

REPORT OF THE COMMITTEE ON TUBERCULOSIS

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Vice Chair: Michael S. VanderKlok, Lansing, MI

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The Committee met on October 29, 2008, from 8:00 a.m. to 1:30 p.m. at the Sheraton Greensboro Hotel, Greensboro, North Carolina. There were over 140 members and guests in attendance. Dr. Kathleen M. Connell and Dr. Michael S. VanderKlok presided. In her opening remarks, Dr. Connell reviewed the day's agenda and welcomed members and guests. The Chair determined that a quorum was present to conduct business.

The Chair made two announcements concerning the Tuberculosis (TB) Scientific Advisory Subcommittee (SAS) and the Bi-National TB and Brucellosis Committee Coordinator. In 2008, the TB SAS did not receive any specific assignments and data was not provided for evaluation and comment. The Subcommittee Chair, Dr. Mitch Palmer, National Animal Disease Center, Agricultural Research Service, United States Department of Agriculture (USDA), notified the TB Committee Chair that the Subcommittee did not meet this year, so no report was provided.

Dr. Billy Johnson, Bi-National TB and Brucellosis Committee Coordinator, was unable to attend the 2008 TB Committee meeting. Dr. Connell submitted a written report on the Bi-National

Committee (BNC) June 23-24, 2008, meeting in Chihuahua, Mexico. The full text of this report is included in these proceedings.

Formal presentations began with Dr. Bruno Oesch, Prionics, Switzerland, who gave a Time Specific Paper entitled Bovigam interferon gamma assay development and its use in international TB programs. This paper is included in its entirety in these proceedings.

Dr. Kathy Orloski, Epidemiologist, National TB Eradication Program, Veterinary Services (VS), Animal and Plant Health Inspection Services (APHIS), USDA, followed with presentations on the current status of the U.S. bovine TB eradication program and an update on the U.S. national surveillance program for bovine TB. The full text of her reports is included in these proceedings.

Dr. John Clifford, Deputy Administrator, VS-APHIS-USDA, addressed the Committee on the challenges faced by the bovine TB eradication program. The full text of this report is included in these proceedings.

A special presentation on Australia's TB eradication program was given by Dr. Bill Scanlan, Senior Principal Veterinary Officer for the Department of Agriculture, Fisheries and Forestry. The full text of this report is included in these proceedings.

Dr. Maria Koller-Jones, Senior Staff Veterinarian, Animal Health and Production Division, Canadian Food Inspection Agency, Ottawa, Ontario, provided an update on the current status of the Canadian bovine TB eradication program. The full text of this report is included in these proceedings.

The current status of Mexico's campaign against TB and an update on Mexico's national surveillance program was delivered by José Alfredo Gutiérrez Reyes, Subdirector de Sanidad en Especies Mayores, Dirección de Campañas Zoonositarias, Dirección General de Salud Animal, Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA). The full text of this report is included in these proceedings.

State updates followed, provided by Dr. Richard E. Breitmeyer, State Veterinarian, California Department of Food and Agriculture; Dr. Mike VanderKlok, Bovine TB Eradication Coordinator, Michigan Department of Agriculture; Dr. Bill Hartmann, Minnesota State Veterinarian and Board of Animal Health Executive Director; Dr. Tim Hanosh, New Mexico Livestock Board; and Dr. Bob Hillman, Texas State Veterinarian and Executive Director of the Texas Animal Health Division.

Dr. Rich Breitmeyer provided the update for California. To date, California has detected three (3) dairy herds in Fresno County affected with bovine tuberculosis (TB), and seven (7) total infected animals, including singleton reactors in two of the herds.

These cases are summarized below to clarify the number of affected herds, number of infected cattle, epidemiological findings, and our joint State/Federal response.

The first affected herd was detected through routine slaughter surveillance on a cow in December 2007. Four additional infected cows were detected in this 5,000-head herd through testing. All five cows were infected with the same strain of *M. bovis*. This dairy was depopulated in late July 2008, with no additional infected animals detected. The dairy has completed its cleaning and disinfection, and is now in the process of restocking. The source of the infection in this herd has not been determined.

The second affected herd was tested because they purchased 16 cows in 2007 from the first affected herd. One of those purchased cows was found to be infected with *M. bovis* when she was removed from the herd. The *M. bovis* strain type from this cow matches that in the first affected herd. This herd was depopulated in early August 2008, with no additional infection in the 1,000 cattle. The facility has been cleaned and disinfected. The few traces from this herd are being completed.

The third affected herd was tested as a trace-in to the index herd (one 4-H heifer from this herd entered the first affected herd). During testing, one infected eight-year old cow was detected. Because of herd movements, two dairies, together containing approximately 13,000 cattle, are now involved in this investigation. These herds have been tested twice, all CFT responders removed, and tissues from over 500 cattle have been examined at necropsy or slaughter with no additional infected animals being detected. The *M. bovis* strain type from this herd differs from the strain type in the first and second affected herds. Traces of cattle (primarily registered Holstein breeding bulls) from this herd since 2003 are ongoing.

Attempts to determine the origin of both strains of bovine TB are ongoing. According to genotyping conducted by USDA, the *M. bovis* isolates from these cases are typical of strains associated with dairy cases in the Southwest U.S. and Mexican-origin cases. They are distinct from the isolates diagnosed in California in 2002-2003, and from the isolates in Michigan and Minnesota. Isolates most closely matching the first (and second) affected herd(s) include a 2008 case from New Mexico and a 1997 slaughterhouse case from a California feedlot. The *M. bovis* strains most closely matching the isolate from the third herd are three Texas slaughterhouse cases in 2006-2007 with either unknown sources or trace-backs to Mexico, an isolate from a 2003 affected herd in Texas, and a 2007 slaughterhouse case from a California feedlot.

In response to detecting the first affected herd, a joint State/Federal TB Task Force was established in early January 2008. Currently, about 80 people are dedicated to analyzing cattle movement records, identifying and testing cattle, and implementing and verifying disease control measures. To assist this ongoing effort, USDA Veterinary Services is now providing Incident Management Teams, rotating on a three week basis. Task Force participants are now deployed from all areas of California and several other states.

To date, approximately 170 herds and 220,000 cattle have been tested. Tracing movements out of these herds has led to traces to 18 states and Canada. In California, it is anticipated that approximately 200,000 additional cattle will be tested over the coming months. We are very encouraged by the fact that we have not yet demonstrated significant, active spread of disease, from any of the affected herds, and the number of positive animals remains very low – including two herds with only a single infected animal each.

We especially want to recognize and thank USDA for their support of this effort and for the many state and federal animal health staff that have sacrificed time away from family to assist with this effort.

Dr. Mike VanderKlok provided the update for Michigan.

Dr. Bill Hartmann provided Minnesota's update. Minnesota has been working to eradicate bovine tuberculosis (TB) since the first infected herd was found in the State in 2005. Now, only three years later, the State has been granted Split State Status. This effectively split Minnesota into two TB zones; a majority of the state is Modified Accredited Advanced (MAA), while a small part of northwestern Minnesota, where TB has been found, remains Modified Accredited (MA). Minnesota signed a Memorandum of Understanding (MOU) detailing the conditions of the approval of Split State Status.

The MA Zone was created to include all 11 previously infected cattle herds. The zone also provides a buffer of 17 miles or more around the area where 24 TB-positive deer were found. As a condition of the MOU, the Minnesota Board of Animal Health will conduct increased surveillance outside the MA Zone. The MOU calls for 1,500 cattle herds to be TB tested, a figure which is weighted for herds deemed 'high-risk'. The Board will be focusing primarily on herds in the six counties surrounding the MA Zone.

The Minnesota Department of Natural Resources (DNR) will also increase its surveillance efforts by testing 1,800 free-ranging white tailed deer in and around the MA Zone. This level of surveillance will continue for five years after no infection is found.

Per the MOU, herds in the MA Zone will undergo a wildlife evaluation and develop a herd plan. All cattle from the zone are required to have official identification before moving off the farm. The State is currently using a combination of a USDA metal ear tag and an RFID tag. Movements of these animals will be routinely and continuously monitored at sales barns through out the state.

Several objectives must be accomplished to meet Minnesota's goal of eradicating TB. The State must detect and depopulate infected cattle herds, eliminate disease transmission in the

Management zone, reduce the cattle population, protect remaining cattle from contact with potentially infected deer, and reduce the deer population. To achieve these objectives, Minnesota has implemented buyout and fencing programs. Forty-five eligible herd owners are taking part in the herd buyout. This will remove approximately 4,000 head of cattle from the Management Zone. All buyout cattle must be removed from the zone by January 31, 2009. Herds remaining in the management zone have had a wildlife risk assessment. It was determined that 28 premises in will be need deer-exclusion fencing to protect cattle herds and feedstuff from deer.

During the 2007-08 deer hunting season, DNR removed 2,656 deer from the Management Zone by using a combination of aerial shooting, sharp shooting, regular hunting season, a special hunt, and land owners shooting deer on their property.

Minnesota is utilizing all of its resources to eradicate TB. The Board would like to thank the many states acknowledging Minnesota's efforts by recognizing its Split State Status. By working together, we can accomplish our goal of eradication.

Dr. Tim Hanosh reported that the state of New Mexico had its TB status reduced from accredited free with a small modified accredited advanced zone in the central eastern part of the state to state wide modified accredited advanced. The reduction in status occurred on September 11, 2008. The reason for the reduction in status involved two incidences of TB in the Clovis, New Mexico area outside of the MAA zone.

The first incident responsible for the reduction in status involved the DoRene/Milagro dairy herd comprised of two dairies, DoRene Dairy and Milagro Dairy and one heifer raising facility. Milagro Dairy is now called Clover Knolls Dairy and is under separate management. The DoRene/Milagro herd was declared TB infected in June 2007. All herds epidemiologically linked to the DoRene/Milagro herd were tested by November 2007 with no other cases of TB diagnosed. The epidemiology report was submitted to the USDA on November 30, 2007. Of the 5981 animals traced out of the DoRene/Milagro herd, 3 remain untraceable. The DNA fingerprint from this herd matches Schuberg Dairy in Arizona, Bromley Feed Yard in Texas and two Mexican origin steers. The owner of the DoRene/Milagro herd accepted a depopulation agreement which was completed December, 2007. The depopulation involved the taking of over ten thousand animals to slaughter. The cleaning and disinfecting was completed by the end of January 2008. At present both dairies are back at full capacity and have undergone their six month assurance TB tests. Both dairies are scheduled to have a 12 month assurance test also.

The second incident responsible for the reduction in status involved the F and F Feed Yard. F and F Feed Yard was mainly involved with feeding steers, approximately 1450, and cull cows, approximately 180 dairy cows; however, the feed yard was also used as a facility to market a small number of recycled dairy cows. Recycled cows are cull cows that, instead of going to slaughter, are bought by cattle dealers and resold to other dairies as replacements. The recycled cows at F and F Feed Yard were in pens with dairy bulls. The cows were kept with the bulls for a few months. If the cows were successfully bred they were sold as replacements, if not they were sold to slaughter. F and F Feed Yard was declared as an infected herd in May 2008 due to a recycled cow that was illegally transported from F and F Feed Yard to Erath County Dairy Sales in Stephenville, Texas. The cow was one of a load of 36 that entered Texas without a CVI, export inspection or current TB test. At Stephenville the load of cows was purchased and was to return to New Mexico. Before entering New Mexico the cattle were TB tested and one cow was positive on Caudal Fold, Gamma interferon and, ultimately, on histopathology and culture. The cow was purchased at a packer sale in Portales, New Mexico on October 4, 2007 and, according to the dealer, was at F and F Feed Yard until he had her transported to Stephenville in late February, 2008.

The dairy of origin for the infected cow is located in southeastern New Mexico. It has been a closed herd since 2001 and culls better than average cows. The management and biosecurity at the dairy are excellent. The dairy underwent a whole herd test, 4880 cows, in April 2008 with no diagnosis of TB. The dairy will undergo an assurance test in January 2009.

All cattle at F and F Feed Yard were TB tested in April and May of 2008 with no cases of TB diagnosed. The feed yard was depopulated with the last animal leaving July 16, 2008. Cleaning and disinfecting has been completed according the depopulation plan.

The DNA fingerprint for the F and F cow is not a match for the DoRene/Milagro herd nor the Mitchell Dairy which is the dairy in New Mexico in its last year of a test and remove herd plan; however, the F and F DNA fingerprint is similar to the Green Valley DNA fingerprint in California and

at least one Mexican origin steer. To date no epidemiological link has been found between F and F and Green Valley. The F and F Feed Yard epidemiology is underway and will take several months to complete.

Mitchell Dairy is the herd that was responsible for the creation of a small MAA zone in eastern central NM in July 2005. The dairy remains under quarantine and has one more whole herd test to undergo before being eligible for being released from quarantine. The next whole herd test is scheduled for July 2009; if no positive cases of TB are diagnosed the dairy will be released from quarantine. The dairy will be required to undergo one assurance test in July 2010.

New Mexico has applied for split state status that will involve creating a new MAA zone encompassing Curry and Roosevelt counties. The proposed zone will be larger than, and will incorporate, the former MAA zone. New Mexico is working with the USDA in completing the tasks required to attain the proposed MAA zone.

Dr. Bob Hillman completed state updates by giving the report for Texas.

During the 2007 TB Committee meeting, five Subcommittees were established to address specific issues. Subcommittee Chairs or their representatives gave updates on Subcommittee activities during the past year.

In Chair Tyler Thacker's absence, Dr. Kathy Orloski, Epidemiologist, National TB Eradication Program, VS-APHIS-USDA, gave the Subcommittee on Diagnostic Test Review update, which is included immediately following this report.

In the Chair Janet Payeur's absence, Dr. Michelle Miller, Disney Animal Programs, Department of Veterinary Services, gave the Subcommittee on Elephant TB Guidelines update. The full report is included at the end of this report.

Mr. Phil Durst, Subcommittee Chair, gave the report of the Subcommittee on TB Test and Remove Policy, which is included immediately following report.

Committee Business

At the conclusion of formal presentations, Dr. Connell reported on the four Resolutions from 2007, Numbers 25 through 28. VS-APHIS-USDA responded promptly in writing to all four resolutions.

Four resolutions were approved and forwarded to the Committee on Nominations and Resolutions.

REPORT OF THE SUBCOMMITTEE ON DIAGNOSTIC TEST REVIEW

Dr. Kathy Orloski
Veterinary Services

Criteria for Evaluating Experimental Tuberculosis Test Performance for Official Test Status

The purpose of these criteria is to provide guidelines to the TB Scientific Advisory Subcommittee for the evaluation of diagnostic tests for the detection of *Mycobacterium bovis* infected animals. It is incumbent upon the sponsor of the test to define the intended purpose of the test (i.e., as a presumptive, supplemental, and/or primary diagnostic test), the proposed interpretation standards, specific application and intended species. Defining the purpose of the new test is critical in establishing the benchmarks for evaluation. The new test will be evaluated according to guidelines described below for Phase I, II, and III. After the evaluation process has been initiated, the sponsor may not make substantive changes in reagents or methods for conducting the test. If substantial changes in the new test are made, the sponsor must reevaluate the test beginning at Phase I. Variances from these guidelines must be approved by the Tuberculosis Committee of the United States Animal Health Association or its designate.

Test Submission and Approval Process

Results may be submitted for review to the Chair of the TB Scientific Advisory Subcommittee (TB SAS) at any time. The TB SAS will review the data by conference call/email or at the regularly scheduled subcommittee meeting at the annual USAHA meeting. The recommendation of TB SAS will be submitted to the Chair of the TB Committee. If needed, the TB SAS will develop and submit a resolution to the TB Committee Chair. The TB Committee Chair will determine whether the recommendation will be immediately released to the TB Committee or held until the annual TB Committee Meeting. At the next TB SAS and TB Committee meeting the results of the TB SAS recommendations will be reported to the TB Committee in its annual report.

PHASE I: Preliminary evaluation for diagnostic sensitivity and specificity

The objective of this Phase is to determine if the proposed test has sufficient diagnostic sensitivity (DSe) and diagnostic specificity (DSp) to be fit for its intended propose.

Diagnostic Sensitivity

The new test must be evaluated on *Mycobacterium bovis* infected¹ animals by the submitting organization and the results submitted to USDA/APHIS/VS for statistical evaluation of test performance. The new test must be evaluated on a sufficient number of animals to reasonable demonstrate that the sensitivity of the new test is fit for its intended purpose. The formula in Appendix A can be used to estimate the number of animals needed to evaluate DSe with a margin of error of 5% ($e = 5\%$). Estimates of DSe and DSp in the U.S. are listed in Appendix B. In this part of the preliminary evaluation, laboratory work (histopathology and/or bacteriology) necessary to determine *M. bovis* infection will be conducted at the NVSL, OIE Veterinary TB Reference Laboratories, National Veterinary Reference Laboratories or a laboratory acceptable to the USDA.

Diagnostic Specificity

The new test must also be evaluated from at least 10 herds from accredited-free states (or herds that are accredited-free and those with no history of exposure to *M. bovis*) to demonstrate that the test is equivalent to or better than that of the test currently used. The formula in Appendix A can be used to estimate the number of animals needed to evaluate DSp with a margin of error of 2% ($e = 2\%$). The testing will be done by the submitting organization and the results will be submitted to the USDA for statistical evaluation of test performance. Herds should be representative of the target industry and be diverse in regard to geographic location, breed/species and age.

Results of Phase I trials will be presented to the TB SAS. If the proposed test has sufficient DSe and DSp to fulfill its intended purpose, the test will be recommended for Phase II.

PHASE II: Side by side blind comparison

The objective of Phase II is to determine if the proposed test is fit for its intended purpose by directly comparing the current test side-by-side with the proposed test. This phase should provide sufficient data to show, with confidence, that the proposed test will meet program needs.

Diagnostic Sensitivity

Both the new test and official test will be evaluated in animals from at a sufficient number of *M. bovis*-infected herds to ensure that the new test is fit for its intended purpose. The formula in Appendix A can be used to estimate the number of animals needed to evaluate DSe with a margin of error of 3% ($e = 3\%$). Both tests will be applied to each animal. Whole herds or randomly selected animals from a herd must yield at least one infected animal, which has been subjected to side-by-side testing. Results of testing with one test will not be available to those responsible for determining the results of the other test. All tested animals will be examined at slaughter for detection of tuberculous lesions. Tissues from different organs and lymph nodes will be examined using histopathologic and bacteriologic procedures. Laboratory work (histopathology and bacteriology) will be conducted at the NVSL, OIE Veterinary TB Reference Laboratories, National Veterinary Reference Laboratories or a laboratory acceptable to the USDA. Results of antemortem testing will not be available to the laboratory. The submitting organization will be responsible to run the new test. At least 50% of the samples must be of North American origin and the origin of samples must be delineated in data presented to the TB SAS Subcommittee.

Diagnostic Specificity

Both the new test and currently used test will be evaluated on animals from at least 10 accredited-free U.S. herds to ensure that the new test is fit for its intended purpose. The formula in Appendix A can be used to estimate the number of animals needed to evaluate DSp with a margin of error of 2% ($e = 2\%$). In this part of the blind comparison, preferably all, or a predetermined random sample, of at least 25% the total animals must be tested side by side. Herds should be representative of the target industry and be diverse in regard to geographic location, breed/species and age.

Results of Phase II trials will be presented to TB SAS. If the proposed test has sufficient DSe and DSp to fulfill its intended purpose, the Committee will recommend that the test be approved for Phase III testing. If the USDA determines that the new test performance in Phase II is equivalent to or better than the current official test, then the new test would be recommended for conditional/temporary approval as an official test for a period of 1 to 5 years, with annual reviews for continuation. The sponsor of the new test must have completed the USDA, Center for Veterinary Biologics requirements for licensure prior to conditional approval.

PHASE III: Field trial of use of new test

The primary objective of Phase III is to determine if the proposed test is sufficiently robust to be used under field trials. In addition DSe and DSp will continue to be evaluated.

During a 1 to 5 year trial, the new test will be performed by accredited veterinarians and/or certified laboratories, under natural field conditions. The USDA will assess the performance of the new test on routine samples.

Diagnostic Sensitivity and Specificity will continue to be evaluated by the USDA. Data from side by side comparisons (in Phase II) between the new test and current official test, for the proposed use, can be applied to complete Phase III. If the new test performance evaluates equivalent to or better than the currently used test, it will be referred to the TB Committee for recommendation as an official test.

Definitions:

Criteria for defining infection with *Mycobacterium bovis*

Infected: An animal will be considered infected when *Mycobacterium bovis* has been isolated from one or more tissues AND/OR the animal has mycobacteriosis compatible lesions with the presence of *M. bovis* confirmed by PCR. Culture and histology will be performed following the current protocols at the National Veterinary Services Laboratories (NVSL), OIE Veterinary TB Reference Laboratories, National Veterinary Reference Laboratories or a laboratory acceptable to the USDA.

Exposed: Animals not meeting the criteria for Infected but residing in a herd that has confirmed *M. bovis* infected animals will be defined as exposed and will not be used to determine specificity.

Non-infected: For determining specificity, an animal will be considered non-infected when it comes from an accredited TB-free herd or from a herd with no history of exposure to *M. bovis*.

Appendix A: Calculation of Sample Size

Sample size for Phase I and II should be calculated using the method of Griener and Gardner² or Jacobson³ using the formula:

$$n = \left(\frac{1.96}{e} \right)^2 \theta(1 - \theta)$$

Where: e =margin of error and θ = estimate of sensitivity or specificity from pilot or preliminary study. Both terms are calculated using the decimal form.

The following table provides an example:

Estimated DSe or DSp	Margin of Error					
	10%	8%	5%	3%	2%	1%
80%	61	96	246	683	1537	6147
82%	57	89	227	630	1418	5670
84%	52	81	207	574	1291	5163
86%	46	72	185	514	1156	4625
88%	41	63	162	451	1014	4057
90%	35	54	138	384	864	3457
92%	28	44	113	314	707	2827
94%	22	34	87	241	542	2167
96%	15	23	59	164	369	1475
98%	8	12	30	84	188	753
99%	4	6	15	42	95	380

Appendix B: 1992 Estimated DSe and DSp of TB Tests

Types and Validity of Official Tuberculosis Tests

Family	Test	DSe	DSp
e Bovida	CFT	82%	96%
	CCT	74%	96%
	SCT	92%	85%
e Cervida	SC-DS	80-85%	61-98%
	CCT	95%	95%

CFT= Caudal Fold Test

CCT= Comparative Cervical

SCT=Single Cervical

SC-DS = Single Cervical Double-strength

From: *Assessment of Risk Factors for Mycobacterium bovis in the U.S. 1992*. USDA-APHIS-VS Centers for Epidemiology and Animal Health, Fort Collins, CO 80521

1. As outlined in Definitions section.
2. Greiner M, and I.A. Gardner. Epidemiologic issues in the validation of veterinary diagnostic tests. Preventive Veterinary Medicine 2000 45:3-22
3. Jacobson RH. Validation of serological assays for diagnosis of infectious diseases. Rev. sci. tech. Off. Int. Epiz. 1998 17:469-486

REPORT OF ELEPHANT TB SUBCOMMITTEE

Michele Miller
Disney Animal Programs

This subcommittee was formed in October 2007 by the chair of the USAHA TB committee, Dr. Kathy Connell, at the request of the American Association of Zoo Veterinarians National Wildlife TB Working Group. In the past, National Tuberculosis Working Group for Zoo and Wildlife Species has been responsible for developing and revising the "Guidelines for Control of Tuberculosis in Elephants". Specifically, the group requested the USAHA TB committee chair to:

- Designate a group of experts to provide comment and input on the current draft guidelines
- Provide recommendations to the Working Group regarding changes or other advisement prior to finalizing the Guidelines

Request that the Committee or the designated group provide recommendations for the composition and direction of the future working group revising the Elephant Guidelines.

The members of the working group felt that due to the increasing public awareness and regulatory aspects of elephant tuberculosis that it would be more appropriate to address these under the auspices of the USAHA TB committee.

The USAHA Elephant and Wildlife TB Scientific Advisory Subcommittee was formed and met to review and revise the draft guidelines. The subcommittee recommends replacing the 2003 Guidelines with the 2008 version of the "Guidelines for Control of Tuberculosis in Elephants". A summary of changes between the versions include:

- Addition of serological testing using the Chembio® ElephantTB STAT-PAK assay to trunk wash cultures for annual testing.
- Mandatory MAPIA follow-up testing for all STAT-PAK positive samples.
- Reclassification of elephant management groups using both culture and serological results (groups 1-5).
- Increased monitoring/surveillance of seropositive culture-negative elephants, although these animals would not have any travel restrictions or requirements for treatment (prophylactic treatment is optional).
- Addition of euthanasia option for culture positive elephants.
- Updated necropsy and reference information.

The subcommittee respectfully submits this report along with the "2008 Guidelines for Control of Tuberculosis in Elephants" to the TB Committee for acceptance.

REPORT FROM THE SUBCOMMITTEE ON TUBERCULOSIS TEST AND REMOVE POLICY

Mr. Phil Durst, Chair
Michigan State University Extension Dairy Agent

Bovine tuberculosis (bTB) Test and Remove Performance and Policy Recommendation: A Report from the TB Test & Remove Policy Subcommittee

Introduction

In the eradication efforts for bovine Tuberculosis (bTB) in the U.S., herd depopulation has been favored. Certainly, within a herd in which infection has been identified, sacrifice of herd mates eliminates the potential of infected, yet undetected animals and therefore, the risk of spread through them to other herds. Yet, as herds become larger, as indemnity dollars become scarcer and as the impact of cattle herds on local economies is evaluated, herd depopulation can be very expensive and viewed as undesirable.

As seen in Michigan, depopulation does not eliminate the risk of new infection of bTB from outside sources. Four of 22 depopulated and subsequently repopulated beef herds were diagnosed with bTB a second time. In addition, depopulation is traumatic for herd owners where through careful breeding and care, a producer has built his or her herd into something better than it was several years before.

Test and removal of infected animals within a herd has been practiced for years in the United States and internationally. Through test and remove, bTB was eliminated in states during the 1940's and 1950's. However, since 1985, only 15 herds in the U.S. have undergone Test and Remove, some of which were subsequently depopulated in the El Paso Milkshed buyout.

Current USDA policy (VS Memo 552.38, March, 2008) defining the bTB status for states or zones prescribes the number of affected herds allowed at each status level. Herds in a Test and Remove program are termed "affected herds" throughout their quarantine period which is generally four to four and a half years. Because of this, states are reluctant to offer Test and Remove as an option if it will mean a potential down-grading of their status.

USAHA TB Committee Subcommittee on TB Test & Remove Policy

At the TB Committee meeting during the 2007 annual meeting of the U.S. Animal Health Association (USAHA), a subcommittee on bTB Test & Remove policy was established with the appointment of P. Durst as chair. The subcommittee members are:

- Phil Durst, MS, Michigan State University Extension - Chair
- Dan Grooms, DVM, Ph.D., Michigan State University College of Veterinary Medicine
- Mike Chaddock, DVM, EML, Associate Executive Director, Association of American Veterinary Medical Colleges
- Tim Hanosh, DVM, New Mexico Livestock Board, Asst. State Veterinarian
- Sharon Lombardi, Executive Director - Dairy Producers of New Mexico
- Al Squire, DVM, Dairy Producers of New Mexico
- Linda Glaser, DVM, Minnesota Board of Animal Health
- Dan Baca, DVM, USDA APHIS, Texas
- Anita Edmondson, BVM&S, MPVM, MRCVS, Staff Veterinarian, California Department of Food and Agriculture
- Mitch Palmer, Ph.D., Veterinary Medical Officer USDA ARS
- Victor Cabrera, Ph.D. University of Wisconsin

This paper looks at the evidence of the effectiveness of Test and Remove (T & R) in eliminating bTB and controlling risk of spread and makes a policy change recommendation in regard to the counting of herds in a test and remove program.

U.S. herds that went through Test & Remove since 1985

The committee examined records of the 15 herds that went through a T & R protocol since 1985. These herds are listed in Table 1, identified by initials, state, year of diagnosis and approximate number of tested head at the time of diagnosis. In addition, the total number of animals diagnosed with bTB in all testing is shown.

Table 1. U.S. Dairy Herds that have gone through bTB Test & Remove Protocols since 1985

Farm	State	Year	Cows	Total pos.	# Head Initially Dx	Current status
DV	TX	1985	1200	16	2	EPMS BO ¹
RG	TX	1985	1400	13	2	EPMS BO
DD	TX	1985	370	4	1	EPMS BO
ID	TX	1990	3700	9	3	EPMS BO
ED	TX	1991	280	1	1	EPMS BO
LD	TX	1992	160	2	2	EPMS BO
WD	TX	1993	600	4	4	Released
GD	NM	1994	7300	1	1	Released
BD	TX	1996	5000	2	1	EPMS BO
TD	MI	2000	150	1	1	Released
KD	MI	2000	100	8	1	Quarantine
MD	NM	2002	1500	2	1	Quarantine
RD	MI	2002	40	1	1	Released

¹ El Paso Milkshed Buyout: 2002 - 2005

Disease prevalence within herds

These herds were low prevalence herds, with apparent prevalence rates upon initial diagnosis of less than 1% in herds greater than 200 head (10), and in herds less than 200 head, four of the five herds had only one animal diagnosed positive initially, the other had two positive animals. Other herds that were diagnosed with bTB during this same period and subsequently depopulated were in some cases high prevalence herds, however, in other cases were similarly low prevalence herds.

Issue of within herd transmission

In 8 of the 15 herds, all bTB positive animals ever identified in the herd were diagnosed in the initial diagnostic test. That is, in just over half the T & R herds, subsequent testing did not reveal any evidence of within herd transmission or latent, undisclosed positive animals. All of these herds were test negative in up to 18 whole herd tests over periods from 5 to 14 years thereafter (Table 2). Some of these herds are intact and continue to be tested annually.

In 7 of the 15 herds, bTB positive animals were subsequently diagnosed upon continued testing as part of the T & R program. Of those, six herds had animals detected within a 4 year period of the initial diagnosis. This is within the current quarantine period. Therefore, if all these herds had been under a herd plan that called for a minimum four year quarantine, almost all would be been detected prior to release of quarantine.

It is true that in the late 1980's that several herds (RG, DV, ID, BD, DD) in the T & R program had cattle diagnosed positive after they were released from quarantine. However, quarantine at that time, following 1980's UM&R rules, was as short as 12 months.

It is also true that a few of those herds (RG, DV, ID) had repeated diagnoses of positive cattle (cows and heifers) of the same DNA strain as the original infection over a period of up to 12 years. However, the total prevalence rate was still very low (less than 2%) in these herds and following the last positive animal detected, went years and many negative WHTs without additional positive animals found. These herds were destroyed in the El Paso Milkshed Buyout.

Impact of time

Within a dairy herd, the herd life of animals follows a routine. According to calculations by Ferris, 2008 (unpublished) using DHI data, 80% of a dairy herd's animals have left a herd four years after a point in time. Ninety-five percent have left the herd by 6 years. This is the general case in non-infected herds.

The Test & Remove protocol which removes CFT responders on the first two tests after diagnosis, increases the rate of herd turnover by removing animals that may indicate exposure to the bacteria. For example, in the DD herd of Michigan, 49 additional cattle were slaughtered after the first two screening tests following diagnosis. Those cattle represented over 17% of the herd. So both the natural management of dairy cattle and the T & R protocol, tend to eliminate cattle that

were in the herd at the time of exposure, within several years of diagnosis. Therefore, confidence in the ability to eliminate bTB in the herd increases with time.

Effectiveness of Test & Remove

The data show that in the 15 herds that went through a T & R protocol, that 6 have been released from quarantine and are still clear of bTB. Three of those have gone over 6 years since the last diagnosed animal. Two herds remain under quarantine, and 7 were destroyed in the EPMS BO. Before those herds were destroyed, four of those Texas dairies had gone over 6 years without further diagnosed animals. Table 2 shows the time (years) and number of whole herd tests that were negative since the last positive animal in these herds.

While it cannot be said with 100% confidence that any of these herds were or are completely free of bTB, the confidence in their freedom is high and increases with time.

Table 2. U.S. Dairy Herds that have gone through bTB Test & Remove Protocols since 1985

Farm	State	# Years since last diagnosed animal	# Negative WHT since last diagnosed animal
DV	TX	6.5	18
RG	TX	3.8	11
DD	TX	9.0	11
ID	TX	3.0	5
ED	TX	9.5	13
LD	TX	8.8	10
WD	TX	11.0	11
GD	NM	14.0	11
BD	TX	1.2	5
TD	MI	8.0	13
KD	MI	4.0	6
MD	NM	3.5	5
RD	MI	6.0	8

Changes in T & R protocol

The science of diagnosis of disease continues to advance and changes have been made in T & R protocols which improve the ability to detect infected animals. We expect those changes to continue. For example, gamma interferon blood levels have been used in Michigan T & R herds in parallel with the caudal fold test (CFT) as an additional screening test in the first two tests after diagnosis. In this protocol, any animal that responds to either the CFT or is identified as a suspect by gamma interferon were taken for slaughter. Improvements in the ability to detect infected animals increases the confidence that bTB can be eliminated from a herd.

Risk of spread of bTB from Test & Removal herds

The January, 2005 UM&R prescribes a T & R program that keeps the herd quarantined for at least 4 years after initial diagnosis. When any subsequent animal is diagnosed, the clock resets on the quarantine period and the testing protocol. Herd plans prescribe rules for additions to herds as well as the removal of animals and products from the farm. A good herd plan should limit risks to other herds specific to the herd operation.

It has not been shown that any other herd has been infected by bTB from these herds in T & R protocol whether during or off quarantine.

Relative cost of Depopulation vs. Test & Removal

Using figures from the New Mexico Livestock Board for the MD herd, both USDA and state of New Mexico testing and indemnity costs of a herd in a Test & Remove protocol can be compared to the indemnity costs if the herd had been depopulated instead. This herd, of approximately 1500 head, was initially diagnosed bTB positive in 2002. There was one positive animal diagnosed at that time. Subsequently, in 2005, another animal was diagnosed as positive. This herd is still under quarantine so costs do continue.

Depopulation costs, based on an initial offer made to the owner, would have totaled about \$3.75 M (Table 3). That is simply the indemnity costs and does not include the personnel who would have to be involved, trucking or disposal. The total costs of T & R, over the period 2002-2008, including personnel, testing and indemnity has been just over \$0.5 M. It is obvious that depopulation of this herd would have cost over seven times that spent in six years on Test & Remove.

Note also that this herd is not an ideal case in that, because a second animal was diagnosed positive later, the protocol began again and indemnity costs increased over \$100,000 as CFT responders were taken for two tests. In addition, the quarantine clock reset resulting in continued testing costs beyond 4.5 years had there been no subsequent infections identified.

Table 3. Costs of testing and indemnity for Test & Removal and indemnity estimate for depopulation

Test & Remove	
Testing (CFT, gamma interferon and CC) ¹	\$ 191,310
Indemnity 2002-2006 (actual)	\$306,608
Indemnity 2007-8 (estimated) ²	\$15,000
Total Test & Remove:	\$ 512,918
Depopulation	
Indemnity (1500 head @ \$2500 ea.) ³	\$ 3,750,000

¹ Testing costs include laboratory fees and per diem personnel costs for testing and reading. Fuel costs are also included.

² Three animals were indemnified in 2008, it is estimated that 2-3 animals were indemnified in 2007.

³ Depopulation costs here do not include personnel per diem or any other costs other than indemnity.

Also note that this herd of 1500 head, though large by some standards, is not the largest herd found infected with bTB. The costs of indemnifying a large herd may be prohibitive.

Loss of income

Communities and states depend on income generated by businesses not only for tax income on profits, but also the turnover of dollars in communities as purchased inputs and services and employee wages and taxes. Again, using this same dairy (MD), we can estimate the loss of income in one year if this herd had been depopulated. Assuming 1500 cows, producing 220 hundredweights (cwt.) of milk annually, valued at \$16 per cwt. There would have been a loss of \$5.28 M in milk income alone, not to mention the value of calves and cull animals. Even small herds have a major impact on the economy of their communities in rural areas. The Pennsylvania Center for Dairy Excellence calculated the multiplier effect of dairy income to be \$2.50 in wages and related business for every \$1 a dairy farm spends.

Strengthening Test & Remove

Test and Remove may be economically better for governments as well as economically better for the community, but there may still be questions about whether it is safe enough for the cattle industry within a state and for neighboring states and trading partners. In addition, one must ask whether it is safe for people and for wildlife.

We believe that the answer is in developing a strong herd plan in conjunction with the producer and then monitoring the compliance with the plan throughout the entire quarantine. A proposed herd plan outline accompanies this document. Note that the herd plan must be practical and feasible in order to be credible with the producer and likely to be followed.

The herd plan should address steps to reduce the chances for transmission on the farm to other cattle and people who work there or that come there, and off the farm to other farms and to wildlife. In addition, the herd plan should address steps that would reduce greatly the potential for reintroduction of bTB from off the farm via cattle purchases, fence-line cattle contact, wildlife or humans.

The latter prudent steps are ones that any farm should take in an area where bTB has been identified. Test and Remove herds are no more likely than their non-infected neighbor to become infected with bTB again through reintroduction.

The actions required to reduce risk will depend on the nature of the risk to the herd. A thorough epidemiological investigation should be conducted to determine the risks. However, every herd that

is diagnosed with bTB suffered a breakdown of biosecurity that allowed the cattle to be exposed to the bacteria. Therefore, every herd in a T & R program needs to evaluate and strengthen their biosecurity practices.

Impact of Current Rules

VS Memo 552.38 (March, 2008) spells out the maximum allowable number affected herds within MAA states/zones with fewer than 30,000 herds and in MA states/zones with fewer than 10,000 herds. According to NASS figures, 42 states including California, New Mexico, Minnesota and Michigan, have less than 30,000 herds, so rather than being the exception, this is the majority case and currently impacts all states with bTB.

For MAA status, a maximum of three affected herd-years are allowed. Affected herds that are not depopulated (T & R herds) are counted each month as 1/12 of an affected herd-year. Each year, therefore, for a minimum of four years they count the same even though confidence increases with time that these herds are bTB-free. Any additional herds diagnosed during that time add to the count.

In addition, the 2005 UM&R - V, D, 2, b, (1) states that to return to TB-free status, a MAA state/zone must be TB-free for 2 years after the last herd is released from quarantine. In the case of T & R, this would add two years on to a four year quarantine, in effect, six years after the last case of bTB diagnosed. Again, this presents states with a significant disincentive to offering T & R.

Proposed changes

We propose that changes be made to the USDA rules in how T & R herds affect the calculation of number of bTB affected herds with respect to determining state/zone status.

In order to assure that T & R is safe for the industry and the nation, we propose that the changes be applied only to herds that meet the requirements as “Approved” T & R herds. Those requirements include four criteria:

- a) A maximum prevalence rate of 1.5% in herds greater than 200 head or up to 3 infected cattle in herds less than 200 head.
- b) A herd plan approved by the state veterinarian and AVIC with concurrence of the APHIS Administrator.
- c) A completed or progressing epidemiological investigation of bTB in the herd.
- d) A review of the approval status annually or upon subsequent diagnosis of infected animals in the herd.

This is not to say that herds which do not meet all these criteria cannot undergo a T & R protocol, but that the benefits to the state as a result of the proposed changes would be limited to “Approved” T & R herds.

Specifically, we propose that USAHA urge the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) to adopt changes to VS Memo 552.38 in the counting of affected herd years for “Approved” T & R herds by reducing the value to 75% of an affected herd after 12 months, 50% after 24 months, and 25% after 36 months when no additional infected animals are found.

The benefit we propose is a less punitive count of herd years during the quarantine period. It would not change the quarantine period, nor the testing program, only the count. Our proposal compared to the current rules is illustrated in Table 4. Affected herd years are calculated as the number of months within the program year that a herd is affected times 1/12 and that is multiplied by a factor which in the current rules is implied as 1.0. This proposal would change the factor.

Table 4. Affected herd years factor:

Time after diagnosis of most recent infected animal	Factor for herd-years for “Approved” T & R herds	Current rules VS Memo 552.38
0 months	1.00	1.0
12 months	0.75	1.0
24 months	0.50	1.0
36 months	0.25	1.0

In addition, we propose that the UM&R rule be changed so that the last two years (24 months) of quarantine for T & R herds be counted for the requirement to apply for advancement to the next higher bTB status.

Adoption of this proposal would enable states to have greater flexibility in providing the opportunity for herds to become approved T & R herds with less threat to state or zone status. Yet, we do not believe that this policy proposal would increase the risk to other herds or states, nor would it deter the U.S. from reaching its goal of being bTB free.

**Report of U.S.-Mexico Binational Tuberculosis and Brucellosis Committee (BNC)
June 23-24, 2008, meeting in Chihuahua, Mexico**

Kathleen M. Connell

As Chair of USAHA's Committee on TB, Dr. Kathleen M. Connell attended the meeting of the U.S.-Mexico Binational Tuberculosis and Brucellosis Committee (BNC) in Chihuahua, Mexico, June 23-24, 2008. Meetings began on June 23, 2008, with a pre-planning meeting held with Veterinary Services Animal and Plant Health Inspection Services United States Department of Agriculture (VS-APHIS-USDA). Agendas were reviewed for the Tick, Brucellosis and TB meetings.

The BNC meeting was held on June 24, 2008. Due to the absence of Dr. Billy Johnson, BNC Coordinator, the meeting was presided over by Mr. Jay Whitten.

Through the efforts of the BNC, the U.S. continues to assist Mexico with its TB eradication and control efforts to ensure equivalency and transparency in the Mexican program. Export documents have been simplified, but adequate tracing can still be assured. Mexican states are not required to brand using their own state brand, but national branding with the "M" brand will continue to indicate Mexican origin cattle. Cattle without adequate "M" or "MX" brands will be rejected at U.S. entry ports when presented for importation into the U.S.

A review of Mexico's national TB program will take place in February 2009. The same team will conduct the review in order to compare changes and advances from the national program review the team conducted three years ago.

Dr. Francisco "Paco" Collazo-Mattei, VS-APHIS-USDA, provided a presentation on pending action items. Many were further discussed in federal meetings held between USDA and Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA).

Dr. Rick Willer, Arizona State Veterinarian and BNC Treasurer, was unable to attend. Dr. Dave Fly, New Mexico State Veterinarian, provided the treasurer's report on his behalf and the report was approved.

Dr. Bob Hillman, Texas State Veterinarian and Executive Director of the Texas Animal Health Division, provided reports for Texas and California.

Dr. Hillman reported that California is Brucellosis-Free. The state had three TB-infected herds and lost its TB-Free status. The index herd was detected through slaughter surveillance. The herd is under quarantine and has been tested.

The second herd was initially tested as a trace-in herd. A singleton responder was found, but the DNA fingerprint did not match that of the index herd, so it this second herd was not the source of infection.

The third California herd was tested as a trace-out herd. Initial tuberculin testing was negative, but this herd is considered exposed. Once animal from this herd was found to have TB lesions at slaughter and they were histopathologically compatible with *M. bovis*.

Texas regained its TB-Free status as of September 2006. This required a vast amount of work by the Texas cattle industry, the Texas Animal Health Commission and USDA. Texas has Brucellosis Class A status, but in the fall of 2007 applied to change its status to Class Free.

Texas is conducting traces on animals it received from New Mexico, California, Colorado and Oklahoma. The majority of these are dairy traces. The focus of infection has been identified in a feedlot.

The feedlot case involves 17 rodeo cattle in two pens of a feedlot with about 400 head of cattle. All 17 rodeo cattle were TB lesioned animals and the entire feedlot has been declared exposed, is under a hold order and will go to slaughter. They were a put together lot of "used" rodeo cattle, mostly from Kansas and Oklahoma. They had no "M" brand or inadequate "M" brands. Only one or two of these animals had a Mexican eartag. This investigation involves Texas, as well as Oklahoma, Kansas and some other states.

Texas has serious concerns about retaining its TB status and Dr. Hillman strongly expressed that Mexico must stop shipping TB-exposed cattle to Texas. Continued and steady progress must be made in Mexico's TB Program to reduce the TB cases coming into the U.S.

Dr. Dave Fly, New Mexico State Veterinarian, provided reports for New Mexico and Arizona. He reported that New Mexico has been Brucellosis-free since 1996. The state earned split status for TB in July 2005, with the majority of the state considered Free. The entire state will be downgraded to Modified Accredited Advanced due to recent TB cases. The state is also conducting traces from Oklahoma. Dr. Fly continued by reporting that Arizona has been Brucellosis-free since 1988 and TB-free since 1978.

U.S. border states continue to receive imported Mexican cattle that are later determined to be TB infected. There is a need for progress in Mexico's non-status states or zones. The U.S. Border State Veterinarians support the need to restrict cattle from Mexico's Accreditation Preparatory states or zones for movement to quarantined feedlots only.

U.S. Border State Veterinarians are very concerned about the risk posed by Mexican-origin rodeo or roping cattle and will implement their own state restrictions requiring a herd of origin test in Mexico and an annual TB test in the U.S. Finally, they would like to see the U.S. and Mexico work on development and implementation of electronic export documents.

Dr. Kathy Orloski, Epidemiologist for the U.S. National TB Eradication Program, gave her report on the U.S. surveillance program. Her presentation included statistics and information on granuloma lesion submissions, bovine TB cases detected at slaughter and tuberculin skin testing.

She provided data listing the number of TB-affected herds in the U.S. from 2000 to 2008 and gave a breakdown of those herds by state. She discussed in detail the granuloma submissions from 2000 to 2007 and submission rates for slaughtered adult cattle.

Dr. Orloski continued her presentation by detailing the TB found in cattle at slaughter from 2001 to 2007. She gave more details on granuloma submissions that were histologically compatible for *M. bovis* from October 1, 2007, to May 31, 2008, and detailed the confirmed TB cases for that same period. There were 28 cases of *M. bovis*-positive cattle detected at slaughter during this period—27 cases in fed cattle and one case in an adult animal.

She provided a map of Mexico, highlighting the origin of the five TB cases found in the U.S. with Mexican eartags. She showed a chart listing the number of TB cases per 100,000 Mexican cattle exported from 1995 to 2007. She concluded her presentation with information on the number of caudal fold tuberculin (CFT) tests conducted in the U.S. from October 1, 2006, to September 30, 2007.

Dr. Orloski was asked what action is taken if U.S. states have a CFT test response rate less than 1%. She replied that each state submits an annual report, documenting its surveillance. Each state is responsible for monitoring its testing veterinarians' response rates.

She was asked about the documents on the second Chihuahua case. She replied that the documents on that case are being prepared and will be provided to Mexico.

Dr. Bill Hench, Senior Staff Veterinarian for the U.S. National TB Eradication Program, gave his report on the U.S. program. His presentation included statistics and information on the National TB Program staff and corresponding activities, current state statuses, TB-affected cattle herds in 2008 and an update on U.S. regulations.

Seven members make up the U.S.'s National TB Program staff:

Dr. Lee Ann Thomas, Ruminant Health Program Director

Dr. Francisco "Paco" Collazo-Mattei, Ruminant Health Program Assistant Director

Dr. Michael Carter, Acting Program Manager

Dr. Kathy Orloski, Staff Epidemiologist

Dr. Bill Hench, Senior Staff Veterinarian

Dr. Alejandro Perera, Veterinary Services/International Services Staff Veterinarian

Dr. Debra Cox, FSIS Liaison

The U.S. National TB Program is assisted by two regional epidemiologists, Dr. Mark Camacho, Eastern Region, and Dr. Bob Meyer, Western Region. In addition to routine workload, staff activities have included conducting the Designated TB Epidemiologist course in July 2008 and a TB retreat held in April 2008. The staff is also evaluating various serological tests from several manufacturers.

Dr. Hench gave details on the history of the TB eradication and control efforts in the U.S. and illustrated that portion of his presentation with a U.S. map showing current TB status for the states

and territories. He focused separately on the Eastern and Western Regions and delineated the TB-affected cattle herds in 2008.

He concluded his presentation by giving an update on pertinent U.S. regulations. Those rules being revised include the bovine TB rule, the captive cervid TB rule, the indemnity rule and the roping steer rule.

Mexican reports followed. Northern Sonora has Brucellosis Class A status, which is similar to the TB status of Modified Accredited Advanced. Dr. Collazo-Mattei reviewed the pending action items to be completed for recognition of Northern Sonora's Brucellosis status.

Dr. José Alfredo Gutiérrez Reyes, SAGARPA/Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA), responded with an update. The next steps are to address and clarify any remaining questions, receive SAGARPA's update on progress with the Norma Oficial de Mexico (NOM) revision, proficiency testing for those laboratory personnel conducting Brucellosis testing, schedule another site review for Northern Sonora and then amend the U.S. Code of Federal Regulations regarding Sonora's status.

Dr. Salvador Solis, SAGARPA, gave a presentation on Mexico's National TB Strategic Plan 2008-2012. The country does not have enough funding available to conduct a test-and-remove program to eliminate TB-positive cattle. Quarantines are imposed on zones of the country where it is not feasible to reach 0.5% prevalence and on dairy zones and a TB elimination program is followed for these zones. Four negative herd tests are necessary before the quarantines will be lifted. Animal health officials are looking for ways to create a fund to pay for depopulation of TB-infected production units.

Reports followed on Mexican border states. These states include Baja California (Zones A and B), Sonora (Zones A and A2), Chihuahua (Zones A and B), Coahuila (Zones A and B), Nuevo Leon (Zones A and B) and Tamaulipas (Zone A). These states export 70% to 80% of the cattle from Mexico to the U.S.

Mexico's Modified Accredited states/zones include Nayarit (Zones A and B), Puebla (Zones A1, A2 and B), Quintana Roo, Veracruz, Zacatecas-Jalisco, Sinaloa and Yucatan. Some of these states do not have B Zones.

Mexico's Accreditation Preparatory states/zones include Colima, Chiapas, Michoacan, Durango, Guerrero and Tabasco. Colima and Durango exported cattle to the U.S.

Mexican and U.S. industry representatives presented their concerns and requests. Chihuahua provided an informative presentation on its centralized database system, TBControl.

A question was asked on the difference between the green and the blue eartag used on Mexican cattle. The green tag signifies the premises of origin. The blue tag is used for export. All identifying eartags should be left on the animal for exportation.

Mr. Andy Groseta, President of the National Cattlemen's Beef Association (NCBA), addressed the group. He said that NCBA supports Chihuahua's electronic database. He mentioned that Sonora is also considering an electronic system similar to Chihuahua's and he would like to see a response to Sonora's proposal of electronic certificates and signatures. He also talked about the U.S.'s Country of Origin Labeling (COOL) and its impact on exportation of Mexican cattle.

Dr. Fly and Dr. Roberto Valdez discussed restructuring of the BNC. Membership would increase to include representatives from U.S. feeders and a Mexican cattleman exporter. No decisions have been made on the number and positions of those who vote on issues or on who should be eligible to participate in discussions during the meetings.

The number of meetings has decreased from three annually to two—one meeting held in conjunction with NCBA's annual meeting and one held during the Mexican cattlemen's annual meeting. The BNC will no longer hold a meeting during the USAHA annual meeting. For the two meetings, all materials will be provided in English and Spanish. The first day of meetings will consist of presentations and reports. The second day will involve discussions.

The BNC's next meeting will be held the last week in January 2009, in Phoenix, Arizona, in conjunction with the NCBA annual meeting. Dr. Johnson, BNC Coordinator, will coordinate with NCBA to choose the specific dates.

Bovine Tuberculosis: Analyzing the Parameters of the Interferon Gamma Assay and Improved Diagnosis with New Antigens

Irene Schiller, et. al.
Prionics, Switzerland

Bovine tuberculosis (TB), a zoonotic disease with a major economic impact, continues to be a significant problem with a global perspective. The BOVIGAM® interferon gamma (IFN- γ) assay constitutes a laboratory-based tuberculosis test and is widely used complementary to the tuberculin skin test. The assay consists of a first step culturing whole blood with antigens and stimulating leucocytes to produce IFN- γ which is quantified by ELISA in a second step. The first step measures the cell-mediated immune response (CMI) and critically depends on the sample quality, stimulation reagents and culture conditions.

The CMI is known to be impacted negatively by stress. We have stimulated fresh blood from animals with or without stress with mitogens resulting in significantly lower IFN- γ production in stressed animals and therefore potentially leading to false negative results. These results furthermore emphasize the utility of a positive control for stimulation.

Tuberculosis-specific stimulation is currently done with tuberculins. We have analyzed tuberculins from different sources to define an optimized and standardized tuberculin concentration for the use with the BOVIGAM® interferon gamma (IFN- γ) assay. The results show that sensitivity and specificity of PPDs from each supplier can be optimized by titrating PPD B vs. PPD A activity in the BOVIGAM® interferon gamma (IFN- γ) assay for positive and negative animals, respectively. The use of alternative antigens, e.g. a cocktail of recombinant antigens for stimulation resulted in improved diagnostic sensitivity and specificity.

These recent developments in measuring the CMI therefore represent excellent tools for control and eradication of bovine tuberculosis.

Current Status of the U.S. Bovine Tuberculosis Eradication Program Fiscal Year 2008

Dr. Kathy Orloski
Veterinary Services-Animal and Plant Health Inspection Services

The cooperative State–Federal–Industry effort to eradicate bovine TB from the United States has made significant progress toward eradication, markedly decreasing the prevalence of the disease. However, the goal of eradication has been elusive despite renewed efforts. Remaining challenges— primarily infected wildlife and infected cattle from Mexico—hinder eradication.

In fiscal year 2008, a total of eleven affected cattle herds were identified. These eleven herds were all located in areas where affected herds have been found in the past. In contrast, seven affected herds were discovered in FY 2007. Slaughter surveillance for tuberculosis (TB) continued to exceed our national goals in FY 2008, and three of the newly affected herds were detected as a result of this surveillance and epidemiologic investigations. This demonstrates the integral role of slaughter surveillance in our eradication program. Nevertheless, TB response plans remain critical in areas where the disease has recently been detected.

In April 2008, as a result of the discovery of four affected herds in a four month period, the State of Minnesota was reclassified to MA status. In September 2008, the State of New Mexico was reclassified as MAA as a result of identifying two newly affected herds in the AF zone during the preceding sixteen months. California was also reclassified as MAA in September 2008 following the discovery of three affected dairy herds in a four month period.

At the end of FY 2008, forty-eight States, Territories and one zone were TB Accredited-Free (AF), including Puerto Rico and the U.S. Virgin Islands. Two States (CA and NM) were modified accredited advanced, one State (MN) was modified accredited and one State (MI) had split State status. Of these, twenty states and the U.S. Virgin Islands have maintained AF status for over twenty-five years; twenty states have been AF for fifteen or more years; five states have been AF for ten or more years; two states and Puerto Rico that have been AF for five or more years; and one state and one zone have had AF status for less than five years.

Three affected herds detected prior to FY 2005 remain under quarantine and test and removal herd plans. The first of these herds is a dairy herd in New Mexico which declined to depopulate. Two dairies in Michigan also remain under quarantine and test and removal herd plans. One of these quarantined dairies in Michigan is a reinfected herd. All three herds continue to undergo regular herd testing as part of their herd plans. Michigan herd plans also include requirements for mitigating the risk of infection from wildlife.

During FY 2008 herd depopulations were accomplished at a cost of \$31,174,028, including \$30,020,355 in the Western Region and \$1,153,673 in the Eastern Region. Indemnity costs for caudal fold tuberculin test positive animals in affected herds, comparative cervical tuberculin test- or gamma interferon-positive and suspect animals in non affected herds and for certain other situations were \$1,675,078 for the Western Region and \$362,713 for the Eastern Region. Total indemnity costs for all purposes were \$ \$33,211,819.

Veterinary Services continues to work with Mexico on ensuring there is equivalency between the two countries' requirements. To accomplish this, reviews of Mexican State TB programs have been conducted under the umbrella of the U.S. & Mexico Binational Committee. Six review trips were completed in FY2008. The review teams examined TB program integrity, progress and the level of prevalence. There were two reviewers working under contract, seven that were VS or IS employees, and eight that were employed by State or industry agencies in Arizona, California, Missouri, and Texas. The contributions of those States and industry groups are recognized and appreciated.

VS has been proposing a number of substantive changes to the Code of Federal Regulations (CFR) to enhance bovine tuberculosis eradication efforts. Changes to the bovine, cervid, "international", "roping steer", and the indemnity regulations were in various stages of revision and review. These rules are under review pending the TB listening sessions and the need to develop new approaches for TB control and eradication in the future. VS expects that major revisions to the CFR will proceed based on input from stakeholders.

Updates on States with Recent Infection

California update: Three affected dairy herds were identified in California during FY 2008. The first herd was identified as a result of a routine slaughter trace from an FSIS inspected slaughter establishment. Further epidemiological investigations found two more affected herds. DNA typing of the bovine TB strains recovered from the three herds shows that they are not the same strain associated with the 2003 outbreak. As a result of finding the second affected dairy herd, California's status was reclassified as MAA in an interim rule published in the Federal Register on September 18, 2008.

A TB Task Force was initiated by Veterinary Services (VS) to assist the California Department of Food and Agriculture in responding to the outbreak of bovine TB detected in three large dairy herds. The Task Force has assisted with epidemiological case development and on-farm herd testing; within California, a total of 178 herds with 233,161 cattle have been tested. Approximately 160 additional herds with an estimated 300,000 head of cattle are scheduled for testing over the next several months. At least 14 other states and Canada have received TB exposed cattle from this outbreak. The Task Force is expected to continue into early 2009.

Two of the three herds involved have been depopulated with federal indemnity. Disposition of the third herd is currently pending.

Michigan update: In Michigan, three beef herds were detected in FY 2008. All three herds are located in northern Lower Michigan in the bovine MAZ and were detected through annual surveillance testing. All herds have been depopulated with federal indemnity.

Minnesota update: Four beef herds were identified as affected in Minnesota between October 2007 and February 2008. These herds were identified as a result of continued surveillance and epidemiologic investigations. The source of this outbreak has not yet been determined and epidemiologic investigations are continuing. In addition to these new beef herds discovered in FY 2008, surveillance of free ranging white-tailed deer is on going through hunter-harvested and targeted culling sample collection. All affected herds in Minnesota identified to date have been depopulated with federal indemnity.

As a result of finding these additional herds, Minnesota was reclassified as MA status in an Interim Rule published in the Federal Register on April 9, 2008. The State of Minnesota and USDA are currently collaborating to implement the agreements and enact the regulations to recognize split state status for Minnesota. Minnesota is seeking to implement two zones for TB status purposes

New Mexico update: In FY 2007, a multi-premises dairy operation was determined to be affected. This dairy operation encompassed two premises in New Mexico's AF zone and totaled approximately 12,000 head of cattle. A "Task Force" was initiated to assist New Mexico with the eradication efforts associated with this herd and was successfully concluded in the first quarter of FY 2008. During second quarter FY 2008 a mixed purpose cattle herd was identified as affected in New Mexico's AF zone. As a result of finding two affected herds in New Mexico's AF zone within a forty-eight month time period, the state of New Mexico was reclassified to MAA status in an interim rule published in the Federal Register on September 11, 2008.

The State of New Mexico and USDA are currently collaborating to implement the agreements and enact the regulations to recognize split state status for New Mexico. New Mexico is seeking to implement two zones for TB status purposes.

Update on the U.S. National Surveillance Program for Bovine Tuberculosis Fiscal Year 2008

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Surveillance for bovine tuberculosis (TB) in the U.S. consists of slaughter surveillance in cattle and live animal testing in cattle and captive cervids. A total of 11 affected cattle herds were detected during federal fiscal year 2008 (FY 2008), including 7 beef herds, 3 dairies and 1 mixed use cattle herd. During FY 2000 – 2008, a total of 72 affected cattle and 2 captive cervid herds were detected. Of these, 64.9 percent were beef herds, 29.7 percent were dairies and 5.4 percent were mixed used cattle and captive cervid herds.

A total of 10,666 granulomas were submitted from 170 U.S. slaughter establishments that slaughtered 33.6 million cattle, including 6.6 million adult cattle. The number of granuloma submissions has increased each year since FY 2000 when 436 granuloma lesions were submitted. When considering only the cattle slaughtered in the 40 largest capacity adult slaughter establishments, 15.9 granulomas were submitted per 10,000 adult cattle slaughtered, exceeding the submission standard of 5 granulomas per 10,000 adult cattle slaughtered for FY 2008. Of these 40 slaughter establishments, 33 (82.5 percent) met the submission standard of 5 granulomas per 10,000 adult cattle killed and 7 establishments did not. This represents a decrease in the number of establishments meeting the submission standard from FY 2007, when 37 establishments met the target submission rate.

A critical component of the granuloma submission program is diagnostic laboratory support. Three diagnostic laboratories provide outstanding support for the national bovine TB surveillance effort. A total of 7,561 (70.9 percent) samples resembling granulomas were evaluated by National Veterinary Services Laboratories (NVSL), 2,261 (21.2 percent) by the Food Safety Inspection Service (FSIS) Pathology Laboratory in Athens, Georgia, and 843 (7.9 percent) by the California State Diagnostic Laboratory located in Tulare, California.

Slaughter surveillance continues to detect TB in both adult and fed cattle. Thirty-four TB cases were found in cattle in U.S. slaughter plants during FY 2008, compared with 24 cases in FY 2007. No cases of TB were detected in bison or captive cervids slaughtered under state or federal inspection during FY 2004 through FY 2008.

Of the 34 TB cases in FY 2008, one case occurred in an adult dairy cow. This case resulted in the identification of one affected dairy herd in California and the subsequent epidemiologic investigation identified two additional affected dairies. Two of these herds have been depopulated with federal indemnity. The decision to depopulate the third dairy is currently under discussion.

The remaining 33 cases were detected in fed steers or heifers considered to be beef-type cattle. These cattle had been fed in Texas (29 cases, 87.9 percent), Washington (2 cases), Nebraska and Kansas (1 case each). The Washington cases occurred in Canadian origin feeder heifers that had been moved directly to a feedlot from the port of entry and were maintained there until slaughter; the State of Washington restricts all cattle in this feedlot to slaughter only. No domestic cattle in the feedlot were exposed. Canadian RFID tags and feedlot tags were collected for each animal and the case was closed by USDA in 2 weeks. The feedlot records were sufficient to trace movements of individual animals and indicated that the two animals were never in contact with each other while in the feedlot. The genotyping results for the isolates from these 2 cases indicate the strain is identical between the 2 animals and is the same strain as a recent Canadian TB case.

Nine fed cattle cases were of Mexican origin. The state of origin for 8 cases with Mexican official eartags include Chihuahua, 4 cases; Coahuila, 2 cases, Tamaulipas, 2 cases. For 1 case from a Kansas feedlot, the Mexican state of origin is under investigation. An outbreak consisting of 19 affected cattle occurred in a Texas feedlot; genotyping results revealed the strain was identical in all animals suggesting disease spread after the animals arrived in the feedlot. These 19 animals were in 2 lots within the feedlot and consisted of retired rodeo and roping cattle that had been assembled from market sales in Kansas and Oklahoma. One case had an official Mexican eartag indicating origin in Chihuahua.

Of the remaining 4 cases in fed cattle, investigations are ongoing. One case occurred in a retired roping steer (unrelated to the Texas feedlot outbreak) that had been in either Utah or New Mexico prior to slaughter. This case had no identification and further tracing may not be possible. One case occurred in a domestic steer and was traced back to an affected herd in Minnesota. No epidemiologic information is available yet for the remaining 2 cases, one of which did not have eartags at the time of slaughter.

Information recently collected on feeder and rodeo/roping cattle from Mexico support the contention that rodeo/roping cattle are present in the United States for substantially longer periods of time than feeder cattle. Mexican origin feeder cattle are in the United States a median of 9.6 months (range 4.5 to 16.6 months, n=26) whereas rodeo/roping cattle are in the United States a median of 24.3 months (range 7.8 to 49.0 months, n=21). The occurrence of TB in roping/rodeo cattle presents a higher risk to domestic cattle, given their frequent movement and longevity, and their identification is often removed, interfering with epidemiologic investigation and risk mitigation. In FY 2007, approximately 1.1 million cattle were imported to the U.S. from Mexico; a small percentage were imported for use in rodeos and roping events.

TB cases detected through routine slaughter inspection resulted in 0.7 TB cases per 100,000 imported cattle, using the 8 FY 2008 TB cases with official Mexican identification and FY 2007 Mexican cattle import records. This represents a substantial decrease from 1995 through 1997, when there were 7.3 to 18.7 infected cattle were detected per 100,000 imports annually. Beginning in 1998 through the present, the annual rate has ranged from 0.7 to 5.4 infected cattle per 100,000 imports. Though this represents a sustained decrease from earlier years, infected cattle continue to be imported from Mexico and present an ongoing risk of TB transmission to U.S. cattle.

National TB surveillance is also accomplished through tuberculin skin and interferon gamma testing. Preliminary data for caudal fold tuberculin tests conducted during FY 2008, show that 1,366,186 tests were conducted on cattle and bison with 20,229 responders (1.5 percent, 48 states and Puerto Rico reporting). The response fraction by state, for states testing greater than 300 cattle, ranged from zero to 3.9 percent (median, 0.6 percent). A national standard for caudal fold testing was implemented in 2005, based on an expected false positive response fraction of approximately one percent (Uniform Methods and Rules, Appendix C, January 2005). At the national level, this standard was met; however, in FY 2008, there were 13 states that did not meet this standard, having a response fraction of less than 0.25 percent.

The gamma interferon test (GI) has been available as an official test in the national eradication program for bovine TB since 2005. Four laboratories throughout the United States are approved to conduct gamma interferon testing (California, Michigan, Texas, National Veterinary Services Laboratory). Collectively, these laboratories reported testing 15,601 blood samples during FY 2008. Cattle from 20 states were tested; however, 93.7 percent of tests were for cattle from five states (California, Michigan, Minnesota, New Mexico, Texas). During Spring, 2008, an increase in the proportion of positive samples was noted in the California and Texas laboratories and was investigated. This problem was determined to be due in part to variability in the reactivity of the stimulating *M. avium* tuberculin used in the test, though this did not fully explain the problem observed. An informal working group was formed involving the laboratories and the test manufacturer and is continuing to address this issue.

During FY 2008, a total of 287 suspects (1.5 percent) were reported to USDA from the 19,147 captive cervids tested by the single cervical test. During routine testing, a fallow deer from a captive herd in New York tested positive by skin testing and was subsequently euthanized. A postmortem examination detected gross lesions that were histologically compatible for mycobacteriosis and polymerase chain reaction was positive for *Mycobacterium tuberculosis* complex (which includes *M. tuberculosis* and *M. bovis*). Culture to identify the *Mycobacterium* species is underway. The affected herd has been quarantined and animals on nearby farms will be tested. In addition, the New York State Department of Environmental Conservation will be conducting surveillance of road- and hunter-killed deer in the area where the suspect case occurred.

Current Status of the Canadian Bovine TB Eradication Program

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Animal Health and Production Division, Canadian Food Inspection Agency

***Insert Maria's report

Current Status of México's Campaign against Tuberculosis and Update on México's National Surveillance Program

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Subdirector de Sanidad en Especies Mayores
Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación
*****Insert Alfredo's report**