



THE FUTURE OF THE NATIONAL TUBERCULOSIS PROGRAM

REPORT

JULY 20-21, 2009



DENVER, COLORADO



Presented by the United States Animal Health Association

**THE FUTURE OF THE NATIONAL TUBERCULOSIS PROGRAM
REPORT**

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EXECUTIVE SUMMARY

The United States Animal Health Association (USAHA) hosted a symposium on the future of the United States' National Tuberculosis (TB) Program on July 20-21, 2009, in Denver, Colorado. As TB in the US has become less prevalent in recent years, the current national program may not be providing the best mitigation for individual states to manage and eliminate the disease. With evolution of the beef and dairy industries and related impacts on wildlife, USAHA organized this symposium to help provide future direction. The symposium was viewed as an important role for USAHA to be active on key issues throughout the year, not just at its Annual Meeting.

The goal was to provide a comprehensive assessment of the current National TB Program and challenges within an evolving cattle industry and to present recommendations to the United States Department of Agriculture (USDA) to help craft a program for the future. Sessions featured updates from USDA on feedback from its internal and external TB Listening Sessions, a preview of new approaches being considered by USDA and key experiences from states dealing with TB.

The audience included a diverse representation of livestock producers, veterinarians, animal agricultural industry groups, laboratories, universities, diagnostic test firms and various state and federal animal health and wildlife agencies. A total of 148 participants engaged in this meeting.

Dr. John Clifford, Deputy Administrator, USDA, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), commented on VS's role during the symposium. He provided an update concerning their "current thinking" about the future of the National TB Program by summarizing the USDA-APHIS-VS draft concept paper, "*A New Approach for Managing Bovine Tuberculosis: Veterinary Services' Proposed Action Plan*", dated July 2009. Copies of this concept paper were distributed to the participants. USDA-APHIS-VS intends to make this document available for public review and comment in the Federal Register. At the conclusion of Dr. Clifford's presentation, a panel of nine VS staff joined him for audience questions.

Dr. Alecia Larew Naugle, National TB Program Manager, National Center for Animal Health Programs, USDA-APHIS-VS, discussed the recent Bovine TB Listening Sessions. USDA-APHIS-VS will consider input from these sessions as they make major revisions to the National TB Program.

State perspectives were given by State Veterinarians of California, Minnesota and Michigan, all TB-affected states. Dr. Richard Breitmeyer, California State Veterinarian, provided a summary of the recent California experience, including challenges and concerns with existing program rules. Dr. Breitmeyer emphasized the need for greater flexibility in program rules, primarily to address the situation on a herd-by-herd basis, rather than penalizing the entire state with unnecessary testing costs and movement restrictions.

Dr. William Hartmann, Minnesota State Veterinarian and Board of Animal Health Executive Director, presented Minnesota's unique perspective, being a state that had been TB-free for 30 years prior to detection of the disease in 2005. He concluded his presentation by stating that he hoped the symposium would reenergize the cattle industry and all states to work together with USDA to develop a more effective, efficient National TB Program.

State reports concluded with Dr. Steve Halstead, Michigan State Veterinarian, who reviewed Michigan's situation and outlined concerns of Michigan disease control officials and livestock producers. Michigan has focused on 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.

Breakout sessions allowed for discussion on priority program areas. Participants helped develop action steps compiled as recommendations for USDA. The intent was not necessarily to reach consensus, but to provide a "menu of options" for USDA to consider. This report is the compilation of those proceedings. Sections appearing later in this report contain detailed background information for each of the six topics, discussion questions, recommendations and additional topics discussed during each breakout session.

KEY RECOMMENDATIONS

Key recommendations resulting from the six facilitated, technical breakout sessions were as follows:

- I. Importation of Infected Cattle – pages *13 to 15*
 - a. Requiring official electronic identification is not warranted at this time, but penalties should be increased if existing identification 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 to 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 to 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 Center for Veterinary Biologics (CVB) reviewer for new TB tests.
 - d. Consider using conditional licensing to decrease time to market for TB tests.
 - e. TB Epidemiological 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 Scientific Advisory Subcommittee or other Committee on Tuberculosis 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 veterinarians.
 - 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 veterinarians administering TB test, with review for reaccreditation.

- V. Modernizing Regulations – pages *29 to 31*

KEY RECOMMENDATIONS

- 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-remove option chosen, evaluation of requirements for test-and-remove 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.

INTRODUCTION

Established in 1897, the United States Animal Health Association (USAHA) is a non-profit, member-driven, science-based organization devoted to prevention, control and eradication of animal diseases in the US. USAHA has 1,200 members representing state and federal agencies, universities, industry and veterinary organizations and other groups with an interest in animal health, disease control, animal welfare, food safety and public health. USAHA serves as a clearinghouse for new information and methods that can be used in development of laws, regulations, policy and programs. Through deliberations of its annual meeting and 32 committees, USAHA works to develop solutions to animal health-related issues.

As an organization becoming more engaged on a year-round basis, USAHA explores relevant, timely issues that would benefit from a topic-specific symposium. Bovine tuberculosis was identified as one of those key issues, thus USAHA organized “The Future of the National Tuberculosis Program” symposium to gather animal health and industry leaders to focus on the needs of the National TB Program.

Changes within the cattle industry, both beef and dairy, as well as the decrease in overall prevalence of TB nationally, give occasion to evaluate the current program and what changes could be made to make it more effective and more conducive to current industry commerce and practices.

While the symposium was not intended to reach consensus on each issue, the input gathered and described in this report represents key animal health and industry experts’ opinions on the future of the National TB Program. Such information will be considered by the USAHA Executive Committee and the Committee on Tuberculosis. USAHA encourages other stakeholders to examine the input found within the report and glean information to collaboratively work toward solutions in the next generation of this program.

USAHA wishes to recognize and thank all participants for their input and involvement in helping to shape the content of this report.

SYMPOSIUM OVERVIEW

A general opening session was held on July 20, 2009, in Denver, Colorado. The first day of the two-day symposium set the stage for the breakout sessions held July 21, 2009, by providing an overview of the National TB Program.

The current USAHA President, Dr. Don Hoenig, Maine State Veterinarian, opened the meeting with welcoming remarks. Dr. Hoenig emphasized that the goal of the symposium was to provide a realistic, achievable menu of options and recommendations that USAHA could compile and provide to USDA for consideration in future planning.

Dr. Hoenig was followed by Dr. John Clifford, Deputy Administrator, USDA Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS). Dr. Clifford commented on USDA-APHIS-VS's role during the symposium, which was to discuss national program standards and challenges, provide current thinking on a new approach, answer questions, clarify information about the current program and serve as Subject Matter Experts.

Dr. Alecia Larew Naugle, National TB Program Manager, National Center for Animal Health Programs, USDA-APHIS-VS, provided a presentation on the recent Bovine TB public meetings and Listening Sessions. USDA-APHIS-VS gathered input through five Listening Sessions held in December 2008, as well as three internal Listening Sessions and eight conference calls with approximately 150 participants representing USDA-APHIS-VS and Wildlife Services. USDA-APHIS-VS will consider input from these sessions as they make major revisions to the National TB Program. Dr. Naugle reviewed the eight breakout topics from the public Listening Sessions. Such sessions were attended by a total of approximately 200 attendees, representing livestock producers, state agencies, industry groups and wildlife agencies.

Dr. Clifford then gave an overview of the National TB Program, challenges facing the program and current status of regulations, budget and staffing levels. The basis of his presentation was the USDA-APHIS-VS draft concept paper, *"A New Approach for Managing Bovine Tuberculosis: Veterinary Services' Proposed Action Plan,"* dated July 2009. Copies of this concept paper were distributed to the participants. USDA-APHIS-VS intends to make this document available for public review and comment in the Federal Register. At the conclusion of Dr. Clifford's presentation, a panel of nine USDA APHIS staff joined him for audience questions.

Dr. Clifford and the panel fielded questions about:

- Wildlife reservoirs and wildlife surveillance;
- Strengths and weaknesses of the current program;
- A risk-based system for TB eradication and control;
- Ensuring compliance in the absence of movement controls through auditing, documentation and oversight; and
- The importance of slaughter surveillance for adult and fed cattle.

Other topics brought up during the panel discussion included captive cervid herds, the issue of human-animal exposure, quarantined feedlots, TB program standards and regulations that are

performance-based, and modeling a TB program after the Pseudorabies program. A couple of participants raised the concern of costs to producers.

State perspectives and challenges presented by the current program requirements were outlined briefly by State Veterinarians of California, Minnesota and Michigan, all TB-affected states. Dr. Richard Breitmeyer, California State Veterinarian, began by providing a summary of the recent California experience with bovine TB, including challenges and concerns with the existing program rules.

California has detected four affected dairy herds during the last two years. Three of the herds had only one infected animal and the fourth had a very low prevalence rate, showing the value of good slaughter surveillance and rapid tracing of high-risk animal movements. Of particular interest is that three unique genotypes were identified, indicating three distinct sources of infection. Despite a very low prevalence rate, the initial herd of 5,000 animals was depopulated, partially driven by an attempt to save California's TB Free status.

Despite there being no epidemiological link to California's beef industry, many states required negative TB tests for movement of feeder cattle at significant cost to California's producers. Lack of identification and record keeping added to workloads and in some cases prevented successful tracing of animal movements. Program requirements to trace all animal movements added tremendous costs, largely due to tracing and testing thousands of low-risk bulls. While a task force approach and rotation of incident command system (ICS) teams were necessary to accomplish the large workload, it was challenging to maintain continuity of information over many months. Specific sources of infection were not identified for any of the genotypes, but all three had been previously identified from southwestern Mexican feeder cattle. It was of interest that one matched a genotype found in three human cases in unrelated counties. Dr. Breitmeyer emphasized the need for greater flexibility in the program rules, primarily to address the situation on a herd-by-herd basis, rather than penalizing the entire state with unnecessary testing costs and movement restrictions.

Dr. William Hartmann, Minnesota State Veterinarian and Board of Animal Health Executive Director, 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 efforts where the disease is known to exist. There needs to be greater flexibility in the program rules so that limited resources are allowed to be used in this manner. Dr. Hartmann concluded by saying it is his hope that this meeting will reenergize the cattle industry and all states to work together with USDA to come up with a more effective and efficient National TB Program.

State reports concluded with Dr. Steve Halstead, Michigan State Veterinarian, who reviewed Michigan's bovine TB situation and outlined the concerns of Michigan disease control officials and livestock producers. 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 bovine TB in Michigan is a unique strain. Over \$100 million in 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 of the disease itself. In view of this, Michigan's response, in partnership with stakeholders and with USDA-APHIS-VS, has been 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.

As Chair of USAHA's Committee on Tuberculosis, Dr. Kathleen M. Connell gave a short presentation of the last five years of resolutions originating from the Committee. The first day's general session then concluded with Dr. Breitmeyer giving participants instructions for the next day's breakout sessions.

The symposium's second day began with six facilitated, technical breakout sessions. Sessions allowed for discussion on priority areas within the National TB Program. A discussion guide on the six sessions had been provided to symposium participants prior to the Denver meeting to stimulate discussion. Two concurrent breakout sessions were held simultaneously and participants chose which of the six sessions to attend. Participants helped develop action steps and facilitators and notetakers compiled the resulting recommendations, which are included in this report.

Participants reconvened in a general session after completion of the breakout sessions, for a review and summation. Those summaries are given in an earlier section of this report entitled, "Key Recommendations."

Background information on each of the six major topics, discussion questions, recommendations and additional topics discussed in each breakout session follow in the remainder of this report. Each meeting participant was provided with a copy of this report.

BREAKOUT SESSIONS

The following sections of this report contain details on each of the six major topics, recommendations, comments on each topic and any additional issues discussed during the breakout sessions. An earlier section of this report listed key recommendations resulting from these sessions. To stimulate discussion and recommendations, a Discussion Guide was provided to registered participants prior to the Denver meeting. The guide gave background information on each major topic, discussion questions and recommendations and is provided below.

Breakout sessions 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; and
- VI. Disease Control Approach.

I. IMPORTATION OF INFECTED CATTLE

Background

Despite significant advancement in the TB programs in many Mexican states, especially in Northern Mexico, the importation of steers and spayed heifers from Mexico into the United States remains a significant risk for introduction of TB.

Each year, approximately 30-40 cases of TB are identified in feeder cattle. From 2000 to 2008, more than 330 cases of TB were identified in feeder cattle at slaughter, with the majority of them Mexican-origin. These cases are identified despite a very poor surveillance effort in fed cattle plants. A recent study in Texas demonstrated that effective slaughter surveillance in fed cattle plants would likely identify several hundred additional TB cases each year.

Genotyping (fingerprinting of TB strains) is now providing valuable information which assists in the epidemiological investigations for TB. Genotyping conducted to date for the isolates from 10 of the 12 TB-affected adult breeding herds detected in the Western Region of the US since 2004 indicate that at least 90% of the cases were similar to strains previously collected from Mexican-origin feeder cattle.

In addition, roping or event cattle originating from Mexico represent an even greater risk to domestic breeding cattle since they often move frequently and live longer. During the time period from 2000 to 2008, 30 cases of TB-positive "roping steers" were identified. These cattle currently move unrestricted and are often found on premises containing breeding cattle.

In 2008, USAHA approved Resolution 50, Restricting Imported Feeder Cattle. This Resolution urged USDA to require that steers and spayed heifers originating from states in Mexico that had never achieved Accredited-Free status only be allowed importation into the

US if transferred from the port of entry or first point of assembly to feedlots, pastures or pens which do not contain breeding cattle.

Recommendations/Discussion Questions for Session I, Importation of Infected Cattle

1. USDA should require permanent official electronic identification on all imported Mexican feeder cattle, in addition to existing required “M” and “Mx” brands, and increase penalties for removal of any official identification.
2. USDA should implement regulations to require registration of each feedlot in the US that feeds Mexican-origin cattle and prohibit these feedlots from also housing breeding cattle (cows, replacement dairy heifers, beef heifers intended for breeding, etc.) on the same premises.
 - a. Alternatively, USDA should require that all cattle entering a feedlot that also feeds Mexican cattle leave only to slaughter, that is, be allowed at terminal feedlots only.
 - b. Could biosecurity measures be developed, implemented and enforced to effectively prevent transmission of TB if both classes of cattle were housed at the same feedlot?
 - c. Should USDA also restrict Mexican-origin feeder cattle on pastures and if so, how would it logistically be enforced?
3. USDA, states and industry organizations should develop a joint outreach plan that educates producers about the risk of commingling Mexican feeder cattle and breeding cattle in feedlots and on pastures.
4. USDA should require annual TB testing for interstate movement of cattle used for specific rodeo events, regardless of origin.
5. USDA should require one additional TB test, conducted by USDA veterinarians, at the port of entry or in approved facilities in Mexico prior to importation. Is this logistically feasible at or near the ports of entry?
6. Should there be required risk evaluations, herd plans, or additional testing requirements for herds exposed to imported animals?
7. Should there be supplemental surveillance in geographic areas that have an increased risk for exposure to imported cattle?

OUTCOMES FROM SESSION I, IMPORTATION OF INFECTED CATTLE

1. **Official electronic identification** – Most participants agreed that electronic identification (EID) should not be required until there is a national system to enter and utilize the information, but efforts should be made to keep existing ID in place. There is currently no national system established and maintained to collect ID information. Some participants expressed concerns about problems with universal readers, functioning readers and lost tags. However, there needs to be a tracking system to capture movement information from the port of entry to first destination and then to the animal’s final destination. This information should then be made uniformly available to the state of destination. There was also strong support for increasing penalties for removal of official ID.
2. **Feedlot registration and restrictions on breeding cattle if feeding Mexican cattle** – Most participants agreed that each US premises that feeds Mexican-origin feeder cattle needs to be identified, registered and/or approved so the animals’ locations are known

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and can be monitored. Producers want the flexibility to purchase Mexican-origin feeder cattle.

Feedlots are already tracking their animals for the Beef Quality Assurance program, residue avoidance programs and Country-of-Origin Labeling (COOL) requirements. There should be rules regarding separation of Mexican-origin cattle on grass, but it is not realistic to expect state enforcement, due to limited budgets and staffing. Some participants felt that it was important to notify dairymen about the presence of high-risk cattle on grass near their dairy cattle.

Most participants agreed that all dairy breeding cattle should be prohibited from being fed with Mexican-origin feeder cattle. Some participants wanted to extend the same prohibition to beef replacements. Other participants thought that beef replacements could be fed safely with Mexican-origin animals with proper biosecurity requirements and procedures. States should be responsible for enforcing the resulting restrictions and requirements and the group supported this concept.

Participants from Texas stated that cattle industry organizations and the Texas Animal Health Commission were working on TB Program recommendations, including a risk-based system for feedlots. This document was completed following the Denver meeting and is provided in Appendix D of this report.

3. **Federal-State-Industry outreach program**—It was generally agreed that a comprehensive educational and outreach program is necessary, but time constraints limited the discussion of this topic.
4. **Annual TB testing for interstate movement of cattle used for specific rodeo events, regardless of origin**—Most participants agreed that rodeo or other timed-event cattle pose a much higher disease risk. They have a longer life span, travel extensively throughout the US and ultimately are fed out in feedlots prior to slaughter. They should continuously be separated from other classes of cattle and their TB test records should follow them. There should be specific rules for event cattle importation. These animals should be specifically and permanently identified upon entry at the US-Mexican border as a specific class of cattle and tracked through slaughter. A unique brand should be considered for identification. The group strongly supported these concepts.

Most participants agreed that regardless of origin, US rodeo and timed-event cattle should be subject to additional testing, such as an annual TB test and/or routine testing for interstate movement. A specific tracking system should be established and maintained to monitor this class of cattle. The group supported these concepts.

5. **Additional port of entry TB test**—Most participants agreed that there is no mechanism to conduct an additional Caudal Fold Tuberculin (CFT) test at the US-Mexican border, but there was general agreement on the idea of an additional port of entry TB test if a validated rapid serological test became available. Currently, there are only 11 US veterinarians at ports of entry. Additional testing may be possible once the proper, reliable, rapid serological test is developed and available.

II. WILDLIFE ASSOCIATED DISEASE TRANSMISSION

Background

Eradicating bovine TB in free-ranging wildlife is problematic and requires a great deal of cooperation between state and federal livestock and wildlife officials as well as with the owners of livestock operations where interaction between wild and domestic species may occur.

Wildlife recreation is a big business in the US and its economic and sociologic importance is often under-recognized. Many varied stakeholder groups will be interested and will expect to be involved in any management decisions involving wildlife. In comparison with 1 million cattle ranchers and farmers nationally, about 13 million Americans hunt and about 82 million participate in wildlife-associated recreation.

TB management and eradication where wildlife is involved must include surveillance of wildlife populations, and education of both wildlife and livestock owners to prevent the interaction of species and potential spread of disease. Many disease problems in wildlife are associated with unnatural or artificial situations. Management of these problems is often extremely challenging, because there are few proven strategies available and because many of the options are extremely expensive and/or politically unpopular to implement.

Livestock herd biosecurity must be considered to minimize spread of the disease. Research will also need to be initiated to determine the epidemiology and management of free-ranging wildlife populations affected with TB. Management strategies may need to consider containment, control, and eradication options with various combinations.

Key points:

- Prevention should be the number one priority;
- Disease control is complex and costly;
- The wildlife-livestock interface is the best place to tackle disease;
- Control programs should incorporate formal risk assessment;
- There are likely to be both technical and financial constraints on what can be done; and
- Public opinion can block some technically feasible and scientifically valid options.

Recommendations/Discussion Questions for Session II, Wildlife Associated Disease Transmission

1. State and federal animal health authorities should drive efforts to mitigate risks to and from wildlife. Priorities should include:
 - a. Development of science-based methodologies for reducing risk of transmission associated with livestock feeding and watering, stored feeds, and environmental exposures.
2. State and federal animal health authorities should conduct wildlife surveillance in geographic areas where TB has been identified in livestock. Surveillance in wildlife should take into consideration risk factors associated with herd type (dairy versus feedlot versus cow/calf, etc.), type of confinement, wildlife vector populations,

environmental features/wildlife habitat (open plains versus cedar swamps, etc.), and known or potential livestock-wildlife interactions. Consider:

- a. If it is determined that there is risk, what cost-effective surveillance options exist?
 - i. Passive (via hunters)
 - ii. Active (wildlife agency or sponsored hunts)
 - iii. Producer options: disease control and crop damage permits
 - b. Cost should be borne by stakeholders that benefit from the program: federal, state and industry/private interest.
 - c. Should these considerations also be applied to privately owned Cervidae livestock operations?
 - d. USDA should establish minimum requirements for targeted surveillance in wildlife as part of a comprehensive, national surveillance plan.
3. 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.
 4. USDA should support research to identify tools (e.g., vaccination) and strategies (e.g., bait delivery strategies) to reduce the prevalence of TB in wildlife and institute those strategies, as appropriate.
 5. 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.

OUTCOMES FROM SESSION II. WILDLIFE ASSOCIATED DISEASE TRANSMISSION

1. **Mitigate risks to/from wildlife**—Participants agreed that risks to and from wildlife should be mitigated by more realistic management tools, flexible risk assessments and restrictions on cervid and cattle herds. Is mass treatment of wildlife (antibiotics, etc.) possible? This could result in a resistant strain. Also, there are very large numbers of healthy animals and an extremely low prevalence. Wildlife risk mitigation methodologies should be based on positive cost-benefit assessments.

Herd buy-outs and management of livestock-wildlife interactions are more realistic management tools than total wildlife depopulation. In other words, management of risk from wildlife by eliminating all wildlife is not a realistic option. Risk assessment must be flexible and not proscriptive. Risk cannot be totally eliminated. Restrictions placed on cattle should also be put on cervid herds.

Pasturing cattle in swamps or other habitats where wildlife is predominant is not acceptable. Bacteria can persist in the environment for a long time. Science has shown that feedstuffs and environment are risk factors. Mitigating risks should be specific to the farm, the farm management and the locale. Risk assessments are different for each farm, provide flexibility in Minnesota and Michigan and some low cost measures are available. Winter feeding of beef in woodlots allows for close association of cattle and wildlife, increasing likelihood of disease transmission through direct and indirect contact.

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Research is done, now we need incentives and disincentives. Incentives and disincentives, such as forfeiture of eligibility for indemnity, should be tied to wildlife risk mitigation herd plans. Risk mitigation herd plans for farms in areas with wildlife associated disease should be required.

2. **Surveillance in wildlife in geographic areas where TB has been identified in livestock** – Participants agreed that targeted active wildlife surveillance should be conducted in geographic areas where TB has been identified in livestock. Passive surveillance should be conducted nationwide when checking for other diseases.

Since the 1990s in Michigan, 180,000 deer have been tested. Nationwide surveillance would be challenging. Should it be based on herd type? With positive farm status, prescribed wildlife surveillance? Surveillance must be flexible depending on species and their habits and should be targeted due to limited budgets. Epidemiological evaluations should be conducted to determine if risk exists to or from wildlife. If risk is determined to exist, then surveillance should be tailored to the herd (type of operation such as dairy, feedlot, cow/calf, etc., the management practices for that herd, etc.), wildlife populations, land cover and other pertinent considerations.

Deer check stations and pictures in hunting guide are passive means. Surveillance should be targeted to where the disease is, or could be, rather than across broad geographic areas, based on risk assessments and dollars available. The program cannot afford widespread surveillance of very low risk populations. USDA-APHIS-VS should provide recommendations for surveillance in areas that do not have known infection because shrinking budgets require a narrowed focus of surveillance. One-size fits all will not work for wildlife surveillance standards. For example, there have been no yearling positive deer in Minnesota since 2006. A national capacity for surveillance needs to be developed and maintained.

3. **State status can/should be disengaged from wildlife disease prevalence/risk** – Participants agreed that state status can and should be disengaged from wildlife disease prevalence and risk. Efforts and resources should be focused in the zones where disease presence and risk are deemed to be the greatest.

Sound science and the usual strategic models would require ownership change of wildlife, but in most cases, wildlife is owned by the public. Millions of dollars have been spent where it does not need to be. For example, required testing of herds 500 miles away from the index herd does not make sense. Indemnity should be withheld if the owner does not adhere to his herd plan. Risk-increasing practices (feeding and baiting of wildlife) lead to more proscriptive, oppressive disease management programs such as large surveillance and movement control zones rather than precise circles. Disease management approaches and practices should be evaluated for benefit related to cost, and those most effective implemented. Disease management approaches need to include flexibility. All risk cannot be eliminated.

4. **Research for vaccination and other tools** – Participants agreed that significant research funding and resources should be directed towards more effective vaccine development and diagnostic tools. Research specific to wildlife-livestock transmission and its

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prevention is also greatly needed. Agencies and stakeholders should advocate for this research on behalf of the researchers and research institutions.

Research needs to include exploration of innovative means of conducting surveillance such as assessments of TB prevalence in predator populations. There is still much we do not know about the disease. For example, we do not know enough about human behavior, such as why producers in Michigan haven't changed their management practices.

Research funding needs to be addressed. Last year, there was no competitive funding for bovine TB. Michigan State University received \$248,000 in a special grant. Is a Coordinated Agriculture Projects (CAP) grant possible? CAP grants have been used to fund multi-university/state John's Disease, Porcine Reproductive and Respiratory Syndrome and Avian Influenza projects. There is national support for research from stakeholders, agencies (USAHA) and producer organizations (Michigan Cattlemen's Association, Farm Bureau, etc.)

5. **Review control strategies in other countries** – Participants agreed that wildlife control strategies used by other countries should be assessed for applicability to US scenarios. New Zealand and England both have wildlife-livestock TB transmission cycles. Strategies employed by managers in these countries should be studied and employed or adapted to unique US situations. With the New Zealand approach, the strategy is more militaristic in that it is “top down” and directed.

Disease management approaches for wildlife vectors vary with the vector and the popularity of the vector species with humans. For example, white tail deer in Michigan and badgers in England are seen as important and desirable species; brushtail opossums in New Zealand are not. The New Zealand reservoir is not valued by the public, whereas deer are economically important in Michigan and the US in general. The group recognized that different models exist, but ran out of time for discussion.

6. **Other topics** – There are 750,000 hunters in Michigan. Before regulations banned feeding and baiting of deer, it was not uncommon to see huge amounts of feed being provided to deer and being hunted over as bait.

Surveillance for TB should be passive. Any livestock or wildlife sample submitted should be evaluated, if appropriate as a specimen for TB analysis. Detection of TB in these specimens should bring rewards, not punishments, for the finder, the farmer and the region/state.

Almost 180,000 deer have been tested in Michigan since the program began in the late 1990s. There are challenges to building a basic capacity for wildlife surveillance nationwide. Michigan tested 16,000 deer in 2008. Many farmers are hunters and like deer and many ranchers make money from hunts. Temporary eradication of deer in Deer Management Unit (DMU) 452, the high prevalence area in Michigan's northeastern Lower Peninsula, would not be possible. Producer-driven models for disease control, in partnership with private accredited veterinarians, should be developed and encouraged through incentives.

III. DIAGNOSTIC TESTING LIMITATIONS AND NEEDS

Background

Testing guidelines for cattle and bison are found in Bovine Tuberculosis Eradication Uniform Methods and Rules (UM&R), Effective January 1, 2005, APHIS publication 91-45-011. This publication recommends minimum standards for maintenance of TB-free accredited herds of cattle and bison and maintenance of state or zone status in the National TB Eradication Program. Adoption of the UM&R does not preclude states or zones from adopting more stringent standards.

Captive cervids are not yet covered by a separate, current UM&R. Publication was delayed pending completion of a comprehensive review of bovine and cervid sections of the CFR. Until then, captive cervid guidelines are found in the Bovine Tuberculosis Eradication Uniform Methods and Rules, Effective January 22, 1999, APHIS publication 91-45-011, referred to as the 1999 UM&R.

Official TB tests are approved by USDA APHIS and are applied and reported by authorized personnel in accordance with Part II B of the UM&R. Official tests for cattle and bison are the caudal fold tuberculin test, the comparative cervical tuberculin test and the cervical tuberculin test. Official tests for captive cervids are the single cervical tuberculin test, the comparative cervical tuberculin test and the blood tuberculosis test.

As described in more detail below, the caudal fold tuberculin (CFT) test is the primary screening test used in the bovine TB program. A major disadvantage is that this test requires cattle to be handled twice, once for injection and again to “read” the test. The person injecting and reading must also be adequately trained to inject the tuberculin correctly, then “read” the test accurately. Determining a “response” may be subjective, especially if the response to the injection is small. An approved serological test would save time during collection of the sample, would only subject the animals to being gathered and handled once and could be conducted more objectively in a controlled laboratory setting, providing more consistent and reliable results.

Tests include:

- Caudal fold tuberculin (CFT) test. The CFT test is an intradermal injection of 0.1 ml of USDA bovine purified protein derivative (PPD) tuberculin (1 mg/ml PPD) into either side of the caudal fold with reading by visual observation and palpation 72 hours \pm six hours following injection. The CFT test is the official test for routine use in individual or herds of cattle or bison where the TB status of the animals is unknown. CFT testing performance standards are given in Appendix C of the UM&R.
- Comparative cervical tuberculin (CCT) test. The CCT test is an intradermal injection of 0.1 ml of biologically balanced USDA bovine PPD tuberculin and 0.1 ml of avian PPD tuberculin at separate sites in the midcervical area to determine the probable presence of bovine TB by comparing responses to the two tuberculins at 72 hours \pm six hours following injection. The CCT injection must occur either within 10 days or more than 60 days following the CFT injection. This test is to be administered only by a state or

federal regulatory veterinarian specifically trained in its application. The CCT test is an official test for retesting cattle or bison tuberculin test suspects.

- Cervical tuberculin (CT) test. The CT test is an intradermal injection of 0.1 ml of USDA bovine cervical PPD tuberculin (2 mg/ml PPD) in the cervical region with reading by visual observation and palpation 72 hours \pm six hours following injection.
- For cattle only, bovine interferon gamma assay (INF-gamma or Bovigam®). Bovigam® is an official supplemental test that may be used in cattle herds with approval of the Chief State Animal Health Official and Area Veterinarian In Charge (AVIC) and used under direction of the Designated TB Epidemiologist and with concurrence of the Regional TB Epidemiologist, as detailed in Part III A4 of the UM&R. This test should only be conducted on blood samples collected between three and 30 days after injection for the CFT test.
- For captive cervids, blood tuberculosis (BTB) test. The BTB test may be used at non-federal expense as a supplemental test to establish a herd's disease status. Blood samples can only be collected by a state or federal regulatory veterinarian or an accredited private veterinarian.
- For captive cervids, single cervical tuberculin (SCT) test. The SCT test is an intradermal injection of 0.1 ml of USDA bovine PPD tuberculin (1 mg/ml PPD) in the midcervical region with reading by visual observation and palpation 72 hours \pm six hours following injection. The SCT test may only be administered by a state or federal regulatory veterinarian or a designated accredited private veterinarian. Captive cervids are not to be subjected to a retest at intervals of less than 90 days.

Routine testing for cattle and bison refers to CFT tests conducted as part of a state or zone eradication or surveillance program. For captive cervids, routine testing refers to CFT tests or SCT tests. Results of all tested animals are reported to state and/or federal animal health officials.

Parallel testing is when two or more tests are applied to an animal or herd simultaneously. If one or more of the test is positive, the animal or herd cannot be classified as negative.

Other supplemental diagnostic procedures approved for use in the national TB program include histopathology, diagnostic bacteriology and Polymerase Chain Reaction (PCR) assay.

Newer Tests

Significant progress has been made in development of serological assays for TB in various species as well as standardization of existing assays. New diagnostics need to be simple, rapid, accurate, inexpensive and host species-independent.

USAHA approved resolutions in 2008, 2007 and 2006 that pertained to diagnostic testing. In 2008, Resolution 47, Fund Expanded Collection of Well-characterized Serum from Cattle and Cervids Routinely Tested for Tuberculosis in Cattle and Cervids to Enhance Bovine

Tuberculosis Eradication Program, was approved. In Resolution 47, USAHA requested that USDA obtain funding and gather the required sample numbers to scientifically validate new TB tests.

In 2007, two resolutions were approved, Resolution 26, Collection of Serum from Cervids Routinely Tested by the Single Cervical Test for Evaluation of the Rapid Test for Tuberculosis in Cervids, and Resolution 27, Designation of Tuberculosis Serological Tests for Provisional Status.

In 2007's Resolution 26, USAHA urged USDA to expedite the validation process for TB serological tests for cervids to enhance TB surveillance. In 2007's Resolution 27, USAHA urged USDA to designate the PriTest SeraLyte-Mbv™, Chembio BovidTB STAT-PAK®, and Chembio Mapia™ tests as provisional tests for *Mycobacteria bovis* diagnosis in cattle.

In 2006, Resolution 21 was approved, Collection of Serum from Cervids Routinely Tested by the Single Cervical Test for Evaluation of the Rapid Test for Tuberculosis (TB) in Cervids. In Resolution 21, USAHA recommended that USDA validate a serological TB test for captive cervids. USAHA also urged USDA to take the lead in organizing a yearlong industry pilot project so that prior to each single cervical test injection in captive cervids a blood sample was collected and serum submitted to the National Veterinary Services Laboratory (NVSL) for evaluation of the VetTB Stat-Pak® rapid test. It was suggested that this project also include banking of serum for evaluation of a future serology test and submission of the results for review by the TB Scientific Advisory Subcommittee (SAS), a Subcommittee of USAHA's TB Committee.

Recommendations/Discussion Questions for Session III, Diagnostic Testing Limitations and Needs

1. USDA should prioritize existing TB program funding to expedite validation and approval of new serological tests.
2. USDA should provide adequate staffing and funding to immediately acquire a serum bank of known TB-positive and negative cattle.
3. If not already in place, USDA Center for Veterinary Biologics (CVB) should immediately develop and make available protocols for companies developing new tests for bovine TB. This process should include a review and incorporation as appropriate recommendations from USAHA's guidelines, 2008 *Criteria for Evaluating Experimental Tuberculosis Test Performance for Official Test Status*, which is available on USAHA's website in the Committee on Tuberculosis 2008 Report.
4. USDA should determine the feasibility of milk tests for detection of bovine TB in dairy cattle populations.

OUTCOMES FROM SESSION III, DIAGNOSTIC TESTING LIMITATIONS AND NEEDS

1. **Prioritize existing funding to expedite validation and approval of new serological tests** – Participants agreed that federal funding should be identified specifically for research and development of new TB tests and vaccines. Needs should be prioritized to

Continued

make the best use of limited funds. Funding and staffing efforts should parallel licensing efforts.

The group agreed that the practice of obtaining samples from national TB incidents should be continued for use in TB test field trial or licensing applications. Participants felt research is needed on the PCR test to reduce costs of bacteriological culturing procedures. Farmed cervid producers and industry representatives agreed that a rapid, one-time test would be well accepted by the farmed cervid industry.

2. **Immediately acquire a serum bank of known TB-positive and negative cattle** – There was strong support for a serum bank of samples from known TB-positive and TB-negative cattle. The group was informed that expenditure of \$250,000 in federal funding is expected by September 2009 for tissues and serum for test validation. Samples from the United Kingdom are expected by late fall 2009, with Mexican samples expected sooner. Some participants suggested that the bank should also include samples suitable for different test platforms, such as whole blood in EDTA tubes and milk, and samples must be well-characterized.
3. **CVB protocols for new tests** – The group supported the identification of one dedicated USDA Center for Veterinary Biologics (CVB) Reviewer for new TB tests for consistency, such as was done successfully for the Transmissible Spongiform Encephalopathy (TSE) test kits.

Some participants supported the use of conditional licensing in order to decrease the time to market for TB tests. Some firms are already in the pre-licensing process. Conditionally licensed products could be used for specific needs, species or investigations after approval by the appropriate state and federal officials. Some participants suggested that conditionally licensed products could be used in parallel with existing tests to compare test performance.

Some participants recommended budgeting for and prioritizing TB Epidemiological staff for Phase III field trials for consideration of tests as official tests. CVB needs to clarify regulatory requirements for field trials and coordinate with the USAHA TB SAS. The field trial phase takes place after licensure of a new test.

4. **Feasibility of milk tests for dairies** – Some participants suggested that an effective milk testing product would be beneficial. Significant research would be necessary to overcome challenges and hurdles with this testing platform.
5. **Other topics** – A participant suggested that outside of the annual, official USAHA meeting, ongoing, interim work should continue by the TB SAS or other interested members of USAHA's Committee on Tuberculosis. Such members could assist with year round reviews as needed.

IV. SURVEILLANCE, TRACEABILITY AND INVESTIGATION DEFICIENCIES

Background

Eradiation of TB in the US depends on early detection and elimination before the disease can spread. It is generally accepted that the sensitivity of detecting TB at slaughter by visual inspection is lower than necessary for eradication. Some herds that are identified by slaughter surveillance have been infected for years and have potentially spread the disease to other herds. However, until more sensitive serological tests are available, slaughter surveillance remains a critical tool for detection of newly affected herds.

In addition to slaughter surveillance, it will be necessary to find ways to enhance surveillance for this disease if eradication is the goal. This includes surveillance in cattle as well as farmed Cervidae.

One way of enhancing surveillance would be to test high risk animals that move interstate. In 2007, USAHA approved Resolution 25, Tuberculosis Test Requirement for Rodeo/Event Cattle. This Resolution urged USDA to implement a regulation requiring that all bucking bulls, roping steers and bulldogging steers be tested negative for TB within 12 months of interstate movement.

The systems in place to trace cattle found infected with TB at slaughter to a herd of origin are good, but could be improved. One challenge has been tracing cattle found infected at slaughter through cattle concentration points, particularly adult cow feedlots.

In the past traceability has been tied to disease control programs. The successes of the Brucellosis and TB programs have led to a decline in the use of permanent identification for breeding cattle. In 2006, USAHA approved Resolution 22, Official Identification of Dairy Animals in Interstate Commerce. This Resolution urged USDA to issue uniform federal requirements for movement of dairy animals in interstate commerce.

Another challenge to our ability to trace animals in a disease investigation is the practice of raising dairy heifers in large dry lot facilities with feeder cattle. These facilities bring in often unidentified cattle in large numbers from multiple sources in multiple states.

Recommendations/Discussion Questions for Session IV, Surveillance, Traceability and Investigation Deficiencies

1. USDA should fund dedicated TB Surveillance Coordinators, to be assigned to all adult cattle slaughter plants and to fed cattle slaughter plants that harvest a significant number of Mexican cattle. These Coordinators should work directly with FSIS veterinarians to assure submission rates for compatible lesions are adequate for each plant.
2. USDA should implement a regulation requiring that all bucking bulls, roping steers and bulldogging steers be tested negative for TB within 12 months prior to any interstate movement. Except that the movement of animals out of the birth herd would be exempt from the TB test provided that an accredited veterinarian places a statement on the Certificate of Veterinary Inspection that the birth herd has had no exposure to Mexican cattle or dairy cattle.

3. USDA should require, at minimum, a mandatory one time herd test for TB in captive cervid herds, except for herds that have a negative herd test within the last three years.
 - a. As an alternative a whole herd test should be required for animals to move interstate.
4. USDA should require a negative TB test within 60 days on all breeding beef cattle over 24 months of age and on all dairy cattle over 12 months of age moving in interstate commerce.
5. USDA should require that feedlots that feed adult cattle maintain records of origin on all cattle entering the feedlot and require individual identification on all cattle in the feedlot.
6. The Designated TB Epidemiologist must have the flexibility, with approval from the AVIC and State Veterinarian, to determine the size and scope of the disease investigation, including traces and testing required, based on risk of transmission and other epidemiological factors. (Note: Limited funding may prohibit tracing and testing every potential exposed animal/herd as is currently recommended under the UM&R.)
7. USDA should require permanent, official, electronic identification of dairy cattle to premises of birth for interstate movement.
8. USDA should establish minimum standards for approving veterinarians to administer the caudal fold tuberculin test nationally, and regularly review test results to assure an adequate response rate is being met.
9. Should USDA, states and industry initiate an educational campaign to encourage cattle producers to TB test breeding cattle before adding to their herd?

OUTCOMES FROM SESSION IV, SURVEILLANCE, TRACEABILITY AND INVESTIGATION DEFICIENCIES

1. **Dedicated TB-Surveillance Coordinators/harvest plants** – Participants agreed that USDA should establish and fund dedicated TB Surveillance Coordinators. Such Coordinators would be assigned to all fed cattle slaughter plants that harvest a significant number of Mexican cattle and all adult cattle slaughter plants. They should work directly with Food Safety and Inspection Service (FSIS) veterinarians to assist in training in-plant FSIS personnel and assure that submission rates for compatible lesions are adequate for each plant.
2. **Rodeo cattle movement test** – Participants agreed that USDA should implement a regulation requiring all bucking bulls and other event cattle be TB tested within 12 months prior to any interstate movement. Movement of animals out of the birth herd would be exempt from the TB test requirement when an accredited veterinarian certifies on the Certificate of Veterinary Inspection (CVI) that the birth herd has had no exposure to Mexican-origin cattle
3. **One-time herd test for captive cervid herds** – Participants agreed that there needs to be continued surveillance of farmed Cervidae. Options discussed were a one-time herd test, slaughter inspection and testing samples collected for chronic wasting disease (CWD) surveillance for TB.

Continued

The program must allow for slaughter surveillance to play a large role, recognizing the challenge of testing cervids. A required one-time herd test for all captive cervid herds would establish a baseline disease prevalence rate and enhance surveillance. This required testing would be very difficult and frankly not practical for many herds because either the ranch is too large and therefore it is impractical to catch farmed cervids for testing or the ranch lacks the ability to handle the cervids for testing.

Many states do not require testing for cervids to move interstate. Passive surveillance should be conducted nationally by testing CWD sample submissions for TB.

Participants agreed there is a need for federal regulation of interstate movement. Requirements for accredited and non-accredited herds should be codified and federal regulation for interstate movement of cervids should be formalized. These requirements have been specified in a UM&R for captive cervids, but the UM&R has never been implemented. Proposed language on cervid testing should be incorporated into the Code of Federal Regulations (CFR).

4. **Test all breeding beef/dairy cattle >24/12 months** – Despite extensive discussion, participants were unable to reach consensus on requirements for testing of cattle for interstate movement. There was discussion about whether doing surveillance for the disease is the purpose of the testing. Texas found two infected herds by testing prior to interstate movement.

There was extensive discussion on whether to test only dairy cattle or test both beef and dairy cattle. There appeared to be more support for testing only dairy cattle. Several ages were considered as the minimum age for testing. No clear consensus was reached, but there appeared to be more support for two months. It was questioned whether the disease can be detected at such a young age. It was pointed out that dairy cattle may move several times by 12 months of age.

It was noted that there needed to be provisions for exemptions for commuter herds. Commuter herd agreements allow animal movement without the requirement for individual animal TB testing. Additionally, there would need to be different guidelines for commuter herd agreements for beef and dairy cattle. Current commuter herd agreements work well for beef cattle, but not for dairy. It was also discussed whether commuter herd agreements should be administered by states or the federal government.

5. **Feedlots that feed adult cattle maintain records of origin/identification** – Participants agreed that “adult” should be defined as cattle 24 months of age and older. Feedlot owners should maintain individual identification of cattle in the feedlot and records of where individual cattle were purchased. Cull cows and bulls moving interstate for feeding should be required to have permanent, individual, official ID. Further, participants felt that all adult breeding cattle should be officially identified when moved into commerce.

Continued

6. **Flexibility on tracing/testing from new herds based on risk** – Participants agreed that there should be stratification of traces by risk. There needs to be consensus on those definitions of level of risk backed by legal authority and national consistency.
7. **ID of dairy cattle to premises of birth for movement** – There was not an expectation among participants that the ID be electronic ID (EID), but participants agreed that it has to be permanent, official and unique. For interstate movement, all dairy cattle should be identified to their birth premises. For interstate movement, all adult beef cattle should be identified to their source.
8. **Standards/review for veterinarians administering TB test** – Participants agreed that there need to be national minimum performance and continuing education standards to certify veterinarians to TB test cattle and farmed Cervidae. There should be periodic review for reaccreditation.

V. MODERNIZING REGULATIONS

Background

Many of the rules governing the national TB program have been in place for decades and attempts to update the program in recent years have failed due to the burdensome federal rulemaking system. The current state classification system is very rigid and proscriptive mandates are often not warranted. A state's status is determined by an allowable prevalence level, and often by a specific number of TB-affected herds that can be detected in a state. A state can lose its free status if just two affected herds are detected, regardless of risk and effectiveness of local mitigation strategies employed.

In addition, multiple risk factors exist in today's cattle operations, in all states, regardless of current TB-program classification, including:

- Lack of or insufficient biosecurity;
- Specialization of producers, such as calf raisers, heifer raisers, etc., often leading to frequent animal movements. There has been a tendency towards increased commingling of cattle from multiple owners and increased commingling of breeding and feeder cattle; and
- Reconditioning of cull dairy cattle and potential exposure to many other cattle, including those in feedlots.

Under the current system, a population of animals at risk for exposure to TB may cross a state boundary yet remain free, while other populations or industry sectors within the same state may be at little or no risk, and be required to follow one set of rigid rules. It is becoming clear that basing bovine TB regulations on state geopolitical boundaries is no longer an effective strategy.

It is also clear that certain inherent risks may be present in free states or regions, which may warrant additional requirements by states outside of those required by the existing federal program. One example is that most states in the Western US now require a TB test for dairy cattle regardless of state status of the exporting state. This is due to the low prevalence of TB assumed to be present in dairy cattle in the Southwestern US.

USDA stated in 2006 that, "based on cost-benefit analysis, qualitative measurement, and some quantitative measurement from previous works, eradication of bovine TB remains biologically and economically feasible and helps in protecting human health and international trade of livestock." The validity of this statement against current economic conditions must be considered. For Fiscal Year 2008, \$15.1 million was available, and this is the expected maximum level of funding for this and future years. Federal deficits will likely prevent additional funding and Commodity Credit Corporation (CCC) funds will not be available to fund TB emergency eradication efforts in the future. Additionally, state revenue dedicated to support of TB surveillance and eradication cannot be expected to increase, and is likely to decrease.

Recommendations/Discussion Questions for Session V, Modernizing Regulations

1. USDA should declare the entire country free of bovine TB and eliminate the state classification system.

2. USDA should establish rules that allow state and federal officials the flexibility at the local level to take steps necessary to control the disease in affected herds (and region if warranted), without unnecessarily impacting low-risk herds or sectors within the state or region; and use performance standards to describe the regulatory goal or desired outcome. Such an effective program would control TB “from within” a state or region, so each state does not need to place controls “from without.”
 - a. Can the epidemiological investigation and animal movement tracing be completed without immediately quarantining an entire state or region?
 - b. If not, what criteria would warrant a control zone or region in addition to quarantine of the known affected herd(s)?
3. USDA should provide for official review teams of state and federal animal health officials to regularly review actions and progress for each TB occurrence to assure that effective control strategies are being met; and if not, determine what additional controls need to be established, including regional or state control zones as warranted.
4. Fiscal realities:
 - a. USDA should continue to provide indemnity for fair market value for individual animals suspected of being infected with TB.
 - b. USDA should finalize rules to stop payment of federal indemnity for any herd owner not following his/her herd plan.
 - c. The current \$3,000 maximum indemnity per animal should be maintained. Exploration of new means of compensation for higher-valued cattle (registered, purebred, etc.) should be explored. State and federal animal health officials should consider alternative or supplemental sources for indemnity funding. These may include cost-sharing with the industry or state, or developing industry-funded insurance programs.
 - d. USDA should coordinate meetings with national beef and dairy cattle organizations to explore the feasibility of alternate/supplemental sources of indemnity funds, including industry-funded insurance programs.

OUTCOMES FROM SESSION V. MODERNIZING REGULATIONS

1. **Declare US bovine TB-free and eliminate state classification system** – Most participants agreed that the current existing classification system assigning TB status to states is outdated and should be eliminated. However, many expressed concerns that the existing system should not be eliminated without being replaced by well-conceived standards. For example, surveillance must be comprehensive, consistent, documented and regularly evaluated for all states.

Although every state has historically been declared TB-free at some point in the past, most participants agreed that the US as a whole should not be declared “Tuberculosis Free”. This classification may send the wrong signal to the US Congress, appropriators, industry representatives and livestock producers. However, use of the qualified World Organization for Animal Health (OIE) definition of “free” may be acceptable.

Continued

Each state must be held to standards for interstate movement and surveillance. State regulations should be consistent to avoid 50 different requirements for each of the 50 US states. There must be good science and risk assessments.

In the past, states have taken action to protect themselves against the program rather than against the disease. Livestock producers also desire protection. Status should be divorced from movement requirements relative to disease in that state. Classification should be based upon disease prevalence rather than solely on one or two TB-positive herds.

Will states have the incentive to conduct adequate surveillance without the existing status system? If the status system is eliminated, what affect would that have on the US's ability to export animals and animal products? TB-free status affects international export ability. Certain segments or sectors do not pose a danger, such as germ plasm.

2. **Allow state and federal officials the flexibility to address TB at the local level** – Most participants agreed that the National TB Program should afford some flexibility, allowing state and federal officials the ability to address TB at the local/state level. In most cases, individual herds should be addressed rather than having blanket restrictions placed on a state or region. A state or region should be restricted only if there is a wildlife reservoir or other unidentified source of possible reintroduction of infection. There must be a nationwide, uniform system without undue testing and regulation.
3. **Official state and federal review teams** – There was general consensus that review teams should be established, composed of state, federal and industry representatives. These reviews would be similar to the customary area reviews. Such independent reviews would provide oversight. USDA will be looked to for general oversight and administration and there must be rapid turn-around on reviews and reporting. Epidemiological summaries must be transparent and made publicly available. They could be made available through the National Assembly of Chief Animal Health Officials and on various websites.
4. **Fiscal realities** – There was general agreement that indemnity payment should continue at fair market value and the \$3,000 cap should be maintained. Indemnity payment should correlate with herd plan adherence and payment should be withheld if an owner is not complying with the herd plan.

Industry groups are exploring insurance programs as supplemental indemnity options. The model for this is the Delmarva fund, which is supported financially by poultry firms.

In general, the indemnity process should be reevaluated. It is variable, not transparent, unclear and slow. The indemnity process should be uniform and consistent, with decisions made quickly.

5. **Other topics** – Some participants felt that, concerning Mexico, efforts should be focused on those states wanting to export cattle to the US, not on all Mexican states.

VI. DISEASE CONTROL APPROACH

Background

The approach to finding a TB-infected herd has been very aggressive. The approach has been depopulation of the herd and exposed cattle in other herds and testing of adjacent, contact and trace herds.

In 2008, USAHA approved Resolution 48, Change in How Test and Removal Herds Affects the Calculation of the Number of Tuberculosis Affected Herds with Respect to Determining State/Zone Status.

A study of bovine TB-infected US dairy herds that have undergone test-and-remove protocols since 1985 provides evidence that test-and-remove is a cost effective and efficacious method to eliminate TB while minimizing risk to other herds, wildlife and humans. In low prevalence herds, current testing protocols and quarantine provide a significant margin of safety. Meanwhile, the cost to depopulate all TB-infected herds has, in some cases, increased beyond what governments can afford. The loss of herds through depopulation also has great impact on community economic conditions.

Since funding for the national TB eradication effort is limited we must realize this limitation and adjust the program accordingly. What this means is eradication is still possible, but it may take longer. These recommendations are based on a less aggressive approach to eradication and less punitive action taken against areas that have TB.

Recommendations/Discussion Questions for Session VI, Disease Control Approach

1. USDA should amend regulations so that a state or region is not affected if a herd chooses the test-and-remove option.
2. USDA should evaluate whether the current requirements for test-and-remove are appropriate.
3. Recognizing that federal funds for future depopulations are not assured, a prevalence rate should be determined that would trigger strong consideration for depopulation if funding is available. USAHA Resolution 48 recommended a prevalence rate of 1.5% in herds greater than 200 head or greater than three infected cattle in herds less than 200 head.
4. USDA should amend regulations to provide for zoning and compartmentalizing areas based on a risk assessment.
5. USDA should immediately establish a working group with Centers for Disease Control and Prevention (CDC) to review the risk of human transmission to cattle. This effort should include the evaluation and sharing of *M. bovis* isolates from cattle and humans in the US, and enhanced investigation for potential human sources, jointly by animal health and public health officials, when new infection is diagnosed in cattle.

OUTCOMES FROM SESSION VI, DISEASE CONTROL APPROACH

- 1. State or regional status not affected if test-and-remove option chosen**— There was general agreement among participants that state or regional status should not be affected if the test-and-remove option was chosen. A better test would increase the comfort level with this approach and perhaps decrease the quarantine time.
- 2. Evaluate current requirements for test and removal**— Participants agreed that the test-and-remove option should be risk-based and flexible and should be structured to encourage rapid depopulation of the disease. Basing depopulation decisions on a prevalence rate is not a good idea. A lot of good work has gone into developing procedures for test-and-remove in the UM&R and this should be used as a starting point for further discussions.
- 3. Determine prevalence rate for depopulation with limited funding**— Participants agreed that a 1.5% prevalence or in herds less than 200 head three animals were not good parameters to determine use of indemnity funds for depopulation. With limited funding, USDA should determine which herds should be depopulated on a case-by-case basis to best benefit the national eradication program.
- 4. Zoning and compartmentalizing areas based on risk assessment**— Participants agreed that when dealing with individual herds, quarantines are adequate. When there is a wildlife component or evidence of significant local spread among cattle herds, a designated surveillance area should be established with appropriate movement controls. Several participants felt that there should be comprehensive, consistent wildlife surveillance to define disease prevalence and spread over time. There should be a designated surveillance area, similar to that for brucellosis in the Greater Yellowstone Area. Participants felt that the cattle industry does not lend itself well to compartmentalization.
- 5. Collaboration with CDC to determine risk to cattle from human sources**— Participants reached consensus that this zoonotic disease should be addressed through a working group. There should be collaboration with the Centers for Disease Control and Prevention (CDC) to determine risk to cattle and other species from infected human sources. There are numerous privacy issues.

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APPENDIX A—PLANNING COMMITTEE, BREAKOUT GROUP FACILITATORS AND NOTETAKERS

The TB symposium’s Planning Committee included:

- USAHA President, Dr. Don Hoenig, Maine State Veterinarian
- USAHA President-elect, Dr. Richard Breitmeyer, California State Veterinarian
- USAHA First Vice President, Dr. Steve Halstead, Michigan State Veterinarian
- USAHA Treasurer, Dr. William Hartmann, Minnesota State Veterinarian and Board of Animal Health Executive Director
- USAHA Committee on Tuberculosis Chair, Kathleen M. Connell

The Planning Committee was responsible for development of discussion points for the six breakout sessions.

Facilitators for the symposium included:

- Dr. Richard Breitmeyer
- Dr. Kathleen M. Connell
- Dr. Steve Halstead
- Dr. William Hartmann

Members of the USAHA Committee on Tuberculosis who assisted by taking notes of the breakout sessions included:

- Mr. Matt Ankney, Coordinator, Bovine TB Eradication Project, Michigan Department of Community Health
- Mr. Phil Durst, Michigan State University Extension Dairy Agent for Northeast Michigan
- USAHA President, Dr. Don Hoenig, Maine State Veterinarian
- Mr. John Lawrence, Senior Research Scientist, IDEXX Laboratories
- Dr. Chuck Massengill

APPENDIX B—LIST OF PARTICIPANTS

Attendee	Affiliation
Ankney, Matthew	Michigan Department of Agriculture
Antognoli, Celia	USDA-APHIS-VS
Ashworth, Chris	Elanco Animal Health
Atchison, Scharee	NIAA
Badley, George	Arkansas Livestock & Poultry Commission
Baker, John	Michigan State University
Barlow, Eric	Wyoming Livestock Board
Barton, Bill	Idaho Department. of Agriculture
Bengtson, Steven	USDA-APHIS-VS
Berrier, Randall	Colorado Serum Co.
Blanchard, Patricia	University of California
Bogges, Edward	Minnesota DNR Division of Fish & Wildlife
Botero, Jorge	Colorado
Breitmeyer, Richard	California Department of Food & Agriculture
Brewer-Walker, Becky	Oklahoma Department of Agriculture
Brigner, Tiffany	Colorado Department of Agriculture
Brown II, Charles E	ABS Global, Inc.
Butchko, Peter	USDA-APHIS-WS
Byrne, Matt	California Cattlemen's Association
Cain, Cliff	Enfer Diagnostics Ltd
Camacho, Mark	USDA-APHIS-VS
Carlson, Beth	North Dakota Board of Animal Health
Carroll, James	Dairy Farmers of America
Carstensen, Michelle	Minnesota Department of Natural Resources
Clarke, John	Enfer Scientific Ltd.
Clifford, John	USDA-APHIS-VS
Connell, Kathleen	Foxglove Consulting
Cowan, Caren	New Mexico Cattle Growers Association
Cowan, John	Texas Association of Dairymen
Crawford, Stephen	New Hampshire Department of Agriculture
Culbertson, Myles	New Mexico Livestock Board
Davis, William	Washington State University
De Grassi, Ria	California Farm Bureau Federation
Desautels, Louis	Canadian Cattle ID Association
Dewell, Renee	American Association of Bovine Practitioners
Dick, Jere	USDA-APHIS-VS
Dinges, Lewis	Texas A & M University
Dokkebakken, Bruce	Minnesota DHIA
Durst, Phil	Michigan State University
Dyess, Reta	Texas Animal Health Commission

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Edmondson, Anita	California Department of Food & Agriculture
Eldridge, Leonard	Washington State Department of Agriculture
Ellis, Dee	Texas Animal Health Commission
Fankhauser, Terry	Colorado Cattlemen's Association
Fly, Dave	New Mexico Livestock Board
Fraley, Jim	Illinois Farm Bureau
Freier, Jerry	USDA-APHIS-VS
Gidlewski, Tom	USDA-APHIS-VS
Goldsmith, Timothy	University of Minnesota
Good, Tony	Select Sires, Inc.
Granger, Larry	USDA-APHIS-VS
Guillossou, Stephane	Synbiotics Corp.
Gutierrez, Alfredo	SAGARPA
Gutierrez-Pabello, Jose	FMVZ-UNAM
Hall, Rod	Oklahoma Department of Agriculture
Halstead, Steven	Michigan Department of Agriculture
Hamann, Marvin	Colorado Cattlemen's Association
Hanosh, Timothy	New Mexico Livestock Board
Hansen, Donald	Oregon Department of Agriculture
Hartmann, William	Minnesota Board of Animal Health
Healey, Burke	USDA-APHIS-VS
Heckendorf, Carl	Colorado Department of Agriculture
Hegeman, Jacob	USDA-APHIS
Hench, Bill	USDA-APHIS-VS
Hickam, Linda	Missouri Department of Agriculture
Hillman, Bob	Texas Animal Health Commission
Hoenig, Donald	Maine Department of Agriculture
Hughes, Dennis	Nebraska Department of Agriculture
Humpries, Rebecca	Michigan Department of Natural Resources
Hunt, John	Arizona Department of Agriculture
Huntley, John	New York State Agriculture & Markets
Ibarra, Luisa	CNOG
Johnson, Jon	Texas Farm Bureau
Jones, Howard	Centaur Inc.
Jonker, Jamie	National Milk Producers Federation
Jordan, Karen	Dairy Farmers of America
Kaneene, John	Michigan State University
Keller, Susan	North Dakota Board of Animal Health
King, Bruce	Utah Department of Agriculture
Kostovic, Miladin	Prionics AG
Lawrence, John	IDEXX Laboratories, Inc.
Leafstedt, James	National Pork Board
Lemieux, Lisa	IDEXX Laboratories, Inc.

Linderoth, Shannon	Food 360
Logan, Jim	Wyoming Livestock Board
Lombard, Jason	USDA-APHIS-VS-CEAH
Lombardi, Sharon	Dairy Producers of New Mexico
Maddox, Stephen	California Dairies, Inc.
Maroney, Susan	USDA-APHIS-VS
Marsh, Bret	Indiana Board of Animal Health
Marshall, David	North Carolina Department of Agriculture
Martin, Joseph	Minnesota Board of Animal Health
Massengill, Chuck	Missouri Department of Agriculture
Metrokotsas, Mark	Centaur Inc.
Meyer, Robert	USDA-APHIS-VS-WRO
Meyer, Rory	Alta Genetics
Miller, Kenneth	Texas Association of Dairymen
Morales, Ernie	Texas Animal Health Commission
Munoz, Ricardo	Applied Biosystems
Nadler, Yvonne	Lincoln Park Zoo
Naugle, Alecia	USDA-APHIS-VS
Nelson, Cheryl	Nelson Reproductive Services
Nelson, Larry	Nelson Reproductive Services
Oedekoven, Dustin	South Dakots Animal Industry Board
Ogden, Alisa	New Mexico Cattle Growers Association
Orloski, Kathleen	USDA-APHIS-VS
Palmer, Mitchell	National Animal Disease Center
Parker, Elizabeth	National Cattlemen Beef Assoc.
Parr, Boyd	Clemson University
Pedersen, Kerri	USDA-APHIS-WS
Portacci, Katie	USDA-APHIS-VS
Ramitez-Godinez, Jose Alejandro	No affiliation listed
Rathe, Chris	PriTest, Inc.
Ray, Tom	North Carolina Department of Agriculture
Ritter, Tonia	Michigan Farm Bureau
Robinson, Nancy	Livestock Marketing Association
Roehr, Keith	Colorado Department of Agriculture
Rogers, Charlie	Livestock Marketing Association
Sauble, Bill	New Mexico Cattle Growers Association
Scarfe, A. David	American Veterinary Medical Association
Schafer, Shawn	North American Deer Farmers Association
Schmitt, Dennis	Missouri State University
Schnackel, John	American Association of Bovine Practitioners
Schwartz, Andy	Texas Animal Health Commission
Schwartz, James	Wyoming Livestock Board
Shere, Jack	USDA-APHIS-VS

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Steinke, Ivan	Colorado Livestock Association
Striegel, Nick	Colorado State University
Sumrall, David	No affiliation listed
Talbot, Thomas	California Cattlemen's Association
Teagarden, Matt	Kansas Livestock Association
Thacker, Eileen	USDA-ARS-NPS
Thomas, Lee Ann	USDA-APHIS-VS
Ugstad, Paul	USDA-APHIS-VS
Van Dam, William	Alliance of Western Milk Producers
Varela, Alejandro	Sonora Cattleman's Union
VerCauteren, Kurt	USDA-APHIS-WS
Waters, Katrina	Texas and Southwest Cattle Raisers Association
Weaver, Todd	USDA-APHIS-VS
Welles, Peter	IDEXX Laboratories, Inc.
Whetten, Jay	Prodigy
Wiley, Garry	Michigan Cattlemen's Association
Williams, Brad	Texas Animal Health Commission
Wilson, Ross	Texas Cattle Feeders Assoc.
Winegarner, Josh	Texas Cattle Feeders Assoc.
Wineland, Nora	USDA-APHIS-VS-CEAH
Winters, David	Texas Animal Health Commission
Zaluski, Marty	Montana Department of Livestock

APPENDIX C—PERTINENT USAHA RESOLUTIONS

This appendix includes select Resolutions from 2004 to 2008. Resolutions were included because of their relevance and reference in various background sections in this report and in the discussion guide provided to meeting participants.

The Resolutions are included in the following order:

2008—

- Resolution 47, Fund Expanded Collection of Well-characterized Serum from Cattle and Cervids Routinely Tested for Tuberculosis in Cattle and Cervids to Enhance Bovine Tuberculosis Eradication Program, discussed in Session III
- Resolution 48, Change in How Test and Removal Herds Affects the Calculation of the Number of Tuberculosis Affected Herds with Respect to Determining State/Zone Status, discussed in Session VI
- Resolution 50, Restricting Imported Feeder Cattle, discussed in Session I

2007—

- Resolution 25, Tuberculosis Test Requirement for Rodeo/Event Cattle, discussed in Session IV
- Resolution 26, Collection of Serum from Cervids Routinely Tested by the Single Cervical Test for Evaluation of the Rapid Test for Tuberculosis in Cervids, discussed in Session III
- Resolution 27, Designation of Tuberculosis Serological Tests for Provisional Status, discussed in Session III

2006—

- Resolution 21, Collection of Serum from Cervids Routinely Tested by the Single Cervical Test for Evaluation of the Rapid Test for Tuberculosis (TB) in Cervids, discussed in Session III
- Resolution 22, Official Identification of Dairy Animals in Interstate Commerce, discussed in Session IV

The USAHA's Committee on Tuberculosis's Resolutions from 2004 to 2008 are available on the USAHA website, www.usaha.org. At that site, select "*Committees*", then "*Tuberculosis*". Resolutions are listed in chronological order, with links to the complete Resolution language and response from the appropriate agency.

UNITED STATES ANIMAL HEALTH ASSOCIATION – 2008 RESOLUTION

RESOLUTION NUMBER: 47 APPROVED
SOURCE: COMMITTEE ON TUBERCULOSIS
SUBJECT MATTER: 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 BOVINE TUBERCULOSIS ERADICATION PROGRAM
DATES: GREENSBORO, N.C, OCTOBER 23-29, 2008

BACKGROUND INFORMATION:

The need for gathering quality samples for new tuberculosis (TB) test validation work has been supported by multiple recent United States Animal Health Association (USAHA) resolutions. This has led to the National Veterinary Services Laboratories (NVSL) working hard to implement a sera bank during the last two years. The initial work focused on cervid sample collection, which has been followed by cattle sample collection. The estimated number of total samples at the NVSL from these efforts is 2,500 cervid samples and 380 cattle samples. Only 53 cervid and fewer than 10 cattle samples are well-characterized positives which are the samples needed for sensitivity validation of any new test. This Resolution seeks to overcome the significant limitation of the current sera bank and ask for the United States Department of Agriculture (USDA) to support the work of collecting up to 1,000 new well-characterized positive cattle and Cervid samples, along with added negative cattle samples from TB Accredited Free States. From the report of the Committee on Tuberculosis updating the criteria for evaluating TB test performance for official test status, the number of positive samples needed per species is estimated to be 500 or more. This is far greater than the 10 and 53 positive samples that are available, respectively, for cattle and cervid test validation in the NVSL sera bank today. Without these samples being collected, no new test will be validated.

At the 2006 USAHA Annual Meeting the following Resolution was approved as Resolution 21: “The United States Animal Health Association (USAHA) recommends that the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) validate a serological tuberculosis test for captive cervids. USAHA urges USDA-APHIS-VS to take the lead in organizing a pilot project with industry so that prior to each single cervical test injection in captive cervids a blood sample is collected and serum submitted to the National Veterinary Services Laboratory (NVSL) for evaluation of the VetTB Stat-Pak™ rapid test for one year. Serum should be banked for evaluation of a future serology test. Results of this evaluation should be submitted for review by the Scientific Advisory Subcommittee on Tuberculosis”.

This Resolution had the following response: “The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) maintains interest in enhancing and approving new, reliable tests for tuberculosis. We specifically look forward to testing methods that will exceed the accuracy of our current tests and reduce the impact of testing on producers and their livestock. For these reasons, VS fully supports this recommendation. Implementation of this project will be heavily dependent on the industry for providing samples, providing assistance with the purchase of suspects and reactors for confirmatory testing, assistance during testing, and with the promotion of this effort within the industry. Implementation of this project is also dependent on the availability of time, personnel, and financial resources. VS fully intends to pursue.”

At the 2007 USAHA Annual Meeting the following Resolution was approved as Resolution 26: “The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) to expedite the validation process for tuberculosis (TB) serological tests for cervids to enhance surveillance for TB.”

This Resolution had the following response: “The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services recognizes the United States Animal Health Association’s

concerns and appreciates the opportunity to respond. The Serology Section of the Diagnostic Bacteriology Laboratory of the National Veterinary Services Laboratories (NVSL) is currently working with various cervid producer associations to obtain serum samples from a variety of cervid species. A cervid serum bank has been established; the number of species and the number of samples for each species are increasing. As of January 1, 2008, there were 1,273 serum samples in the bank. The NVSL continues to create panels of blind samples to assist in the evaluation of cervid TB serological tests being developed.”

There are promising tests awaiting these additional samples to complete their validation work. At the 2007 USAHA Annual Meeting the following Resolution was approved as Resolution 27: “The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) to designate the PriTest SeraLyte-Mbv™, Chembio BovidTB STAT-PAK™, and Chembio Mapia™ tests as provisional tests for *Mycobacteria bovis* diagnosis in cattle.” These tests are being developed for cervid TB testing as well.

The Resolution had the following response: “The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) recognizes the United States Animal Health Association’s concerns and appreciates the opportunity to respond. Official use of specific test kits is determined by VS National Animal Health Program and Policy staff, with input from the TB Scientific Advisory Subcommittee. Due to confidential business information constraints, the Center for Veterinary Biologics (CVB) cannot comment on the licensure status of these three kits, but it is the CVB’s opinion that these products should follow the standard process for licensure.”

RESOLUTION:

The United States Animal Health Association (USAHA) requests the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to request funding and establish specific goals and timelines to gather the required numbers of well-characterized samples that will allow new and promising tests for tuberculosis (TB) to be scientifically validated.

UNITED STATES ANIMAL HEALTH ASSOCIATION – 2008 RESOLUTION

RESOLUTION NUMBER: 48 **APPROVED**
SOURCE: COMMITTEE ON TUBERCULOSIS
SUBJECT MATTER: **CHANGE IN HOW TEST AND REMOVAL HERDS AFFECTS THE
CALCULATION OF THE NUMBER OF TUBERCULOSIS AFFECTED
HERDS WITH RESPECT TO DETERMINING STATE/ZONE STATUS**
DATES: GREENSBORO, N.C, OCTOBER 23-29, 2008

BACKGROUND INFORMATION:

A study of bovine tuberculosis (bTB) infected United States (US) dairy herds that have undergone test and remove (T&R) protocols since 1985 provides evidence that T&R is a cost effective and efficacious method to eliminate bTB while minimizing risk to other herds, wildlife and humans. In low prevalence herds, current testing protocols and quarantine provide a significant margin of safety. Meanwhile, the cost to depopulate all bTB infected herds has, in some cases, increased beyond what governments can afford. The loss of herds through depopulation also has great impact on community economic conditions.

While T&R is scientifically, socially and economically a good option for low bTB prevalence herds, current United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) policy (VS memorandum 552.38, March, 2008) on the equal count of affected herd years throughout the quarantine period make T&R unattractive as an option because of the potential downgrade of a state's bTB status. In Modified Accredited Advanced (MAA) states/zones with less than 30,000 herds and in Modified Accredited (MA) states/zones with less than 10,000 herds, an affected herd going through T&R will count fully throughout the approximately 4.5 year quarantine even as confidence in the herd's elimination of bTB increases with each subsequent negative whole herd test over time. The requirement for an additional two to five years (dependent on the current status of the state/zone) of being bTB free after the end of the quarantine period is overly burdensome to a state to advance to the next higher status, when there have been no identified infected cattle for four years. Since 42 states currently have less than 30,000 cattle herds, the USDA-APHIS-VS policy memorandum has potentially widespread impact.

There is now enough evidence of the effectiveness of T&R in low prevalence herds to change the counting of affected herds that meet specific criteria of prevalence rate, approved herd plan development, epidemiological investigation and regular review. Meeting the criteria would define a herd as an approved T&R herd and, therefore, qualify it for the benefit of a change in affected herd year counting. The counting can be changed by a multiplication factor that decreases with increasing years and negative testing results in a T&R program.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to adopt changes to VS Memorandum 552.38 in the counting of affected herd years for approved Test and Remove herds by reducing the value to 75 percent of an affected herd in year two, 50 percent in year three, and 25 percent thereafter when no additional infected animals are found.

UNITED STATES ANIMAL HEALTH ASSOCIATION – 2008 RESOLUTION

RESOLUTION NUMBER: 50 **APPROVED**
SOURCE: COMMITTEE ON TUBERCULOSIS
SUBJECT MATTER: **RESTRICTING IMPORTED FEEDER CATTLE**
DATES: GREENSBORO, N.C, OCTOBER 23-29, 2008

BACKGROUND INFORMATION:

Mexican origin steers and spayed heifers meeting United States (US) import requirements are allowed to enter the US without restriction and little consideration for risk to commingled or adjacent livestock that may be exposed to Mexican origin cattle that may be incubating tuberculosis (TB).

Cases of TB continue to be found in Mexican origin steers and spayed heifers, and genetic fingerprinting suggests epidemiologic links and their involvement in transmitting tuberculosis to native US cattle. This has been determined to be a major deterrent in successfully completing the national tuberculosis eradication program in the US.

To adequately address this significant impediment to the successful completion of the US TB Eradication Program, cattle import regulations in the Code of Federal Regulations (CFR) must be modified to require that steers and spayed heifers originating from non accredited free states or zones in Mexico or from any other zone which historically has not achieved accredited tuberculosis free status meet import testing requirements and be restricted to facilities which contain no breeding cattle.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to modify Title 9, Code of Federal Regulations (CFR), Part 93.427 to require that steers and spayed heifers originating from states or zones which have never historically achieved Accredited-Free Status only be allowed importation into the United States if import requirements are met and transported directly from the port of entry or first point of assembly to feedlots, pastures or pens which do not contain breeding cattle.

UNITED STATES ANIMAL HEALTH ASSOCIATION – 2007 RESOLUTION

RESOLUTION NUMBER: 25 APPROVED
SOURCE: COMMITTEE ON TUBERCULOSIS
SUBJECT MATTER: TUBERCULOSIS TEST REQUIREMENT FOR RODEO/EVENT CATTLE
DATES: RENO, NEVADA, OCTOBER 18 – 24, 2007

BACKGROUND INFORMATION:

The 2006 discovery of two separate instances of bovine tuberculosis (TB), one case in a bucking bull and the other in a roping steer, has resulted in traces to cattle in several states as well as the destruction of a herd of beef cattle. The relative risk posed by rodeo/event cattle is much greater than the risk from feeder cattle. Compared to feeder cattle, roping and bull dogging steers may remain in the population much longer, are more likely to be commingled with breeding beef cattle, may have multiple owners in a comparatively short time period and are frequently commingled with event/rodeo cattle of various owners at roping events and rodeos. In addition, current events indicate that there is a need for more tuberculosis surveillance in bucking bulls. This is clearly demonstrated by the number of exposed cattle traces related to the positive bucking bull.

Most United States (US) breeders of eventing cattle are cattle producers whose ranches are located in bovine TB Accredited Free states. These cattle producers follow management practices identical to those of other purebred and commercial beef producers and their cattle seldom commingle with Mexican origin cattle or dairy cattle. It should be recognized that these cattle pose a low risk of transmitting TB. Testing these cattle provides little if any benefit to the efforts to control and eradicate bovine TB from the US.

It should also be recognized that a testing requirement for native cattle that have never been exposed to Mexican origin cattle or dairy cattle as a condition for interstate movement for cattle shows and for sale as breeding stock may discourage the development of an alternative, low risk source of eventing cattle.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) to implement a regulation requiring that all bucking bulls, roping steers and bulldogging steers be tested negative for tuberculosis (TB) within 12 months prior to any interstate movement. Except that the movement of animals out of the birth herd would be exempt from the TB test provided that an accredited veterinarian places a statement on the Certificate of Veterinary Inspection that the birth herd has had no exposure to Mexican cattle or dairy cattle.

USAHA also urges USDA-APHIS to implement a regulation requiring that an official Certificate of Veterinary Inspection accompany the aforementioned cattle that required a test and the test date of the last negative tuberculosis test for each animal is indicated on the Certificate.

UNITED STATES ANIMAL HEALTH ASSOCIATION – 2007 RESOLUTION

RESOLUTION NUMBER: 26 **APPROVED**
SOURCE: COMMITTEE ON TUBERCULOSIS
SUBJECT MATTER: **COLLECTION OF SERUM FROM CERVIDS ROUTINELY TESTED BY THE SINGLE CERVICAL TEST FOR EVALUATION OF THE RAPID TEST FOR TUBERCULOSIS IN CERVIDS**
DATES: RENO, NEVADA OCTOBER 18 – 24, 2007

BACKGROUND INFORMATION:

At the 2006 United States Animal Health Association (USAHA) meeting the following Resolution was approved as Resolution Number 21: “The United States Animal Health Association (USAHA) recommends that the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) validate a serological tuberculosis test for captive cervids. USAHA urges USDA-APHIS-VS to take the lead in organizing a pilot project with industry so that prior to each single cervical test injection in captive cervids a blood sample is collected and serum submitted to the National Veterinary Services Laboratory (NVSL) for evaluation of the VetTB Stat-Pak™ rapid test for one year. Serum should be banked for evaluation of a future serology test. Results of this evaluation should be submitted for review by the Scientific Advisory Subcommittee on Tuberculosis”.

This Resolution had the following response: “The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) maintains interest in enhancing and approving new, reliable tests for tuberculosis. We specifically look forward to testing methods that will exceed the accuracy of our current tests and reduce the impact of testing on producers and their livestock. For these reasons, VS fully supports this recommendation. Implementation of this project will be heavily dependent on the industry for providing samples, providing assistance with the purchase of suspects and reactors for confirmatory testing, assistance during testing, and with the promotion of this effort within the industry. Implementation of this project is also dependent on the availability of time, personnel, and financial resources. VS fully intends to pursue”.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) to expedite the validation process for tuberculosis (TB) serological tests for cervids to enhance surveillance for TB.

UNITED STATES ANIMAL HEALTH ASSOCIATION – 2007 RESOLUTION

RESOLUTION NUMBER: 27 **APPROVED**
SOURCE: COMMITTEE ON TUBERCULOSIS
SUBJECT MATTER: **DESIGNATION OF TUBERCULOSIS SEROLOGICAL TESTS FOR PROVISIONAL STATUS**
DATES: RENO, NEVADA OCTOBER 18 – 24, 2007

BACKGROUND INFORMATION:

Preliminary data presented at the Scientific Advisory Subcommittee (SAS) on Tuberculosis (TB) on October 20, 2007, indicates that the PriTest SeraLyte-Mbv™, Chembio BovidTB STAT-PAK™, and Chembio Mapia™ *Mycobacterium bovis* test technologies show promise for potential use in the national Bovine TB Eradication Program. Test sensitivity values reported were 81.5%, 70.4% and 70.4% respectively. Additional data is now needed to more critically evaluate these tests according to proposed use in an official capacity. Designation of these tests as provisional, as per applicable United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) memoranda will support the collection of additional data for evaluation by the TB SAS and USDA-APHIS.

This designation will initiate a more formal process allowing USDA-APHIS to work with the test developers in identifying specific uses for these tests in the national Bovine TB Eradication Program and to provide guidance regarding additional test samples needed for further consideration and evaluation as official TB program tests.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) to designate the PriTest SeraLyte-Mbv™, Chembio BovidTB STAT-PAK™, and Chembio Mapia™ tests as provisional tests for *Mycobacteria bovis* diagnosis in cattle.

UNITED STATES ANIMAL HEALTH ASSOCIATION – 2006 RESOLUTION

RESOLUTION NUMBER: 21 APPROVED

SOURCE: COMMITTEE ON TUBERCULOSIS

SUBJECT MATTER: **COLLECTION OF SERUM FROM CERVIDS ROUTINELY TESTED BY THE SINGLE CERVICAL TEST FOR EVALUATION OF THE RAPID TEST FOR TUBERCULOSIS (TB) IN CERVIDS**

DATES: MINNEAPOLIS, MINNESOTA, OCTOBER 12-18, 2006

BACKGROUND INFORMATION:

Recent advances in the science of tuberculosis testing has led to the development of serological tests. The availability of serological tests for captive cervids would decrease the need for handling of these species, and would allow for increased interest in tuberculosis testing by producers. In order to provide information needed to assess the sensitivity and specificity of these tests, collection of serum samples during tuberculosis (TB) testing is needed. This serum could be used to evaluate currently available tests, and create a serum bank for use in evaluation of tests which may be developed in the future. Serum-based tests for use in cervid species would lead to increased participation of captive cervid herds in the tuberculosis eradication program.

RESOLUTION:

The United States Animal Health Association (USAHA), recommends that United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) validate a serological tuberculosis test for captive cervids. USAHA urges USDA-APHIS-VS to take the lead in organizing a pilot project with industry so that prior to each single cervical test injection in captive cervids a blood sample is collected and serum submitted to the National Veterinary Services Laboratory (NVSL) for evaluation of the VetTB Stat-Pak™ rapid test for one year. Serum should be banked for evaluation of a future serology test. Results of this evaluation should be submitted for review by the Scientific Advisory Subcommittee on Tuberculosis.

UNITED STATES ANIMAL HEALTH ASSOCIATION – 2006 RESOLUTION

RESOLUTION NUMBER: 22 APPROVED

SOURCE: COMMITTEE ON TUBERCULOSIS

SUBJECT MATTER: OFFICIAL IDENTIFICATION OF DAIRY ANIMALS IN INTERSTATE
COMMERCE WITH INTERNATIONAL STANDARDS ORGANIZATION
APPROVED RADIO FREQUENCY IDENTIFICATION

DATES: MINNEAPOLIS, MINNESOTA, OCTOBER 12-18, 2006

BACKGROUND INFORMATION:

The Board of Directors of the National Milk Producers Federation (NMPF) recognizes the importance of eradicating the last vestiges of bovine tuberculosis (TB) from dairy cattle in the United States. NMPF is concerned that a very low prevalence of TB may still exist, particularly in dairy herds and dairy heifer raising operations which market breeding animals in interstate commerce. The NMPF recommends and supports separate interstate movement requirements for all dairy animals. NMPF supports individual animal identification with radio frequency identification (RFID) International Standards Organization (ISO) approved ear tags so that all interstate dairy movements will be in compliance with the TB movement requirements in Title 9 of the Code of Federal Regulations , Part 77, the January 2005 Bovine Tuberculosis Eradication Uniform Methods and Rules, as well as the National Animal Identification System (NAIS) requirements for ear tagging individual animals. Uniform federal requirements for movement of dairy animals in interstate commerce will alleviate different individual state entry requirements for dairy animals. The NMPF is aware of at least 34 states now requiring more stringent requirements for entry of dairy cattle than required in federal regulations. Requiring RFID ISO compliant ear tags containing the official animal identification number (AIN) will make it more likely that dairy animals will be properly identified at each change of ownership and location where animals are being commingled. Registry tattoos are hard to read and most dairy animals are not branded to avoid damage to the hide. The button RFID ISO approved ear tags are less likely to be missed as opposed to the official metal ear tags which are easier to remove and more difficult to read.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to issue uniform federal requirements for movement of dairy animals in interstate commerce. Furthermore, USAHA urges USDA-APHIS-VS to require individual dairy animal identification with USDA approved radio frequency identification (RFID) International Standards Organization (ISO) approved individual identification (ear tags) devices which contain the official animal identification number (AIN), this will provide additional assurance that all dairy animals moving in interstate commerce can be traced back to the herd of origin.

APPENDIX D—BOVINE TB PROGRAM RECOMMENDATIONS FOR INCLUSION IN THE CFR

**Developed and Presented for Consideration by the Cattle Industries of Texas and the Texas Animal Health Commission
August 17, 2009**

Classes of cattle

Low risk—Cattle not known to be exposed to TB and cattle not from high risk populations. To maintain their low risk status, they can only be pastured separate and apart (no shared water or feeding equipment) from cattle from a higher risk category and/or fed in an unrestricted feedlot.

- a. Breeding/replacement cattle—Sexually intact male and female cattle used for beef or dairy production or intended for use for beef or dairy production. Breeding or replacement cattle that are commingled with high risk cattle should be reclassified to high risk status. In order to remove the high risk status from the breeding or replacement cattle, all of the Mexican-origin high risk cattle would have to be tested for TB with negative results or the breeding and replacement cattle would be placed under hold order until they are tested negative on two TB tests not less than 60 days apart.
- b. Low risk stocker/feeder cattle—US-origin cattle that have not been commingled with animals from a higher risk category, which are grown on pastures and/or feedlots for finish feeding.
- c. Low risk exhibition/rodeo cattle—US-origin cattle temporarily used for rodeos, team penning competitions, cutting horse events, and other exhibitions where no commingling with cattle from a higher risk category has occurred.

High risk—High risk cattle are stocker, feeder and exhibition cattle of Mexican-origin. In addition, low risk cattle commingled with high risk cattle will be reclassified as high risk. High risk animals can only be fed in restricted, quarantined, or the restricted or quarantined portions of dual purpose feedlots.

- a. High risk stocker cattle—Light weight or young Mexican-origin cattle, or domestic cattle classified as high risk, which need to be grown on pastures or grazing areas before movement to feedlots for finish feeding.
- b. High risk feeder cattle—high risk cattle as defined above ready for finish feeding.
- c. High risk exhibition/rodeo cattle—Mexican-origin cattle or domestic cattle classified as high risk, that are used for rodeos or other exhibition purposes.

TB-exposed—cattle from a herd known to be infected with TB or cattle that have been exposed to TB-infected cattle. These animals may only be fed in quarantined lots and only after a negative tuberculosis test.

Classes of feedlots

Unrestricted feedlot

- Used for feeding of low risk cattle only.
- Cattle may be removed from the feedlot for pasturing, breeding or replacement. Tracebacks of lesioned cattle to an unrestricted feedlot from which cattle have been removed for breeding or replacement may result in the feedlot being classified as a herd, and could count against state status as an infected herd.

Restricted feedlot

- Used for finish feeding cattle for slaughter only
- Provisions for short term grazing and return to the feedlot
- Can accept high risk cattle, but not TB-exposed
- Can accept low risk cattle, but animals will be reclassified as high risk upon entry
- Tracebacks of lesioned cattle to the restricted lot would not result in classification of the feedlot as a herd

Quarantined feedlot

- A feedlot approved for feeding TB-exposed cattle
- Can accept lower classes of cattle, but they will be held to the same standards upon entry to the quarantined lot
- No provisions for grazing or pasturing
- Approval by agreement between feedlot and chief state/federal animal health officials
- All animals must move directly from the quarantined feedlot to slaughter or another quarantined feedlot
- Traceback of lesioned cattle to a quarantined feedlot would not result in classification of the feedlot as a herd

Dual purpose feedlot

A restricted feedlot may designate a pen or portion of their facility as either “Quarantined” or “Unrestricted”, but not both. Quarantined and unrestricted statuses cannot be maintained on a single premises. These pens and the animals contained therein would be held to the same standards as a quarantined or unrestricted feedlot. A system would be developed that eliminates the risk of disease transmission from the higher risk of cattle to the lesser risk. This system would include:

- a. Buffer zone separated by two fences and a distance of at least 30 feet must be maintained between classes of facilities
- b. Drainage from higher risk areas cannot flow through areas of a lesser risk
- c. No shared watering or feeding troughs between classes of facilities
- d. Separate hospital/sick pen facilities
- e. Separate processing/receiving facilities for the different classes of livestock or these facilities must be cleaned and disinfected prior to being used for cattle of a less restricted class. In addition, a standard operating procedure that can verify that this system is being followed must be implemented and documented.
- f. To reclassify “quarantined” pens as “restricted” pens:
 - i. All exposed animals and animals in contact with exposed animals are removed from the pens

- ii. Pens must be cleaned and disinfected as directed by a Designated Tuberculosis Epidemiologist.
- g. To reclassify “restricted” pens to “unrestricted pens”
 - i. 30 days must have passed since any exposed animals or animals in contact with exposed animals are removed from the pens.
 - ii. Pens must be cleaned and disinfected as directed by a Designated Tuberculosis Epidemiologist.

Other points

Grazing of high risk cattle – High risk stocker or feeder cattle may be grazed before entering a restricted feedlot or may be processed at a restricted yard and then be removed for grazing so long as there is no commingling with other classes of cattle. Separation from other classes of livestock can be accomplished by an effective fence, either a well-maintained stock fence or a hot wire fence. The grazing of high risk cattle across a fence from low risk cattle is considered a low risk practice so long as the fence is sufficient to maintain separation and there is not common water or other facilities shared across or through the fence. In addition, these cattle must be returned to the feedlot for finish feeding following the grazing period.

Herd – As defined in the Code of Federal Regulations, except for livestock assembled at feedlots, any group of livestock maintained for at least four months on common ground for any purpose, or two or more groups of livestock under common ownership or supervision, geographically separated but that have an interchange or movement of livestock without regard to health status, as determined by the Administrator.

Feedlot – A facility for congregating and feeding cattle, including Unrestricted Feedlot, Restricted Feedlot, Quarantine Feedlot and Dual Purpose Feedlot.

APPENDIX E – REFERENCE LINKS

External resources pertinent to the discussion of bovine tuberculosis in the United States.

“Criteria for Evaluating Experimental Tuberculosis Test Performance for Official Test Status,” in Report of the Committee on Tuberculosis. Proceedings of the 112th Annual Meeting of the United States Animal Health Association, 2008.

This report is a revision of the 1995 guidelines developed by the Diagnostic Test Review Subcommittee of USAHA.

Link: <http://www.usaha.org/committees/tb/tb.shtml>

Analysis of Bovine Tuberculosis Surveillance in Accredited Free States, January 30, 2009.

United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services.

Link:

http://www.aphis.usda.gov/vs/nahss/cattle/tb_2009_evaluation_of_tb_in_accredited_free_states_jan_09.pdf

Comments to the USDA Bovine Tuberculosis Listening Sessions, December 2008.

LINK: http://www.aphis.usda.gov/newsroom/hot_issues/bovine_tuberculosis/tb_ls.shtml



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