The Committee met on October 13, 2009, from 8:00 a.m. to 5:30 p.m. at the Town and Country Resort and Convention Center, San Diego, California. There were 173 members and guests in attendance. Dr. Kathleen M. Connell and Dr. Tim Hanosh presided. Dr. Hanosh served as Acting Vice Chair in Dr. Michael S. VanderKlok’s absence.

In her opening remarks, Dr. Connell reviewed the day’s agenda, welcomed members and guests and made a few housekeeping announcements. The Chair determined that a quorum was present to conduct business.

Regarding Subcommittees, five Subcommittees were established in 2007 to address specific issues. These Subcommittees included the Diagnostic Test Review Subcommittee, chaired by Dr. Tyler Thacker; the Elephant TB Guidelines Subcommittee, chaired by Dr. Janet Payeur; the TB Test-and-Remove Assessment Subcommittee, chaired by Mr. Phil Durst; the Eventing Cattle Subcommittee, chaired by Dr. Chuck Massengill; and the Education and Communication Subcommittee, chaired by Dr. John Maulsby. The Subcommittees accomplished their assigned tasks in 2008 and have been inactivated, so there are no reports forthcoming from any of the five Subcommittee Chairs.

Formal presentations began with Dr. John Clifford, Deputy Administrator, U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS), who gave brief remarks. Dr. Clifford was followed by Dr. Alecia Larew Naugle, National TB Program Manager, National Center for Animal Health Programs, USDA APHIS VS, who gave a presentation entitled “A New
A Time Specific Paper was presented, entitled “Response of Sensitized Elk to Single Cervical Tuberculin (SCT) and Comparative Cervical Tuberculin (CCT) Tests”. The paper was presented by Ms. Shylo R. Johnson, Biologist, USDA APHIS Wildlife Services, National Wildlife Research Center, Fort Collins, Colorado. This paper’s abstract is included in its entirety in these proceedings.

Dr. Connell followed with a report on the National TB Symposium, which was held July 20-21, 2009, in Denver, Colorado.

USAHA hosted its first topic-specific symposium. The goal was to have a forum for animal health leaders and experts to gather to discuss the direction of the National TB Program and provide input to assist in changes to better meet the needs of beef and dairy production today. The written report of the symposium is available on USAHA’s website, http://www.usaha.org/.

A Discussion Guide was provided prior to the symposium. It contained questions and proposed solutions on six key topics to spark discussion among the participants. The six Breakout Sessions held during the symposium included:

I. Importation of Infected Cattle
II. Wildlife Associated Disease Transmission
III. Diagnostic Testing Limitations and Needs
IV. Surveillance, Traceability and Investigation Deficiencies
V. Modernizing Regulations
VI. Disease Control Approach

Key recommendations that resulted for each Breakout Session and the pertinent pages in the symposium’s written report:

I. Importation of Infected Cattle, pages 13-15
   a. Requiring official electronic ID is not warranted at this time. Penalties should be increased if existing ID is removed.
   b. Require feedlot registration and implement restrictions on breeding cattle if feedlots are feeding Mexican cattle.
   c. A Federal-State-Industry outreach program is needed.
   d. Develop specific rules for rodeo and other timed-event cattle imported from Mexico.
   e. Requiring an additional port of entry TB test is only feasible with advent of a rapid test.

II. Wildlife Associated Disease Transmission, pages 17-20
   a. Mitigate risks to/from wildlife based on cost-benefit assessments.
   b. Targeted, active wildlife surveillance is necessary in areas where TB has been identified in livestock.
   c. Disengage state status from wildlife disease prevalence/risk.
   d. Direct research funding and resources towards vaccination and diagnostic tools.
   e. Review and adapt other countries’ control strategies.

III. Diagnostic Testing Limitations and Needs, pages 21-24
   a. Prioritize existing funding to expedite validation and approval of new tests and vaccines.
   b. Immediately acquire a serum bank of known TB-positive and TB-negative cattle.
   c. Establish one dedicated CVB reviewer for new TB tests.
   d. Consider using conditional licensing to decrease time to market for TB tests.
   e. TB Epi staff need to be budgeted for and prioritized for Phase III field trials.
   f. Consider the feasibility of milk tests for TB surveillance on dairies.
   g. USAHA TB SAS or other TB Committee members can assist with test review processes.

IV. Surveillance, Traceability and Investigation Deficiencies, pages 25 to 28
   a. Dedicated TB-Surveillance Coordinators should work directly with FSIS vets.
   b. Implement event cattle movement test requirement.
   c. Continue surveillance of farmed Cervidae.
   d. Federal regulation of interstate movement of farmed Cervidae.
   e. No consensus could be reached on testing cattle for interstate movement.
   f. Feedlots that feed adult cattle should maintain records of origin/ID.
   g. Identify all adult breeding cattle when moved into commerce.
   h. Establish flexibility on tracing/testing from new herds based on risk.
   i. Identify dairy cattle to birth premises for movement.
j. Set national standards for vets administering TB test, with review for reaccreditation.

V. Modernizing Regulations, pages 29 to 31
   a. The current state classification system is outdated and should be eliminated, but not before an acceptable replacement plan is in place.
   b. Allow state and federal officials flexibility to address TB at the local level.
   c. Provide for official state and federal review teams.
   d. Continue indemnity at fair market value and correlate with herd plan adherence.

VI. Disease Control Approach, pages 33 to 34
   a. Status should not be affected if test-and-removal option chosen, evaluation of requirements for test-and-removal is needed.
   b. Prevalence rate should not be used for determining depopulation with limited funding.
   c. Zoning areas should be based on a risk assessment.
   d. Address human/cattle TB through a working group in collaboration with the CDC.

Appendices in the symposium include Planning Committee, Breakout Session Facilitators and other Volunteers; List of Participants; Pertinent USAHA Resolutions, 2004-2008; Bovine TB Program Recommendations for Inclusion in the CFR and External Resource Links.

State perspectives on the National TB Program were given by State Veterinarians from Michigan, Minnesota, California and Nebraska.

Reports began with Steven L. Halstead, DVM, MS, State Veterinarian, Michigan Department of Agriculture, Animal Industry Division, gave Michigan's report. Dr. Halstead stated that Michigan is the only state with a confirmed and well-established wildlife reservoir and is known to have on-going disease transmission between wildlife and livestock. The *M. bovis* in Michigan is a unique strain, and to date the measures in place have prevented the spread of this strain from the endemic area to other areas of Michigan or the US. Over $100 million of state and federal dollars have been spent over the past 10 years, keeping the disease contained through a combination of mandatory testing, electronic identification (EID) of cattle, movement permitting and controls and aggressive and positive animal management. Stakeholder patience with the program, however, is wearing thin. The cash, lead time, productivity and marketability costs of testing, EID, movement restrictions and on-going wildlife-associated disease risk have made producers more fearful of the program than the disease itself. In view of this, Michigan's response, in partnership with stakeholders and with USDA APHIS Veterinary Services, is to uncouple disease in wildlife from impacts on livestock by focusing on and rewarding on-farm wildlife disease risk mitigation. Additional effort is necessary to develop this risk-based, stakeholder-driven philosophy and to institutionalize it in the National TB Program.

Dr. Halstead was followed by William Hartmann, DVM, MS, Minnesota State Veterinarian and Board of Animal Health Executive Director. Dr. Hartmann presented a unique perspective from Minnesota, a state that had been TB-free for 30 years prior to detection of the disease in a beef cattle herd in 2005. In Minnesota's four year battle with the disease, it became apparent that the current program rules were more useful in the initial eradication effort than they were for reintroductions of the disease. Of particular note is the state status system which is outdated, cumbersome and leads to waste of valuable resources. Minnesota has made significant progress in its effort to eradicate this disease by focusing on and rewarding on-farm wildlife disease risk mitigation. Additional effort is necessary to develop this risk-based, stakeholder-driven philosophy and to institutionalize it in the National TB Program.

The next state report was given by Richard E. Breitmeyer, DVM, MPVM, State Veterinarian, California Department of Food and Agriculture, A Review of Recent California TB Cases.

In 2008-09 four TB-affected dairy herds were detected in California. Three were located in Fresno County and one in San Bernardino County. These four herds totaled about 20,000 head of cattle, and all had very low prevalence rates – three with only a single reactor detected. Of particular interest was that three separate genotypes were detected, meaning three unique sources of infection.

Despite investigation of 660 traces representing 21,000 animals, and testing more than 400,000 cattle in 300 herd tests, the sources of infection were not identified. However, all three genotypes matched previously detected strains in Southwest Mexican feeder cattle. Two of the herds were depopulated and
two are testing out. To date, more than $21 million has been spent on this eradication effort and many state and federal personnel were mobilized to assist with the large testing effort.

Lessons Learned – Rigorous slaughter surveillance for bovine TB is effective for detecting affected dairy herds. Test and removal protocols can be effective in eliminating TB from herds, especially if prevalence is low. Providing indemnity at fair market value is necessary for rapidly evaluating test-positive animals and high-risk exposed animals that have moved from an affected herd. Lack of identification and record keeping added greatly to workloads and in some cases resulted in the inability to complete a trace; and if not already in place, most owners of dairy herds that required testing were very willing to utilize electronic ID. Despite low prevalence in all herds with little or no evidence of disease transmission, traces and associated testing were conducted in most cases per UMR; and of the 660 traces, only one led to a new animal/herd associated with an affected herd – an adult cull cow sold through a market to different dairy (a very high-risk animal). Much of the work load involved tracing movements of low-risk bulls from a low-risk herd. With scarce resources, these traces need to be prioritized.

Impact of Losing “Free Status” – Despite the beef sector in California not being linked epidemiologically to these cases, movement restrictions caused significant economic impact. While USDA “delayed” interstate movement testing requirements, some states had statutes in place that required testing of cattle, and in some cases, feeder cattle as well. Companies that sell semen and embryos to international markets were also negatively impacted.

Recommendations for the Future National TB Program – The current national program has had tremendous success in eliminating bovine TB from the U.S. However, now that every state has previously achieved “free” status, it is time to change the program to address risks of reintroduction and provide flexibility to States. The following are key topic areas and recommendations presented for consideration and further discussion.

The current state status system should be eliminated. Unless there is a regional risk of continued transmission – such as wildlife reservoir – quarantines and movement restrictions should apply only to individual herds associated epidemiologically with the known affected herd. However, each state should be required to meet national surveillance standards as well as be held accountable to investigate and respond appropriately to any new disease introduction. National oversight by federal, state and industry cooperators should be required; and regional or state-wide movement restrictions of other penalties only be implemented if a state is not meeting program standards.

Allow program flexibility that considers risk and available national resources. It is clear that adequate staffing and funding may not be available to depopulate every affected herd nor to conduct every possible trace or test, irrespective of risk. Therefore, under the direction of state and federal epidemiologists, the program must allow for utilization of resources in the most cost-effective manner – for example – to identify and address the highest risk movements and potential for transmission, and not be held accountable for very rigid and prescriptive requirements that may not be warranted.

Imported Mexican feeder cattle continue to present a risk for introduction of bovine TB and must be addressed. Rules are necessary to prohibit comingling of native breeding cattle with Mexican feeder cattle. Feedlots should not be allowed to feed Mexican-origin cattle and dairy replacement heifers on the same premises. While enforcement is generally not feasible in grazing situations, industry awareness and management practices should also be enhanced to assure separation of breeding and feeding classes of cattle. The Texas tiered system for feedlots is a good proposal from which to begin a national discussion on risks and mitigation requirements (Appendix D, The Future of the National TB Program, USAHA, July 20-21, 2009). Rodeo/timed-event cattle from Mexico pose additional risk and may require specific rules – such as additional testing requirements annually or for interstate movement.

Expedite and enhance investment in new diagnostic tests for bovine TB. We commend USDA for providing funding to expedite establishment of a serum bank of known TB-positive and TB-negative cattle. This is desperately needed by companies attempting to develop new tests. All stakeholders should work with USDA to assure that funding, personnel and resources are available to “fast-track” approval of new tests.

Apply “One Medicine” concepts to bovine TB. More work needs to be done with Centers for Disease Control and our public health partners to determine the risk of transmitting bovine TB from humans to cattle. While the public health officials did not believe it likely, we could not rule out this potential mode of transmission. The genotype of one of our strains matched three human cases from Mexican immigrants in California, but none were associated with dairies or the affected counties.

The morning’s session of state reports ended with Dennis A. Hughes, DVM, State Veterinarian, Bureau of Animal Industry, Nebraska Department of Agriculture.
In February 2009, a domesticated herd of elk and fallow deer in Knox County was discovered with TB. In spite of previous accredited herd status, the herd had a high infection rate. The initial diagnosis was made when an adult elk was found with TB lesions at slaughter. Obviously, the single cervical test had low sensitivity for this herd. The herd was depopulated in June 2009.

In April 2009, a cull cow from Rock County was found at slaughter with TB. The two cases are unrelated epidemiologically and are different strains. The herd of 800 adult beef cattle was tested and another infected cow found. Since then, the Nebraska Bureau of Animal Industry has focused a majority of our resources and manpower towards testing of herds that are epidemiologically linked to the infected herd. The testing of cattle herds involved in the epidemiology of our TB-infected beef herd continues. As of October 2009, just over 14,500 head of cattle from over 40 herds have been tested negative. There are still approximately 3,000 head of cattle that were fenceline contacts to the infected herd yet to be tested.

Testing of trace-ins into the infected herd will be Phase 2 of testing herds that are epidemiologically linked to the infected herd. At the present time, it appears that fenceline contact testing and trace-in testing should be concluded by the end of November 2009. The tracing process has been cumbersome and frustrating. Testing of epidemiologically linked herds has been a massive project by state and federal personnel.

Challenges to Nebraska’s efforts—

- Lack of funding for depopulation of beef herd.
- Inability to trace epidemiological links in a timely manner without the National Animal Identification System.
- Slaughter plants do not want to purchase TB-exposed/quarantined animals moving on a VS-127 or TB branded animals.
- Inadequate testing procedures (caudal fold tuberculin test or single cervical tuberculin test)
- Possible loss of state status because of two 13-year-old animals with lesions (14,500 others in 45 epidemiologically linked herds tested so far are negative).
- Test and removal procedures for release of quarantine currently outlined in the 2005 UM&R require eight negative whole herd tests and approximately five years. This protocol is economically devastating to producers as well as to the state attempting to regain status.

A question and answer and discussion period followed the four state reports.

Dr. Connell completed the morning session with an overview of resolution format, the 2008 Resolutions and the proposed 2009 resolutions submitted so far.

There were four 2008 Resolutions:

- Resolution 47, Fund expanded collection of well-characterized serum from cattle and cervids routinely tested to support the evaluation of new rapid tests for Tuberculosis in cattle and cervids to enhance the Bovine Tuberculosis Eradication Program
- Resolution 48, Change in how test-and-removal herds affect the calculation of the number of Tuberculosis-affected herds with respect to determining state/zone status
- Resolution 49, Elephant Tuberculosis Guidelines
- Resolution 50, Restricting imported feeder cattle

Dr. Connell read each Resolution, followed by the response from USDA. Resolutions can be accessed at USAHA’s website by selecting “Committee”, then “Tuberculosis”.

The Committee took a lunch break and the meeting recommenced at 1:00 p.m. The afternoon sessions began with a second Time Specific Paper. Ms. Ailam Lim, graduate student with the Department of Pathobiology and Diagnostic Investigation, Michigan State University, Lansing, Michigan, presented the paper, entitled “Differential gene expression study of bTB-positive cattle and bTB test-false positive cattle in Michigan”. This paper’s abstract is included in its entirety in these proceedings.

The next presentation was provided by Doug Corey, DVM, Chair of the Professional Rodeo Cowboys Association’s Animal Welfare Committee and Past President of the American Association of Equine Practitioners, Adams, Oregon. Dr. Corey’s presentation was entitled “Use of Mexican Cattle in Rodeos in the United States”. The full text of this report is included in these proceedings.

The report of the USAHA Committee on Tuberculosis’s TB Scientific Advisory Subcommittee (SAS) followed, provided by Mitch Palmer, DVM, PhD, TB SAS Chair. The TB SAS met Monday, October 12, 2009, from 1 pm to 6 pm. The full text of this report is included in these proceedings.
After the TB SAS report, there was a continuation of state perspectives on the National TB Program. The afternoon’s state reports began with Bret D. Marsh, DVM, State Veterinarian, Indiana State Board of Animal Health.

In November 2008 Indiana received tuberculosis trace information on a beef cow sold from an Indiana farm and slaughtered at a Pennsylvania packing plant. The cow was determined to be a suspect on ante-mortem inspection because of an eye lesion, and tissues collected from suspicious lesions in the cow later cultured positive for *Mycobacterium bovis*. After successfully tracing the animal to an Indiana beef herd, two complete herd tests of the 15 cow herd did not reveal any infection. An adjacent herd of goats was also tested and all of the animals were determined to be negative for tuberculosis.

Within months of conducting the two herd tests in the beef herd, a captive cervid herd, a half-mile from the trace beef herd, sold some red deer for slaughter. The animals were presented to an Indiana meat plant under state inspection, and personnel from the Indiana State Board of Animal Health discovered extensive lesions in the animals consistent with bovine tuberculosis. Culture results later confirmed the diagnosis. This index herd has since been completely depopulated, and an exhaustive epidemiological investigation has found two other infected cervid sites in Indiana. The investigation at these two sites revealed that the only positive animals were those that were recently purchased from the index herd. One of the two sites has been depopulated, and the third site is scheduled to be empty by the end of October 2009.

During the depopulation of the index herd, a few small wild mammals were harvested within the fenced area and examined for lesions. Additionally, thirty head of wild white-tailed deer were harvested in the area immediately outside the fenced area, and each was examined. Although there were no lesions in any of these animals consistent with tuberculosis, tissues were submitted for culture and all of the results were negative.

Hunter-harvested deer in a five-mile area around each of the three infected sites are scheduled to be sampled during the 2009 hunting season. Additionally, all cattle herds within approximately three miles of the index farm are being tested. The testing of cattle herds is underway, and the wild white-tailed deer samples will be collected during the opening weekend of gun season in mid-November.

The DNA typing of the tuberculosis cultured from the beef cow is similar to elk isolates identified in several areas of the United States and Canada over the last 15 years. Further, the typing of the tuberculosis cultured from the cervids on the index herd is also similar to these elk isolates.

Although to this point Indiana has not been in jeopardy of losing the tuberculosis-free status it attained in 1983, the concept paper prepared by USDA titled, *A New Approach for Managing Bovine Tuberculosis* offers a unique perspective. Indiana offers at least the following comments to this initiative:

1. **Imported Cattle** Although there has been significant progress in the reduction of tuberculosis in cattle imported into the United States, most of the diagnosed cases of bovine tuberculosis in the country still are traced to imported cattle. Clearly, if the United States is to be successful in the eradication of tuberculosis, there must be more definitive action taken to protect the native cattle herd. These additional steps must include enhanced testing requirements of imported cattle, specified destinations for imported cattle, and restricting imported cattle to sites that will not allow them to become commingled with breeding cattle.

2. **Diagnostics** A high priority must be placed on the rapid development of effective diagnostic tests. The national tuberculosis program cannot be successful without the infusion of new science and technology. Every effort must be made to support research initiatives that may include multiple nations, the further development of serum banks to support the validation of new diagnostic tools, and providing an environment for investigating innovative approaches through scientific discovery.

3. **Status** The state status classifications have been effectively used for many years, and while there is a proposal to abandon this system, there must be a very clear vision of what will replace it. The current situation seems to suggest that it is not simply the title of the classification, but rather the conditions with each classification that are so onerous. Therefore, simply eliminating the classification system will not address all of the challenges with the system, but rather an alternative may be to modernize each classification. For example, it seems that the current “Free” classification could be redefined to include new performance metrics that must be attained by each state to maintain status.

4. **Engagement** As the program transitions, there must be an entity established that will engage federal, state and industry partners for the purpose of reviewing and acting upon the reported tuberculosis activity of the states. For example, for many years the National Pseudorabies Eradication Program utilized the input of the Pseudorabies Control Board to determine the status levels of states. This body decided when a state was not meeting the standards and
communicated to that state the specific steps it must take to attain or maintain a status. Through this approach there was much broader acceptance of the program standards and a better appreciation of the importance of performance metrics. A similar approach to the tuberculosis program will greatly enhance it.

Indiana congratulates the USAHA on a very successful tuberculosis meeting in July 2009 and further appreciates the opportunity to offer these comments.

Dr. Marsh was followed by Dave Fly, DVM, State Veterinarian, New Mexico Livestock Board, followed with New Mexico’s report.

The current TB status of New Mexico is split. The majority of the state is TB Accredited Free with two counties in east central New Mexico, Roosevelt and Curry Counties, Modified Accredited Advanced. New Mexico welcomes the opportunity to comment on the National TB Program.

- The word “flexibility” has been used extensively when describing the future National TB program. Flexibility is a good option as long as it is based on solid science and risk.
- The shift from depopulation to test and remove programs is a double edged sword. New Mexico has proven that a well planned and managed test and remove program is a valid, fiscally responsible option in dairies (Mitchell Dairy). However, there is concern that a test and remove program in an average size beef operation in New Mexico will not be acceptable to the producer nor the State. Most of the beef ranches in New Mexico are tens of thousands of acres in size with stocking rates of 50 acres per unit (cow/calf pair) to over 200 acres per unit. It is not practical to expect a rancher to gather his cattle from such a large area as often as is required in a test and remove program and maintain the possibility of profitability. Also, the question of how the rancher will market calves has to be addressed. Where will the ranch be able to sell its calves without experiencing a significant reduction in price. Quarantined pastures and feedlots sound like a reasonable option but the reality is that there are a limited number of quarantined feedlots and few, if any, quarantined pastures. Wildlife must also be addressed. The possibility of establishing a wildlife component due to exposure to a TB affected beef herd must be considered. Finally, fence to fence contact with neighboring cattle is an unavoidable reality in ranches located in the southwest, again increasing the risk of spreading TB.
- Indemnity for TB exposed trace cattle is a must. These cattle need to be considered as potential TB time bombs scattered throughout the country. They must be removed from the cattle population and undergo enhanced inspection to determine the possibility of further TB exposure.
- The need for an improved test is obvious. New Mexico supports all reasonable efforts in development of such tests along with the continued improvement of the TB serum bank.
- Industry must become more involved if TB eradication is to be accomplished. Producers must avoid high risk situations such as co-mingling potential breeding replacement animals with all animals that may pose a higher risk for TB.
- The possibility of human to bovine spread of TB, although rare, should be further explored. The delicacy of such an investigation is appreciated, however, as bovine TB continues to “pop up”, all aspects of the disease should be explored.
- A nationwide sport cattle TB surveillance program needs to be developed and implemented.

State perspectives concluded with a report from Bob Hillman, DVM, State Veterinarian and Executive Director of the Texas Animal Health Division.

The infected Texas herd had approximately 3,000 animals. The herd was found when tested by practitioners for a herd dispersal. There were 50 caudal fold tuberculin test responders and subsequently, five lesioned animals were found at slaughter. These were culture positive with one histo compatible. On the second test, more than 120 caudal fold responders were found, with two more culture positive animals identified.

Disposition of the herd is via test and removal. The owner has reduced the herd size to approximately 1,100 head (700 cows and 400 heifers and bulls).

The epidemiological work on this herd revealed four trace-ins from three states, over 5,100 head traced out to at least 12 states. In Texas, at least 23 dairies are being tested and wildlife sampling is being conducted.

- Risky business included the continued importation of TB-exposed Mexican-origin cattle, less than optimum application of tuberculin tests, insufficient funding to effectively apply the Bovine TB Program and ineffective ID and traceability.
- Risky practices include pasturing and grazing of Mexican-origin cattle with native breeding and replacement cattle; feeding of breeding and replacement cattle in feedlots containing high risk
cattle, with subsequent removal of breeding and replacement cattle; commingling or other exposure of Mexican-origin performance cattle with native breeding, replacement and dairy cattle; and acquisition from many sources and extensive commingling of dairy replacement cattle.

Issues include

• State status—current provisions for removal of state status inequitable and not based on sound science, loss of status very costly to portion of industry that does not have evidence of disease, and elimination of status provisions may have the unintended consequence of removing incentive for cattle producers to support the TB program.

• Zoning

• Designation of risk areas

• Dairy commuter herds—calves from multiple dairies, often from multiple states commingled at one location; how we address identification of exposed or test positive and lesioned animals on the calf-raising facility.

• Tiered feedlot system—unrestricted, restricted to slaughter only and approved/quarantined feedlots.

A question and answer and discussion period followed the afternoon’s state presentations.

Committee Business

At the conclusion of formal presentations, Dr. Connell reported on the 2008 Resolutions, Numbers 47-50, and USDA’s responses. VS-APHIS-USDA responded promptly in writing to the 2008 Resolutions. Four resolutions were approved and forwarded to the Committee on Nominations and Resolutions. Topics included expedited Center for Veterinary Biologics approval of new bovine TB antibody tests and the National bovine TB Eradication Program.

Due to time constraints, updates and summary reports were not presented during the meeting on the National TB Programs for the United States and Canada. The full text of those reports is included in these proceedings.
During the TB SAS meeting on Monday, Oct. 12, the following presentations were made:

1. **An overview of TB test approval process** was given by Drs. Larry Elskin of CVB, Alecia Naugle of the APHIS TB Program staff and Mitchell Palmer of the USAHA TB Scientific Advisory Subcommittee.

2. Dr. Jeff Nelson, APHIS, NVSL gave an **update of activities of the NVSL TB serum bank**. Six companies are currently known to be developing serologic tests to detect bovine TB in animal species. Most of these companies have been in contact with the TB serum bank to obtain samples. The companies include:
   - Chembio- Stat-Pak, MAPIA, Dual Path Platform (DPP)
   - Diachemix- FPA
   - Enfer Group- Two-step ELISA
   - IDEXX- IDEXX M. bovis Antibody ELISA
   - Modern Veterinary Therapeutics, LLC- Not disclosed
   - PriTest- SeraLyte-Mbv

   Funding for an enhanced serum bank collection effort was provided by USDA- Veterinary Services in April of 2009. Most of the samples in the TB serum bank contain only 1-3 mls of serum and will not meet of the demands of the industry partners currently developing tests for repeatability and reproducibility studies. It was determined that a minimum of 10mls of serum from each animal would be adequate to meet the demands of multiple test developers. The goal of the enhanced serum bank effort is to collect:
   - 1,600 negative TB samples from cattle and white tail
   - 893 TB negative cattle samples and 103 white tail deer samples collected using the enhanced serum bank effort protocols
   - 250 TB positive samples from cattle and white tail
   - 5 TB positive cattle samples

   Numbers of samples to collect in the enhanced serum bank effort were determined from the Criteria for Evaluating Experimental Tuberculosis Test Performance for Official Test Status document that was approved by the TB committee last year.

   Protocols for the enhanced serum bank effort were developed and have been sent out to all AVICs and State Veterinarians.

   International collaboration with Mexico, Canada, and the United Kingdom has occurred to submit serum samples from TB positive cattle to the TB serum bank at NVSL.

**Total numbers of samples received in FY2009:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>White Tail</td>
<td>108</td>
</tr>
<tr>
<td>Elk</td>
<td>62</td>
</tr>
<tr>
<td>Fallow</td>
<td>54</td>
</tr>
<tr>
<td>Reindeer</td>
<td>16</td>
</tr>
<tr>
<td>Red</td>
<td>16</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>256</strong></td>
</tr>
<tr>
<td>Cattle:</td>
<td>1259</td>
</tr>
</tbody>
</table>

Total number of all serum samples submissions to the TB serum bank that have been characterized include:
- Cattle- 1687
- Cervid-2713
The TB serum bank is in the process of developing a user fee to access samples in the bank. This is being established to recover the cost of:

- Supplies
- Shipping
- Time for collection of samples
- Making aliquots
- Serum panel creation

Any questions regarding the serum bank effort can be answered by Dr. Jeff Nelson at NVSL by contacting him at 515-337-7966 or Jeffrey.T.Nelson@aphis.usda.gov.

3. Chris Rathe of PriTest presented a cost effective serology assay for identification of M. bovis infected cattle.
   PriTest made a presentation to the Scientific Advisory Subcommittee of their SeraLyte-Mbv™ test with performance evaluation of their test in a number of confirmed positive and presumed negative sample sets. The performance data of the PriTest assay demonstrated that this their test method meets or exceeds the required performance characteristic on the required number of positive and negative samples to move to Phase II in the new TB test Guidelines that were updated at last year's TB Committee meeting as guidelines for TB SAS.
   From various sources, 95 confirmed positive Bovine samples were tested, 81 were positive with the SeraLyte-Mbv test, showing an overall Sensitivity of 85.3 %. Presumed negative Bovine samples were sourced from ten Accredited Free states that have been accredited-free (TB) for at least 15 years as of 2007. Of the 1,394 samples tested, 1,358 were negative, showing an overall Specificity of 97.4 %.

4. John C. Lawrence of IDEXX Laboratories presented a performance update of the IDEXX M. bovis antibody test a prototype antibody ELISA developed for cattle and cervid applications
   - Sensitivity of 82%-88% confirmed positive sets (cattle, n=81)
   - Detection of antibody starting as early as 42 days post experimental challenge with more consistent response by 3-4 months
   - ELISA detects positive samples missed by other methods
   - Specificity of 98% on samples from TB-free states (cattle, n=5101)
   - Defined cross-reactivity with other mycobacteria
   - Promising results on limited set of cervid samples (SN=63%, SP=96%)
   - 3 hour test protocol, familiar laboratory format
   - Utilizes serum samples - no special handling or shipping routines

5. Dr. William Davis of Washington State University presented Diagnosis and Control of Tuberculosis.

6. Dr. Maria Koller-Jones of the Canadian Food Inspection Agency presented Comparison of Mycobacterium bovis PPD Tuberculins from Canada, Mexico, New Zealand, and the United States.
   A bovine PPD tuberculin study was carried out as part of a larger body of work dealing with the harmonization of North American tuberculins under the Security & Prosperity Partnership (SPP) initiative. The data from this study will be given to the SPP TB Working Group to further the work of harmonizing TB diagnostic tests used in North America.
   The objective of this study was to compare the performance of the M. bovis PPD tuberculins of Canada, Mexico, New Zealand & United States on a large number of known TB infected cattle and known negative cattle using side-by-side intradermal cervical testing. Tissues were collected to confirm each animal's true infection status for comparison to the skin test results. Sera were also collected for future blood tests. The study was carried out in 2007-08.
   The positive cohort comprised of 199 cattle from two known infected herds in Mexico, and the negative cohort consisted of 52 cattle from herds in a TB-free area in the United States. Field issue Mycobacterium bovis PPD tuberculins from Canada, Mexico, New Zealand, and the United States were re-bottled into identical bottles and labelled: A, B, C, and D (not in this order). Each animal in the positive and negative cohorts was skin tested with each of the four tuberculins in a Latin Square design (two PPDs on each side of the neck), with PPDs blinded to the testing veterinarians and randomly assigned.
   Skin thickness measurements of each injection site were taken at before injection and 72 hours post-injection. For each animal and each PPD, a skin test value was determined by subtracting the pre-injection measurement from the post-injection measurement. The cattle in the positive cohort were then
slaughtered in Mexico, where samples for histopathology and culture were collected and shipped to NVSL for testing. The cattle in the negative cohort were immediately slaughtered in the United States for similar tissue collection and testing.

In the positive cohort, the following mean skin test values were obtained: A: 7.5 mm; B: 7.77 mm; C: 6.94 mm; D: 5.22 mm. For the negative cohort, mean skin test values were: A: 0.40 mm; B: 0.85 mm; C: 0.44 mm; D: 0.40 mm. This study found that each of the four tuberculins produced a significant difference in the skin test values of the positive cohort as compared to the negative cohort. This indicates that each PPD can be used to screen cattle for bovine TB, subject to the limitations of this study. The measure of the performance (sensitivity and specificity) of an individual tuberculin depends on the cut-off skin test value established for that PPD.

Analysis of the skin test values obtained from this study was used to calculate estimated sensitivity and specificity at various cut-off values. This study confirmed that any of the four tuberculins can give a low or nil skin test value in an individual M. bovis infected animal. However, at the herd level, all four tuberculins would have correctly classified the herds as infected. The low skin test values obtained for all four tuberculins in the negative cohort indicate that these PPDs will be able to indicate non-infected animals with a high confidence level, within the limitations of this study.

During 2009, the TB committee chair, TB SAS, and APHIS TB Program Staff met with officials at the USDA, Center for Veterinary Biologics (CVB) to review the process of licensing and approval of novel diagnostic tests for bovine tuberculosis.

It was clear from review of CVB directives, memos and regulations associated with the licensing/approval process, that diagnostic companies should engage CVB involvement very early in the licensing/approval process. This critical and early involvement with CVB is not explicitly emphasized in the current "Criteria for Evaluating Experimental Tuberculosis Test Performance for Official Test Status" as published in the 2008 USAHA Proceedings.

Most importantly, it was noted that in order to accomplish certain elements of Phase II, approval from CVB is required. Specifically, in accordance with CFR 10.3, a letter of approval to ship experimental biological products must be obtained.

**Recommendation:** The TB SAS recommends to the USAHA TB committee that the current 2008 version of "Criteria for Evaluating Experimental Tuberculosis Test Performance for Official Test Status" be amended to require CVB approval to ship experimental biological products (CFR 10.3) before proceeding to Phase II.

It was also noted that in some cases the first contact a diagnostic test manufacturer may have with USDA, is with CVB. The TB SAS further recommends that, upon submission of the license application and supporting data to CVB, that CVB in turn notify APHIS, TB Program Staff that such an application has been received and that CVB strongly encourage the submitting manufacturer to make direct contact with TB Program Staff.

In this way coordination of the license/approval process is directed by CVB in accordance with APHIS Directive 6910.1. The TB Program Staff, with input from USAHA, will work in cooperation with CVB in field evaluations necessary for use of the assay as an approved test in the TB eradication program.

TB SAS was asked to evaluate data submitted by diagnostic test manufacturers on two different serologic assays for bovine tuberculosis.

PriTest of Redmond, Washington submitted data with the specific request that Phase II trials begin (as described in "Criteria for evaluating experimental tuberculosis test performance for official test status.") and that their SeraLyte-Mbv assay be considered as a replacement for tuberculin skin testing of cattle.

IDEXX Laboratories of Westbrook, Maine submitted data on the IDEXX M. bovis antibody test kit, with the request that the assay be considered as a supplemental test, to be used in series or in parallel with currently approved skin testing and gamma interferon assays.

The development of new means of diagnosis of bovine tuberculosis that are faster, less subjective, and require a single animal handling event is of extreme importance to APHIS TB Program Staff, USAHA and the future of the bovine tuberculosis eradication campaign. The work of private manufacturers in development of novel diagnostics is greatly appreciated. CVB, APHIS TB Program Staff and USAHA should continue to work cooperatively to assist, as appropriate, with assay development, evaluation, licensing, and approval of promising tests.

To evaluate test sensitivity, both manufacturers have evaluated naturally and experimentally M. bovis infected cattle from both domestic and non-domestic sources. The assays use different platforms to detect antibodies to specific M. bovis proteins. Sensitivity estimates for the SeraLyte Mbv range from 78-92%, depending on the sample set analyzed, with an overall sensitivity of 85.3%. Sensitivity estimates for
the IDEXX *M. bovis* antibody assay ranged from 82-88% on domestic cattle samples. For unknown reasons, much lower sensitivities were seen in sample sets from Mexico.

To evaluate test specificity, large numbers of cattle from TB free sources have been evaluated by both manufacturers. Little cross reactivity with non-tuberculosis mycobacteria has been noted. SeraLyte Mbv specificity is reported to be 97.4%. Specificity of IDEXX *M. bovis* assay is reported to be 97.9%. To further evaluate these assays as potential replacements or supplements to existing approved tests, evaluations such as those described in Phase II trials are needed.

**Recommendation:** In context of the recommendation to amend “The Criteria for Evaluating Experimental Tuberculosis Test Performance for Official Test Status,” the TB SAS recommends that both PriTest and IDEXX, with their respective assays, move from Phase I to Phase II testing once CVB approval to ship experimental biological products is obtained.

**STATUS OF THE STATE AND FEDERAL COOPERATIVE BOVINE TUBERCULOSIS ERADICATION PROGRAM, FISCAL YEAR 2009**

U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services

Tuberculosis Eradication Program

The cooperative State-Federal-industry effort to eradicate bovine tuberculosis (TB) from the United States has made significant progress, markedly decreasing the prevalence of the disease. However, the goal of eradication remains elusive as animal health officials continue to detect TB sporadically in U.S. livestock herds. Several challenges continue to hinder our efforts to eradicate the disease:

- Infected cattle imported from other countries
- Infected wildlife as a reservoir
- Changes in the dairy and beef cattle industries
- The limitations of available diagnostic tests
- Inability to trace some infected animals identified at slaughter to a herd
- Outdated regulations
- Antiquated approaches to disease control
- Flat or decreasing Federal budgets

These factors demand a new approach to managing this disease. The Animal and Plant Health Inspection Service (APHIS) is evaluating the existing bovine TB program, gathering input from stakeholders, and developing regulations to craft a TB program that protects the health of U.S. livestock and is responsive, timely, and cost-effective.

**TB Public Meetings and Concept Paper**

APHIS held a series of public meetings for external and internal stakeholders during fiscal year (FY) 2009. These meetings were formatted as listening sessions so that stakeholders could discuss challenges and new approaches for TB eradication and control. Summaries of these public meetings are posted on the APHIS Web site at www.aphis.usda.gov/newsroom/hot_issues/bovine_tuberculosis/tb_ls.shtml.

Based on input received from these meetings, APHIS’ Veterinary Services (VS) developed a concept paper titled, “A New Approach for Managing Bovine Tuberculosis: Veterinary Services’ Proposed Action Plan.” This document presents VS’ current thinking about changes being considered for the TB program. This concept paper was published October 5 in the Federal Register, and we are accepting comments through December 4. To submit comments, go to www.regulations.gov and enter APHIS-2009-0073 in the keyword search.

**TB-Affected Herds Identified in FY 2009**

In FY 2009 (October 2008 to September 2009), a total of 12 TB-affected herds have been identified: three beef herds, two dairy herds, and seven captive cervid herds. While the total number of TB-affected herds identified in FY 2009 is comparable to the 11 herds identified during FY 2008, the identification of seven TB-affected captive cervid herds is unprecedented. Only four affected captive cervid herds were identified between FY 1998 and FY 2008.
Slaughter surveillance for bovine TB exceeded our national goal in FY 2009. Four of the TB-affected herds identified this year (two cattle and two cervid) were detected as a result of slaughter surveillance and subsequent epidemiologic investigations to trace the slaughter cases to their herd of origin. This demonstrates the integral role of slaughter surveillance in our program.

Of the TB-affected herds found during FY 2009, two beef herds and four captive cervid herds were depopulated with Federal indemnity. The disposition of one beef herd and one captive cervid herd is pending. Two captive cervid herds in Michigan identified as “shooter” herds were not depopulated. These herds are in an area where TB is endemic; also, they pose no risk of disease spread because no live animals leave the facilities.

Four dairy herds are under test-and-remove herd plans. Two of these herds were identified in FY 2009; two herds continue under test-and-remove herd plans from previous years. One dairy in Michigan identified a TB-infected cow at the last herd test for quarantine release and continues under quarantine as an affected herd. In Texas, a dairy was identified through dispersal sale testing, and it remains under quarantine and a test-and-remove herd plan. Two dairies in California remain under quarantine and test-and-remove herd plans. All four 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.

Bovine State Status
At the end of FY 2009, 46 States and Territories and two zones were TB accredited-free (AF), including Puerto Rico and the U.S. Virgin Islands. California was modified accredited advanced (MAA), and three States had split-State status. Michigan has AF, MAA and modified accredited (MA) status. Minnesota was recognized as having MAA and MA status in October 2009. New Mexico again gained split-State status as AF and MAA. Of the AF States and zones, 20 States and the U.S. Virgin Islands have maintained AF status for over 25 years; 20 States have been AF for 15 or more years; five States have been AF for 10 or more years; one State and Puerto Rico have been AF for 5 or more years; and one State and one zone have had AF status for less than 5 years.

Captive Cervid State Status
All States and territories have MA status.

Policy on the Use of Federal Funding for Whole-Herd Depopulation
During the summer of 2009, APHIS adopted a new policy where the use of Federal funding to depopulate entire TB-affected herds and indemnify herd owners would no longer be recommended as the primary management option. Rather, whole-herd depopulation will be implemented when the data indicate that other options will not mitigate disease spread, an imminent public or animal health risk exists, or it is cost-beneficial to do so. APHIS will determine the best course of action for each TB-affected herd by evaluating several factors, including the prevalence of disease within the herd, risk of disease transmission, effectiveness of management practices, and cost-effectiveness. When appropriate, VS is proposing to manage specific TB-affected herds under a test-and-remove policy in conjunction with quarantines and restricted movement of animals to limit the spread of TB from these herds.

Collaborations with Mexico
APHIS continues to work with Mexico to ensure equivalency between the two countries’ requirements. To accomplish this, reviews of the State of Coahuila, the MA zone of Veracruz, and the Mexican National TB Eradication Program were completed in FY 2009. The review teams examined TB program integrity, progress, and the level of prevalence. Eleven reviewers were VS or International Services employees, and one worked for the State of California. We recognize and appreciate the contributions of these reviewers.

TB Serum Bank
In FY 2009, APHIS approved $250,000 to expand its TB serum bank. The serum bank will provide well-characterized serum samples with skin test results for samples from uninfected animals, and skin test, histopathology, and TB culture results for samples from infected animals. The serum bank samples will be available to researchers and diagnostic companies as they develop and evaluate serologic tests for bovine TB using the criteria recommended by the U.S. Animal Health Association. Our goal is to obtain blood from 250 TB-infected and 1,600 uninfected cattle and 1,600 uninfected white-tailed deer.
Because of the limited availability of naturally infected white-tailed deer, APHIS expects to obtain samples from only 20 to 30 infected animals.

The majority of serum samples will be collected from uninfected animals in the United States during routine TB skin testing events. Samples from infected cattle are being sought through collaborations with countries that have endemic TB. We are collaborating with Mexico, Canada, and the United Kingdom (UK) to collect and receive serum and tissue samples from TB-infected cattle. Sampling in the UK for our serum bank will begin this fall. Participation by Mexico is pending. So far we have collected serum samples from approximately 150 cervids (including 36 TB-infected animals) and 700 cattle (including five that are TB-infected).

Updates for Selected States and Additional Details Concerning TB-Affected Herds

California Update: One affected dairy herd was identified in FY 2009 during continuing epidemiological investigations from affected dairy herds identified during FY 2008. This herd is under a test-and-remove herd plan.

Molecular epidemiology conducted on the four affected dairy herds recently identified in California has revealed three different DNA types, indicating three different outbreaks. The strain of Mycobacterium bovis identified during the 2003 outbreak has not been found in any of the recent detections, indicating that the current outbreaks are not related to the 2003 outbreak.

VS initiated a TB Task Force in FY 2008 to assist the California Department of Food and Agriculture in responding to the TB outbreak. This task force continued through February 2009, assisting with the epidemiological case development and on-farm herd testing of 246 herds and approximately 377,000 head of cattle. In addition, 24 more herds containing nearly 20,000 cattle have been tested subsequently as part of the epidemiologic investigation of the infected dairy discovered during FY 2009.

Indiana Update: A captive cervid herd was identified through targeted slaughter surveillance. This herd was located in close proximity to a cattle herd implicated in a routine slaughter inspection finding of M. bovis. Regulatory personnel, who were present when several animals from this herd were routinely slaughtered, collected lesions consistent with M. bovis infection from several carcasses. After M. bovis was isolated, the herd was declared affected and an epidemiological investigation initiated.

Two additional affected captive cervid herds were located through tracing animals sold out of the herd. The index herd and one traceout herd have been depopulated with Federal indemnity. The disposition of the second affected traceout herd is pending. Other captive cervid herds identified during the epidemiological investigation remain under quarantine until they can be tested during the winter season.

Michigan Update: One beef herd and two captive cervid herds were detected in FY 2009. All three herds are located in northern Lower Michigan in the bovine MA zone. The affected beef herd was detected through annual surveillance testing while the two captive cervid herds were identified through combined TB and chronic wasting disease slaughter surveillance. The beef herd has been depopulated with Federal indemnity. The two captive cervid herds remain under quarantine. They are “shooter” herds and represent a low risk for disease spread because no live animals leave the premises; also, the herds are in an area known to have endemic TB infection.

One dairy in Michigan’s MA region continues under a test-and-remove herd plan. This dairy was identified as affected a second time in 2004, the first infection being found in 2000. During the last herd test for release of quarantine an M. bovis-infected cow was identified. As a result of this finding, the quarantine was not released and the dairy herd is still considered affected. Under the terms of the herd plan, testing will revert to the disease removal phase of the test-and-remove protocol and continue until the freedom-from-disease phase is successfully concluded and all requirements for quarantine release have been achieved.

Minnesota Update: Minnesota was reclassified to a split-State status of MAA and MA in October 2008. One beef herd was identified as affected in Minnesota in FY 2009 through routine slaughter surveillance. This herd was participating in the Minnesota State-sponsored buyout program for cattle herds in the core area of the MA region. To date, all affected cattle herds have been found in a small geographic area in northwest Minnesota. All affected herds in Minnesota identified to date have been depopulated with Federal indemnity. Surveillance of free-ranging white-tailed deer continues through
hunter-harvested and targeted culling sample collection. Twenty-five infected free-ranging white-tailed deer have been identified to date.

**Nebraska Update:** One beef herd was identified as affected following an epidemiological investigation of a routine slaughter surveillance detection of *M. bovis*. Testing of the herd of origin confirmed infection in the herd. The herd remains under quarantine and disposition is pending at this time. The epidemiologic investigation associated with this herd has involved testing 33 Nebraska herds and over 13,000 cattle through mid-September 2009. No evidence of spread of the disease has been discovered to date.

A captive cervid herd was identified as affected through slaughter inspection. This herd has been depopulated with Federal indemnity. Wildlife surveillance has been conducted in the area surrounding the herd, and no signs of infection in free-ranging deer have been found.

**New York Update:** One captive cervid herd was identified through routine testing for sale purposes. One aged fallow deer was identified as a test responder and taken to necropsy. *M. bovis* infection in this animal was confirmed and the herd depopulated with Federal indemnity.

**New Mexico Update:** New Mexico applied for split-State status, which it received in March 2009 after two program reviews and the implementation of a memorandum of understanding. No affected cattle herds were identified in New Mexico in FY 2009. One affected dairy herd that had been under quarantine since 2002 completed a test-and-remove herd plan and was released from quarantine in July 2009.

**Texas Update:** One dairy was identified as affected through testing for sale purposes. This dairy has been placed under a test-and-remove herd plan. Epidemiological investigations continue. As of September 17, at least 15 States have received over 5,000 exposed heifers believed to have left this dairy over the past several years. In Texas alone, testing has been completed for over 21,000 cattle in 19 herds as part of this epidemiological investigation. A wildlife survey surrounding the infected dairy is also in progress.

**Bovine Tuberculosis Surveillance in U.S. Livestock Fiscal Year 2009**

U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services
Tuberculosis Eradication Program

Surveillance for bovine tuberculosis (TB) in the United States consists of slaughter surveillance in cattle and live animal testing in cattle and captive cervids. Twelve affected herds were detected during Federal fiscal year (FY) 2009, including three beef, two dairy, and seven captive cervid herds. During FY 1998 to 2009, 92 affected herds were found. Bovine herds included 53 beef, 26 dairy, and two mixed use, comprising 58 percent, 28 percent, and 2 percent of the total, respectively. Eleven captive cervid herds were detected in that time period, comprising 12 percent of the total.

The seven captive cervid herds detected in FY 2009 represented an unprecedented number: only four affected captive cervid herds had been detected from FY 1998 to 2008. Throughout the 1990s, TB-affected captive cervid herds were detected in at least 14 States. The cervid species involved in these outbreaks included axis deer, elk, fallow deer, red deer, and Sitka deer; in some cases, affected premises also had infected cattle and bison. TB isolates from two FY 2009 TB cattle cases were determined through genotyping to match strains isolated from captive cervid cases from the 1990s.

**Slaughter Surveillance**

For the period October 1, 2008, through June 30, 2009, 7,683 granulomas identified during postmortem slaughter inspection were submitted for diagnostic testing. These lesions originated from 162 U.S. establishments that slaughtered 21.4 million cattle, including 4.9 million adult cattle. The minimum standard for slaughter surveillance is 5 granulomas submitted per 10,000 adult cattle slaughtered annually. This standard is applied to each slaughter establishment. Many establishments substantially exceeded the minimum submission rate in FY 2009. Of the 40 highest volume adult cattle slaughter establishments, 34 (85 percent) met or exceeded the submission standard, and 6 (15 percent) establishments did not. To date, 15.2 granulomas were submitted per 10,000 adult cattle slaughtered nationally.
A critical component of the granuloma submission program is diagnostic laboratory support. A total of 5,351 granulomas (or 70 percent of the total obtained) were submitted to the National Veterinary Services Laboratories (NVSL); another 1,215 (16 percent) were submitted to the Food Safety Inspection Service (FSIS) Pathology Laboratory in Athens, GA; and 1,117 (14 percent) were evaluated at the California State Diagnostic Laboratory in Tulare, CA. Of the 7,683 granulomas submitted by slaughter establishments through the third quarter of FY 2009, 25 (0.3 percent) had histology consistent with mycobacteriosis. Of these 25 cases, TB was confirmed in 14 cattle and two captive cervids. TB is confirmed by a combination of polymerase chain reaction (PCR) testing of formalin-fixed tissue and culture of fresh tissue.

Slaughter Cases and Affected Herds: Cervids

Slaughter inspection detected a lesioned elk from a Nebraska elk and fallow deer herd. The second slaughter case occurred in a red deer from an Indiana cervid herd consisting of elk, red deer, Sitka deer, and fallow deer. The subsequent investigation led to the detection of two additional affected captive cervid herds in Indiana. The Nebraska herd, two of the three captive Indiana cervid herds, and a small captive cervid herd in New York, were depopulated with Federal indemnity in FY 2009. The disposition of one captive cervid herd in Indiana is pending. An additional two captive cervid herds in Michigan, identified as “shooter” herds, were not depopulated. They are in a TB-endemic area and do not represent a risk of disease spread because no live animals leave the facilities.

Slaughter Cases: Cattle

Of the 13 TB cases detected in cattle at slaughter during FY 2009, seven cases occurred in adult cattle over 2 years of age, and six cases occurred in feeder cattle. The seven adult cattle cases include six cases in beef cows and one cow of an unidentified type that was slaughtered in Pennsylvania. Investigations related to these cases identified two TB-affected cattle herds.

Of the seven TB cases in adult cattle, three were in adult beef cows from a single herd located in the modified accredited (MA) zone of northwestern Minnesota. The herd was depopulated through the State-funded herd buyout program, resulting in the identification of the lesioned cows during slaughter inspection. Additionally, nine yearling calves originating from the same herd were later confirmed infected with TB.

The fourth TB case in an adult cow was traced back to a beef herd in Nebraska, where infection was confirmed in an additional cow from the herd. The herd was then classified as a TB-affected herd. The decision to depopulate this herd is pending. Genotyping of *Mycobacterium bovis* isolates from the affected Nebraska beef herd and elk/fallow deer herd indicate these herds were infected with different TB strains.

TB-affected herds were not found for the remaining three adult slaughter cases found in FY 2009. One case in an adult cow was traced back to a North Dakota beef herd, which was tested twice without confirming TB. Another adult cattle TB case occurred in a cow slaughtered in a Pennsylvania establishment. Individual animal identification was not collected at the time of slaughter and, as a result, an epidemiologic investigation was required for each of six cattle that had been in a pen together at the establishment. One of the six animals was traced to a small beef herd in Indiana. Initial testing of this herd did not find any additional infected animals, and additional herd testing is planned. Genotyping results indicated that the isolate from this slaughtered cow was similar to strains isolated from cervids during the 1990s. Because of this finding, Indiana officials conducted surveillance on a nearby captive cervid herd and TB was confirmed in that herd as referenced above.

The most recent case occurred in a beef cow from South Dakota. The epidemiologic investigation for this case is ongoing.

Six TB cases were detected in fed cattle at slaughter during FY 2009. These cattle were all beef-type cattle and were from Texas (three cases), Kansas, South Dakota, and Florida (one case each). Two of these cattle (one each from Texas and Kansas) had official Mexican ear tags collected at slaughter. The tags indicated that one animal had been exported from Chihuahua and one from Veracruz. Culture is pending on a seventh slaughter feeder animal from Texas with Coahuila ear tags that had tissues compatible with mycobacteriosis.

The Florida case occurred in an aged roping steer that had been moved throughout the southeastern United States. The resulting epidemiologic investigation in this case did not identify other infected cattle. The *M. bovis* isolate obtained from a heifer from South Dakota was similar to strains isolated from captive cervids during the 1990s. Individual animal identification was not available for this animal and multiple consignors contributed to the feedlot where the animal originated. The epidemiologic investigation is ongoing. Epidemiologic investigations are also ongoing for two Texas TB cases that did not have Mexican-origin ear tags.
Mexican-Origin Slaughter Cases

As described above, only two Mexican-origin fed cattle cases were detected through slaughter surveillance in FY 2009. This represents a substantial decrease compared to FY 2006 through FY 2008, when there were 26, 17, and 11 Mexican-origin TB cases, respectively. During FY 1998 to FY 2008, the rate of TB cases in Mexican-origin cattle ranged from 0.7 to 5.4 infected cattle per 100,000 imported animals. As only two TB cases occurred in FY 2009 and approximately 828,000 cattle were imported into the United States from Mexico during the 2008–2009 export cycle (September 1 to August 31), the overall rate of TB in Mexican-origin cattle for FY 2009 is 0.2 cases per 100,000 imported cattle. Notably, 2008 cattle imports from Mexico substantially decreased from earlier years. There were 1.4 million cattle imported from Mexico in 2004 and 1 million in both 2006 and 2007. However, the recent decrease in the number of Mexican-origin cattle imported into the United States does not fully explain the decrease in the observed rate of TB cases in Mexican-origin cattle; other factors may be contributing to the decrease.

Live Animal Testing

Tuberculin skin testing in live animals also is part of our national TB surveillance. In FY 2009, 1,164,967 caudal fold tuberculin tests of cattle and bison were reported, with 19,164 responders (1.6 percent, 46 States and Puerto Rico reporting). The response fraction by State, for States testing more than 300 animals, ranged from zero to 4.5 percent (median, 1.0 percent). Caudal fold test performance appears to be improving, because 24 States had a response fraction of 1 percent or greater in FY 2009, compared to 13 States in FY 2008 and 16 States in FY 2007. The number of States having a response fraction of less than 0.25 percent was 12, 13, and 12 in FY 2007 through FY 2009, respectively.

The gamma interferon test has been available as an official supplemental test in the TB program since 2005. Five laboratories are approved to conduct gamma interferon testing: California, Michigan, Nevada, Texas, and NVSL. Data were available from four of these laboratories (all but Nevada) that conducted a total of 17,972 tests in cattle from 24 States in FY 2009. A total of 97 percent of these tests, or 17,523, were conducted on cattle from California, Georgia, Idaho, Nebraska, New Mexico, Oklahoma, Oregon, and Texas.

During FY 2009, 21,472 single-cervical tests were conducted in captive cervid species with 381 suspects (1.6 percent) reported to the Animal and Plant Health Inspection Service. There are no standards for granuloma submissions for establishments that slaughter cervids, so tuberculin testing is the primary means of surveillance for TB in captive cervids. The number of captive cervids tested annually has ranged from 25,000 in FY 2006 to just over 10,000 in FY 2007.
A New Approach to the National Tuberculosis Program
Dr. Alecia Larew Naugle, National TB Program Manager
National Center for Animal Health Programs
USDA-APHIS Veterinary Services

[Note: Dr. Naugle based her presentation on "A New Approach for Managing Bovine Tuberculosis: Veterinary Services’ Proposed Action Plan, July 2009", published by USDA APHIS Veterinary Services.]

Bovine tuberculosis (TB) is a serious disease with animal health, public health, and international trade consequences. The cooperative Federal-State-industry effort to eradicate bovine TB from cattle in the United States has made significant progress since the program’s inception in 1917. However, the goal of eradication remains elusive. This proposed action plan presents Veterinary Services’ (VS’) current thinking about changes we are considering for the TB program to address our current challenges.

This action plan will:
1. Reduce the introduction of TB into the U.S. national herd from imported animals and wildlife by:
   • Applying additional requirements to cattle imports from Mexico
   • Enhancing efforts to mitigate risks from wildlife
2. Enhance TB surveillance by:
   • Crafting a comprehensive national surveillance plan
   • Accelerating diagnostic test development to support surveillance
3. Increase options for managing TB-affected herds by:
   • Conducting epidemiological investigations and assessing individual herd risk
   • Applying whole-herd depopulation judiciously and developing alternative control strategies
   • Applying animal identification (ID) standards to meet animal ID needs
4. Modernize the regulatory framework to allow VS to focus resources where the disease exists
5. Transition the TB program from a State classification system to a science-based zoning approach to address disease risk

To succeed, this new approach will require VS’ continued partnership with State animal health and wildlife officials, other Federal agencies, industry, international partners, academia, and other stakeholders. Successful partnerships will allow us to use available resources efficiently to achieve program objectives and protect our nation’s herd.

Implementation of the VS proposed action plan will benefit Federal and State animal health officials, the regulated industries, and producers by allowing a more rapid response that employs up-to-date science and can adapt rapidly to changing situations.

Introduction: The Need for Change
Bovine TB is a serious disease with animal health, public health, and international trade consequences. The cooperative Federal-State-industry effort to eradicate bovine TB from cattle in the United States has made significant progress. Since the program’s inception in 1917, the disease prevalence rate in cattle herds dropped from 5 percent to less than 0.001 percent. Many consider this one of the great animal and public health achievements in the United States. However, our ultimate goal of eradication remains elusive as animal health officials continue to detect TB sporadically in livestock herds.

Numerous challenges hinder our efforts to eradicate the disease:
• Epidemiological investigations conducted by VS and the States indicate that most TB-infected cattle detected at slaughter were imported. Most of these cases originated from Mexico despite significant reductions in the prevalence of TB in all Mexican States.
• In 1995, animal health officials found an endemic focus of TB infection in free-ranging white-tailed deer in the northeastern lower peninsula of Michigan. More recently, TB has been confirmed in free-ranging white-tailed deer in Minnesota. This wildlife TB reservoir continues to impact the program.
• Today’s cattle industries feature fewer herds of increased size. Producers are more specialized and often transport animals long distances. This frequent movement of some classes of cattle among multiple premises and herds has led to increased risks of TB transmission.
• The absence of a fully implemented national animal ID system negatively impacts the ability to identify affected herds.
The primary diagnostic tool for TB, tuberculin skin testing, requires multiple veterinary visits to administer the test and interpret results. The tuberculin skin test and all other available diagnostic tests for TB fail to detect all infected cattle, especially in populations with low-disease prevalence. The TB program is primarily supported with Federal funds, including appropriated funding and emergency funding. The Federal annual appropriation for the TB line item has grown substantially since fiscal year (FY) 2000, but reached its plateau at approximately $15 million since FY 2003. Approximately $207 million of emergency funding has been infused into the TB program since 2001. The Animal and Plant Health Inspection Service (APHIS) obtained these emergency funds through Commodity Credit Corporation requests or APHIS contingency funds when the costs of investigation, control, and eradication activities exceeded the appropriated program budget. However, Federal budget deficits are forecast to continue. We expect federally appropriated funds to remain constant or decrease and do not anticipate having emergency funds available.

Compounding these challenges is a lack of flexibility in the regulations. The current bovine TB regulations in title 9 of the Code of Federal Regulations (9 CFR), parts 50 and 77, the 1999 Uniform Methods and Rules (UM&R) incorporated by reference, and other related regulations (e.g., 9 CFR 71) contain detailed standards and requirements. This means that additional rulemaking is necessary every time we must change any details. VS, like other regulatory agencies, faces a complex, lengthy process to implement changes or develop new regulations. This results in rigid, outdated requirements that cannot adapt to a changing agricultural landscape.

It is time for a new approach.

This document presents VS' current thinking about changes we are considering for the TB program. We hope it will stimulate critical feedback from our partners and stakeholders.

The Proposed Action Plan: A New Approach for Managing Bovine TB

This action plan will:

1. Mitigate the introduction of TB into the U.S. national herd from imported animals and wildlife
2. Enhance surveillance for TB
3. Increase options for managing TB-affected herds
4. Modernize the regulatory framework to allow VS to focus resources where the disease exists
5. Transition the TB program from a State classification system to a science-based zoning approach to address disease risk

1. Mitigate Disease Introduction

Apply Additional Requirements to Cattle Imports from Mexico

Each year, the United States imports approximately 1 million cattle from Mexico. The prevalence of TB-affected herds in virtually all Mexican States and the number of TB cases in imported Mexican cattle have declined substantially from the late 1990s. However, epidemiological investigations indicate that the majority of TB-infected cattle detected at slaughter in the United States originated in Mexico. Exposing U.S. cattle not intended for immediate slaughter to Mexican TB-infected cattle poses a significant risk.

Working with our stakeholders, VS will develop new standards to supplement existing import requirements that will further mitigate this risk. VS will continue to collaborate with the Mexican Government to provide technical support to their TB program.

The alternatives VS is considering include:

- Requiring additional testing of livestock prior to entry into the United States (including tests conducted at the port of entry)
- Requiring certain classes of imported cattle be sent to quarantined feedlots or terminal feedlots where animals are only destined for slaughter
- Prohibiting the exposure of domestic cattle not destined for slaughter with high-risk imported cattle in feedlots
- Requiring risk evaluations, herd plans, or additional testing requirements for herds exposed to imported animals
- Conducting supplemental surveillance in geographic areas that have an increased risk for exposure to imported cattle
- Requiring annual TB testing for interstate movement of cattle used for rodeo events, regardless of origin

Enhance Efforts to Mitigate Risks from Wildlife

The discovery of an endemic TB infection in free-ranging white-tailed deer in the northeastern lower peninsula of Michigan in 1995 was the first report of self-sustaining bovine TB in wild, free-ranging U.S.
cervids. More recently, TB has been confirmed in free-ranging white-tailed deer in Minnesota. TB in wildlife can be transmitted to domestic livestock. VS believes TB in wildlife is the primary reason we continue to find affected cattle and captive cervid herds in Michigan. Identifying TB in wildlife has impacted the direction and success of the TB program for the last decade and will continue to be a significant challenge in the future.

VS will partner with wildlife agencies and other entities to enhance our TB control and elimination efforts. We must establish measures to detect TB in wildlife, reduce the prevalence of the disease in wildlife, and mitigate the risks for transmission of TB between livestock and wildlife.

The alternatives VS is considering include:

- Conducting supplemental surveillance in wildlife in geographic areas where TB has been identified in livestock
- Establishing minimum requirements for targeted surveillance in wildlife as part of a comprehensive, national surveillance plan
- Developing on-farm mitigations to control the risk of disease transmission between wildlife and livestock and evaluate the effectiveness of these mitigations
- Supporting research to identify tools (e.g., vaccination) and strategies (e.g., bait delivery strategies) to reduce the prevalence of TB in wildlife and instituting those strategies as appropriate

2. Enhance Surveillance

Crafting a Comprehensive National Surveillance Plan

Since its inception, the TB program has shifted from a “down-the-road,” systematic testing approach, where all cattle herds were individually tested using tuberculin skin testing, to the designation of entire geographic areas as TB free with slaughter surveillance as our major case-finding tool. Current Federal regulations require States to conduct routine surveillance to maintain their TB status for cattle and domestic bison (i.e., permanently captive and privately owned free-range animals). The Bovine TB Eradication UM&R, dated January 1, 2005, includes guidelines for surveillance, and the World Organization for Animal Health (OIE) has established international guidelines for declaring a country free from bovine TB. Surveillance has been and will continue to be an integral component of the TB program.

A cornerstone of VS’ future TB program will involve enhancing our existing surveillance to create a comprehensive national surveillance plan that includes ongoing surveillance in cattle, domestic bison, and captive cervid herds (both in live animals and at slaughter) as well as targeted surveillance in wildlife. As a first step, VS is evaluating its current system to determine how well we can detect TB and demonstrate freedom from the disease in individual States.

An enhanced comprehensive national plan will integrate slaughter surveillance, herd testing, and other possibly novel surveillance streams to establish minimum requirements necessary to detect infected cattle, domestic bison, and captive cervid herds nationally. Additionally, VS will improve existing practices to enhance the overall efficiency and effectiveness of our surveillance system.

We envision components of this comprehensive national surveillance plan to include:

- Slaughter surveillance as our primary case-finding tool. VS plans to continue our collaboration with the Food Safety and Inspection Service to ensure slaughter surveillance remains a priority so we may achieve surveillance standards at the national, State, and slaughter establishment levels.
- Live animal testing in cattle, domestic bison, and captive cervid herds. VS may require a minimum level of herd surveillance in areas without documented cases of TB. This testing may be conducted for herd accreditation, movement testing, or to meet requirements of the Grade “A” Pasteurized Milk Ordinance.
- Minimum requirements for surveillance in wildlife. Similarly, VS may incorporate ongoing surveillance in wildlife populations to monitor the risk of TB exposure for domestic livestock. This type of surveillance will require developing and implementing alternative surveillance streams such as testing in sentinel species (e.g., coyote), integrating with existing surveillance for other diseases of hunter-killed cervids (e.g., chronic wasting disease), or other novel approaches.
- Supplemental surveillance in areas with TB-affected livestock or wildlife. Increased sampling rates or “targeted” testing in nearby cattle, domestic bison, and captive cervid herds and surveillance in wildlife will ensure rapid disease detection and prevent further spread. The perceived risk of exposure resulting from observed herd management and biosecurity practices may also be used to “target” cattle, domestic bison, and captive cervid herds for supplemental surveillance testing.
- Surveillance standards that integrate sampling from these streams. VS will establish Federal surveillance standards necessary to support claims about the TB status of the United States, or
zones within the United States, consistent with OIE guidelines. While we will no longer certify and publish the TB status of individual States, State and Federal animal health officials will still be expected to meet established surveillance standards, including reporting deadlines, to substantiate the national TB status claim.

- A national standardized, integrated, electronic data collection system for TB surveillance and case management. As with any surveillance effort, collecting, validating, and reporting accurate surveillance data demonstrate effectiveness and enable rapid response. We will use existing data collection and management systems, including the Mobile Information Management System, the Animal Health Surveillance and Monitoring System, and animal ID standards, to enhance future surveillance capabilities.

**Accelerating Diagnostic Test Development to Support Surveillance**

Tuberculin skin testing was first recognized as a useful diagnostic tool in the late 1800s and continues to be the primary diagnostic tool in both human and animal medicine. However, this test has limitations. Aside from the need for multiple veterinary visits to administer the test and interpret the results, tuberculin skin testing fails to detect all infected cattle, especially those tested too early or too late in the course of infection, while as many as 15 percent of infected cattle will test negative. At the same time, approximately 3 percent of uninfected cattle may test positive. Because of these limitations, APHIS evaluates an individual animal's infection status using a combination of tests requiring multiple visits to the farm.

Despite the considerable need for improved diagnostic methods for bovine TB, significant breakthroughs in developing new tests are not likely in the immediate future. While several technologies are being developed, these methods still require further testing and evaluation.

To partially address this need, VS established a serum bank in 2006 to support research and validation of new technologies for TB testing. In 2009, VS provided additional funding to collect a large number of high volume serum samples from both infected and uninfected cattle and white-tailed deer. The objective of the serum bank is to provide well-characterized samples that are linked with skin test results for samples from uninfected animals, and skin test, histopathology, and TB culture results from infected animals. We hope this bank will assist stakeholders in the research, development, and timely validation of bovine TB serologic tests.

In addition to the expansion of the serum bank, VS will continue to collaborate with other U.S. Department of Agriculture (USDA) agencies such as the Agricultural Research Service and the Cooperative State Research, Education, and Extension Service to identify priorities and conduct critical research to develop and validate diagnostic methods and tests. VS will clearly describe the process to obtain licensure and approval as an official test for the TB program and identify approaches to expedite this process.

VS is considering other possibilities to accelerate the development of diagnostic tests, including:

- Identifying alternative sources of funding within the Federal Government to support test development and validation
- Expanding existing partnerships with international animal health agencies to further support diagnostic test development
- Exploring new partnerships with public health agencies and human health companies to better leverage the limited funding and personnel available to support this process
- Investigating novel detection methods that do not rely on organism or antibody detection

**3. Manage TB-affected Animals and Herds**

**Conducting Epidemiological Investigations and Assessing Individual Herd Risk**

VS will continue to require epidemiological investigations of affected herds. Upon the disclosure of a TB-affected herd, VS will continue to rely on State animal health agencies to issue an immediate quarantine of the herd and will collaborate with these entities to initiate an epidemiological investigation. Epidemiologically linked herds (i.e., herds that have supplied or received cattle from the affected herd) will be quarantined and tested as appropriate.

VS is proposing to modify certain practices and to implement additional actions in conjunction with these epidemiological investigations. These alternatives include:

- Revising program definitions, such as those for “herd” and “feedlot,” to reflect current industry practices
- Developing a standardized tool to evaluate and classify the risk of TB transmission associated with individual herds under investigation based on producer-identified risks (e.g., wildlife exposure), management practices, and biosecurity
• Using observations from these assessments to establish supplemental surveillance requirements in nearby cattle, domestic bison, and captive cervid herds and wildlife

**Applying Whole Herd Depopulation and Developing Alternative Strategies**

Traditionally, VS has encouraged producers to voluntarily depopulate TB-affected herds as the only approach certain to eliminate infection. VS continues to offer indemnity (depending on the availability of funding) to compensate producers considering depopulation. However, as herd size continues to increase, it becomes difficult for VS to justify depopulating herds that often exceed 1,000 animals when only one or two animals are diagnosed with TB. In addition, the public perceives whole-herd depopulation as a less acceptable approach for disease control. Changing social values concerning the care and well-being of livestock, the recognition of the environmental consequences of animal disposal, and the value of proteins derived from livestock also drive the need to develop new approaches to disease control. Finally, the costs of depopulation have increased with herd sizes at a time when we expect future indemnity funds to be limited and emergency funding to be unavailable.

VS is considering these alternatives:

- Revising our regulations to include a performance standard for eliminating TB from affected herds and identifying options to achieve this standard. This could include multiple test-and-removal protocols to control disease spread, whole-herd depopulation, and other options.
- Developing objective criteria to determine if whole-herd depopulation is economically viable and to prioritize how limited indemnity funds should be used either to remove specific animals or depopulate entire herds.
- Providing incentives for producers to remove exposed animals from the herd through early culling.
- Reducing the maximum amount of Federal indemnity paid per individual animal.
- Linking Federal indemnity payments to the implementation of specific risk mitigation and biosecurity practices within a herd.
- Identifying alternative or supplemental sources for indemnity funding and exploring the feasibility of these options. These may include cost sharing with the industry or State or developing industry-funded “insurance” programs.

**Applying Animal ID Standards to Meet Animal ID Needs**

While slaughter surveillance has proven to be effective, traceback to herds-of-origin has been limited by lack of information. The lack of ID for a particular animal and incomplete documentation kept by owners, dealers, or brokers continue to hamper successful tracebacks and epidemiological investigations. These limitations and the frequent movement of some classes of cattle among multiple premises and herds prolong the time required to complete traces and require additional resources. Therefore, rapid and effective response to TB occurrences will depend on full implementation of an animal ID system.

VS is proposing that official animal ID and electronic movement certificates be used for animals leaving affected herds or zones to ensure compliance with necessary testing requirements. This would provide assurance that the risk of disease spread is minimal and would ensure that animal health officials can perform effective trace investigations. Individual State authorities will be responsible for applying and enforcing these movement controls to ensure that only low-risk cattle are moving outside affected herds or zones and that high-risk cattle are moving only to slaughter or terminal feeding operations where the risk of spread can be controlled.

**4. Modernize the Regulatory Framework**

The mission of VS is to prevent, control, and eliminate animal diseases and to monitor and promote animal health and productivity. These activities are vital to the health of the U.S. cattle and livestock industries and to the safety of the U.S. food supply. VS’ regulatory activities are authorized by the Animal Health Protection Act, which consolidates laws related to animal health and quarantine and includes key provisions for VS animal health programs and services.

VS’ regulations, including the bovine TB regulations, are largely written as design standards (also sometimes called prescriptive or “command-and-control” standards). Design standards contain details that regulated entities must follow. Having such details in the regulations means additional rulemaking is necessary every time a detail must change. This tendency to include design standards, coupled with the lengthy regulatory process, means that VS’ animal health regulations become outdated quickly and cannot adapt to a changing agricultural landscape.

VS is proposing to revamp the regulatory framework underlying several of its animal disease programs, including the TB program. We must structure underlying regulations to allow us to respond
quickly, employ up-to-date science, and be flexible to changing situations. These proposed changes are consistent with the VS 2015 Vision to place greater emphasis on disease prevention, create a more agile national veterinary strike force to direct emergency response activities, and increase cooperation between animal and public health organizations.

VS envisions the characteristics of these proposed regulatory changes to include:

- Developing regulations that use performance standards to describe a regulatory goal or desired outcome rather than including prescriptive, inflexible design standards
- Stating specific guidelines or approaches for meeting the regulatory goal in program standard documents, surveillance plans, and other policy documents rather than in the regulations
- Using a science-based zoning approach that addresses disease risk more appropriately than a geopolitical State-based approach
- Maintaining a description of zones on our Web site, rather than in the regulations
- Notifying the public of changes through notices published in the Federal Register, rather than through rulemaking, making the process more timely and flexible

5. Transition to a Zoning Approach

Historically, VS has classified States according to a multi-level system based on TB prevalence. A State’s status is the primary determinant for requirements for interstate movement of livestock. A lower rank requires controls that are more restrictive. As a result, there is considerable economic incentive for a State to have the highest status level possible.

This State status approach was successful in managing TB when the prevalence of TB was high. Enforcement of interstate movement and testing requirements assisted animal health officials to identify infected animals and affected herds. Requirements associated with State status encouraged States to investigate cases promptly and mitigate the spread of disease.

Given the current low prevalence of TB in the United States, reclassifying the status of an entire State when a disease is present only in a small geographic area may not be necessary to contain the disease and can be costly for the industry. When a State’s status is downgraded, every producer in the State incurs additional costs to meet restrictive movement and testing requirements.

To minimize the impact on industry during these outbreaks, our current regulations allow States to create zones within the State, commonly referred to as establishing split-State status. This means one or more zones have a separate disease classification from the rest of the State.

One benefit of split-State status is that zones considered free of disease are able to ship livestock interstate and internationally with minimal restrictions. However, the application process for split-State status can take over a year to complete. Implementing the zone requires regulatory changes at both State and Federal levels, further prolonging the time required to increase or decrease the size of the zone.

The system also fails to consider factors that may either contribute to or limit the risk of further disease transmission such as clustering of affected herds in a defined geographic area, geographic barriers, or even industry practices. Many States find the current system rigid, prescriptive, and unable to adapt to changing conditions.

Therefore, VS is proposing to replace the current State status system. Instead, VS envisions a risk-based approach that imposes testing requirements and movement restrictions that associate with a zone rather than an entire State. Such zoning is consistent with OIE standards. Adopting this approach will enable us to move quickly to protect animal health and focus limited resources on geographic areas where the disease exists, while simultaneously adapting to changes in agricultural practices and minimizing the economic impact on industry. VS envisions the elements of this proposed approach will include:

- Promulgating performance-based regulations that allow VS to establish and dissolve TB elimination or containment zones around clusters of affected herds or other high-risk areas.
- Defining testing requirements and movement restrictions associated with these zones that States will apply and enforce.
- Identifying conditions that would initiate establishing a TB elimination or containment zone.
- Developing criteria to define or redefine boundaries to increase or decrease zone size and eventually dissolve the zones. These boundaries would be unique for each situation and may cross State lines.
- Establishing requirements within the zone for supplemental surveillance in areas with TB-affected livestock herds or wildlife.

Implementation, Oversight, and Monitoring of the New Approach
VS’ proposed action plan represents a dramatic change for one of VS’ longstanding disease eradication programs. Modernizing the Federal regulatory framework by implementing performance-based regulations, including those needed to officially establish TB elimination or containment zones according to internationally accepted guidelines, will take time. State-level regulatory changes may also be required. Once promulgated, however, these new rules will benefit Federal and State animal health officials, the regulated industries, and producers by allowing a more rapid response that employs up-to-date science and is flexible to changing situations.

VS is aware that these proposed changes will impact the regulated industries and our stakeholders. Prior to publishing the proposed rule to establish these regulations, VS intends to work closely with our stakeholders to obtain input on these proposed strategies, program standards, surveillance plans, and other policy concepts. VS has already initiated these discussions with various stakeholders.

**Resources**

VS assumes the Federal annual appropriation for the bovine TB program will remain at $15.1 million, with potential decreases and without additional Federal emergency funds. State resources face similar limitations. This fiscal scenario will require careful prioritization of program activities that focus on affected or high-risk geographic areas to ensure that we achieve program objectives within this limited budget. Coordination and collaboration among various Federal, State, and industry partners will be essential. Finally, we may need to consider broader cost sharing or other new alternative sources of funding.

**Roles and Responsibilities**

The success of this new approach will depend on the longstanding cooperation among Federal and State animal health officials, regulated industries, and producers. Each cooperator will have specific roles and responsibilities.

In addition to rulemaking, Federal animal health officials will be responsible for:

- Developing program standards, surveillance plans, and other policy documents that describe specific guidelines and approaches for meeting the performance standards stated in the regulations
- Establishing the national program objective and priorities
- Designing and implementing a national standardized, integrated, electronic data collection system for TB surveillance and case management
- Monitoring data and supplemental documentation regularly to verify that minimum standards and national program objectives are met
- Providing States with timely feedback, guidance, and technical expertise as we implement regulations and policies
- Collaborating with other Federal agencies, stakeholders, and industry to leverage resources and ensure integrated planning

State animal health officials will be responsible for:

- Revising State regulations where necessary to be consistent with Federal regulations
- Implementing program standards, surveillance plans, and other policies to achieve the performance standards in the regulations
- Overseeing, monitoring, and enforcing testing requirements and movement controls associated with established zones
- Monitoring data on a regular basis to document progress and submitting data and additional documentation as required
- Collaborating with other State agencies, Federal agencies, and industry to leverage resources and ensure integrated planning
- Serving as a liaison with individual producers

In this new approach, producers and industry will also have responsibilities:

- Advancing their knowledge about bovine TB and risk factors for introducing TB into their herds
- Evaluating their management practices to identify if any of these risk factors are present and implementing mitigations to reduce these risks
- Developing industry- and producer-driven components of the TB program and generating the funds necessary to support these activities
- Continuing to engage in discussions with State and Federal animal health officials concerning the TB program

**Potential Obstacles to Implementing this New Approach**
VS recognizes that our partners, stakeholders, and regulated industries may have reservations about these new concepts. While there will likely be others, we can address three reservations already expressed to VS through stakeholder dialog.

*Replacing the current State status system may reduce or eliminate incentives for States to promptly investigate cases and mitigate the continued spread of TB.*

Under the proposed approach, movement restrictions and testing requirements would be limited to zones where the disease exists, rather than applying these restrictions statewide. However, VS believes that the costs of the restrictions and testing applied to an affected zone will provide the same market incentive for producers and States managing such zones to implement the necessary disease control measures. Furthermore, VS will continue to cooperate with and provide financial support to States to implement minimum TB surveillance and program standards.

The described zoning approach may be inappropriate to manage a chronic disease such as TB and cannot be applied consistently across the country.

VS only proposes to establish TB elimination or containment zones in distinct geographic areas that present a high risk for TB exposure or transmission to domestic livestock herds. For example, zones may be established when multiple affected herds are identified or when infected wildlife exists in a geographic area. Otherwise, we expect States to quarantine and manage individual affected herds, including implementing movement restrictions and herd testing, within the guidelines of the program.

Furthermore, to ensure transparency and consistency, VS will clearly describe in our regulations the risk criteria that will initiate the establishment of a zone and define zone boundaries. These criteria will use a risk evaluation that incorporates epidemiology, disease dynamics, and ecological factors related to livestock and wildlife; information from investigations of TB outbreaks in livestock; surveillance data from both domestic livestock and wildlife populations; livestock marketing practices; and wildlife movement patterns. Our goal will be to define zones with distinct and identifiable boundaries that will contain the potential risk for TB exposure and transmission, while allowing herds at low risk to operate without increased requirements or restrictions.

*It will not be possible to enforce program requirements without specifically including them in the text of the regulations contained within the CFR.*

While developing official rules establishing these concepts, VS intends to work closely with USDA’s Office of the General Counsel to ensure our regulations include well-designed performance standards that can be enforced.

For example, standards in 9 CFR 77.17(a) include specific instructions that regulated entities must follow precisely for identifying TB reactor cattle. These include the type and method of applying eartags; the dimensions and locations of branding; and the type, location, and color of tattoos. Alternatively, these standards could be written as performance-based regulations that only require that TB reactor cattle must be individually identified and visibly marked as a reactor in a manner approved by the Administrator. Various methods for meeting this performance standard would be defined in program standard documents that can be revised readily and updated as technology and market practices change.

Such standards will provide greater regulatory flexibility while still ensuring that the core requirements of the regulation remain enforceable.

**Conclusion**

There are numerous challenges that hinder our efforts to eradicate bovine TB. VS recognizes that it is time for a new approach to managing this disease. Our proposed action plan will:

1. Reduce the introduction of TB into U.S. livestock from imported animals and wildlife
2. Enhance nationwide TB surveillance
3. Increase options for managing TB-affected herds
4. Modernize the regulatory framework to allow VS to focus resources where disease exists
5. Transition the TB program from a State classification system to a science-based zoning approach to address disease risk that will enable us to respond quickly to changing conditions

To succeed, this new approach will require VS’ continued partnership with State animal health and wildlife officials, other Federal agencies, industry, international partners, academia, and other stakeholders. Successful partnerships will allow us to use available resources efficiently to achieve program objectives and protect our nation’s herd.
RESPONSE OF SENSITIZED ELK TO SINGLE CERVICAL TUBERCULIN (SCT) AND COMPARATIVE CERVICAL TUBERCULIN (CCT) TESTS

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Elk, Cervus elaphus, are subject to the regulations concerning intradermal tuberculin testing under the USDA’s uniform methods and rules for the eradication of bovine tuberculosis. Though the single cervical tuberculin (SCT) and comparative cervical tuberculin (CCT) tests are approved methods of anti-mortem detection of Mycobacterium bovis infection, few studies quantify the response of elk to these tests. Furthermore, results are acquired after the injection sites are palpated and measured at 72 hours post injection requiring rehandling of the animals. Infrared thermography, the remote measure of surface temperature, may be able to reduce the time to results and eliminate the second handling of the animals by measuring temperature changes associated with inflammation at injection sites. Our objective was to examine the response of sensitized and non-sensitized elk to the tests by palpation, skin thickness measurement and IRT.

To this end, 10 elk were sensitized to M. bovis, 9 elk were sensitized to M. avium and 19 elk were not sensitized. The sensitized elk were tested 119 or 120 days after injection of 0.1 ml derivatives of the selected bacterium. The animals from the three different groups were randomly divided into two blocks; block 1 received 0.1 ml of 2 mg/ml of the purified protein derivative (PPD) and block 2 received 0.1 ml of 1 mg/ml of the PPD for the SCT test. Testing of block 1 was offset by one day from block 2 testing. The SCT and the CCT were conducted concurrently on each animal on the right side and left side of the neck, respectively. In addition to the PPD injection sites which were measured for skin thickness and palpated, two additional sites for the SCT and CCT were measured and palpated, a saline injection site and a control site. IRT images were taken at 0, 10, 24, 48, and 72 ± 3 hrs post injection of all sites.

No significant difference ($\chi^2=1.09, \ P=0.78$) for detecting a response occurred between the two different concentrations of the PPD for the SCT. Increase in skin thickness for the SCT ranged from 0.0 mm to 8.5 mm and the mean for sensitized animals at the PPD injection site was 3.0 mm (± 0.5 SE). Based on palpation results, 78.9% of the sensitized elk and 36.8% of the control elk had a response to the PPD injection on the SCT. For the CCT, skin thickness increased from 0.0 mm up to 10.0 mm. The mean at the bovine PPD site was 4.1 mm (± 0.9 SE) for M. bovis sensitized, 1.8 mm (± 0.4 SE) for M. avium sensitized, and 0.9 mm (± 0.1 SE) for the control elk. Ninety percent (9 of 10) of M. bovis sensitized were suspects or reactors. Of the 9 elk that had M. avium senstinogen and of the 19 elk that were controls, 26 plotted in the negative zone for M. bovis and 2 of the control elk plotted in the suspect zone for 92.9% specificity. Preliminary IRT analysis has not indicated any significant temperature changes associated with the different sites.

The changes due to the PPD injections are often small and changes in the concentration of the PPD for the SCT did not result in significant changes in detecting a response. The small changes, however, may mean less inflammation that could be masked by ambient conditions making IRT difficult to use on elk.
Bovine Tuberculosis (bTB) is a disease caused by *Mycobacterium bovis* infection. Under current federal regulations, cattle that test as reactors on two successive federally approved diagnostic tests are examined post mortem for bTB. Currently, in Michigan, <1% of cattle that test as reactors on two successive tests are confirmed as positive for bTB. We are in need for an alternative test that can differentiate the test-false positive reactors from true bTB infected animals.

We conducted a microarray-based comparative genomic hybridization study to examine the altered gene expression patterns in three groups of cattle. Those groups included cattle that had bTB (bTB+), cattle that did not have bTB but tested positive for bTB by two successive tests (double reactors), and cattle that did not have bTB but tested positive for bTB by the caudal fold skin test only (single reactors). Cellular RNA from peripheral blood mononuclear cells (PBMCs) was harvested at four hours or overnight post-stimulation with purified protein derivative made from *Mycobacterium bovis* (bovine PPD). The RNA from individual cattle was co-hybridized with a pooled control RNA from healthy cattle that were non-reactors on both the CFT and on the whole blood gamma interferon assay for bTB.

Hybridization for the four hour study was done using a mononuclear leukocyte derived bovine cDNA microarray (BOTL5) with duplicated spot features representing 1,391 genes. At a 1.5 fold or greater change in expression level compared with healthy cattle (*p* ≤ 0.01), we detected 8 genes differentially expressed in single reactor cattle, 38 genes in double reactor cattle, and 13 genes in the true bTB positive cattle. All except one of these genes are unique to each of the groups of cattle; one gene is significant for both the reactor groups. Gene expression level was further compared among each of the three groups of cattle. Expression level of 17 genes were significantly different (*p* ≤ 0.01) in bTB+ group compared with single reactor group, and 14 genes in bTB+ group compared with double reactor group. We detected 9 genes that significantly differentiate (*p* ≤ 0.01) bTB+ group from the composite of all reactors at greater than 1.5 fold in expression level.

A bovine long-oligo microarray (BLO Plus) representing 10,219 bovine genes was used for hybridization of the overnight stimulation study. Comparing gene expression level with healthy cattle at adjusted *p*-value cut off of 0.01 (adjusted for multiple testing); we detected 146 genes differentially expressed in single reactor cattle, 154 genes in double reactor cattle, and 151 genes in the true bTB positive cattle. At a 1.5 fold or greater change in expression level compared among each animal group, 36 genes were found significantly different in bTB+ group compared with double reactor group (*p* ≤ 0.01, false discovery rate [fdr] = 0.3826) and 75 genes different in bTB+ group from reactor group (*p* ≤ 0.01, fdr = 0.4405); of which only 4 genes differentiate bTB+ group from both reactor groups. Analysis of bTB+ group compared with the composite of all false-positive reactors uncovered an additional 18 genes that differentiate bTB+ group from both reactor groups by 1.5 fold or greater change in expression level (*p* ≤ 0.01, fdr = 0.3787).

Preliminary data from these experiments supports the hypothesis that differential gene expression patterns will provide a sufficient number of uniquely regulated genes to develop a real-time quantitative PCR assay that can be used to differentiate false test-positive cattle from cattle that have bTB. This test will help to reduce the expense of indemnification and needles slaughter of healthy cattle.
Use of Mexican Cattle in Rodeos in the United States
Doug Corey, DVM, Chair
Professional Rodeo Cowboys Association’s Animal Welfare Committee
Adams, Oregon

What is the PRCA? The Professional Rodeo Cowboys Association (PRCA) is the largest sanctioning body of professional rodeos in the world. It has 7,000 members, with 600 sanctioned rodeos in 41 states and 4 Canadian provinces, attended by 25 million fans attend annually.

Cowboys competed for more than $40 million in prize money each year. The PRCA’s premier event is the Wrangler National Finals Rodeo held in December each year selling more than 170,000 tickets and offering more than $5 million in prize money. The PRCA headquarters in Colorado Springs, Colorado, employs nearly 100 people.

Regarding livestock welfare, the PRCA has 60 rules to protect the livestock. For example, horn wraps must be used on team roping and steer roping steers. Rules are enforced by on-site rodeo judges. Rules require a veterinarian to be present at all rodeo competitions. Judges inspect animals before all competitions to insure only healthy animals compete. Livestock welfare surveys to show the rate of injury to rodeo livestock to be less than five hundredths of one percent.

It is estimated that there are at least 5,000 rodeos annually in the US. This does not include the number of team roping and timed event jackpots. The United States Team Roping Championships (USTRC) alone has 35,000 members and conducts thousands of events each year across the US.

Why use Mexican cattle? The Mexican bred Corriente has been found to be the most suitable to rodeo events. There have been some breeding of American Corrientes and these are being approved for use in PRCA rodeos, but there are currently not enough being bred in the US to supply the rodeo and team roping industries.

Steer wrestling, team roping and single steer roping all use Mexican cattle. PRCA stock contractors import approximately 5,000 Mexican Corrientes yearly. The USTRC imports approximately 20,000 yearly.

Issues that affect rodeo include:
- Ease of obtaining Mexican cattle
- Ease of crossing border
- Animal ID
- Annual TB tests
- Education of PRCA membership on commingling of Mexican cattle and domestic cattle
- Disposition of Mexican rodeo steers
- Bucking bulls/interstate transport
- State regulations/test requirements

The PRCA takes the health of the US’s livestock herd very seriously and is committed to working with regulatory officials to take the necessary steps to combat any and all diseases.
Overview of Bovine Tuberculosis (TB) Eradication Program in Canada
To September 30, 2009

CATTLE AND FARMED BISON

Eradication: Canada continues to near the complete eradication of bovine tuberculosis (TB) from cattle and farmed bison. During the six-year period from September 2003 through September 2009, M. bovis was confirmed in three (3) herds of cattle in Canada. The last finding of bovine TB in farmed bovines in Canada occurred in May 2008. The last finding of bovine TB in farmed bison in Canada occurred in 2001.

Two of the three infected cattle herds detected in Canada during the past six years were located in the province of Manitoba: one was found in 2004 and the other was found in May 2008. Both herds are believed to have acquired bovine TB from contact with diseased wild elk or deer in or around Riding Mountain National Park (RMNP). In both herds, the infection was found in a single animal in the herd. Investigations using molecular techniques determined that both isolates were identical to the unique strain of M. bovis found in wildlife in and around RMNP. The infected herd found in 2008 was detected during area surveillance testing the one in 2004 through routine slaughter inspection.

One infected cattle herd was detected in the province of British Columbia in September 2007. The infection was found in a single animal in the herd and was detected during routine slaughter surveillance inspection in Canada. Tracing activities found no spread of the infection to other herds. Molecular characteristics of the M. bovis organism isolated from this herd indicate it was an isolate not previously reported in Canada, but one commonly isolated from cattle in the United States, Mexico, Great Britain and South America. The epidemiological evidence supports a conclusion that the source of the infection found in this herd was latent M. bovis infection of North American origin.

These findings indicate that, with sustained aggressive surveillance and eradication strategies, excellent progress continues to be made in eradicating the residual latent bovine TB infection that may still be present in Canadian livestock herds. The remaining challenge are the sporadic new infections that occur in livestock as a result of direct or indirect contact with diseased wildlife.

Since 1983, all cattle and farmed bison herd in which M. bovis infection has been found have been subjected to strict stamping out procedures. All animals found to have been exposed to the infection, both those on the infected farm and those on trace-out or other contact premises, are ordered destroyed. This is followed by the testing of livestock in a surveillance zone around the infected farm, the application of appropriate cleaning and disinfection procedures on the infected farm, and
comprehensive investigations to trace and identify the source of the infection. Compensation is paid for all animals that are ordered destroyed during the investigation of suspect or confirmed cases of bovine TB.

Refer to Table 1 for a summary of findings of bovine TB in farmed bovines (cattle and farmed bison) during the past 10 years.

**Surveillance:** General surveillance of cattle and farmed bison herds is based on routine inspection at slaughter and the collection of granulomatous lesions for laboratory examination, with trace-back investigation and testing for all histopathological diagnoses of mycobacteriosis. In 2008, a total of 556 granulomatous lesions observed at routine slaughter inspection of cattle and farmed bison were submitted to the laboratory for testing. Histopathological and culture examinations of these tissues identified 27 animals infected with a Mycobacterium species that was found not to be *M. bovis*. These included *M. avium* complex, *M. avium paratuberculosis*, *M. terrae* complex, *M. flavescens*, *M. gordonae*, and *M. nonchromogenicum*. No *M. bovis* infection was detected during the slaughter surveillance of farmed bovines in 2008 and to 30 September 2009.

**Targeted on-farm area testing is used to supplement slaughter surveillance:** Area surveillance testing continued around RMNP in Manitoba in 2008 and 2009, an area where 51 bovine TB-infected wild cervids (41 elk & 10 white-tailed deer) have been found since 1997. Since October 2002, surveillance testing has required the periodic testing of cattle and farmed bison in a special eradication established around the park. The Riding Mountain TB Eradication Area (RMEA) consists of two provincial game hunting areas, encompasses approximately 50,000 breeding cattle on 650 farms, and represents approximately 10% of Manitoba's cattle herds and 1% of Canadian cattle herds. All cattle and farmed bison herds in the RMEA undergo periodic testing for bovine TB, with the interval determined by the risk of exposure to diseased wild cervids. From October 2002 through September 2009, approximately 382,000 tuberculin tests of livestock were carried out in the RMEA.

Area surveillance testing in the RMEA involves the screening of animals 12 months of age and older using the intradermal tuberculin test and re-testing of all reactors using a gamma interferon (gIFN) assay. All animals classified as positive on the gIFN assay are required to be slaughtered and tissues are submitted for confirmatory laboratory tests. Animals classified as suspect on the gIFN assay may be retested or slaughtered. However, if the owner elects to retest the animal and it is negative on the gIFN retest, the herd is scheduled for a herd test in the following year. If the animal is classified as suspect on the gIFN retest, it is required to be destroyed and tissues are submitted for confirmatory laboratory testing.

In 2008, a total of 95,167 bovines (89,073 cattle and 6,094 farmed bison) were tuberculin tested in Canada. Surveillance testing of cattle and farmed bison in Canada during 2008 and to September 30 of 2009 detected bovine TB in one beef breed cow located on one farm in the RMEA in Manitoba.
FARMED/CAPTIVE CERVIDS

Eradication: Canada continues to near the complete eradication of bovine TB from farmed/captive cervids, which consist mainly of commercially farmed elk, red deer, elk/red hybrids, fallow deer and white-tail deer. During the first 14 years (1989 through 2002) following extension of the National Bovine TB Eradication Program to include farmed/captive cervids, a total of 37 infected herds were found in five provinces. During the last six years (2003 through September 2009), *M. bovis* infection was confirmed in one (1) herd of farmed cervids, detected in Ontario in 2006.

This infected herd, consisting of farmed elk and red deer, was detected during routine slaughter inspection in Canada. While significant intra-herd spread had occurred, tracing activities found no spread of the infection to other herds. Molecular characteristics of the *M. bovis* organism isolated from this herd indicated that it was an isolate not previously reported in Canada, but one commonly isolated from cervids in New Zealand. The infected herd had been established using elk and red deer imported from New Zealand in 1991. The epidemiological evidence supports a conclusion that the source of the infection found in this herd was latent *M. bovis* infection in one or more elk or red deer, most likely in an animal imported from New Zealand in 1991. This was the first and only finding of bovine TB in the farmed cervid sector in Canada since 1999.

All infected farmed/captive cervid herds detected in Canada since 1990, except one, have undergone complete depopulation of all exposed susceptible animal species. Compartment, quarantine, investigation, trace-out and trace-in, contact and perimeter premises, cleaning and disinfection, and restocking were all carried out in the same manner as for infected cattle and farmed bison herds. The single exception, which occurred in 1993, involved a zoological collection that underwent partial depopulation followed by a 10-year period of quarantine of exposed primates and several endangered species. This was followed by implementation of a further five-year management plan of on-going surveillance, all with no findings of disease.

Refer to Table 2, for a summary of findings of bovine TB in farmed/captive cervids during the past 10 years.

Surveillance: Because relatively few adult farmed/captive cervids are routinely slaughtered, surveillance for bovine TB in this sector has been based on the testing (every three years until 2006 and every five years since January 2006) of all cervid herds involved in the commercial trade of these species. In 2008, a total of 11,613 farmed cervids were tuberculin tested in Canada. No cases of bovine TB were detected in farmed cervids in Canada during this surveillance testing in 2008 and to 30 September 2009.

During 2008, a total of 29 granulomatus lesions observed during routine slaughter surveillance inspection of 10,144 farmed cervids were submitted to the laboratory. Histopathological and culture examinations of these tissues did not identify any cases of *M. bovis* infection. No cases of bovine TB
were detected in farmed cervids in Canada during routine slaughter surveillance of farmed cervids in 2008 and to 30 September 2009.

**BOVINE TB ACCREDITATION STATUS**

**Cattle & Farmed Bison**: Under legislated program standards set out in the *Health of Animals Regulations*, all provinces in Canada, except Manitoba, are classified as bovine TB-free areas for farmed bovines. Under the regulations, the province of Manitoba was assigned split status in January 2003, with the RMEA classified as bovine TB-accredited-advanced and the rest of Manitoba classified as bovine TB-free. In September 2006, the status of the RMEA portion of Manitoba was upgraded to bovine TB-free, resulting in all areas of Canada being classified as bovine TB-free since that time.

All areas of Canada, including the province of Manitoba, are officially free from bovine TB in accordance with Article 2.3.3.2 of the Terrestrial Animal Health Code of the World Organization for Animal Health (OIE).

Table 3. lists the last year in which bovine TB was detected in farmed bovines for each province in Canada.

**Farmed Cervids**: Under legislated program standards set out in the *Health of Animals Regulations*, all provinces in Canada are classified as bovine TB-free areas for farmed cervids. Since 1991, all movements of farmed cervids in Canada, including those in the RMEA, have required a movement permit.

Table 3. lists the last year in which bovine TB was detected in farmed cervids for each province in Canada.

**M. BOVIS IN WILDLIFE**

**Wood Buffalo National Park Area**: Bovine TB (and bovine brucellosis) are endemic in free-roaming herds of approximately 4,500 wood bison in and around Wood Buffalo National Park which straddles the northern boundary between Alberta and the Northwest Territories. Due to their remote location distant from areas of agricultural production, these bison poses the greatest threat to adjacent disease-free wild bison herds. An interim bison management plan includes: no-bison buffer zones; controlled access of livestock to risk areas; the killing of stray bison; and other measures to minimize the risk of disease spread to other wild bison, farmed bison, or cattle.

**Riding Mountain National Park Area**: Since 1998, bovine TB has been known to be present in a free-roaming herd of approximately 2,000 elk in and around Riding Mountain National Park (RMNP), located in the southwestern part of the province of Manitoba. A similar number of elk in Duck...
Mountain Provincial Park & Forest to the north of RMNP are believed to be free of the disease; however, surveillance continues in this population. The Riding Mountain ecosystem is also home to approximately 7,500 white-tailed deer.

To 30 September 2009, bovine TB has been confirmed in 51 wild cervids (41 elk and 10 white-tailed deer) in and around RMNP. The seven cattle herds in Manitoba in which bovine TB has been found since 1997 were all located close to the RMNP boundary or associated with a herd close to the park, with five of these herds located within two kilometres of a positive wild elk or deer.

Of these 51 cases, 18 cases (11 elk and 7 deer) were detected through a hunter-harvest surveillance program targeting animals outside the park, which has screened more than 9,000 animals since 1997.

Thirty (30) cases (28 elk and 2 deer) were detected through a capture, test and removal program that targets animals inside the park and is used to augment hunter-harvest samples as well as to validate blood tests. Under this program, which began in 2003 and has tested more than 900 animals, wild elk and deer are captured, blood samples collected, and a radio-tracking collar attached before the animal is released. Samples are tested using a number of blood tests, including the lymphocyte stimulation test (LST) and a fluorescent polarization assay (FPA). Animals that are positive on one or more tests are tracked using the radio-collar, humanely destroyed and necropsied, and tissues are collected for confirmatory laboratory testing.

A wildlife culling program was commenced in the winter/spring of 2009, wherein wild elk and deer are killed and removed from the western part of RMNP in the area where the vast majority of positive wildlife cases have occurred. This program was responsible for finding the remaining three case (2 elk and 1 deer) of bovine TB.

In response to the identification of bovine TB in wild cervids in the Riding Mountain area, a comprehensive management strategy was implemented in 2000. Its objectives are: surveillance to determine the distribution (geographic and species) and prevalence of the disease in wildlife; prevention of the spread of the infection from wildlife to livestock; and elimination of the disease in wild cervids. The major elements of the program include:

- **On-going surveillance sampling** of wild cervids inside and outside both parks using: regular hunter-harvest samples; passive surveillance of road-kills; special land-owner hunts to augment samples from selected areas; and use of the capture, collar & test program inside both parks, incorporating new diagnostic methods as they become available;

- **Separation of wild cervids from livestock** through: the barrier fencing of forage/feed storage yards to discourage elk and deer from coming onto the farm and to prevent infected elk and deer from contaminating stored forage/feed (by the end of 2009, more than 95% of farms located within 5 kilometres of the RMNP boundary [a total of 160 feed/forage storage yards] ...
will have been fenced); prohibitions on the feeding and baiting of elk or deer; changes to crop insurance programs for hay depredation to encourage owners to remove hay from their fields into fenced areas; the use of livestock guardian dogs to deter wild cervids from interacting with cattle herds; and the barrier fencing of cattle feeding yards on farms where risk assessment findings support doing so.

- **Elk population management** through: increased hunting opportunities outside RMNP, including inside Duck Mountain Provincial Park & Forest; habitat improvement inside RMNP; the selective removal of infected animals through the capture, collar & test program and the culling of elk and deer from the western part of RMNP to further reduce the number of infected and potentially infected animals in the area where positive cases have continued to occur.

Prepared By: Dr. Maria A. Koller-Jones
Senior Staff Veterinarian
Animal Health Directorate
Canadian Food Inspection Agency

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M.Koller-Jones/CFIA   Pg 6 of 10   September 30, 2009
<table>
<thead>
<tr>
<th>Year</th>
<th>Province</th>
<th>No. of Infected Herds</th>
<th>Species/Type</th>
<th>Description</th>
<th>Most Likely Source of Infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>Saskatchewan (SK)</td>
<td>1</td>
<td>cattle/buffalo</td>
<td>detected during routine slaughter in Canada; single lesion in 15-year-old cow from closed herd that was born &amp; continually resided in herd; no intra- or inter-herd spread detected; infected herd &amp; exposed trace-outs depopulated;</td>
<td>residual long-standing latent infection</td>
</tr>
<tr>
<td>2000</td>
<td>N/A</td>
<td>0</td>
<td>N/A</td>
<td>no infected herds detected</td>
<td>N/A</td>
</tr>
<tr>
<td>2001</td>
<td>Manitoba (MB)</td>
<td>1</td>
<td>cattle/buffalo</td>
<td>detected during area surveillance testing initiated around Riding Mt. National Park following finding of bovine TB in a wild elk; no intra- or inter-herd spread detected; infected herd &amp; exposed trace-outs depopulated; molecular typing of isolate identical to isolates from surrounding wild cervids;</td>
<td>exposure to infected wild elk/Deer</td>
</tr>
<tr>
<td>2001</td>
<td>Alberta (AB)</td>
<td>1</td>
<td>mixed/bison/cervids</td>
<td>detected during routine slaughter in Canada; 20-year-old bison bull purchased from zoo in Quebec in 1997; no intra- or inter-herd spread detected; infected herd &amp; exposed trace-outs depopulated;</td>
<td>zoological collection in Quebec believed to have been infected in early 1980s at time of birth of index animal</td>
</tr>
<tr>
<td>2002</td>
<td>Ontario (ON)</td>
<td>1</td>
<td>cattle/DB dairy</td>
<td>detected during investigation of clinical disease in 7-month-old Jersey calf born in infected herd which had been closed herd for at least 10 years; significant intra-herd spread observed; no inter-herd spread found; infected herd &amp; exposed trace-outs depopulated; also partial depopulation of 1 exposed herd in ON;</td>
<td>residual long-standing latent infection</td>
</tr>
<tr>
<td>2003</td>
<td>Manitoba (MB)</td>
<td>3</td>
<td>cattle/buffalo</td>
<td>detected during area surveillance testing of newly established Riding Mt. National Park; no inter-herd spread detected; all 3 infected herds &amp; exposed trace-outs depopulated; partial depopulation of 1 exposed herd in MB; molecular typing of all isolates identical to isolates from surrounding wild cervids;</td>
<td>exposure to infected wild elk/Deer; each of 3 cattle herds appear to have been independently infected</td>
</tr>
<tr>
<td>Year</td>
<td>Province</td>
<td>No. of Infected Herds</td>
<td>Species/Type</td>
<td>Description</td>
<td>Most Likely Source of Infection</td>
</tr>
<tr>
<td>------</td>
<td>----------</td>
<td>-----------------------</td>
<td>--------------</td>
<td>-------------</td>
<td>--------------------------------</td>
</tr>
<tr>
<td>2004</td>
<td>Manitoba (MB)</td>
<td>1</td>
<td>cattle dairy</td>
<td>detected during routine slaughter inspection in Canada; no inter or intra-herd spread detected; infected herd depopulated &amp; exposed trace-outs depopulated; herd established in 2002 from several sources including large number of animals from dispersal of dairy herd located in vicinity of Riding Mtn National Park; molecular typing of isolate supported epidemiological findings that dispersed herd was source of infection</td>
<td>exposure to infected cattle or infected wild elk/deer in Riding Mtn area</td>
</tr>
<tr>
<td>2005</td>
<td>N/A</td>
<td>0</td>
<td>N/A</td>
<td>no infected herds detected</td>
<td>N/A</td>
</tr>
<tr>
<td>2006</td>
<td>N/A</td>
<td>0</td>
<td>N/A</td>
<td>no infected herds detected</td>
<td>N/A</td>
</tr>
<tr>
<td>2007</td>
<td>British Columbia (BC)</td>
<td>1</td>
<td>cattle beef</td>
<td>detected during routine slaughter in Canada; single lesion in 4-year-old bull; no intra- or inter-herd spread detected; infected herd &amp; exposed trace-outs depopulated; birth herd of index bull, from which animal was sold at one year of age, underwent extensive testing with no evidence of infection found; tracing &amp; testing of possible source herds continued; molecular typing of isolate indicates infection did NOT originate from any known wildlife reservoir in Canada</td>
<td>residual long-standing latent infection</td>
</tr>
<tr>
<td>2008</td>
<td>Manitoba (MB)</td>
<td>1</td>
<td>cattle beef</td>
<td>detected during area surveillance testing of Riding Mtn TB Eradication Area; no intra- or inter-herd spread detected; infected herd &amp; exposed trace-outs depopulated; molecular typing of isolate identical to isolates from surrounding wild cervids;</td>
<td>exposure to infected cattle or infected wild elk/deer in Riding Mtn area</td>
</tr>
<tr>
<td>2009 to 30 Sept</td>
<td>N/A</td>
<td>0</td>
<td>N/A</td>
<td>no infected herds detected</td>
<td>N/A</td>
</tr>
</tbody>
</table>
### Table 2:

**Summary of Findings of Bovine TB in Farmed Cervids: January 1999 through Sept. 2009**

<table>
<thead>
<tr>
<th>Year</th>
<th>Province</th>
<th>No. of Infected Herds</th>
<th>Species/Type</th>
<th>Description</th>
<th>Most Likely Source of Infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>Ontario (ON)</td>
<td>1</td>
<td>elk</td>
<td>detected during diagnostic investigation of cervid that died; intra herd spread observed; infected herd &amp; exposed trace-outs depopulated; no inter herd spread detected; molecular typing of isolate indicated it is same as 1996-97 isolates from farmed cervids in Quebec &amp; 1999 isolate from zoological collection in Quebec;</td>
<td>Intact infection in one or more farmed cervids;</td>
</tr>
<tr>
<td></td>
<td>Quebec (QC)</td>
<td>1</td>
<td>elk, red deer, hybrids</td>
<td>detected during routine slaughter inspection in Canada; intra herd spread observed; infected herd &amp; exposed trace-outs depopulated; no inter herd spread detected; molecular typing of isolate indicated it is same as isolates found in outbreak that occurred in farmed cervids in Ontario from 1990-94;</td>
<td>Intact infection in one or more farmed cervids;</td>
</tr>
<tr>
<td>2000</td>
<td>N/A</td>
<td>0</td>
<td>N/A</td>
<td>no infected herds detected</td>
<td>N/A</td>
</tr>
<tr>
<td>2001</td>
<td>N/A</td>
<td>0</td>
<td>N/A</td>
<td>no infected herds detected</td>
<td>N/A</td>
</tr>
<tr>
<td>2002</td>
<td>N/A</td>
<td>0</td>
<td>N/A</td>
<td>no infected herds detected</td>
<td>N/A</td>
</tr>
<tr>
<td>2003</td>
<td>N/A</td>
<td>0</td>
<td>N/A</td>
<td>no infected herds detected</td>
<td>N/A</td>
</tr>
<tr>
<td>2004</td>
<td>N/A</td>
<td>0</td>
<td>N/A</td>
<td>no infected herds detected</td>
<td>N/A</td>
</tr>
<tr>
<td>2005</td>
<td>N/A</td>
<td>0</td>
<td>N/A</td>
<td>no infected herds detected</td>
<td>N/A</td>
</tr>
<tr>
<td>2006</td>
<td>Ontario (ON)</td>
<td>1</td>
<td>elk, red deer, hybrids</td>
<td>detected during routine slaughter inspection in Canada; intra herd spread observed; infected herd &amp; exposed trace-outs depopulated; one exposed herd also depopulated, with no evidence of inter herd spread detected; molecular typing of isolate indicate it is an isolate not previously reported from any farmed species in Canada; herd established in part with elk &amp; red deer imported from New Zealand in 1991;</td>
<td>Intact infection in one or more farmed cervids, most likely in cervids imported into North America from New Zealand in 1991</td>
</tr>
<tr>
<td>2007</td>
<td>N/A</td>
<td>0</td>
<td>N/A</td>
<td>no infected herds detected</td>
<td>N/A</td>
</tr>
<tr>
<td>2008</td>
<td>N/A</td>
<td>0</td>
<td>N/A</td>
<td>no infected herds detected</td>
<td>N/A</td>
</tr>
<tr>
<td>2009 to 30 Sept</td>
<td>N/A</td>
<td>0</td>
<td>N/A</td>
<td>no infected herds detected</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Table 3:

**Bovine TB Status of Canadian Provinces and Year Last Case Detected in Livestock**

<table>
<thead>
<tr>
<th>Province or Part of Province</th>
<th>TB Status 1; Farmed Bosvines</th>
<th>Last Case Detected: Farmed Bosvines</th>
<th>TB Status 1; Farmed Cervids</th>
<th>Last Case Detected: Farmed Cervids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newfoundland</td>
<td>TB-free</td>
<td>1978 (cattle)</td>
<td>TB-free</td>
<td>never detected</td>
</tr>
<tr>
<td>Nova Scotia</td>
<td>TB-free</td>
<td>1973 (cattle)</td>
<td>TB-free</td>
<td>never detected</td>
</tr>
<tr>
<td>Prince Edward Island</td>
<td>TB-free</td>
<td>1987 (cattle)</td>
<td>TB-free</td>
<td>never detected</td>
</tr>
<tr>
<td>New Brunswick</td>
<td>TB-free</td>
<td>1985 (farmed bison)</td>
<td>TB-free</td>
<td>never detected</td>
</tr>
<tr>
<td>Quebec</td>
<td>TB-free</td>
<td>1994 (farmed bison)</td>
<td>TB-free</td>
<td>1999</td>
</tr>
<tr>
<td>Ontario</td>
<td>TB-free</td>
<td>2002 (cattle)</td>
<td>TB-free</td>
<td>2006</td>
</tr>
<tr>
<td>Rest of Manitoba*</td>
<td>TB-free</td>
<td>2004 (cattle)</td>
<td>TB-free</td>
<td>never detected</td>
</tr>
<tr>
<td>RMEA*</td>
<td>TB-free</td>
<td>2008 (cattle)</td>
<td>TB-free</td>
<td></td>
</tr>
<tr>
<td>Saskatchewan</td>
<td>TB-free</td>
<td>1999 (cattle)</td>
<td>TB-free</td>
<td>1994</td>
</tr>
<tr>
<td>Alberta</td>
<td>TB-free</td>
<td>2001 (farmed bison)</td>
<td>TB-free</td>
<td>1993</td>
</tr>
<tr>
<td>British Columbia</td>
<td>TB-free</td>
<td>2007 (cattle)</td>
<td>TB-free</td>
<td>1990</td>
</tr>
</tbody>
</table>

1  
**tuberculosis status according to the requirements set out in the Health of Animals Regulations**

*  
In January 2003, for the purpose of conducting surveillance and ascribing area status, the province of Manitoba was split into two eradication areas: the Riding Mountain TB Eradication Area (RMEA) which surrounds Riding Mountain National Park, and the rest of Manitoba.