Administrator.

As listed on the following page, APHIS has established five bovine TB classifications for States and zones, based on the percentage of prevalence (or number of infected herds) found in that area.⁶ The classification of a State or

³ Bovine Tuberculosis Eradication, Uniform Methods and Rules, effective January 1999, Part II.

⁴ Bovine Tuberculosis Eradication, Uniform Methods and Rules, effective January 1999, Part III.

⁵ Bovine Tuberculosis Eradication, Uniform Methods and Rules, effective January 1999, Part VII.B.1.

⁶ Title 9, Code of Federal Regulations (CFR), Part 77.

a particular zone within a State determines the TB testing requirements that must be met before animals can be moved out of the affected area.

States are currently impacted by the first three TB classifications. Testing and movement restrictions increase with each subsequent classification. Accredited free areas are those where no TB problem has been identified, and movement of livestock from these areas is unrestricted. A modified accredited advanced State/zone is one that has identified the disease in less than 0.01 percent of its herds, or in 1 to 3 herds in States/zones with fewer than 30,000 herds. In a modified accredited advanced State/zone, APHIS only requires a negative TB test prior to interstate or interzone movement of breeding animals. The modified accredited status is warranted if TB is found in less than 0.1 percent herds, or a maximum of 10 herds in a States/zone with fewer than 10,000 herds. In a modified accredited zone, APHIS requires a negative TB test for the entire herd of origin prior to the movement of breeding animals, and a negative TB test prior to the movement of non-breeding animals. The following list represents APHIS' TB classifications:

1. Accredited Free,
2. Modified Accredited Advanced,
3. Modified Accredited,
4. Accreditation Preparatory, and
5. Non-Accredited.

Currently 46 States are classified as accredited free. Effective April 19, 2004, Michigan became the only State with two zones: modified accredited advanced and modified accredited. California, New Mexico, and Texas are classified as modified accredited advanced because they have reported a lower number of herds infected with bovine TB than Michigan.

Michigan Evolution of Testing, Permitting, and Movement Requirements

On June 28, 2000, Michigan's status became modified accredited, due to the prevalence level of the TB infection in the State. The Michigan Department of Agriculture (MDA), working closely with the APHIS area office, determined that the disease was contained to the northeast corner of the State. In order to maximize its resources, in March 2002, MDA established three zones for identification, on-farm tuberculin testing and movement requirements. These included four counties in the infected zone that required annual testing, six counties in the surveillance zone that required biennial testing, and the remaining counties (disease free zone) that passed one whole-herd test by December 31, 2003. At this time, movement permits were required to move livestock from any premises in the infected zone, except if the animals were moving to slaughter.

In October 2002, MDA implemented a statistically-based random sampling surveillance plan, to test for bovine TB in Michigan's modified accredited advanced zone (disease free zone), which encompasses the majority of the State. Under this plan, MDA has initiated whole herd bovine TB testing on a random sample of 1,800 cattle herds in this zone every 2 years. The computerized statistical sample is generated by Michigan State University from a database of over 10,000 known herds.

Due to the detection and spread of bovine TB to a northwestern county in 2004, three additional counties were added to the infected zone. On April 19, 2004, APHIS amended its bovine TB regulations⁷ to establish a split-State status, which included a 13-county modified accredited zone (infected zone) and a modified accredited advanced zone for the remainder of the State (see Exhibit A).

As of June 1, 2004, MDA required all herds in the 13-county infected zone to complete whole-herd testing within a 9 to 15 month range following the anniversary date of the initial test. MDA also required that permits be obtained for any movement of cattle in the infected zone, even if going to slaughter. Also, as of June 1, 2004, MDA required the use of radio frequency identification (ID) eartags for all cattle in the infected zone. Approximately 95 percent of Michigan cattle are slaughtered at seven facilities that are equipped with electronic ID readers. Therefore, when animals from the infected zone arrive at these plants, the ID's are automatically scanned into the Farm Animal Identification Record (FAIR) database, where the animal record is updated to show the status of the animal. MDA manually updates FAIR for the remaining 5 percent that are slaughtered at smaller facilities or on the farm.

Objectives

The objectives of the audit were to identify and assess APHIS' internal controls related to the Bovine Tuberculosis Eradication Program in Michigan, and to determine whether the established safeguards and protocols were followed in Michigan.

⁷ *Federal Register* Vol. 69, No. 75: Tuberculosis in Cattle and Bison; State and Zone Designations; Michigan, dated April 19, 2004.

Findings and Recommendations

Section 1: Controls Over Tuberculosis-Infected Zone

Although we noted significant improvements over the past two years, we found weaknesses in controls over the testing, movement, and depopulation of animals within Michigan's infected zone. We performed a test on a sample of TB-infected herds and determined that neither APHIS nor MDA could account for the disposition of 113 of 645 animals in four of eight herds. In a separate analysis of annual testing in Michigan's infected zone, we selected a sample of four herds and found that MDA could not provide documentation to account for 105 of 287 animals in these herds. We also found that MDA, in following APHIS policy, released infected herds from quarantine before completing the definitive laboratory analysis, which resulted in the movement of 22 animals from an infected herd to a farm outside the infected zone.

Finding 1

Controls Over the Disposition of Infected Herds Need Strengthening

We reviewed 8 of the 32 herds that were infected with bovine TB between 1999 and 2004, and found that neither APHIS nor MDA could account for the disposition of all animals in four of the eight herds. This occurred because APHIS procedures did not require verifying the disposition of all animals from infected herds. As a result, APHIS and MDA could not document that 113 of the 645 animals from the infected herds were depopulated or remained on the farm after testing TB-free.

APHIS rules state that herds with animal(s) testing positive for bovine TB shall: (1) be depopulated; or (2) remain under quarantine under an individual herd plan. All animals moved from the farm shall be shipped directly to slaughter and shall be accompanied by a slaughter permit issued by a State or Federal representative.⁸ According to the APHIS Designated Tuberculosis Epidemiologist (DTE), Michigan's depopulation process for an infected herd consists of sending all suspects (cattle testing positive to an on-farm tuberculin test) to the Michigan State University laboratory for necropsy and histopathology, and all animals testing negative for TB to slaughter facilities.

A herd plan is a written disease management plan approved by State animal health officials and APHIS Area Veterinarian-In-Charge.⁹ The herd plan

⁸ Bovine Tuberculosis Eradication, Uniform Methods and Rules, effective January 1999, Part III, Section I.3.

⁹ Bovine Tuberculosis Eradication, Uniform Methods and Rules, effective January 1999, Part I, "Individual herd plan."

should include appropriate herd test frequencies, tests to be employed and any additional disease management practices deemed necessary to eradicate the disease from the herd in an efficient and effective manner. Under an individual herd plan animals testing positive to the TB test are depopulated, and animals testing negative are required to remain on the farm for a minimum of three years, passing a series of tuberculin tests, until it is determined that the herd is TB-free. During this process, the farmer also has the option to obtain a permit to send negative testing animals to slaughter.

For each of the eight TB-infected herds that we reviewed, we requested that the APHIS area office provide documentation showing that the animals were either depopulated or remained on the farm under an individual herd plan. The APHIS DTE provided us with copies of the movement permits (VS Form 1-27), test charts, orders of destruction, quarantine notices, and quarantine releases. APHIS requires all movement of animals from infected herds to be under permit. The permit is to be signed and dated by the veterinarian and the herd owner or shipper, then shipped to the lab or slaughter facility, where it is to be signed and dated by a representative from the facility and returned to MDA and the APHIS area office.

We found that APHIS and MDA could not provide documentation to account for the disposition of 113 of 645 animals in four of the eight herds in our review. APHIS and MDA officials stated that they had not established procedures to verify the disposition of animals from infected herds with signed movement permits from slaughter facilities and laboratories; and test charts over the duration of an individual herd plan.

The following table depicts our analysis:

<u>SAMPLE NUMBER</u>	<u>DATE INFECTED</u>	<u>HERD SIZE</u>	<u>DEPOPULATED</u>	<u>REMAINING ON FARM UNDER HERD PLAN</u>	<u>UNACCOUNTED FOR ANIMALS</u>
1	12/28/98	18	18		
2	2/4/00	168	30	73	65
3	9/19/00	124	35	66	23
4	5/7/01	91	91		
5	7/17/02	103	103		
6	1/21/03	45	22		23
7	5/23/03	73	71		2
8	11/10/03	23	23		
TOTALS		645	393	139	113¹⁰

¹⁰ The 113 animals without evidence of disposition were from 4 herds totaling 410 animals.

Infected Herds Under Herd Plans

Two of the eight herds were under herd plans for testing and removing animals (sample numbers 2 and 3 from the table above). For these two herds, we requested all movement permits (VS Form 1-27) issued after the quarantine to identify the animals that were depopulated, and the test charts (VS Form 6-22) at the time of the quarantine release to determine the animals remaining on the farm. We compared the animal ID numbers on the herd plan listing to those on the movement permits and test charts, and found that MDA and the APHIS area office were unable to provide evidence of the disposition of 88 of 292 animals from these two herds. Under a herd plan, the herd remains under quarantine and must pass three annual whole herd tuberculin tests before it is considered TB-free. During the plan, all suspects are depopulated. Animals testing negative can also be moved to slaughter, but only under permit. Because APHIS and MDA do not reconcile animal inventories during and at the conclusion of a herd plan, they cannot provide documentation to verify the disposition of 88 animals from these two infected herds.

Infected Herds to be Depopulated

For the six infected herds that were to be depopulated, we requested all movement permits (VS Form 1-27) issued after the quarantine to identify the animals that were depopulated. We compared the animals on the test chart with those that were listed on the movement permits to determine if all of the animals from the infected herds were depopulated. We found that MDA and the APHIS area office were unable to provide evidence that 25 of 118 animals in 2 infected herds (sample numbers 6 and 7 from the table on the previous page) were depopulated. For sample number 6, we obtained a permit for movement of 23 animals to slaughter; however, it was not signed and dated at the recipient establishment. For sample number 7, MDA and APHIS did not have any evidence of the depopulation of 2 of the 73 animals from the infected herd.

The APHIS DTE stated that they did not always follow up with the slaughter facilities when the facilities did not return signed movement permits. He further stated that APHIS ensured that the animals from infected herds were depopulated since an APHIS veterinarian verifies that all animals from the infected herd are loaded onto the truck, the truck is sealed, and the “slaughter only” movement permit is signed and dated. However, in these situations, neither APHIS nor MDA were able to provide documentation to verify that these animals reached the appropriate destination. An APHIS National official stated that the area office should have maintained proof of slaughter documentation and verified the disposition of all animals from infected herds. This APHIS Official also noted their procedures need to be clarified to better reflect these requirements.

As a result of our reviews, as described in the above sections, we concluded that APHIS had no assurance that 113 of 645 animals (18 percent) in eight TB-infected herds were depopulated or remained on the farm after testing negative for TB.

Recommendation 1

Enhance procedures to include: (1) verifying depopulated animals with movement permits; and, (2) reconciling animal inventories of infected herds over the duration of a herd plan with test charts and movement permits to document that all animals were either depopulated or remain on the farm as TB-free.

Agency Response

In its response, dated March 31, 2005, APHIS stated that they would enhance VS policy to include reconciliation of animals within infected herds by August 1, 2005.

OIG Position

We accept APHIS' management decision. For final action APHIS needs to provide OCFO with the updated VS policy that includes the reconciliation of animals within infected herds.

Finding 2

All Animals Are Not Accounted for During the Annual Testing Process in the Infected Zone

We analyzed the annual testing process in the infected zone and determined that APHIS and MDA could not account for 105 of the 287 animals in four herds. This occurred because APHIS procedures did not ensure that all animals are annually tested or accounted for in the infected zone. APHIS and MDA officials said that the animals had likely been slaughtered or died on the farm, but could not provide documentary evidence, or assurance that these animals were not diverted outside of the infected zone.

Through a Memorandum of Understanding (MOU) between APHIS and MDA, dated March 26, 2002, MDA agreed to perform: (1) annual whole herd testing of all herds in the infected zone; and (2) individual animal tests within 60 days of movement of breeding livestock and sexually intact feeders to another zone, unless going directly to slaughter. Animals may be moved to slaughter without meeting these testing requirements.

In a separate sample of herds than those described in Finding 1, we reviewed: (1) two dairy herds from the infected zone (herd numbers B2253 and A5406, which were TB-tested in fiscal years 2001-2002 and 2002-2003 respectively); and (2) two cattle herds from the infected zone that were TB-tested in fiscal years 2003 and 2004 (herd numbers A4231 and A4831). For each of the four sampled herds, we obtained the TB test charts (VS Form 6-22) for two consecutive years, and prepared schedules listing the animal ID number for each animal tested in each year. We sorted and compared the animal ID numbers to reveal those animals that had been tested in the first year, but not the next.

The following table summarizes the results of our review.

<u>HERD NUMBER</u>	<u>NUMBER OF ANIMALS ON FIRST YEAR TEST</u>	<u>UNACCOUNTED FOR IN YEAR TWO</u>
B2253	90	28
A5406	51	1
A4231	61	17
A4831	85	59
TOTALS	287	105

We asked MDA and APHIS area office personnel to provide explanations for the animals not tested or accounted for in the second year. They stated that the unaccounted for animals had likely been sent to slaughter or had died on the farm. In addition, MDA personnel said that they did not have documentary evidence to support the unaccounted for animals because, prior to June 1, 2004, animals were not required to have movement permits if being sent directly to slaughter, and MDA has never required producers to report on-farm deaths.

On June 1, 2004, APHIS and MDA adjusted their March 26, 2002, Memorandum of Understanding to include a requirement that permits be obtained for all animal movements from premises within the infected zone.¹¹ Also as of this date, MDA required all cattle in the infected zone to be tagged with the radio frequency ID tag prior to movement. Although APHIS officials stated that these adjustments would make it easier for veterinarians to account for all animals during annual TB-testing, they had not considered making reconciliations a requirement. APHIS currently performs herd reconciliations in Michigan, but only for accredited herds¹², which at the time of our audit represented approximately 70 of Michigan's 11,000 herds.

We concluded that the tracking of animal movements for herds in the infected zone is integral to the bovine TB eradication program in Michigan.

¹¹ Memorandum of Understanding between MDA and APHIS-VS, Article 5, dated April 5, 2004.

¹² An accredited herd is one that has passed at least two consecutive annual TB tests, and is annually tested thereafter.

APHIS officials agreed with the importance of tracking herds in the infected zone, but said that they would need to determine whether they have enough resources to perform reconciliations for the entire infected zone.

Recommendation 2

Establish procedures to reconcile herd inventories and account for all animals during annual testing in Michigan's infected zone.

Agency Response

In its response, dated March 31, 2005, APHIS agreed that the tracking of animal movements for herds in the infected zone is integral to the bovine TB eradication program in Michigan, and stated that it would establish procedures to reconcile herd inventories in order to improve the accountability of animals on retests. APHIS further stated that it would make maximum use of its existing resources to reconcile cattle inventories. This includes expanded use of its current system, radio frequency identification system, and hand-held computers. In addition, APHIS intends to utilize fiscal year 2005 funding to purchase additional electronic identification equipment that will make the reconciliation process easier to conduct.

OIG Position

To reach management decision, APHIS needs to provide us with timeframes that establish and implement procedures to reconcile herd inventories during on-farm testing in Michigan's infected zone.

Finding 3

Herd Quarantines Were Released Prior to Completing Lab Analysis

During its testing process, MDA released two herds in Michigan's infected zone from quarantine before the lab analysis was completed. Once the definitive lab culture¹³ was completed, it indicated that these two herds were infected with bovine TB. This occurred because APHIS' rules considered animals to be TB-free when the initial laboratory test (histopathology¹⁴) discloses no evidence of bovine TB. APHIS had not taken added precautions in the higher risk infected zone of Michigan to maintain herds under quarantine until the definitive lab test (culture) was completed. As a result,

¹³ The National Veterinary Services Laboratory in Ames, Iowa attempts to grow the bacteria in the laboratory from tissue samples taken from the animal.

¹⁴ Tissues collected during necropsy are prepared in a special solution, sliced thin, and placed on slides. The slides are examined under a microscope for evidence of the disease.

22 animals were moved from one of the infected herds to a farm outside the infected zone in Michigan, which could have spread the disease. However, in this instance, APHIS was able to find and depopulate the 22 animals, and all other animals at the recipient farm have tested negative for the disease.

APHIS rules state that, “If animals are slaughtered as suspects [from comparative cervical test] but show no gross lesions, selected tissues are found negative on histopathology, and a complete epidemiologic investigation, including herd test of all eligible animals, fails to disclose evidence of bovine TB or exposure thereto, upon concurrence of State and Federal officials the herd may be considered free of bovine tuberculosis.”¹⁵

We reviewed the documentation for the entire testing process for eight infected herds. In one of these herds, the primary on-farm TB test (caudal fold test) identified four suspect animals. A supplemental TB test (comparative cervical test) was administered to these animals. The supplemental test identified one problem animal. This animal was transported to the Michigan State University (MSU) laboratory for necropsy and histopathology. The necropsy and histopathology report from the MSU laboratory disclosed that the animal showed no evidence of bovine TB. Based on this, MDA released the quarantine on the herd. In accordance with Federal and State procedures, MSU sent samples from the animal’s carcass to the National Veterinary Services Laboratory (NVSL) in Ames, Iowa, to perform the lab culture, which is the definitive test. After completing the culture, NVSL reported that the animal was positive for bovine TB.

Based on our review of the permits for movement of restricted animals (VS Forms 1-27), and discussion with the APHIS DTE, we learned that the herd owner had shipped 22 of the 45 animals to another farm located outside the infected zone. This occurred during the period that the quarantine was released after the negative histopathology test was reported by MSU, but before the lab culture results were received from NVSL. Through trace back procedures, APHIS identified the location of the 22 animals and required that those animals be depopulated. They also had to test all animals on this farm and no others were found positive with TB.

The APHIS DTE said that their procedures have always been to release herds from quarantines after a negative histopathology test. He stated that the histopathology is generally very reliable, and that there was no scientific basis for keeping the herd under quarantine after a negative histopathology test. However, he also informed us of a second herd that was found positive for TB in the culture after being released from quarantine based on a negative histopathology. He said that these were the only two instances where this happened.

¹⁵ Bovine Tuberculosis Eradication, Uniform Methods and Rules, effective January 22, 1999, Part III.I.5.

Based on these two occurrences, we are recommending that APHIS revise its policy for herds in the infected zone with animals having a positive response (suspects) to the primary and supplemental on farm tuberculin tests, such that the herd quarantine is maintained until the lab culture is completed. The Director of APHIS' National Center for Animal Health Programs – Eradication and Surveillance Team agreed that herds in Michigan's infected zone should not be released from quarantine, or declared TB-free, until after a negative culture is obtained from the necropsy because of the prevalence of bovine TB in that area of the State.

Recommendation 3

Revise the policy to maintain quarantines on herds with animals (suspects) having a positive response to the primary and supplemental on farm tuberculin tests in Michigan's infected zone, until the lab culture is completed.

Agency Response

APHIS stated that their revised Bovine Tuberculosis Eradication Uniform Methods and Rules, effective January 1, 2005, required herds with suspects that are sent to slaughter remain under quarantine until the histopathology and lab culture are completed. APHIS also stated that they would be adding clarifying language to the tuberculosis UM&R and/or policy memorandums to emphasize this recommendation, and to define when deviations to the policy are allowed.

OIG Position

To reach management decision, APHIS needs to provide us with timeframes for issuing the cited clarifications.

Finding 4 Prevalence of Bovine Tuberculosis in Wildlife Is Not Incorporated in APHIS' Classification Standards

APHIS' current bovine TB classification standards do not include a measurement of bovine TB in wildlife in Michigan's infected zone. Bovine TB is contagious, and its presence in Michigan wildlife has been directly linked to the TB outbreaks in livestock, leading the Secretary of Agriculture to declare an emergency¹⁶ in October 2000. APHIS-VS officials stated that since they do not have authority over wildlife, their classification system is solely based on livestock infection levels. However, APHIS-VS is responsible for protecting livestock from the spread of TB, and it does assign and control State/zone status, such that it could incorporate wildlife prevalence rates into its classification standards. Without doing so, it is possible that Michigan can improve the classification status for its infected zone without reducing TB in wildlife. Such a change could result in a reduction in vigilance and disease detection efforts because significantly less testing occurs at the next classification status designation.

States are subject to an annual review by the APHIS Administrator in order to retain their bovine TB classification status designation. The classification of a State or a particular zone within a State determines the livestock testing requirements that must be met before animals can be moved out of the affected area. Michigan is unique in that it is the only State with two zones, modified accredited and modified accredited advanced. Under the current classification system, if for each of the two most recent years Michigan's modified accredited (infected) zone does not have more than three infected herds, the zone could achieve the less restrictive status of modified accredited advanced. In fiscal year 2004, Michigan reported three TB positive cattle herds in the infected zone, thus it is possible, if this rate of incidence continues or decreases, that the infected zone would be eligible to upgrade its status after fiscal year 2005.

There is a significant difference in testing requirements between Michigan's two zones. Michigan currently tests all livestock in the modified accredited zone annually (which represents over 1,000 herds). Furthermore, a negative test within the last 60 days is required prior to moving any cattle in or out of the modified accredited zone. Herds in the remainder of the State (the modified accredited advanced zone) are only subject to random testing, where a statistical selection of at least 1,800 herds (from over 10,000 herds)

¹⁶ Secretary of Agriculture's emergency declaration is discussed further in the Background section of this report.

are tested over a 2-year period. A negative TB test is not required within 60 days prior to moving cattle within the modified accredited advanced zone.

The presence of bovine TB in Michigan wildlife has been directly linked to TB outbreaks in livestock. Scientific analysis (DNA fingerprinting) identified that the same strain of bovine TB affecting Michigan's wildlife was affecting its livestock. Based on this scientific analysis, the Secretary of Agriculture declared an emergency in October 2000 after eight Michigan cattle herds were infected with bovine TB. Since that time, 24 additional cattle herds in Michigan have become infected with bovine TB.

An APHIS-VS strategic goal is to eradicate bovine TB, and its strategic plan refers to the wildlife problem as one of the "most significant issues" facing its eradication program. Accordingly, VS participates in a cooperative approach to address the wildlife problem with MDA, Michigan Departments of Natural Resources and Community Health, Michigan State University and APHIS' Wildlife Services. In 2003, this cooperative effort led to Michigan recording its lowest level of infected deer since 1995.

Despite the harvesting of thousands of deer every year, numerous cases of infection continue to be detected. Prior to 2003, infection rates had not declined, but remained static. However in 2003, only 32 wild deer tested positive for bovine TB in the infected zone, of the 17,301 voluntarily submitted for testing throughout the State. The State recorded 51 positive cases in 2002, and for the period 1995-2002 there were 447 positive-testing deer (an average of 56 per year). Since 1996, 42 non-cervids including black bears, coyotes, red fox, opossum and raccoon have also tested positive for bovine TB. In Michigan, two humans have tested positive for this particular DNA strain of bovine TB. Michigan's TB eradication activities report for 2003¹⁷ quotes a source that states "with continued intervention and population reduction of deer population, bovine TB should be down to an undetectable level in white-tailed deer by 2012". In spite of this, Michigan could seek to upgrade the infected zone's status to modified accredited advanced, if there are no more than three positive livestock herds in 2005, even though the disease will not have been eradicated and could still infect cattle. The modified accredited advanced zone has less testing requirements and fewer restrictions on cattle movements.

In response to this concern, VS officials agreed that bovine TB in wildlife is a problem, but noted their authority was limited to only livestock. However, because APHIS does control the criteria for State and zone status and it approves the related State testing plans, we believe APHIS can better reflect the overall eradication effort, and control of the disease, if it were to include

¹⁷ Michigan Bovine Tuberculosis Eradication Project Activities Report 2003, page 22, quotes *Dynamics of Bovine TB in Wild White-tailed Deer in Michigan* report.

wildlife disease measurement as a classification factor for Michigan's infected zone. Testing in the infected zone is directly linked to its modified accredited status. However, status in the infected zone is dictated only by livestock infections, even though over 30 deer have tested positive in each year since 1995. Without an adjustment to classification system, further transmission of bovine TB from wildlife to livestock will remain as a high risk, but the current level of controls and testing may not be in place to timely detect and eradicate any potential new cases.

Recommendation 4

Revise the classification standards for Michigan's infected zone to include bovine TB in the wildlife population by incorporating wildlife measurements as a status-determining factor.

Agency Response

APHIS stated that the new provisions in their revised Bovine TB Eradication Uniform Methods and Rules (UM&R), implemented on January 1, 2005, will result in the revision of classification standards for Michigan's infected zone by requiring provisions to reduce the prevalence of TB in wildlife be enforced within a realistic timeframe. It also requires that the prevalence of TB in the wild cervid population be determined annually. They further stated that the revision requires free-ranging cervid surveillance in zones like Michigan's infected zone, however there is not a target prevalence specified. APHIS stated that they plan to include a requirement that such surveillance be adequate to at least detect a prevalence of 2 percent in the free-ranging cervid population with 95 percent confidence. APHIS stated that these measures must be in place and followed before any change in testing requirements for cattle in the infected zone of Michigan will be considered.

OIG Position

To reach management decision, APHIS needs to provide us with its plan, including timeframes, for revising the classification standards for Michigan's infected zone to include bovine TB in wildlife as a status-determining factor. Status is currently dictated by livestock infections only, either the number of positive herds or as a calculated percentage. By including wildlife as a factor, status will be determined by the number of positive herds, the number of infected wildlife and/or a combination of the two. As noted in our Finding, under the current status structure, Michigan could seek to upgrade the infected zone's status to modified accredited advanced, if there are no more than three positive livestock herds in 2005. Potential new wording, for example, may include a provision that states no more than three positive livestock herds, or five positive wildlife cases (cervid or other), and a mixed factor combining livestock herds with wildlife.

Scope and Methodology

We performed our audit fieldwork from April through October 2004, and covered the period fiscal years 1999 through 2004. The audit was conducted at the: (1) APHIS National Office in Riverdale, MD; (2) APHIS area office in East Lansing, MI; and (3) Michigan Department of Agriculture (MDA) in Lansing and Atlanta, MI. We judgmentally selected the State of Michigan, one of the four States affected by bovine TB, for review. Michigan was selected because it had the highest prevalence of bovine TB in the United States.

We conducted a test to determine whether MDA was meeting the requirement to annually test all herds in the infected zone. We reviewed records for 339 of the 400 (85 percent) herds that were to be tested by July 28, 2004, and found that the herds were tested as required.

In order to test whether whole herd testing was being accomplished, we initially selected 2 of 184 dairy herds in the infected zone, as of May 17, 2004, and obtained the TB-test charts for 2001 through 2003. After finding that all animals were not tested or accounted for in consecutive years, we expanded our analysis to include two beef herds that were tested in 2003 and 2004.

We also tested the controls over animals in infected herds, by selecting a judgmental sample of 8 (25 percent) of the 32 cattle herds infected with bovine TB in Michigan during the period fiscal year 1999 through fiscal year 2004, to verify that all animals were depopulated or under herd plans. We selected the sample to include dairy and beef herds from each of the original four infected counties, plus two additional counties.

To accomplish our audit objectives we:

- Interviewed APHIS National Office, APHIS area office, and MDA officials;
- Reviewed APHIS and the State of Michigan regulations, policies, and procedures related to the BTEP;
- Reviewed memoranda of understanding between MDA and APHIS;
- Reviewed annual and monthly reports for TB-affected States and non-affected States, as maintained at the APHIS National Office; and,

- Examined documentation from APHIS' and MDA's files and automated systems regarding the testing and movement of animals.

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

Exhibit B – Agency Response to the Draft Report

Exhibit B – Page 1 of 4



MAR 31 2005

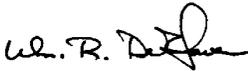
United States
Department of
Agriculture

Marketing and
Regulatory
Programs

Animal and
Plant Health
Inspection
Service

1400 Independence
Ave SW
Room 317E W
Washington, DC
20250

TO: Robert W. Young
Assistant Inspector General
for Audit

FROM: W. Ron DeHaven 
Administrator

SUBJECT: APHIS Response to OIG Report, "National Cooperative State/Federal
Bovine Tuberculosis Eradication Program" (Report No 33099-0005-Ch)

Thank you for the opportunity for the Animal and Plant Health Inspection Service (APHIS) to comment on the above report. We have provided our responses to each of the report's four recommendations.

Recommendation No. 1

Enhance procedures to include verification of depopulated animals with movement permits and reconcile animal inventories of infected herds over the duration of a herd plan.

APHIS Response

Veterinary Services (VS) is interested in enhancing these procedures as recommended. VS policy, as documented in VS Memorandum 552.32, requires a report on the destruction of all exposed animals destroyed immediately following completion of an indemnity claim. In the currently drafted updates to VS policy, we will include language to enhance reconciliation of animals within infected herds. These documents will be completed by August 1, 2005.

Recommendation No. 2

Establish procedures to reconcile herd inventories and account for all animals during annual testing in Michigan's infected zone.

APHIS Response

We agree with OIG that tracking of animal movements for herds in the infected Modified Accredited (MA) zone is integral to the bTB eradication program in Michigan.

APHIS will establish procedures to reconcile herd inventories, in order to improve the accountability of animals on retests, APHIS' Michigan Veterinary Services office,



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

and the Michigan Department of Agriculture (MDA) will utilize the animal identification and tracking program to accomplish this task. This program's tools include Radio Frequency Identification (RFID) tags, hand-held computer/scanners and wand and stationary scanners. The latter scanners are now in place at stockyards, cattle auctions, and slaughter plants in Michigan. These devices are also commonly placed in other states that slaughter Michigan-origin cattle. More identification requirements are being planned for animals in high risk herds. By July 2006, the program plans to issue additional handheld computers with software to allow on-the-farm determinations of missing animals and herd additions. Program funding for FY 2004 is exhausted. Therefore, we will have to use FY 2005 funding to purchase this equipment.

Additionally, since movement permits are now required for any animal moving from any premises located in the MA zone of Michigan, a plan is being developed to enter this data into the tuberculosis eradication database to allow rapid retrieval of data on animals that have been moved into or out of the herds being retested. The completion date of this plan is contingent upon the completion of National Animal Identification System tracking database, which is expected to be fully implemented in FY 2007.

Our program goal is to achieve 100 percent herd inventory reconciliation in the MA zone. The current program has most of the tools to accomplish this goal. To maintain adequate human resources and a supportive regulatory environment that will allow continued improvement, our Michigan VS office and the MDA will continue to make maximum use of its existing system and human resources to further enhance its ability to reconcile cattle inventories. The expanded use of RFID tags and handheld readers will improve the ability to achieve the goal.

Recommendation No. 3

Revise the policy to maintain quarantines on herds with animals (suspects) having a positive response to the primary and supplemental on farm tuberculin in Michigan's infected zone, until the lab culture is completed.

APHIS Response

The 2005 Bovine Tuberculosis Eradication Uniform Methods and Rules (Part III, J) state the following:

- Herds in which at least one suspect and no reactor animals are disclosed shall be quarantined until all suspects are retested and classified negative, or shipped directly to slaughter under permit and no evidence of *M. bovis* infection is disclosed.
- If animals are slaughtered as suspects according to Part III, A., but show no gross lesions and selected tissues, to include representative head and thoracic lymph nodes, are found negative on histopathology and bacteriological culture

for *M. bovis* and a complete epidemiologic investigation, including a herd test of all eligible animals, fails to disclose evidence of bovine tuberculosis or exposure thereto, the herd, with the concurrence of the DTE and Regional Tuberculosis Epidemiologist, may be considered free of bovine tuberculosis. A 90-120 day herd retest is recommended.

This newly implemented policy supports the OIG recommendation. Clarification language will also be added to the tuberculosis UM&R and/or policy memorandums to emphasize this recommendation. In addition, the DTE and Regional Tuberculosis Epidemiologist will be given discretion to deviate from this policy, but only when adequate evidence, such as recent herd history, herd test history, wildlife disease prevalence in the area, and other facts, supports such action.

Recommendation No. 4

Revise the classification standards for Michigan's infected zone to include bovine TB in the wildlife population by incorporating wildlife measurements as a status-determining factor.

APHIS Response

The 2005 Bovine Tuberculosis Eradication Uniform Methods and Rules (Part V, A) state the following:

- If bovine tuberculosis is diagnosed within any State or zone in an animal not specifically covered by this UM&R or the UM&R for captive cervids and a risk assessment conducted by APHIS determines that the outbreak poses a tuberculosis risk to livestock within the State or zone, the State must implement a tuberculosis management plan, approved jointly by the Chief State Animal Health Official and the APHIS Administrator, within 6 months of the diagnosis. The management plan must include provisions for immediate investigation of bovine tuberculosis in animals held for exhibition and in livestock and wildlife; the prevention of the spread of the disease to other animals held for exhibition and to livestock and wildlife; increased surveillance for tuberculosis in livestock, wildlife, and animals held for exhibition; eradication of tuberculosis from individual herds; provisions to reduce the prevalence of tuberculosis in wildlife; and a realistic timeline for the eradication of tuberculosis.
- The plan must also include surveillance of free-ranging cervids at a rate to determine the annual prevalence of tuberculosis in the cervid population within an area or zone that is not classified as Accredited-free. Feeding and baiting of free-ranging cervids should be banned in any county in which *M. bovis* infection has been disclosed in livestock or wildlife. Performance standards, as appropriate, must be implemented to measure yearly progress toward eradication. If a State or zone does not implement such a plan within

Exhibit B – Agency Response to the Draft Report

Exhibit B – Page 4 of 4

APHIS Response to OIG Report 33099-0005-Ch

Page 4

the required 6 months, the State or zone could lose its current status and could be reclassified to the next lower status.

These new provisions will result in the revision of classification standards for Michigan's infected zone by requiring that provisions to reduce the prevalence of tuberculosis in wildlife be enforced within a realistic timeframe. It also requires that the annual prevalence of tuberculosis in the wild cervid population be determined annually. Although this language clearly requires free-ranging cervid surveillance in zones like Michigan's MA zone, there is not a target prevalence specified. To provide quantitative guidance for evaluating such zones, we plan to include a requirement that such surveillance be adequate to at least detect a prevalence of 2 percent in the free-ranging cervid population with 95 percent confidence. We think this standard will provide a clear basis for evaluating a zone's surveillance efforts. These measures must be in place and followed before any change in the testing requirements for cattle in the infected zone of Michigan will be considered. In addition, a change in the measurement of herd prevalence is being proposed for the program, which will more equitably measure the tuberculosis eradication activities within a state or zone and encourage rapid depopulation of infected herds in order to maintain classification status.

Thank you again for allowing us to comment on this report. We believe our planned efforts in this area would enhance our Tuberculosis Eradication Program in Michigan.

Informational copies of this report have been distributed to:

Administrator, APHIS	
ATTN: Agency Liaison Officer	9
U.S. Government Accountability Office	1
Office of the Chief Financial Officer	
Director, Planning and Accountability Division	1
Office of Management and Budget	1