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The Committee met on October 4, 2011 at the Adam’s Mark Hotel in Buffalo, New York, from 1:00 p.m. to 5:30 p.m. There were 90 members and 64 guests present.

Dr. William Hartmann, State Veterinarian and Executive Director of the Minnesota Board of Animal Health, welcomed members and guests to the Committee on Tuberculosis. Dr. Hartmann introduced the Vice-Chair, Dr. Dustin Oedekoven, South Dakota State Veterinarian. Dr. Hartmann then introduced Dr. David Fly, State Veterinarian from New Mexico. Dr. Fly announced that New Mexico’s TB status was upgraded and published in the Federal Register this morning; New Mexico is now TB-free. Additionally, Dr. Hartmann announced the upgrade in status for Minnesota, also to TB free.

Dr. Hartmann explained that due to time constraints, state reports would be in written format only. The state reports are included in this Committee report. The program was turned over to Dr. Oedekoven.

Dr. Oedekoven introduced Dr. Dan Grooms. Dr. Grooms presented on his Time Specific Paper, “Validity of the Bovine TB Gamma Interferon Assay on Blood Collected After Exsanguinations.” Dr. Grooms is with the Department of Large Animal Clinical Sciences, College of Veterinary Medicine, Michigan State University. The paper’s abstract is included in its entirety in this report.

The Time Specific Paper was followed by a report of Scientific Advisory Subcommittee by Dr. Mitchell Palmer, the Chair of that Subcommittee. The Subcommittee met on October 3, 2011. The Subcommittee submitted its report to the TB Committee for acceptance.

A motion was made to accept report of the Scientific Advisory Subcommittee. There was a second. The motion was passed. The report of the Scientific Advisory Subcommittee is included at the end of this report.
The Scientific Advisory Subcommittee report was followed by the report of the Bi-national TB Committee, presented by Dr. Chuck Massengill, Co-chair. The report of the Subcommittee is included at the end of this report.

The Bi-national TB Committee report was followed by the Report of the Elephant TB Subcommittee, also given by Dr. Chuck Massengill, a member of that committee. The Elephant TB Subcommittee report is included at the end of this report.

Dr. Massengill’s report was followed by Dr. Alecia Naugle, National Tuberculosis Program Manager, USDA, APHIS, VS. Dr. Naugle presented an Update on the National Tuberculosis Program. The report, The Annual Update for the State and Federal Cooperative, Bovine Tuberculosis (TB) Eradication Program, is included in this report.

Dr. Naugle’s report was followed by Dr. José Alfredo Gutiérrez Reyes, Director, Animal Health Programs, SAGARPA/SENASICA who gave the Mexico National Tuberculosis Report.

Dr. John R. Clifford, Deputy Administrator and Chief Veterinary Officer for APHIS’ Veterinary Services made comments after the break. Dr. Clifford discussed indemnity for TB infected herds.

After Dr. Clifford’s remarks, the following six presentations were part of a follow up to the USAHA meeting held in Denver, Colorado in 2009, “The Future of the National Tuberculosis Program.”

Dr. LeeAnn Thomas, Director of Ruminant Health Programs for USDA, APHIS, VS addressed Modernizing Regulations. Dr. Thomas’ presentation is included in this report as The Annual Update for the State and Federal Cooperative, Bovine Tuberculosis (TB) Eradication Program.

After Dr. Thomas’ presentation, Dr. Elizabeth Parker, National Cattlemen’s Beef Association, presented on Importation of Infected Cattle.

Following Dr. Parker’s presentation, Dr. Kurt VerCauteren, Supervisory Research Wildlife Biologist from the National Wildlife Research Center presented on Wildlife Associated Disease Transmission. Dr. VerCauteren’s report, Wildlife Associated Disease Transmission: Follow up to “The Future of the National Tuberculosis Program” USAHA meeting in 2009, is included in this report.

After Dr. VerCauteren’s presentation, Dr. Mitch Palmer, Infectious Diseases of Livestock Research Unit of the National Animal Disease Center presented on Diagnostic Testing Limitations and Needs. Dr. Palmer’s report is included in this.

Based on Dr. Palmer’s presentation, Dr. Hartmann appointed a Subcommittee to amend the document, Evaluating the Experimental TB Test Performance for Official Test Status. The Subcommittee includes the following persons: Larry Ludeman, Alecia Naugle, Ray Waters, Dustin Oedekoven, James Averill.

Following Dr. Palmer’s report, Dr. Aaron Scott, Director, National Surveillance Unit, USDA, APHIS, VS reported on Surveillance, Traceability and Investigative Deficiencies. Dr. Scott’s report is included in this report.

Following Dr. Scott’s report, Dr. Robert Ehlenfeldt, State Veterinarian from Wisconsin and Dr. Susan Keller, State Veterinarian, North Dakota, reported on the Disease Control Approach. Their report is included in this report.

At the conclusion of formal presentations, Dr. Hartmann determined there was a quorum.

Three resolutions were approved and forwarded to the Committee on Nominations and Resolutions. Topics included quarantine release procedures for TB infected herds, the Cervid TB Stat-Pak and a multi-state initiative for mycobacterial diseases of animals.

Dr. Massengill reported on a response received from USDA-APHIS-Animal Care regarding 2010 Resolution 36, “Elephant Tuberculosis Guidelines”. The response is as follows:
“USDA-APHIS-AC intends to utilize the 2010 guidelines after following a transparent process that includes notification of stakeholders and development of an implementation plan.”

The Committee adjourned at 5:30 p.m.
Arizona was declared free of bovine tuberculosis since 1978. Free status was temporarily suspended due to an incident in 1979, but was reinstated in 1981 after prompt elimination of the disease. In early June 2011, the Arizona Department of Agriculture announced a single steer in a Pinal County rodeo stock operation had tested positive for bovine tuberculosis. The affected steer had been recently imported into the state from Mexico, and had tested negative for TB at the time of importation. The positive diagnosis was determined when the steer was retested to meet another state’s entry requirements. The event steer operation of 332 was depopulated, and no animal tested positive on post-mortem examination.

California Gained Bovine TB Free Status in 1999

- April 2003 - lost “Free Status” when bovine TB was confirmed in three dairy herds in the central valley
- Depopulated affected herds, traced and tested associated cattle
- April 2005 – California regained “Free Status”
- December 2007 - bovine TB detected again in a dairy cow through routine slaughter surveillance
- May 2008 - two associated herds confirmed, for a total of three affected dairies in Fresno Co.
- September 2008 – California downgraded to Modified Accredited Advanced (MAA)
- January 2009 - fourth affected herd identified in San Bernardino Co.
- Two herds were depopulated (5,000 & 1,000 cattle), two herds were released per “test & removal” plan
- Traces ~21,000 cattle in ~659 investigations, and tested ~419,000 cattle in ~254 herds (310 separate herd tests)
- Detected a total of 8 infected cows with three different M. bovis genotypes.

2011 TB Investigations

- March 2011 - M. bovis cultured from a granuloma collect during slaughter surveillance
- Genotype is unique to U.S. cattle but matches three Mexican isolates in NVSL database
- No human genetic matches found in CDC database
- Granuloma traced back to cow slaughtered 1-29-2011, sold at auction Dec 2010, from dairy herd in Southern California
- Test >5,000 adult cattle in trace herd, 82 CFT responders, necropsy 4 gamma reactors; 3/4 had lesions compatible with TB and 3/3 cultured M. bovis
- Depopulate, clean and disinfect holding facility used for feeding cow for a month
- Detected 2 additional culture positive cows when removed remaining CFT+/Gamma negative animals
- Affected herd quarantined and TB model generated a “Test and Removal Plan” for 3 geographically separated groups: main herd requires three additional 60 day tests (last two must be negative), a 6 month test, then a test every 12 months for 5 years; young stock (no infection detected) require two negative 60 day tests, a 6 month test, then a test every 12 months with adult herd; purchased young stock (no infection detected) require a 60 day CFT and parallel gamma test, and a 6 month retest.
- Results of the first 60 day retest:  tested >6,500 cattle, 146 CFT responders removed, 6 were gamma reactors, 2 cultured M. bovis
- All 7 cultures match genotype of index cow.
- Traced movements out of herd back 5 years (>9,000 cattle)
  - In California to 5 auctions (~5, 000 slaughter cattle), 3 slaughter buyers, 26 CA dairies (1,200 cattle), 2 calf feeders (2,196 cattle), 6 dealers (403 cattle), 38 “back-yard” traces (280 cattle)
  - OOS: 1 dairy, 1 auction, 1 slaughter plant, 1 other
- Traced movements into herd back 5 years (~1,700 cattle)
  - 8 dairies (1,300 cattle), 2 heifer raiser, 24 others (untraceable, dealer, backyard)
- Tested 12 trace herds: 14,022 cattle tested, 1.40% CFT response rate
- Feral cats trapped and tested on affected premises – all negative
- To date ~367 cattle slaughtered/necropsied with culture - no spread of infection to other herds
Sept. 2011: M bovis culture positive granuloma from slaughter surveillance

- Cow slaughtered July 2011, testing herd of origin
- Genotype unique – not match any prior U.S. herds, match a Mexican isolate in NVSL database
- >2,700 cattle tested in trace herd, 142 CFT responders, 37 gamma reactors to be removed

Indiana

- Indiana has investigated four (4) head of cattle with lesions of bovine tuberculosis since November 2008. The origin of each of the animals has been extensively researched, and herd tests were conducted on all herds associated with the traces. The four head of cattle were determined to be of beef breeds and none of the animals were genetically related. Although the investigation is focused in the southeastern portion of the state, the traces have not been linked epidemiologically. The spoligotyping determined that the bovine tuberculosis in these cases was all of the “cervid” type.

- The first case was a beef cow found to have lesions consistent with bovine tuberculosis at a slaughter plant in Pennsylvania in November 2008. A backtag was collected from the cow at slaughter. A test of the Indiana herd of origin and all adjacent herds determined the herds to be negative. A cervid herd of mixed species existed less than one mile from the trace herd, and it was found to be bovine tuberculosis positive when several red deer were sold to slaughter in the spring of 2009. The red deer were slaughtered at an Indiana state-inspected meat plant where appropriate tissue samples were collected to determine the bovine tuberculosis diagnosis. The cervid herd was depopulated in July 2009. All cattle herds within three miles of this affected site were tested and found negative for bovine tuberculosis. Additionally, wild white-tailed deer in the area around the affected site were harvested in August 2009, and all of the deer were found to be negative for bovine tuberculosis. Two sites that had recently purchased red deer from the affected site were also depopulated. The only positive animals found on these two additional sites were those purchased from the affected cervid herd. Wild white-tailed deer surveillance was established around all three sites during the hunting season.

- The second and third cases were associated with fed cattle found to be positive for bovine tuberculosis after tissues were collected at a slaughter plant in Pennsylvania. Neither of the two animals had identification collected at slaughter. These positive animals were shipped from an Ohio livestock market, and Ohio state and federal animal health officials advised Indiana in July 2010 that seven Indiana farms could have contributed to the loads. All seven of these farms were investigated, and the sites with cows were tested and found to be negative. The sites that were feedlots were restricted to sales to slaughter only, and the origin of their feeder cattle was determined. Herds that contributed feeder cattle to these sites or to feedlots in Ohio were tested. All tested herds were found to be negative for bovine tuberculosis.

- The fourth case was a beef cow slaughtered at a packing plant in Michigan. No identification was collected from the cow. The consignors that made up the load of cows slaughtered at the plant were evaluated and six Indiana farms were tested. One of the tested herds was determined to be positive for bovine tuberculosis and the herd was depopulated in April 2011. All adjacent herds were tested and found to be negative for bovine tuberculosis. Twenty-six (26) Indiana farms were quarantined and tested after exposed animals were removed from the herds. These exposed animals had been purchased from the affected herd, and they were all subjected to an intensive inspection either at the Animal Disease Diagnostic Laboratory (ADDL) at Purdue or at a state-inspected meat facility. All of the exposed animals were determined to be negative for bovine tuberculosis. Additionally, 76 traces were sent to other states as a part of the investigation. Wild white-tailed deer and small mammals were harvested from the affected site, and all of these animals were found to be negative for bovine tuberculosis. The range of the wild white-tailed deer hunter –harvested surveillance will be expanded because of this additional affected herd.

- Indiana has received exceptional cooperation from the cattle industry, the state-inspected meat plants as well as the veterinary community throughout these investigations.

Michigan
Livestock

Michigan has been involved in the control and eradication of bovine tuberculosis (TB) since the finding of TB in a free-ranging white-tailed deer in 1994. Since that time, the State of Michigan, along with USDA and the cattle industry have been working statewide to identify areas of disease risk and
confirming areas where the risk is negligible. In instances where the disease has occurred, strict controls to prevent the movement of the disease through quick and thorough responses are conducted.

- Due to the work of thousands of producers and disease eradication personnel, on September 14, 2011, Michigan was granted TB Free status for the majority of Lower Michigan (the entirety of the Upper Peninsula was granted TB Free status in October 2005). A 7-county area of northwestern Michigan is designated as Modified Accredited Advanced. The 4-county area of northeastern Lower Michigan which contains over 92% of all TB found remains at Modified Accredited Status and continues to be the focus of intensive control and eradication activity.

- The TB program in the Modified Accredited Zone (MAZ) includes RFID identification of animals, annual surveillance testing, animal movement testing, movement certificates, compliance and enforcement activities at livestock saleyards and through monitoring of herd inventories, and mobile patrols along zonal boundaries. Much of the program is the same in the Modified Accredited Advanced Zone (MAAZ) except that surveillance activities include whole herd testing at an interval that is consistent with the marketing risk that a herd poses: herds selling breeding animals are tested annually, feeder cattle producers are tested every two years, and feedlots are tested every three years.

- During the time period September 2010 – August 2011, the following TB testing was conducted:

<table>
<thead>
<tr>
<th>Zone</th>
<th>Number of Animals on WHT</th>
<th>Number of Animals on MVMT test</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAZ</td>
<td>18,341</td>
<td>2,799</td>
</tr>
<tr>
<td>MAAZ</td>
<td>12,018</td>
<td>508</td>
</tr>
<tr>
<td>TB Free</td>
<td>14,102</td>
<td>15,030</td>
</tr>
</tbody>
</table>

- During this same time period movement tracking included 34,166 animals to and from farms in the MAZ and MAAZ.

- An innovative project focusing on reducing the risk of transmission of TB from wildlife to cattle was started in 2009 and is in the final stages of completion. This project requires herds to manage their herd in a way that reduces the risk that stored feed, feeding and watering sites, and pasture locations will serve as a source of transmission of the disease from deer. Over 800 of the 1,000 herds located in the MAZ and MAAZ areas of Michigan have entered the project. Beginning January 1, 2012 animals sold from herds in these areas that are not wildlife risk mitigated will require post-movement TB testing at owner expense.

- Since 1998 there have been 52 instances of a cattle herd being found to be infected with bovine tuberculosis (43 in the MAZ and 9 in the MAAZ). Through whole herd surveillance testing during Fiscal Year 2011, two (2) TB infected herds were identified. Both herds were located within the MAZ and have completed depopulation. No evidence of transmission of TB to any other herds was identified following thorough investigation.

### Wildlife

- Since 1994, the state of Michigan has recognized a problem with *Mycobacterium bovis* in free-ranging white-tailed deer from a 14-county area in northeastern Lower Michigan. In 2010, surveillance activities for *M. bovis* continued, with an emphasis on the 5-county area of Alcona, Alpena, Montmorency, Oscoda and Presque Isle counties in the northern half of the Lower Peninsula. There was also increased surveillance in a 10-mile radius around positive deer in Cheboygan, Emmet, losco and Shiawassee. Twenty-four (24) white-tailed deer cultured positive from 4,946 deer submitted for testing.

- Since the index cases were first identified, over 188,977 free-ranging deer have been tested for bovine tuberculosis and 687 infected deer have been found. Increasingly, the spatial epidemiology of the disease is revealing a highly focal, clustered pattern. Approximately 96% of all positive deer identified to date originated from a 5-county area. Moreover, within that area, the vast majority of positive deer were from Deer Management Unit (DMU) 452. Even within DMU 452, the spatial arrangement of cases is highly clustered, in spite of the fact that sampling effort has been relatively uniform geographically.

- White-tailed deer are the maintenance host and primary reservoir for TB in the Michigan outbreak. If eradication is to be achieved, control strategies must focus on the disease in deer. Strategies for eradication of TB from Michigan wildlife continue to focus on

1) reducing deer population densities to biological carrying capacity and 2) reducing artificial congregation of deer by restriction or elimination of baiting and feeding. These strategies have been implemented through provisions of a late firearm antlerless deer season, sufficient
antlerless deer licenses to reduce the deer population, and by prohibition of deer baiting and feeding.

- Population estimates based on reconstruction techniques similar to the sex–age–kill method described by Creed et al. (1984) suggest that the deer population in the 5-county area has declined approximately 39% since 1995 (161,415 to 99,148).
- The achievement of this substantial population reduction highlights the critical role that hunters have played in the control of TB in Michigan. Nonetheless, persistent focal areas of high density on private land remain problematic. Baiting and feeding have been prohibited in the seven counties from which 97% of all TB positive deer have originated. The overall scope of feeding has declined dramatically since 1997, with large scale feeding largely a thing of the past. While some illegal baiting and feeding continues to occur, the size of these sites is substantially reduced, and it is hoped that heightened enforcement is expected to reduce the practice further over the next several years.
- While much work remains, substantial progress has been made towards eradication of TB from Michigan wildlife. Apparent prevalence in the core area of the outbreak Deer Management Unit (DMU) 452 was 1.8% in 2010. Trend analysis of prevalence data from 1995 to 2010 indicates a statistically significant decreasing trend. However, prevalence and transmission rate have been flat for the last seven years.
- The intervention strategies have been successful in bringing down the average prevalence in DMU 452; however, there are clusters of disease that will be more difficult to manage. The Michigan Department of Natural Resources is working with USDA researchers in Ames, Iowa to develop a TB vaccine for use in free-ranging deer. Preliminary results are encouraging and the vaccine appears to give some protection from disease. Vaccinated groups of deer given the vaccine orally or subcutaneously and then challenged with *M. bovis* had statistically significantly fewer visible TB lesions and less severe TB lesions than unvaccinated deer.
- In summary, Michigan is showing progress in eradicating bovine TB from its free-ranging deer population. However, this success is fragile and we need to be diligent in maintaining our control strategies.

**Minnesota**

Minnesota received an upgrade in status on October 1, 2010. The majority of the state is TB-free, with a small zone in northwestern Minnesota at Modified Accredited Advanced (MAA). Since the upgrade, movement regulations, testing requirements and official identification requirements remain in place for the MAA zone. All herds in the zone receive a yearly whole herd test and a 60-day test for breeding cattle moving out of the herd. Permits are required for both movements of cattle into and out of these herds, and a movement certificate must accompany the cattle moving out of the zone. Producers also continue to track their inventories.

In early May 2011, the Board of Animal Health requested an upgrade in status to TB-free for the entire state, and a documentation review by a USDA team followed. Publication is pending for the interim rule that will reclassify Minnesota to TB-free.

After the upgrade in status, the Board will continue enforcement of the majority of regulations that are in place for the Management zone, that zone within the MAA zone where the TB positive wild white tail deer have been found. The Minnesota Department of Natural Resources has agreed to continue surveillance testing in the wild white tail deer population for a period of five years after the last TB positive deer. The Board will continue with the movement, testing and official identification requirements for the producers in that zone for the period of DNR surveillance.

**New Mexico**

New Mexico has been free of bTB for five years.

A USDA review team examined the New Mexico Bovine Tuberculosis program in June 2011. Based on the review findings, the team has recommended that the Bovine Tuberculosis MAAZ encompassing Curry and Roosevelt Counties (NMLB inspection district 13) be removed.

The State of New Mexico will be classified as Bovine Tuberculosis free.

It is anticipated the rule will be published on or around October 1, 2011.

**Ohio**

- Herd at peak of 2200 cattle in January 2009
Prior to April 2010, all cattle removed from herd went to slaughter
April 2010 – herd went into receivership
401 cattle sold to Wisconsin – some moved on to Minnesota
64 cattle sold to OH producer
662 cattle tested for movement to IN – 3 suspects on CCT
Bank wanted to necropsy 3 head and send rest to slaughter - Bank did not want to operate under quarantine
Of the 3 necropsied, 2 were negative, 1 positive
Sprangers/cows purchased from Kansas (1711 head), IN (439 head), and OK (100 head)
Positive cow’s ID traced to Kansas dairy
KS verified cow came from NM, where she tested negative for TB prior to movement
Calves were not traced out in this investigation
Facility cleaned & disinfected in August 2010
October 2010 – farm sold and began operating under the name Flatland Dairy

**Dairy 2**
- Repopulation began in January – all animals required to have a negative TB test and permit
- Herd re-tested in August 2011, approx. 2300 animals
- 4 suspects necropsied; NGL & neg histopath; quarantine released September 2011

**Dairy 3**
- All 64 head identified and sent to slaughter; no further cases
- Whole-herd tested via CFT (4800 head)
- 353 suspects tested with Bovigam
- 49 positives on first test; 24 positive on second Bovigam
- 24 reactors moved to slaughter in November 2010
- All were histopath and culture negative
- Quarantine released January 19, 2011

**Producer Group, Eaton, OH**
- 7 owners from Ohio
  - One was a feedlot
    - 2 Ohio owners provided animals to the feedlot
  - One farm was excluded by carcass weight
  - Remaining farms were tested
    - 658 head tested neg between 7/29/2010 and 9/23/2010
- Potential sources of animals to Ohio and Indiana feedlots needed to be identified
- Returned to UPI Eaton for additional records
- Reviewed records to determine if animals listed on the receipts could reach carcass wt.
  - Purchase weights too low to reach wt.
- Returned to UPI Eaton to obtain records from 2009
- 70 receipts were of interest
- 20 receipts eliminated
  - Based on weight, sex and color
- Remaining receipts involved 17 farms
  - 7 resulted in dead ends
    - Craig’s list, source not determined, etc.
  - 10 herds identified as needing testing
- 1 herd sold out
- 3 herds not genetically related

**Trace herd**
- December 17, 2010 - Ohio notified of PCR-positive on submission from JBS Packerland, Michigan
  - Cow was one of 36 in load; No ID; Hot weight was 868#
  - MI ruled out 20 cattle based on weights
  - Probable Angus or possibly Chianina cross
  - Load originated from Egbert Livestock in OH
  - Egbert assembled cattle from 2 IN dealers and 2 IN markets
  - IN narrowed investigation to 6 IN herds and 1 OH herd
• OH herd – 35 head tested negative (one suspect – neg CCT)
• IN herds
  • 5 herds – 150 head tested negative (5 suspects – neg on Bovigam)
  • Trace herd – 100 cattle tested
    • 6 suspects – 5 positive on Bovigam; went to necropsy
    • On necropsy, 4 of 5 had lesions compatible with TB
    • Feb 25 – IN notified that 3 of 4 cows had positive PCR
• April 2011 – IN began sending traces to OH/WV
  • Some lacked ID, number of cattle, breed (expected to have Limousine, Limflex, and Angus cattle)
• 17 OH/WV traces for 37 animals
  • Slaughtered before investigation started – 4 premises/6 animals
  • Sold/transferred to other states – 3 premises/11 animals
  • Indemnity paid – 9 premises/19 animals
  • Unable to find animal – 1 premises/1animal
  • 10 herds tested/257 animals

| Personnel | Federal | $136,709 |
| Travel | $24,388 |
| Indemnity | $111,908 |
| Misc | $8,129 |
| Total | $281,135 |

Nebraska
Fallow Deer & Elk Herd in Knox County
TB was confirmed in a fallow deer and elk herd in Knox County in March 2009. The entire herd was depopulated the first week of June, 2009, with 60% of the elk, and 60% of the fallow deer showing visible lesions compatible for TB. Final culture results from the USDA APHIS NVSL showed approximately 70% of the elk and the fallow deer, cultured positive for M. bovis, even those with no visible lesions.

Cattle Herd in Rock County
In May 2009, an affected cattle herd in north-central Nebraska was detected by means of a slaughter trace of a cull cow. (The spoligotype of this M. bovis organism was different than the cervid herd and labeled a “south west” or Mexican strain) Subsequently, a whole herd test revealed one additional cow to be positive for TB. We had hoped that the index herd of approximately 800 cows would be depopulated, but USDA-VS declined. The finding of this herd resulted in the epidemiological testing of approximately 22,000 head of cattle from 61 different herds in 20 counties (39 were across the fence contacts, and 22 involved trace-in/trace-outs).

Fortunately, no more infected cattle associated with the index herd were found. The index herd was evaluated by a CEAH model, which determined that a test and removal protocol would be implemented to release quarantine. After a total of four whole herd tests (including 2 whole herd gamma tests) 60+ days between each test, plus euthanasia and post mortem of over 100 responders, the quarantine was released in March 2010. Another whole herd assurance test was completed in March 2011, with all animals testing negative.

Cattle from South Dakota
In January 2009, a 20–month old fat heifer that was slaughtered in Schuyler, NE, was found to be positive for TB. The only ID was a back tag that showed she was from a feedlot in Yankton County, South Dakota. By process of elimination, South Dakota traced her to a herd of origin near Irene, SD. Unfortunately they weren’t able to test that herd until December 2009, and we were notified in January 2010 of possible trace backs to Nebraska.

Continued testing in South Dakota revealed four more positive animals, and all five were part of a group of 189 heifers that had entered the South Dakota herd in February 2008. Many of these animals had been sold through the Bassett Livestock Market and originated from 4 Nebraska herds, with a 5th herd having summer grazing fence line contact with the infected herd in SD.

All five herds were quarantined and all tested negative for TB.

Trace outs from the South Dakota infected herd revealed 5 northeast Nebraska herds that had purchased heifers from the South Dakota herd. Those herds were also quarantined and tested. The cows that had been purchased from the infected herd were euthanized and examined for TB lesions.
Unfortunately, one of the purchased cows was found to be positive for *M. bovis*. This gave us a second TB positive beef herd in Nebraska. That herd was depopulated and no more infected animals were found. There were 8 fence line contact herds, and all of them have been tested negative. Testing around the Nebraska herd with the infected South Dakota animal amounted to another 3,000+ head of Nebraska beef cattle that had to be tested.

**Wild Deer Surveillance**

The spoligotype of the *M. bovis* from the South Dakota herd is the same as the spoligotype of the positive cervid (deer and elk) herd. In May 2009, Nebraska Game and Parks collected and sampled 42 wild white-tailed deer within 2 miles of the location of the cervid herd. Head lymph nodes (parotid, retropharyngeal and mandibular) were collected and examined for TB lesions, but no lesions were found.

A much larger sample encompassing Knox and Cedar counties was collected during the hunting season in the Fall of 2010. The head lymph nodes from 487 deer were examined. Nodes from 12 deer with suspicious lesions were submitted to NVSL for histopathology and culture. The histopath results were negative. For the other 475 deer, 95 pooled samples (5 deer / sample) were submitted for culture. All culture results were negative. In addition, lymph nodes from 1,098 deer were collected without examination of the animal. These nodes were examined for lesions and any suspicious nodes were examined histopathologically. All were negative.

We have completed surveillance of possible wildlife-exposed cattle herds within a 2 mile radius of the infected elk herd pasture. Seventeen herds were quarantined and all have been released after testing negative.

**Dairy Herd Testing**

In February and March 2010, NDA conducted TB testing on 3 dairies in Nebraska. This work was done based on information that a dairy herd in Texas had announced their TB positive status. The trace ins/outs from that Texas herd implicated three dairy herds in Nebraska. At this time, NDA has tested 14,857 dairy animals with all test results being negative.

**Synopsis through March 2011:**

- Twenty six (26) counties affected by TB testing and surveillance;
- Over 23,000 beef cattle tested (CFT) as a result of Rock County TB testing;
- Over 4,700 beef cattle tested as a result of the South Dakota traces;
- Over 3,700 beef cattle tested for the Knox/Cedar County TB surveillance;
- Dairy testing added around 14,857 more head;
- To date only two (2) cattle have tested positive in Rock County (the original two identified) and one in Cedar County (South Dakota trace);
- Involved 95 herds: Original herd in Rock County; fence line contacts from original; traces in and out from original; South Dakota traces in and out; dairies; additional fence lines for herd in Dixon County, and positive cervid herd surveillance testing.
- This equals approximately 50,000 cattle that were tested for TB by NDA since June 2009. (49,757)
- Over 35,000 hours by BAI field personnel involved in testing between March 2009 and March 2011.

**UPDATE SINCE MARCH 2011**

In late June, a cow with TB compatible lesions was discovered at a slaughter plant in Nebraska. Follow-up testing at NVSL revealed and confirmed *M. bovis*, and was subsequently labeled a “south west strain”. The cow was part of a group of cows sent to slaughter by a dealer who purchased cull cows from livestock markets in Nebraska and Colorado. An OCV tag was recovered from the cow, which was tied to a herd in western Nebraska. The individual who OCV’ed the animal claimed that the cow had been sold sometime in the past, but could not prove that. The herd was quarantined for testing and performed in spite of the owner’s vociferous protests! Testing of 573 head in four pastures was performed in July resulted in 33 responders, which were all gamma interferon negative. The herd will undergo another whole herd test (60+ days after the first test) on September 30. Results will not be known until the first week of October.
VALIDITY OF BOVINE TB GAMMA INTERFERON ASSAY ON BLOOD COLLECTED DURING EXSANGUINATION AT SLAUGHTER

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Bovine tuberculosis (BTB) is of economic, regulatory, and zoonotic importance. It is caused by Mycobacterium bovis. The gamma-interferon (γ-IFN) assay is a blood based test for BTB, which measures cell-mediated immunity to M. bovis. Integrating γ-IFN assay with currently used visual inspection of carcasses in post-mortem slaughter surveillance could help detect more BTB herds. However, it is not known if a γ -IFN response, sufficient to produce a valid test, can be obtained using blood collected at exsanguination. We hypothesized that there is no change in γ -IFN interpretations between blood collected pre-slaughter and at exsanguination. Sixteen cattle were experimentally sensitized with killed M. bovis creating an immune response similar to that found in BTB infection. Four controls received mineral oil only. The γ -IFN assay was performed on blood samples collected pre-slaughter and exsanguination. The probability that M. bovis sensitized cattle would remain γ -IFN positive on blood collected at exsanguination was 0.75 (95% CI 0.54, 0.88). Using paired t-test analysis, there was significant decrease in the mean ELISA optical density (OD) readings from pre-slaughter and at exsanguination (p=0.03). Although ELISA OD readings of individual cattle dropped at exsanguination, a change in the ELISA interpretation only occurred in animal that were borderline positive pre-slaughter. Potential factors responsible for the drop in γ -IFN response are being investigated. Our results suggest that the majority of cattle with a positive γ -IFN response pre-slaughter will remain positive at exsanguination. Therefore, γ -IFN assay may provide a useful tool for BTB surveillance at slaughter.
This Subcommittee was formed in October 2007 by the Chair of the USAHA Committee on Tuberculosis, Dr. Kathleen Connell, at the request of the American Association of Zoo Veterinarians Working Group. Since 1996, the National Tuberculosis Working Group for Zoo and Wildlife Species had been responsible for developing and revising the “Guidelines for Control of Tuberculosis in Elephants” in 1997, 2000, and 2003.

The USAHA Elephant and Wildlife TB Scientific Advisory Subcommittee (Subcommittee) was formed and met to review and revise the 2003 guidelines in 2008. It was asked again in 2010 to review and revise the 2008 guidelines in light of new scientific publications, public health concerns by CDC at an elephant facility, and data collected from official USDA diagnostic testing. The Subcommittee recommends replacing the 2008 Guidelines with the 2010 version of the “Guidelines for Control of Tuberculosis in Elephants”. A summary of changes between the versions include:

- Additional clarification and requirements on the classification of treated and exposed elephants within the TB management group options for culture positive or serologically reactive elephants.
- The 2008 guidelines called for annual testing by the triple culture method (3 trunk wash samples) and a single sample of serum collected for analysis by the ElephantTB Stat-Pak® Assay and, where warranted, by the Chembio Diagnostic Systems Inc., MAPIA™. The ElephantTB Stat-Pak® Assay was approved and licensed by United States Department of Agriculture (USDA), Center for Veterinary Biologics in 2007. The 2010 proposed guidelines allow use of a newly developed serological test – Chembio Diagnostic Systems, Inc., Dual Path Platform (DPP®) VetTB Assay which was evaluated by Greenwald et.al in 2009. The proposed guidelines for treatment and movement restrictions would also include serological results and Mycobacterium tuberculosis complex exposure history.
- Added flowcharts for the TB management groups in the appendices.
- Updated reference information.

The Subcommittee submitted the “2010 Guidelines for Control of Tuberculosis in Elephants” to the TB Committee for acceptance. The report was accepted by the Committee on Tuberculosis with the following resolution. The Resolution passed the committee last year and USDA accepted it. However, USDA/APHIS/AC has not responded to the communication from USAHA.

2010 RESOLUTION:

The United States Animal Health Association (USAHA) requests that the United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care adopt and implement the “Guidelines for the Control of Tuberculosis in Elephants 2010.”
The following is an excerpt from the presentation to the Committee on Tuberculosis in 2005 by Dr. Billy G. Johnson. This is intended to serve as historical reference on the BNC.

The U.S.-Mexico Bi-National Tuberculosis and Brucellosis Eradication Committee was formed in 1993 based on a recommendation by the USAHA with responsibility to provide oversight on the eradication programs in each country and to provide recommendations for the minimum requirements for the exportation of cattle from Mexico to the United States. This followed other cooperative efforts between the two countries that have eradicated animal diseases such as Foot and Mouth Disease, screwworms and Venezuelan Encephalomyelitis. The BNC has sixteen members with representation from the livestock industries, research, and State and federal officials. From 1995 until 2000 the Committee assumed the responsibility for coordinating reviews in Mexico for compliance with the Consensus Document developed by the border states officials. This document was developed pending the publication of USDA regulations covering the importation of cattle from Mexico. The Consensus Document placed responsibility on the states in Mexico to initiate programs that would quickly reduce the prevalence of tuberculosis in that country and therefore reduce the risk of infected cattle entering the United States. USDA, APHIS then published a regulation establishing authority to control the importation of cattle regarding tuberculosis. The BNC worked closely with APHIS officials in developing these requirements and in developing review procedures to be followed in Mexico. By June 1, 2005 federal officials in Mexico were required to certify those states meeting the Modified Accredited requirements.

The Bi-National Committee is similar to the USAHA committees in that it does not establish the eradication procedures in Mexico but makes recommendations. Since APHIS now requires countries exporting cattle to the United States to have eradication procedures equivalent to those in the United States, the recommendations established by the Tuberculosis Committee of USAHA are important not only to the U.S. but also to those countries exporting cattle to the U.S. Although the BNC was originally established for tuberculosis procedures, brucellosis was later added to the Committee responsibilities. Although the brucellosis programs in most states in Mexico are not progressing at the same rate as their tuberculosis eradication programs, the state of Sonora has progressed well and is looking at Brucellosis Free status. Also a U.S.-Mexico Tick Committee meets at the same time as the BNC and provides a summary of their meeting to the BNC since most of the BNC members are also involved with tick eradication programs.

The BNC currently meets twice yearly. Once at the CNOG annual meeting and once at the NCBA annual meeting.
Development of Proposed TB/Brucellosis Regulations

APHIS formed a joint working group to discuss overarching regulatory concepts for the bovine TB and brucellosis programs since both programs are undergoing similar changes. The joint TB and Brucellosis Regulatory Working Group met weekly from September 2010 through April 2011, and developed a regulatory framework that was published in the Federal Register on May 6, 2011. This framework described a single rule for both the TB and brucellosis programs that ensures consistency and flexibility while reducing administrative burdens.

Public meetings to solicit comments were held in May and June 2011. Transcripts of the meetings are available at www.aphis.usda.gov/animal_health/tb_bruc/meetings.shtml. Based on the comments we received from the Federal Register notice, during the public meetings, and through other outreach efforts, APHIS is developing new regulations and supporting standards for the TB and brucellosis programs. The Code of Federal Regulations will provide the legal authority for the programs while the details of the programs will be described in a program standards document. The proposed rule is targeted for publication in early 2012.

Policy for Management of TB-Affected Herds

APHIS continued to utilize a new approach for the management of TB-affected herds that was implemented in 2009. Briefly, APHIS decides whether to provide Federal funding for whole herd depopulation or to manage the herd under a test-and-remove plan for each TB-affected herd on a case-by-case basis. APHIS uses an epidemiologic model and economic analysis to aid in decision making. During FY 2011, APHIS provided Federal funds to depopulate seven TB-affected herds. A test-and-remove management plan was recommended for one herd that was eventually depopulated with State funds. One large dairy herd is under test-and-remove management.

In January 2011, APHIS hosted a series of three webinars for State Animal Health Officials, Area Veterinarians in Charge, Area Epidemiologist Officers, and designated TB epidemiologists to provide more information about the technical aspects of the epidemiological model and the decision-making process for TB affected herds. APHIS worked closely with members of the National Assembly of State Animal Health Officials during FY 2011 to obtain input concerning a draft policy memorandum that provides guidance for classifying and managing livestock herds affected with TB under this new approach. APHIS plans to finalize the memorandum in early FY 2012.

Bovine State Status

As of September 15, 2011, 46 States, two Territories, and three zones are TB accredited-free (AF), including Puerto Rico and the U.S. Virgin Islands. California is modified accredited advanced (MAA) and three States have split-State status. New Mexico and Minnesota have AF and MAA status. Michigan continues to have AF, MAA, and modified accredited (MA) status. However, 57 counties of the lower peninsula were advanced from MAA to AF status on September 14, 2011. In FY 2011, APHIS determined that the MAA zones in both Minnesota and New Mexico meet the requirements for AF status. Publication is pending for interim rules that will advance the MAA zones and reclassify the entire States of both Minnesota and New Mexico as AF.

Captive Cervid State Status

All States and territories have MA status.

TB Program Reviews

APHIS conducted TB program reviews in the States of Michigan, Minnesota, New Mexico, and Indiana in FY 2011. Reviews in Michigan, Minnesota and New Mexico were conducted to evaluate compliance with the memorandums of understanding that are required for split-State status and to evaluate requests for status advancements. An on-site review was conducted in Michigan during May 2011. Documentation reviews of Minnesota and New Mexico were conducted in May through July. An on-site review was conducted in Indiana during September 2011 to evaluate response and management
activities conducted after the detection of three TB-affected cervid herds and one TB-affected beef herd since FY 2009.

**TB-Affected Herds Identified in FY 2011**

Nine TB-affected herds were detected during FY 2011 as of September 15, in seven beef and two dairy herds. These herds are located in Arizona (one roping steer herd, categorized as a beef herd), California (one dairy), Colorado (one dairy, three beef), Indiana (one beef), and Michigan (two beef). Six (67 percent) of the TB-affected herds identified this year (two dairy and four beef herds) were detected as a result of slaughter surveillance and subsequent epidemiologic investigations.

Seven cattle herds were depopulated with Federal indemnity. The California dairy herd is under test-and-remove management. State indemnity funds were used to depopulate one Michigan beef herd.

**National TB Surveillance**

**Granuloma Submissions:** From October 1, 2010, through June 30, 2011, 9,734 granulomas were identified during postmortem slaughter inspection and submitted for diagnostic testing. These lesions originated from 166 U.S. establishments that slaughtered 24.8 million cattle, including 5.3 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. Of the 40 highest volume adult cattle slaughter establishments through June 30, 36 (90.0 percent) met or exceeded the submission standard, and 5 (10.0 percent) establishments did not. These 40 highest volume establishments slaughtered approximately 95 percent of all adult cattle slaughtered in the United States.

Of the 9,734 granulomas submitted by slaughter establishments through June 30, 2011, 27 (0.28 percent) had histology consistent with mycobacteriosis. Of these 27 cases, TB was confirmed in 20 (74.0 percent) cattle. TB is confirmed by a combination of polymerase chain reaction testing of formalin-fixed tissue and culture of fresh tissue.

**Slaughter Cases:** Of the 20 TB cases detected in cattle at slaughter through June 30 2011, four cases occurred in adult cattle over 2 years of age, and 16 cases occurred in feeder cattle. The four adult cattle cases include an adult beef cow that led to detection of an affected Indiana beef herd, an adult Holstein cow that led to detection of an affected California dairy, an adult beef cow that led to the detection of an affected beef herd in Canada, and an adult beef cow from Nebraska. The fed cattle cases were all beef-type cattle and were from slaughter establishments in Texas (11 cases) and Colorado (five cases). Seven cases were in Mexican-origin cattle and the remaining nine cases are under investigation.

**Mexican-Origin Slaughter Cases:** A total of seven TB-infected animals were determined to be of Mexican origin through slaughter surveillance. The official Mexican ear tags collected at slaughter indicated origin from the States of Chihuahua (four cases), Nuevo Leon (one case), Tamaulipas (one case), and Veracruz (one case). Two cases are believed to have originated from Mexico based on the epidemiological investigations, but the definitive Mexican State-of-origin could not be determined.

Two clusters of TB cases including cattle of Mexican origin were detected in feedlots. One cluster involved four cases from a Texas feedlot where one animal had official Mexican identification indicating origin from Chihuahua. The second cluster involved four cases from a Colorado feedlot where two had eartags indicating Chihuahua origin. The other animals in these two clusters did not have official identification present at the time of slaughter and are being investigated. A fifth Chihuahua-origin case was detected in a roping steer in Arizona as a result of TB testing for interstate movement.

The number of Mexican origin cases increased this year, after substantial declines in FY 2009 and 2010. The number of cases with official Mexican identification during FY 2006 through 2011 are 26, 17, 11, 3, 1, and 8, respectively. Cattle imports ranged from 1.1 to 1.4 million during 2004 through 2007, then declined during the 2008 and 2009 import cycles, to just over 800,000 imports. In FY 2010 and 2011, import numbers increased to 1.1 and 1.4 million live cattle from Mexico, respectively.

**Live Animal Testing:** Tuberculin skin testing in live animals is another component of national TB surveillance. As of June 30, 2011, 792,634 caudal fold tuberculin tests of cattle and bison were reported, with 9,762 responders (1.2 percent, 49 States and Puerto Rico/U.S. Virgin Islands reporting). The response fraction by State, for 44 States testing more than 300 animals, ranged from 0.0 to 4.2 percent (median, 0.82 percent). During FY 2008 through 2011, 13, 24, 23, and 18 States, respectively, had a response fraction of 1 percent or greater. The number of States having a response fraction of less than or equal to 0.25 percent was 13, 12, 5, and 6 from FY 2008 through FY 2011, respectively.

Tuberculin testing is the primary means of surveillance for TB in captive cervids as there are no standards for granuloma submissions for establishments that slaughter cervids. As of June 30, 2011, 20,080 single cervical tuberculin skin tests were conducted in captive cervid species with 323 suspects.
(1.6 percent) reported to APHIS. The number of captive cervids tested annually has ranged from 25,000 in FY 2006 to just over 10,000 in FY 2007.

The gamma interferon test has been available as an official supplemental test in the TB program since 2005. Laboratories in four States (California, Michigan, Nevada, and Texas) and the NVSL are approved to conduct gamma interferon testing. A total of 7,974 tests were conducted in cattle in through August 31, 2011.

**Collaborations with Mexico**

APHIS continues to work with Mexico to ensure equivalency between the two countries’ requirements for controlling TB. To accomplish this, APHIS conducted reviews in Chiapas and Veracruz during FY 2011. As a result of these reviews, the MA zone in Veracruz maintained its MA status. The final review report for Chiapas is pending. APHIS appreciates the contributions of the individuals that served on these Mexican review teams.

Notably, the MA zone of Chihuahua was downgraded to AP status effective August 25, 2011. Mexico’s efforts to address the recommendations from a 2010 review of Chihuahua were insufficient to reduce the risk of TB in imported Mexican cattle. Five cattle imported from Chihuahua were found with TB during FY 2011, exceeding the allowable standard.

**TB Serum Bank**

APHIS’ is continuing to obtain well-characterized serum samples with skin test results for samples from uninfected animals, including skin test, histopathology, and TB culture results for samples from infected animals. The serum bank contains 2792 serum samples from cattle, of which 444 are positive, and 3584 samples from cervids, of which 92 are positive. Serum bank samples continue to be available to researchers and diagnostic companies for serologic test development.

In FY 2012, the serum bank will continue to accept blood and tissue samples from potentially infected cattle and white-tailed deer and blood samples from all States, and from presumably uninfected cattle and white-tailed deer from AF States.

**Cervid Serology Project**

The Center for Veterinary Biologics licensed the CervidTB Stat-Pak® (Stat-Pak) in late 2009, for use in elk and red deer. The cervid serology project was conducted during FY 2011, to evaluate the Stat-Pak as a primary test for official TB program use in captive and free ranging *Cervus canadensis* (North American elk), *Odocoileus virginianus* (white-tailed deer) and reindeer (*Rangifer tarandus*). Samples from 1,574 presumably uninfected animals were tested by the Stat-Pak. A total of 14/842 elk (1.6 percent), 17/547 white-tailed deer (3.1 percent) and 15/185 reindeer (8.1 percent), were non-negative on the Stat-Pak, resulting in specificity estimates of 98.3 percent in elk, 96.9 percent in white-tailed deer and 91.9 percent in reindeer. In contrast, the estimated specificity of the single cervical tuberculin skin test in presumably uninfected animals during routine TB program testing is 98.54 percent for elk, 97.40 percent for white-tailed deer, and 82.72 percent for reindeer. A report on this project was provided to the TB Scientific Advisory Subcommittee for review.
Selected State Updates on Tuberculosis

**Colorado Update:** In FY 2010, a TB-affected dairy was identified in Colorado. The resulting epidemiological investigation found an additional five TB-affected herds in Colorado in FY 2010 and FY 2011, including three beef herds and two dairy herds. In these herds, TB was only detected in purchased cattle originating from the index herd. All herds were depopulated with Federal indemnity.

**Indiana Update:** TB was confirmed in a seedstock beef herd as a result of routine slaughter surveillance detection of *Mycobacterium bovis* in a culled beef cow. The investigation of this herd of approximately 220 cattle resulted in trace investigations of over 150 cattle in 11 States. To date, no additional infected animals or herds have been found outside the index herd. Initial wildlife surveillance of white-tailed deer on and adjacent to the infected farm has not detected infected animals. The beef herd was depopulated with Federal indemnity.

Indiana continues to investigate two domestic beef feeder cattle cases identified through routine slaughter inspection in June 2010. Genotyping analysis indicates the isolates from these cases match isolates from TB-affected captive cervid herds detected in Indiana and Nebraska and beef cattle cases in Kentucky, Nebraska, and South Dakota in FY 2009 through 2010, in addition to the FY 2011 affected beef herd in Indiana.

**Michigan Update:** Two TB-affected beef herds were detected through surveillance testing in FY 2011. One Michigan dairy is continuing under a test-and-remove herd plan from 2004; the herd was scheduled for quarantine release but an infected animal was detected during the final test for quarantine release. One Michigan beef herd detected in FY 2010 remains under a test-and-remove herd plan in the MA zone. A second beef herd detected in FY 2010 was released from quarantine in FY 2011. Two captive cervid herds detected in FY 2009 remain under quarantine in the MA (bovine) zone of Michigan.

**Nebraska Update:** An epidemiological investigation of a routine slaughter surveillance detection of *M. bovis* in a beef cow is underway in Nebraska. The initial whole-herd test did not identify any other infected cattle. A second whole-herd test is planned and other possible source herds are being investigated.
Bovine tuberculosis (bTB) is a serious disease in cattle in terms of its global economic impact. Often times, free-ranging wildlife has been linked as the bTB reservoir for infection. At the 2009 meeting, participants identified 5 recommendations for the National TB Program relative to Wildlife Associated Disease Transmission:

- State and federal animal health authorities should drive efforts to mitigate risks to and from wildlife. These efforts should include development of science-based methodologies for reducing transmission risk associated with livestock feeding and watering, stored feeds, and environmental exposure.
- State and federal animal health authorities should conduct wildlife surveillance in areas where bTB has been identified in livestock.
- State and federal animal health authorities should consider means by which state status can be and should be disengaged from wildlife disease prevalence/risk, including, but not limited to, wildlife risk mitigation commitments by producers, livestock movement controls, and establishing surveillance zones surrounding positive livestock.
- USDA should support research to identify tools (e.g., vaccination) and strategies (e.g., bait delivery strategies) to reduce the prevalence of bTB in wildlife and institute those strategies, as appropriate.
- State and federal animal health authorities should review existing control strategies in other countries where wildlife species are identified as reservoirs with the aim to modify them for our own purpose.
Follow-up on recommendations regarding Diagnostic Testing Limitations and Needs resulting from “The future of the National Tuberculosis Program”, USAHA meeting in Denver, CO, July 20-21, 2009

Mitchell V. Palmer, DVM, PhD

Recommendation #1A: Identify funding for research and development of new TB tests and vaccines. Prioritize funding to use resources most efficiently.

**Follow-up:** USDA’s research and development efforts on tuberculosis diagnostics and vaccines are conducted primarily through the Agricultural Research Service (ARS), specifically the National Animal Disease Center (NADC) in Ames, IA. Objectives of the bovine tuberculosis research effort in USDA are:
1. Characterize the immunopathogenesis of \textit{M. bovis} infection in cattle and deer.
2. Determine new strategies for the detection of \textit{M. bovis} infection in cattle and white-tailed deer.
3. Develop new tuberculosis vaccines.

ARS, APHIS Veterinary Services (VS) TB Program Staff, Center for Veterinary Biologics (CVB), and industry scientists continue to collaborate in the evaluation of promising tests for bovine tuberculosis. Limited funding requires prioritization and investigation of only the most promising tests. In spite of limited funding, since 2000, USDA scientists have produced >120 peer-reviewed scientific manuscripts, representing dozens of experiments and projects on tuberculosis transmission, pathogenesis, diagnostics, and vaccines. Since 2009 12 peer-reviewed scientific papers on tuberculosis diagnostics have included ARS, APHIS, and industry scientists as co-authors.

Recommendation #1B: Use TB positive herds to obtain samples for use in test evaluation, licensing, and approval.

**Follow-up:** USDA’s APHIS VS and ARS have a rich history of agency cooperation in regards to maximizing information gained from TB positive herds. Such cooperation has increased over the past 5 years yielding presentations and publications obtained from TB positive dairy herds in New Mexico, Colorado, and Mexico. Similarly, information has been gleaned from research on TB positive deer, both wild and captive. A few of the presentations and publications resulting from such cooperation include:

- Bovine tuberculosis in a Nebraska herd of farmed elk and fallow deer: A failure of the tuberculin skin test and opportunities for serodiagnosis. WR Waters et al., Vet Med Int 2011 Apr 14:953985.

Recommendation #1C: Conduct research on PCR tests to reduce costs of bacteriological testing.

**Follow-up:** Joint ARS and APHIS, VS efforts continue on investigating the methods and feasibility of PCR testing of tissues, as evidenced by publications such as,

“Improved specificity for detection of \textit{Mycobacterium bovis} in fresh tissues using IS6110 real time PCR” by TC Thacker et al., BMC Vet Res 2011; 7:50.

Recommendation #2: Immediately acquire a serum bank of know TB-positive and negative cattle.

**Follow-up:** In 2008 USDA, APHIS, VS, dedicated funds to create a serum bank for use in evaluation of TB serological tests. The bank is housed at the National Veterinary Services Laboratories (NVSL) in Ames, IA and was established with the following goals:
1) Collect well-characterized samples that can be used in the development and evaluation of serum based diagnostic tests for bovine tuberculosis.
2) Collect 1600 samples from TB negative cattle and white-tailed deer.
3) Collect 250 samples from TB positive cattle.
4) Collect as many samples as possible from white-tailed deer.
5) Obtain samples from the US, Canada, Mexico and the United Kingdom.
At the close of FY 2010 approximately 2730 bovine samples had been collected, 418 of which were from TB positive animals and 2996 deer samples had been collected, 88 of which were from TB positive animals.

**Recommendation #3:** Identify 1 reviewer from the Center for Veterinary Biologics (CVB) for new TB tests to provide consistency. Use “conditional license” status to allow experimental tests to be used in parallel with existing tests to compare test performance. Clarify requirements and coordinate test evaluation with CVB, TB (Scientific Advisory Subcommittee) SAS, and TB Program Staff.

**Follow-up:** One CVB veterinarian reviews applications for new diagnostic tests for bovine tuberculosis. The “conditional license” status has been available, but is seldom requested. In 2008 an ad-hoc USAHA TB Subcommittee on Diagnostic Test Review drafted a document entitled; “Criteria for evaluating experimental tuberculosis test performance for official test status”. This document, published in 2008 USAHA Proceedings, outlines phases through which a candidate diagnostic assay must pass for consideration as an approved test for use in the national eradication program. In 2010, in accordance with 9 CFR 103.3, the requirement of CVB licensure was added for phase I completion. 9 CFR 103.3 requires CVB approval for interstate shipment of biological products.

**Recommendation #4:** Explore the feasibility of a milk test for TB.

**Follow-up:** USAHA TB SAS and APHIS TB Program staff have considered and reviewed data from developers of milk-based detection of *M. bovis*. As with any test, factors such as sensitivity, specificity, proposed use in the eradication program, side-by-side comparison with existing tests, and ramifications of a non-negative result must all be considered.

**Recommendation #5:** Ongoing, interim work by the TB SAS should continue year-round outside of the official USAHA meeting.

**Follow-up:** According to the 2008 USAHA document, “Criteria for evaluating experimental test performance for official test status”

“Data may be submitted to the TB SAS for review at any time. The TB SAS will review the data by conference call/email or at the regularly scheduled annual subcommittee meeting. The recommendation of the TB SAS will be submitted to the Chair of the TB Committee. The TB Committee Chair will determine whether the recommendation will be immediately released to the TB Committee or held until the annual meeting.”

In summary, many of the recommendations concerning the needs and limitations of bovine tuberculosis diagnosis were in place in 2009. The remaining recommendations have since been implemented and exist in various stages of progression.

**Report on Surveillance, Traceability and Investigative Deficiencies:**

A summary of key accomplishments and future actions that VS plans to complete that are relevant to recommendations from the 2009 Tuberculosis (TB) symposium in Denver sponsored by USAHA; specifically Session IV: Surveillance, Traceability, and Investigative Deficiencies from the symposium. Topics that were of concern in Denver include slaughter surveillance, granuloma submission standards for adult as well as fed cattle, traceability, and issues under consideration for the proposed TB-brucellosis rule. Several activities are underway supporting TB surveillance including: VS visits to slaughter plants, monitoring granuloma submissions, quarterly meetings with FSIS, and a pilot study for fed-cattle granuloma submission. VS has adopted a flexible approach to disposition of TB herds. In collaboration with State officials, VS decides whether to depopulate or enter into a test and removal program. The decision is informed partially by initial test data analysis that predicts probability of success versus cost of test and removal. The current traceability rule is open for public comment with sections pertinent to TB. Items under consideration in the proposed TB-brucellosis rule include: captive cervid testing, recordkeeping for feedlots, prioritization for trace-outs, and standards for Qualified Accredited Veterinarians.
The Future of the National Tuberculosis Program
Disease Control Approach
Dr. Robert Ehlenfeldt - Wisconsin
Dr. Susan Keller – North Dakota

Over the past fifteen years the US has experienced an average of ten or more newly infected herds annually. Many of these infected herds have been disclosed in states that have been Tuberculosis free for many years. The size of the infected herds has increased, increasing the cost of herd depopulation. At the same time the apparent in-herd prevalence of Tuberculosis has remained low in the vast majority of infected herds. Over two years ago USDA-APHIS-VS began consideration of proposals to change the management of Tuberculosis and Brucellosis in the US.

Many factors have been identified as impacting Tuberculosis eradication. These include imports, interstate movement, diagnostic tests lacking sensitivity and specificity, improper application and reading of CFT, wildlife reservoirs, negative impacts on a statewide basis under the current state classification system for a single infected herd and inadequate traceability of trace outs and sources.

The frameworks for the national tuberculosis and brucellosis programs provides for increased flexibility for handling infected herds. However many questions remain that must be answered in any future rulemaking. What will trigger state program reviews? How and when will results of the reviews be communicated? Who will contribute to the reviews? What will define an epidemiologically sound disease investigation? How will resources be fairly distributed across the fiscal year? Will creating a consistent, inconsistent classification system motivate or demotivate producers and accredited veterinarians?

While flexibility in managing infected herds will be useful, we must avoid the appearance of being arbitrary and capricious. Regulatory officials need and producers deserve program standards that are spelled out and adopted by rulemaking for their protection. Without this there will be legal challenges delaying herd clean-ups no matter if test and remove or depopulation fits a statistical model.

Key to any future eradication efforts is complete transparency in the program while protecting producer confidentiality. Information on disease investigation efforts must be clearly and rapidly communicated to all stakeholders. Failure to address all the factors and questions pertaining to the Tuberculosis program, in the US, will also result in the continued failure of eradication efforts.