Report from Washington Meeting on Bovine Tuberculosis

Washington, DC
December 8, 2008

The Animal and Plant Health Inspection Service held a series of public listening sessions on the future of the national bovine tuberculosis (TB) program. In attendance were various State agriculture and wildlife officials, industry representatives, producers, public health officials, and members of the general public. This document summarizes comments and suggestions from focus group sessions at the Washington meeting (held December 16, 2008), public comments from the meetings, and written comments to USDA officials.

Description of Respondents

Representation at Meeting

12 Industry Representatives
5 State
3 Ag Industry Group
2 Producers
1 Public Health Officials
1 Non-APHIS USDA
1 Foreign government
0 Wildlife Officials
5 Other
30 Total

Public Comments

John Hunt, Arizona Department of Agriculture
Nancy Robinson, Livestock Marketing Association
Steven LeVan Pennsylvania Private Practitioner
Larry Samples, Pennsylvania Practitioner
Michael Gilsdorf, National Association of Federal Veterinarians

Written Comments

Document from National Cattlemen's Beef Association
Arizona Cattle Growers Association/Arizona Cattle Feeders Association

Biosecurity

APHIS Summary/Interpretation of Comments and Suggestions:
Producers are responsible for herd management, disease prevention, and control and risk mitigation. Providing education and outreach will be helpful to producers (see section on Education and Outreach). Transmission between humans and cattle is a particular biosecurity concern which may require better collaboration with public health agencies.

Comments from focus groups:
- Interesting issue with workers – could transfer human to cow.
- Producers and States are trying to meet the *Code of Federal Regulations* (CFR) so they are legally protected, but they may not be not biologically protected.
- Plausible path for infection when culls become replacements.

Comments from public and written comments:
- Recognize low-grade infection in dairy replacement herd.
- The National Cattlemen's Beef Association (NCBA) is fully supportive of appropriate producer responsibilities in regards to herd management, disease prevention and control, and risk mitigation. That being said, we have significant concerns that this proposed rule, while attempting to address a possible problem with a very small number of inadequate biosecurity and herd health plans, will actually cause harm to the majority of producers.
- Complicated disease-long incubation period, silent carriers, wildlife component in certain locations, biosecurity challenges, import challenges, many unknowns.

Suggestions from focus groups
- Test farm workers for TB.
- Worker transmission risks – need to plug into CDC to help with research etc.
- Need better coordination with public health agencies.
- Two participants also discussed modeling collaborative approaches/authorities as the Pasteurized Milk Order, which is used by other agencies. Another participant concurred that the Pasteurized Milk Order could be modified to encourage biosecurity practices on dairy farms.

Control vs. Eradication

APHIS Summary/Interpretation of Comments and Suggestions:
There were mixed views about whether the goal of the program should be eradication or control. While eradication should be the priority, or is preferable, without the necessary funding the TB program can only be a control program. Even with the long term goal being eradication, the focus now should be control.

Comments from focus groups:

- Eradication should be the priority.
- One group's participants each agreed that an eradication program is preferable; however, they also acknowledged that an eradication program is not possible without additional program funding.
- One person stated that without the necessary funding the TB program can only be a control program.
- Another stated that funding is key to a successful TB eradication program, and without it, the best USDA could achieve is a high risk mitigation program.
- Another stated that eradication is costly, but the safest and most effective way to ensure animal health. He also believes that a control program leaves too wide a margin for error and disease occurrence.
- Eradication in the long run.
- Eradication is the goal but need control now.
- Eradication but first control.
- Work towards eradication but settle for control.
- Control while working towards eradication.

Education and Outreach

APHIS Summary/Interpretation of Comments and Suggestions:
Increase educational efforts focusing on 1) public health, 2) high risk populations, 3) biosecurity, 4) good management practices (GMPs), 5) event cattle, 6) cattle from Mexico, 7) wildlife, and 8) the National Animal Identification System (NAIS). These more aggressive campaigns can be funded through public/private partnerships and Cooperative State Research and Extension Service (CSREES) partnerships with APHIS. The Council on Agricultural Science and Technology can prepare some of the TB eradication informational material.

In addition, the program needs to maintain a knowledgeable, skilled workforce; this can be accomplished by using resources for training and developing an effective succession plan so experienced personnel can help impart their knowledge to less experienced personnel.

Comments from focus groups:
- Enhance TB eradication education to cover a broad audience.
- Education in California was bumped up recently. Some producers are out ahead and some lag behind; lots fall in between.
- There has not been enough done on biosecurity education. We have not helped our producers enough.
- Always useful to "update the knowledge of the producers."
- Educate people on the right things to do, like letting them know the good management practices (GMPs) they should follow.
- Public opinion of the issue of TB in wildlife is significant and should be managed through the dissemination of informative material.

Comments from public and written comments:
- Must do better job of encouraging industry to do better job.
- Training and education: Experienced field personnel who have worked with naturally occurring bovine tuberculosis must be available as needed, allowing the testing program to increase its reliance on knowledgeable animal health personnel and accredited veterinarians.

Suggestions from focus groups:
- Target education to specific groups or high-risk populations.
- Implement a more aggressive TB eradication education/public relations campaign.
- Education campaign should also focus on public health issues because TB is zoonotic.
- APHIS could use existing resources from public/private partnerships for educational outreach.
- The Council on Agricultural Science and Technology can prepare information for TB eradication informational material.

- CSREES can work partner with APHIS and other organizations to develop TB eradication educational materials.
- Enhance outreach efforts regarding NAIS.
- Increase educational and promotional material on NAIS. (All participants agreed.)
- Better educational campaigns – especially regarding event cattle and MX cattle.

Suggestions from public and written comments

- To ensure that new scientific programs and technologies are used effectively, APHIS' Veterinary Services (VS) should allocate the resources necessary to expand training of current and newly hired animal health workers and accredited veterinarians.
- VS needs to develop and implement a succession plan that provides a way for knowledgeable epidemiologists, technicians, and veterinarians to review eradication and control procedures within States in order to identify areas that could be improved, and also to pass their knowledge and experience on to less experienced personnel.

Funding

APHIS Summary/Interpretation of Comments and Suggestions:
There needs to be more USDA funding for research and the TB program. That funding can come from 1) Congress for the Federal portion (States and Industry can help by lobbying Congress for adequate funding), 2) States and 3) Industry. Public Health agencies should contribute since there is a public health component of this disease. States, industry and USDA should collaborate (the Pasteurized Milk Order is a good example of collaboration) especially on a budget for the TB program.

Comments from focus groups:
- Everyone in the group stated that funding will directly impact the success of a national TB program.
- One participant explained that, in some countries, industry directly funneled money into their national animal health programs. Another person agreed that this avenue is possible, but was unsure how it could be done or if the funding would be enough to make any impact.
- One participant agreed with another's sentiments in that non-Federal entities (such as industry and States) would be more successful at soliciting additional money from Congress.

Comments from public and written comments:
- The United States needs more funding for the APHIS program and adequate, sustained funding for research to provide more answers and better solutions.
- Lack of adequate funds for APHIS TB program (approximately $15 million/year total).
- Lack of optimal coordination among Federal agencies, Federal and State agencies, and among animal health, wildlife and human health agencies.

Suggestions from focus groups
- One person felt that national groups and industry should provide monies for the TB program, if only to be a catalyst for funding increase requests to be made to Congress.
- Each participant in the group also believed the method for acquiring additional money is to encourage the industry and States to solicit the funds from Congress.
- Need to get serious about the needs of the program and fund them accordingly and not rely on Commodity Credit Corporation (CCC) funds
- One participant suggested that APHIS collaborate with industry and States to develop a budget for the TB program. Another agreed that this cooperative effort would allow for non-Federal input and might help encourage Congress to appropriate additional funds.
- Two participants suggested that USDA reach out to public health groups to acquire additional funds since TB can be linked between man and animals.

- Two participants also discussed modeling collaborative approaches/authorities such as the Pasteurized Milk Order, which is used by other agencies.

Suggestions from public and written comments:

- The TB program has not been adequately funded for more than 30 years, and yet we still have made progress. The program's progress has been significant but has been countered with the continual importation and movement of diseased animals within the U.S. APHIS/VS must continue to request the funds needed to complete the eradication program. Those needs must be developed in partnership with the States and industry.
- USDA should adequately address the chronic Federal underfunding of the APHIS TB Program, as well as inadequate Federal research funding through the Agriculture Research Service (ARS) and the Cooperative State Research and Extension Service (CSREES). Chronic Federal underfunding of all of these programs has contributed to the current situation and lack of available tools to adequately address them.
- NCBA requests that USDA ensure adequate funding of the TB program to complete long-standing eradication efforts and better address future needs for the program, including surveillance efforts. This includes adequate U.S. government funding and support of the development and approval of serologic or other tests that would improve specificity and sensitivity over the current testing methodology.
- The livestock industry, State officials, and the general public must work with APHIS/VS to identify the real needs of the program. They must then convince Congress to secure the funding needed to protect the food security of our country through well-managed disease eradication programs.
- APHIS/VS should partner with the livestock industry and State officials in the development of the tuberculosis program budget.
- Monies should be used to enhance TB methods and surveillance.

Imports and Mexican Cattle

APHIS Summary/Interpretation of Comments and Suggestions:
There are problems with importing cattle from Mexico that need to be addressed: 1) Mexico has a high level of TB; 2) lots of cattle are imported each year from Mexico; 3) some are sent to feedlots for finish feeding; 4) some are used for rodeos; 5) testing of Mexican-origin cattle is not adequate 6) traceback is a challenge; and, 7) biosecurity practices are not adequate once Mexican-origin cattle become part of the U.S. herd.

To address these issues, it is suggested that 1) the U.S. limit the import of spayed heifers from Mexico; 2) event and breeding cattle shouldn't be mixed; 3) movements should be generally restricted (especially regarding event animals) to minimize disease risk; 4) open-range pasturing should be prohibited; 5) rodeo stock should be tested annually; 6) there needs to be more testing of cattle imported from Mexico; 7) USDA should help Mexico improve its disease status; 8) importation of cattle from Mexico should be limited to quarantine feedlots only, with the exception of imports from Mexican States that are officially recognized as TB-free; 9) permanent radio frequency identification device (RFID) -equipped eartags and/or implants and tattoos should be required on all event cattle; 10) for the first three years after importation, testing for TB on a quarterly basis should be required—after that, the imported cattle should be tested annually; 11) U.S.-born timed event/sport cattle that have not been exposed to cattle of another national origin should be exempt from testing; 12) timed event/sport cattle should be tested for TB within 12 months prior to crossing State lines; 13) USDA should ensure unique ID of Mexican cattle by brand and Mexican eartag and the identification should not be tampered with; and, 14) the collection and recording of all identification at slaughter to enable proper traceback should be improved.

Comments from focus groups:
- One person stated that a regulatory measure to limit commingling of Mexican-origin cattle with the U.S. breeding herd might be enforceable with feedlot industry support; however, industry does not currently support such action.
- One person believed that placing such restrictions on Mexico would necessitate placing similar restrictions on all countries. He felt that to do so would result in a tit-for-tat response from other nations through trade sanctions against U.S. exports. The participant also stated that successful enforcement of commingling requirements is unlikely.
- Some emphasized the importance of acquiring State and industry buy-in for the enforcement of commingling requirements through actions such as surveillance and certifications. Moreover, they suggested that USDA meet with States to encourage that States propose these concepts to obtain stakeholder support.
- Veterinarians are involved in the global economy —they must follow World Organization for Animal Health (OIE) standards.
- We've known for a while about cattle from Mexico: One owner in California spent $36 million on one positive animal.

Comments from public and written comments:

- Why not stop Mexican cattle and quarantine and test them at the ports, prior to entry into the U.S.
- There's concern about cattle in the rodeo business. Participants were encouraged by United States Animal Health Association (USAHA) resolution to test these animals that are in interstate commerce for TB
- Mexican cattle importations: For more than two decades, disease control officials have been increasingly concerned about tuberculosis found at slaughter in steers and spayed heifers imported from Mexico. Mexico exports between 400,000 and 1,500,000 cattle annually to the United States. These cattle are frequently pastured in the United States prior to being sent to feedlots for finish feeding. In addition, Mexican-origin roping steers traverse the United States without restrictions and recently several have been found to be infected with tuberculosis at slaughter. These practices provide ample opportunity for Mexican cattle to commingle with U.S. breeding stock. Many feedlots custom-raise dairy heifers, in addition to feeding Mexican steers in adjacent pens, allowing easy aerosol transmission of tuberculosis. There have been numerous documented cases of cattle imported from Mexico transmitting tuberculosis to U.S. cattle as a result of all these exposures.
- Mexico has continued problems with TB in their national herd.
- There are challenges to ensuring that imports are TB free due to poor testing tools; current testing for importation has not been adequate to prevent tuberculosis infection from Mexican imports. Solutions need to be explored.
- There are challenges with biosecurity of imports, such as mixing of Mexican feeder cattle with breeding stock and challenges with event cattle, whether imported or domestic-origin (testing, biosecurity, mixing with breeding and other stock). Pasturing of imports is possible with appropriate biosecurity. Solutions should be thoroughly discussed, with active industry input prior to decisions.
- There are challenges with tracking of Mexican-origin cattle. For example, under current practice, often the country of origin information does not follow the ianimal once it leaves the original U.S. State into which it was imported. This hinders biosecurity as well as traceback capability.

Suggestions from focus groups

- One person stated that one of the greatest causes of TB spread was animal commingling. To that end, the person believed that USDA needs to 1) control and eliminate TB in wildlife, and 2) immediately limit the import of spayed heifers from Mexico.
- Several people suggested implementing incentives to gain the support of animal owners and States. Such incentives might include shipment refusal without certification, or instituting regulations that set requirements to ship or move products interstate. One participant explained that such requirements were typically used as last resort measures as they adversely impacted the livelihoods of businesses.
- Mixing event and breeding cattle is not a good idea.

- Restrict movement/minimize disease risk from cattle imported from Mexico and event animals.
- Prohibit open-range pasturing to decrease commingling risks.
- Restrict movements of event animals.
- We currently only test rodeo stock once; annual testing may be needed.
- Close loopholes by testing cattle from Mexico.
- More testing on Mexican imports: We need to be able to trace Mexican-origin cattle (with ID/brands) and help Mexico improve its disease status.

Suggestions from public and written comments:

- Address concerns for livestock used in rodeo events.
- USDA should vigorously and immediately pursue regulations that limit the importation of cattle from Mexico to quarantine feedlots only, with one exception; from Mexican States that are officially recognized free of the disease. This would only affect a small number of U.S. importers compared to the number of producers in the nation. We know those importers have significant political influence that will make this proposal difficult to implement. However, as long as we continue to import the disease we will not be able to eradicate it. Therefore, it is imperative that this be accomplished. In addition, by moving to this type of policy it would eliminate the need of spending time and funding to constantly review Mexican states for compliance with zoning and U.S. program requirements, except in those Mexican States that wish to be recognized as tuberculosis-free.
- Require permanent RFID equipped eartags and/or implants and tattoos on all roping cattle used in shows and rodeos in the United States. Require that they only be moved interstate with a Federal or State issued electronic permit for movement tracking purposes. These animals should be required to be tested for TB on a quarterly basis for the first three years after importation. After that they should be tested annually.
- There are challenges to cleaning up the disease in Mexico. USDA needs to continue working aggressively and collaboratively with Mexico in this regard. APHIS should closely monitor, and appropriately follow through with, Mexican states that continue to have positive TB cases.
- Approach and management of event cattle should be re-evaluated:
    - U.S.-born timed event/sport cattle that have not been exposed to cattle from another origin should be exempt from TB testing when they move directly from the premises of birth to another premise;
    - NCBA supports regulations that would require timed event/sport cattle to be tested for TB within 12 months prior to crossing State lines.
    - Event cattle (both domestic and international origin) have specific challenges that need to be addressed. One potential solution that should be explored for high-risk imported event cattle is an initial quarantine and retest policy.
- USDA should ensure that the unique identification of Mexican cattle—the “M” brand and Mexican eartag—is implemented and not tampered with, and improve

the collection and recording of all identification at slaughter to enable proper traceback of infected animals.

Indemnity/Depopulation

APHIS Summary/Interpretation of Comments and Suggestions:
Whole-herd depopulation when there are only a few positives is a waste of protein and finances, and current Federal funding is not adequate. There has been an overreliance on depopulation. Suggestions for change include 1) stopping depopulation, 2) using depopulation but not as the primary approach, 3) making indemnity dependent on adequate funding under the right conditions, 4) having producers/industry pay part of the indemnity costs, 5) get USDA funding to adequately support depopulation/indemnity, and, 6) consider the test-and-removal strategy as another option.

Comments from focus groups:
- Overreliance on depopulation over the use of Commodity Credit Corporation (CCC) funds (emergency funds).
- One person said indemnity is costly but also rewards “bad behavior”, while another says indemnity does not necessarily cause “bad behavior”.

Comments from public and written comments:
- There’s a lack of adequate Federal research of TB in order to increase knowledge of the disease and improve testing, surveillance, diagnosis and treatment (none exists), and decrease the need for depopulation.
- Depopulation of an entire herd when there is only one or a few positives within the herd is a waste of protein, a waste of finances, and too costly to producers, taxpayers and State/Federal government resources; current Federal funding of the program is not adequate for entire herd depopulation
- APHIS recently published a proposed rule regarding indemnity payments being tied to approved herd health plans; full indemnity payment for depopulation of a producer's herd would not be done until that producer proved to Federal and/or State officials that the approved herd plan had been followed.
- NCBA is concerned that this proposed rule will increase problems associated with indemnity. NCBA is concerned that this proposed rule, combined with the lack of adequate knowledge, epidemiology, testing capabilities, surveillance and control, including no treatment options, will cause unintended consequences for producers, put increased pressures on States, and allow the Federal government to abdicate their responsibilities regarding the APHIS TB program. The El Paso, Texas area history is an example of how difficult this disease can be to control even with proper adherence to biosecurity and good herd health plans. It also highlights the complexities regarding adequate biosecurity, the unknown of wildlife components, and another issue of current concern -adequate control of the disease in North America.

Suggestions from focus groups
- Need to stop depopulation — don’t have the money in the States.
- May still need depopulation for a while, but should not be primary approach; need a better test.

Suggestions from public and written comments:

- USDA should ensure that adequate indemnity funding for herd owners be available so that mandatory depopulation of all TB-infected herds in the U.S. is economically feasible.
- Depopulation of large herds needs to be dependent on funding availability, the prevalence of tuberculosis in the herd, and other risk factors that are evaluated on a case by case basis. If a State has taken all the precautions to mitigate the risk but cannot afford to depopulate the herd, then the producer-generated fund, or similar strategies, should be used.
- Producers of all affected species would financially support the eradication program through either a fund for depopulation of infected herds or other similar strategies.
- Indemnity: Recognizing the constraints on public funds and the benefits from eradication that accrue to livestock enterprises, the National Research Council (NRC) committee recommended that producers of all affected species financially support the eradication program. The committee states that in sharing responsibility for funding an eradication program with taxpayers, the livestock industry's involvement will promote attainment of a mutually beneficial goal and simultaneously acquire a direct interest in ensuring that the program is operated effectively. The optimal extent of producer participation and the choice of eradication strategy (e.g., herd depopulation or test-and-remove of individual animals) could be evaluated with the use of bioeconomic models, updated to reflect changes in industry structure and public attitudes.
- If a herd owner decides to go with the option of test-and-remove instead of depopulating an entire herd, then the industry should be able to operate under that herd quarantine and not put the entire State at risk.

Public Health

APHIS Summary/Interpretation of Comments and Suggestions:
There are a number of public health concerns related to TB. Foreign employees who come from an area where TB is endemic is a concern. Unpasteurized products pose a threat. Perhaps all employees working on dairy herds should have TB tests since there is not a standard for health certificates. Potential for spread of TB to people is a reason to eliminate the disease in livestock and wildlife populations. VS should make sure that any decision made on the program should be based on maintaining protection of public health. Coordination with public health agencies is suggested.

Comments from public and written comments:
- The health of employees from foreign regions where TB is endemic is a concern.
- There are also public health concerns about the illegal transport of unpasteurized milk products across the Mexican border.
- Need better coordination with public health agencies.

Suggestions from public and written comments:
- All employees working on dairy herds should have health tests, including TB test.
- Not certain that there is any standard of health certificates for these workers.
- Public Health: From a public health perspective, the potential for direct transmission from animals to humans, particularly in farm families and others exposed by virtue of their occupation, remains a concern. In addition, the potential for spread from one infected animal in a petting zoo to large numbers of people cannot be ignored. These are reasons for continuing to control and eliminate the disease from the livestock and wildlife populations.
- VS should make sure that any decision to change disease control activities within the program is based on maintaining protection of public health.

Regulations

APHIS Summary/Interpretation of Comments and Suggestions:
Regulations need to be changed. They need to have the following qualities: 1) uniformity, 2) flexibility, 3) up-to-date with current technology, and 4) based on the latest assumptions. Consider changes to the program without changing the regulations. Consider changes such as implementing policy, using program standards (like the pseudorabies program), updating the Uniform Methods and Rules (UM&R) or implementing good management practices. Some specifics need revision as well: 1) better definitions (ex: quarantine, feedlot); 2) address practices such as backgrounding; 3) change status designations to reflect OIE requirements (regions and zones); and, 4) clarify movement controls (interstate and from Mexico). Review Industry & USAHA 2005 UM&R recommendations, and the Industry & State 2004 Comprehensive Strategic Plan should be incorporated into the regulations. There will need to be good cooperation among USDA and the States to achieve a consistent national program. One person commented that this is not a legal issue but rather an enforcement issue.

Comments from focus groups:
- USDA's regulatory process is too cumbersome and incompatible with current technology practices. USDA stated that regulations need to be flexible to adapt to the changing scientific technology. Moreover, the requirements for test approval were too long and inconsistent with the costs involved.
- Regulations need to be drastically revised.
- Regulations should be uniform; same regulations throughout the States.
- Every inspection certification should be completed by an accredited veterinarian.
- Some current USDA regulations conflict with States' TB regulations. Consequently, cooperative approaches with States will be necessary to ensure regulations do not overlap.
- Supposed to update the regulations from the last time you asked for our input yet they are still not updated and it is late 2008.
- Best management practices are exactly where we were 20 years ago.
- Some of these are not legal issues but enforcement issues.
- We need more consistency across the country, so there is no squabbling among States on movement.

Comments from public and written comments:
- The current APHIS program was designed around an absence of TB in our national herd. The program needs to be adjusted due to the current situation involving low incidence of the disease in the U.S.
- The Uniform Methods and Rules (UM&R) is antiquated and uses now-invalid assumptions. For years now, our industries have awaited USDA's publication of the comprehensive domestic and international rules for bovine TB. The situation has obviously changed since the formulation process for these rules began. While we have repeatedly advocated for their timely release, we are concerned

that because they have been in the pre-publication process so long that, as formulated, they will no longer be valid. Therefore, NCBA strongly encourages USDA to consider the following suggestions as APHIS finalizes these important rules and develops future plans for combating TB.

- The regulation writing process has been ineffective for several years in adequately addressing changes needed in all animal disease eradication programs. A different system is desperately needed. The entire pseudorabies eradication program was handled with minimal regulations. All activities were implemented by the States and industry under "program standards".

Suggestions from focus groups

- Implement harsh measures to eradicate TB in the U.S.
- Modify bad regulations by initiating good policy.
- How to fix regulations in the States: Educate people on the right things to do. If we can't do that, we need to deal with the outdated regulations.
- Revise and clarify the current regulations for the entire TB program, specifically as they relate to definitions and restrictions for quarantines and feedlots.
- The TB regulations should be changed to reflect the minimum requirements needed for compliance with USDA standards, rather than setting requirements. The person added that States could require additional measures, but not fewer.
- Change status designations to conform with OIE, i.e. regions and zones.
- Regulations need to be clarified regarding feedlots and backgrounding.
- Clear and absolute descriptions of types of quarantine.
- Movement controls should be clarified and consistent, including interstate and across the borders, especially Mexico.

Suggestions from public and written comments:

- Industry and USAHA 2005 UM&R recommendations should be reviewed, updated as needed for evolved situation(s), and incorporated.
- The Industry and State 2004 Comprehensive Strategic Plan for the Eradication of Bovine Tuberculosis should be incorporated.
- A streamlined regulation implementing system must be implemented, whether it be through program standards or memorandums of understanding.

Research

APHIS Summary/Interpretation of Comments and Suggestions:
Research should focus on a new test and testing procedure that is faster, more sensitive and more reliable. Also research is needed on 1) basic understanding of the infection, 2) role of epidemiology in test evaluation and usage, 3) efficacy of current and future management practices, 4) epidemiology of TB in wildlife, and 5) control points to preclude transmission between wildlife and livestock. A CEAH-type study was suggested to learn about the risk factors. Consider streamlining test licensing procedures to get tests in use more quickly.

Comments from focus groups:
- Need to understand the biology of this complex disease—look for its Achilles heel—do risk modeling and combine epidemiology with economics. We need better research but we are not helpless—need a study on TB, perhaps from APHIS' Centers for Epidemiology and Animal Health (CEAH), so we can know the risk factors.

Comments from public and written comments:
- Detection of bovine tuberculosis is the first step in any eradication or control effort. Improvements in test accuracy and application to non-bovine species as well as detection of infected animals at slaughter is a constant goal of the program, with new and anticipated developments in the basic scientific understanding of the infection. Much of the current work is focused on detection of tuberculous lesions *M. bovis* organisms, *M. bovis* antigens, or the animal's response to infection. Newer immunologic-based tests need more testing before they can be fully developed. In addition to development of better tests and greater understanding of the basic biology of bovine tuberculosis, the role of epidemiology in test evaluation and usage is crucial.
- There's a lack of adequate Federal research of TB in order to progress knowledge of the disease and improve testing, surveillance, diagnosis, and treatment (none exists), and decrease the need for depopulation.
- Regarding APHIS' proposed rule on indemnity payments and approved herd health plans: Given the inadequacies of knowledge and tools for this disease, this proposed rule is of concern and makes it all the more imperative that adequate information is available regarding other species' (especially wildlife) roles in bovine TB**,** and that better epidemiological, testing and surveillance tools be made available.

Suggestions from focus groups
- Start researching yesterday.

Suggestions from public and written comments:
- APHIS/VS should institute ongoing evaluation of new diagnostic technologies by ARS and private companies to complement the routine application of existing tests. Ongoing collaborative research should investigate pathogenesis,

immunology, diagnostic approaches, genetic resistance, and the epidemiology of bovine tuberculosis.

- APHIS/VS should also provide a tuberculosis tissue/blood bank for agencies and companies to use in the development of new technologies. The licensing procedures for new tuberculosis tests needs to be amended and streamlined to allow effective tests to be more rapidly evaluated and utilized by program officials.
- Since limited tools are available for eradicating tuberculosis from free-ranging wildlife, a better understanding of the epidemiology of tuberculosis in wildlife and livestock may identify additional or alternative eradication methods. Additionally, the efficacy of current and future management actions and vaccines must be continuously evaluated to identify the best strategies and methods for tuberculosis eradication.
- Research must be continued to identify key control points at which transmission among wild animals and transmission between wildlife and livestock can be precluded.

State Status

APHIS Summary/Interpretation of Comments and Suggestions:
State status is outdated; the regulations need to allow healthy animals to move unfettered. However, there was some caution about getting rid of State status as a regulatory concept: 1) public perception of animal disease threats is too great for consumer confidence in regionalization; 2) State status provides a buffer zone for States unaffected by disease; 3) to implement cross-State regionalization, buy-in would be necessary from State and industry; and, 4) State status classification system is the only incentive for individual States to improve.

If State status is removed, a risk-based approach should be used in its place. There was some discussion about whether an adequate ID system and test are available to make a risk-based system work. If it is decided to keep State status, it should be based on prevalence in the State and not two finds, and there should be a more streamlined approach to regaining status.

Comments from focus groups:

- All participants except one agreed that such a concept (free from TB in the U.S. but regionalization for a few outbreaks/finds) might be feasible so long as several factors were first put into place.
- One participant felt that with the right technology and animal identification in place, such regionalization was workable. However, States would need testing done to prove to State officials that the concept was stable enough to work.
- One person believed that public perception of animal disease threats is too great for consumer confidence in regionalization. The person cited the Washington State bovine spongiform encephalopathy (BSE) case as an example of all countries closing their borders to U.S. beef over a single case in one State.
- One participant stated that his confidence in such a program would come once the United States was able to ensure imports were TB-free and the U.S. areas harboring the TB cases were identified.
- Several participants stated that in addition to the previously mentioned requirements, they believed more accurate TB tests were needed for a concept such as regionalization to work.
- One person preferred testing individual animals rather than using State classifications as State status punishes industry in the entire State.
- One person stated that States may be more cautious about accepting cattle from a State where a TB case was found. Moreover, the person stated that State status provides a buffer zone for States unaffected by disease. Therefore, without additional mitigations in place, they feel that State status protects disease-free States.
- A participant suggested the possibility of addressing TB on a case-by-case basis based on prevalence of the disease. In order to accomplish this however, modifications are required to current USDA regulations. The participant also stated that regionalization might be a viable alternative to State status.

- One participant also expressed reluctance to ending the State status classification system as it is the only incentive for States to improve standards.
- One participant felt that USDA should follow guidelines set by the World Organization for Animal Health (OIE).
- Two participants shared concern regarding blurred lines of authority and enforceability of cross-State regionalization. One of them did not think interstate tracking and surveillance practices were successful enough to try moving animals in regionalized zones that crossed State lines.
- One participant suggested that to implement cross-State regionalization, buy-in would be necessary from State and industry.
- One participant stated that the United States has regionalized parts of Mexico. As a result, the expense for Mexico to maintain the standards in these specified regions is great. In addition, there are intense marketing and political pressures in Mexican States that share a regionalized disease status zone. Consequently, these States have been unable to work together when addressing animal disease responses.
- The participants in this group agreed that geographical boundaries (i.e. State boundaries) are easier to work with than zones. However, they were also unanimous in their belief that, if regionalization were to work, its success would hinge on the support of industry and States.
- One participant pointed out that a particular status assigned to a State would not necessarily require other States to accept or decline animals from the classified State.
- State status is outdated.
- Allow healthy animals to move unfettered.
- Allow split-State status already being used:
    - Zoning is a good approach vs current State status system;
    - If we stay with State status then need to move to connect it to prevalence, not finds.

Comments from public and written comments:

- Cattlemen would like USDA to consider risk-based approach. If a State is actively testing, USDA should take that into account when evaluating State status before downgrading status if a case is found.

Suggestions from public and written comments:

- Some are suggesting that we remove the State status requirements of the program and replace them with something else-like regionalization. While this might work, I think it is not the proper time to remove the State status requirements until we have better determined the true presence of tuberculosis within the country as a result of exposure to Mexican cattle. It would be better to create a zoning within a State than to eliminate State status. In addition, if we eliminate the incentive for eradicating the disease in those states that still have tuberculosis-infected animals by removing the status-imposed movement and surveillance restrictions, we then will perpetuate the development of multiple reservoirs of tuberculosis in these states, and TB will eventually spread to other

areas and States. What we do with status will also affect our cooperative activities with Mexico.

- APHIS State classification and regulation needs to be updated to better reflect the disease challenges and the limitations of current technology.
    - The disease also does not recognize State borders. APHIS' UM&R should be updated in its approach regarding State status when a TB positive animal has been identified. This should include the exploring pros and cons of elimination of State status classifications.
    - TB funding for States is limited if not nonexistent.
    - The number of herds required to be found infected with TB to trigger a drop in status should be based upon prevalence of herds within a State, as opposed to the current system (two herds regardless of the number of cattle or herds within a State).
    - Prior to making a determination to adjust the State status, the type of cattle operation should be considered in the review of the State. The impact of cattle confinement versus pasture on the rate and spread of infection should be taken into consideration.
    - The exemption that provides for eliminating the need for testing of feeder steers and feeder heifers should become a permanent part of the rule applying to all States.
    - There needs to be a streamlined approach for States to regain status.
- USDA should explore the ideas of regionalization and/or compartmentalization, as appropriate, for this disease, especially in states that are currently affected.
    - The OIE has international standards regarding regionalization and compartmentalization relating to disease control and trade. Any regionalization or compartmentalization plans should follow OIE guidelines.
    - If USDA explores regionalization and/or compartmentalization, they should actively engage industry and State collaboration and input as plans are developed.
- Change the program to end the State status system and make it more risk-based. Consider regional or individual quarantines especially if the State is active in testing and surveillance.

Surveillance

APHIS Summary/Interpretation of Comments and Suggestions:
National surveillance requires an ID system that works. Michigan has one; it should be doable nationally, though States and USDA should collaborate on such a system to ensure consistency. Slaughter surveillance needs to be improved in a number of specific ways: 1) collect ear tags, 2) note brands at slaughter, 3) cooperate better with FSIS, and 4) determine where is traceability breaking down. New surveillance techniques need to be developed to detect TB without lesions. Other species, including wildlife and humans, need to be considered in surveillance efforts.

Comments from focus groups:
- One person favored national surveillance. Another also believed that a national surveillance program would simplify the health certification process for the movement of animals.
- One person stated a short-term solution to surveillance would be requiring that all animals leaving a farm be given identification. They explained that Michigan has implemented a successful, mandatory identification program; therefore, it has proven to be doable.
- One person stated that a stigma has become attached to the National Animal Identification System (NAIS). Therefore, he suggested that a surveillance system compatible with NAIS be established for the TB program.
- A State person encouraged collaboration between USDA and States before implementing such a system, in order to ensure consistency between State and Federal laws.

Comments from public and written comments:
- National TB program is outdated- needs improved testing methodologies and surveillance methods.
- Surveillance needs to be updated.
- TB control is dependent on adequate surveillance of appropriate populations of cattle and other species, exhaustive attempts to indentify all possible sources of infection, and appropriate biosecurity protocols. Surveillance and traceout capabilities need to be improved. It is known that there is a contributing wildlife reservoir and this is becoming more problematic in several States. To date there has not been enough coordinated attention paid to the extra complexities this requires.

Suggestions from focus groups
- Improve slaughter surveillance: collect ear tags, prevent brands from getting lost, cooperate better with FSIS, stop rewarding bad behavior, determine where traceability is breaking down.

Suggestions from public and written comments:

- The possible human component that might sometimes be a factor needs to be further evaluated scientifically. NCBA promotes the development of new diagnostics within and outside of APHIS for TB infection in other species; include these species under the current national eradication program.
- Several years ago the dairy industry asked APHIS/VS to promulgate new regulations requiring that all dairy cattle over a certain age be negative on an official test for tuberculosis prior to being moved interstate. This was requested because of the concern that bovine tuberculosis had infiltrated the national dairy herd through Mexican imports. Based on the recent detections of tuberculosis infection in large dairy herds it appears their concerns were valid. Therefore, it is critical that surveillance for tuberculosis be enhanced and that the proposed regulation be published as soon as possible.
- New surveillance methods for bovine tuberculosis at slaughter need to be designed to detect *Mycobacterium bovis* infection in the absence of gross lesions and compatible with Hazard Analysis Critical Control Point (HACCP) inspection. This could be accomplished in part by incorporating newly developed serology tests into the decision making process for carcass dispositions.
- Additional surveillance techniques for both livestock and wildlife need to be incorporated into the program. This should be a high priority for the National Surveillance Unit within VS.
- An improved review of the risk factors that contribute to the spread of this disease, including control methods to protect against it, is required.
- Surveillance: Comprehensive surveillance measures need to be re-evaluated and updated for tuberculosis.
- Several aspects of slaughter surveillance inspection issues need to be addressed.
    - There needs to be an improved coordination between APHIS and FSIS. And APHIS policy regarding FSIS personnel performing their inspection duties needs to be re-evaluated.
    - Aspects of TB surveillance at slaughter that need improvement/re-evaluation include but are not limited to: the lack of collection of eartags, and the policy of not noting brands at slaughter (specific to Mexican and Canadian brands).

,

Testing

APHIS Summary/Interpretation of Comments and Suggestions:
Need a good diagnostic test that is fast, sensitive and reliable. Industry is already spending money on this effort of test development. It needs to be a USDA spending priority too. The procedures for testing also need to be revised and streamlined.

Comments from focus groups:
- Several participants were vocal in their frustration that not enough funding for diagnostic testing is made available for laboratories and companies developing these tests.
- Two participants expressed the need for additional funding to improve and implement new tests. They also explained that the improved tests would decrease the number of tests necessary for TB confirmation while providing more accurate results, thereby reducing costs and TB exposure in the long- term.
- One person stated that a significant portion, and in some cases all, of the money spent on testing trials came from the industry itself. They want to see Federal or State funds made available for cost recovery.
- The lag in the program is the need for improved diagnostics.
- While it is true that we need better diagnostics, we need to fight with the army we have, not with the one we wish we had.
- How far are we from a good test? 5 years or more away?
- Some say they are close; see if claims are real.
- Test farm workers for TB.
- Testing is key; we need to solve this issue and fund it.
- Two people expressed the need for additional funding to improve and implement new tests. They also explained that the improved tests would decrease the number of tests necessary for TB confirmation while providing more accurate results, thereby reducing costs and TB exposure in the long-term.

Comments from public and written comments:
- We used to do annual herd tests in certified herds? Don't exist anymore.
- Where do we stand on blood test for TB? It would be great to have.
- Need to provide incentive to conduct annual herd tests. Farmers pay veterinarians. Roll technology out to do the testing. Cannot ship product (milk) unless the test is done.
- Arizona procedures:
    - Test older cattle; and,
    - Dairy industry tests entire breeding herd every three years.
- 60,000 head of cattle are tested in Arizona each year; whole herds are tested every three years. Heifers are tested as they come to Arizona.
- Testing is done every three years in Arizona and that contributed to keeping Arizona TB-free all these years. Arizona also tests all animals older than 6 months whenever they cross the State line.
- New and improved testing methods are needed.

- We know testing protocol is not perfect. There's concern about the ability to trace the disease after problems are found.
- Testing is important.
- Testing and depopulation strategies need to be updated.
- There must be adequate United States government funding and support for the development and approval of serologic or other tests that would improve specificity and sensitivity over the current testing methodology. These new tests must also eliminate the need for repeat handling of livestock and allow for more rapid test results. The ultimate goal would be to develop a test that would be sensitive enough to 1) allow removal of infected animals without depopulation of entire herds, and/or 2) enable APHIS to explore the possibility of compartmentalization or regionalization in regards to this disease.
- Improved TB diagnostic tests will actually save tax dollars, as well as minimize cattle losses due to this disease. The expenditure of funds to approve an improved test would have far reaching benefits and would be a better long-term investment than continuing to fund the depopulation of affected cattle operations.
- Caudal fold testing (CFT) requires too much time and handling of cattle multiple times.
- There is an urgent need for the exploration of other diagnostic technologies and innovative applications of epidemiology towards eradication of this disease.
- Need sensitive and specific blood serum test. Need "field" test — chute-side test for accurate initial screening at import or initial screening in preparation for movement.
- Test and hold/quarantine program would require more timely and accurate tests than we currently have.
- Heifers under 6 months of age should not require testing.
- USDA should promote the development of new diagnostics within and outside of APHIS for tuberculosis infection in other species and include these other species under the current national eradication program.

Suggestions from focus groups

- New diagnostic tests should be developed.
- APHIS' Center for Veterinary Biologics (CVB) should ease the burden of conditional approval of test kits.
- Decide on testing priority, i.e. eradication testing, export testing, or control testing.
- Develop better TB testing/diagnostics and provide training to veterinarians on the new testing procedures.
- Provide better TB diagnostic/testing capabilities.
- Need lots of research and development.

Suggestions from public and written comments:

- Use money to develop new test and testing protocols.
- We respectfully request that USDA make research and development of improved TB diagnostic tests a priority in helping to combat this disease and eradicate it

from our U.S. cattle herds. To advance the development of more efficient, accurate and effective diagnostic tests, we support the allocation of funds within USDA to do what is necessary to advance TB testing technology, validate the efficacy of new potential tests, and approve successful tests that meet the appropriate regulatory requirements.

Traceability

APHIS Summary/Interpretation of Comments and Suggestions:
While some say the NAIS is a solution, especially if it is mandatory, most agree that traceability is key to the success of the TB program.

Comments from focus groups:
- NAIS should be Federally mandated.
- RFID tags are an advantage and should be promoted to producers. (All in agreement)
- Traceability is key to success of the TB program—cows move more now.
- National animal ID is key and necessary.
- The beef industry was less enthused, or less convinced that national mandatory ID was needed because members would not support it.
- Mandatory ID needed–it was needed long ago or at least work to segregate and evaluate. Zoom in on ways to ID animals.
- Epidemiology: Often comprehensive traceouts for full epidemiology of positive cases are not accomplished.

Comments from public and written comments:
- There's a need for traceability and national animal ID.
- Traceability is wanted for export sales. It's not easy to do.
- Need better traceability system.
- Until premises ID is mandatory, there will not be a workable traceability system. We need standards established.
- Traceability will be key to finding the last case of TB in the U.S.
- Traceability is critical.
- Proposed rule in Arizona: All breeding dairy replacements will be able to be traced to their birth premises. Implementation delayed. Don't get so far ahead that you cannot find replacement. There's some degree of traceability—50 percent in the last 6 months have some traceability; 75 of 200 were totally traceable to birth herds. Need to be realistic as purchase a lot of replacements; work with industry.
- Traceability is key. It's a tool to help conduct investigations once infected animals are identified, treat replacement heifers like show animals, pass records where the animals go. Raised the bar with surveillance and traceability in Arizona. The whole idea of an identification system has been debated in our country.

Wildlife

APHIS Summary/Interpretation of Comments and Suggestions:
With the acknowledgement of TB in wildlife here and in Canada, and the number and density of wildlife near livestock, action needs to be taken. There were good ideas for addressing the wildlife issue in both the 2000 and 2004 strategic plans. The 2000 plan was not fully implemented because of funding inadequacies. Goals in the 2004 plan also were not achieved.

Some suggestions include: 1) implement a surveillance program for TB in cervids; 2) develop risk assessments; 3) create critical control points/zones; 4) separate heifers from the rest of the cattle population; 5) develop a vaccine for wildlife, manage public opinion with dissemination of informative material; 6) develop working groups including hunters to develop approaches for wildlife surveillance; 7) work with North American partners; 8) develop working groups to identify actions needed and make recommendations to USDA, States and Industry; and, 9) if those recommended actions are not taken, the USDA Secretary, State governors, and State Agriculture secretaries should come to some agreement on how issues can be resolved.

Comments from focus groups:
- Canada has endemic TB in its wildlife population, which has led to the infection in the Minnesota and Michigan herds.
- There are more white-tailed deer today than in the time of Christopher Columbus. They had to be reintroduced in the 1930's.
- Farmed cervids and alternative livestock have become more valuable than regular livestock.

Comments from public and written comments:
- There are wildlife issues in our country in this program and in other programs. There is a reservoir in wildlife.
- Approach and management of risks imposed by cattle imported from Canada need to be reassessed. TB is endemic in Canada's wildlife population.
- Control and elimination of infection in wildlife-In the 2000 TB strategic plan actions were developed to complete the eradication of tuberculosis. The plan recommended improved wildlife disease management strategies, risk mitigation, and increased information dissemination and education. The total cost of these measures was estimated to be over 33 million dollars. This plan was not fully followed because of funding inadequacies.
- Since the current amount of surveillance in wildlife is limited, the 2004 TB strategic plan called for early, aggressive, and sustained management intervention to eradicate tuberculosis in wildlife. These interventions included: expanded wildlife and livestock surveillance to define the scope of the problem and to monitor progress of eradication efforts; immediate cessation of activities that increase disease risks including supplemental feeding and baiting; population density reduction in specific locations to a level where tuberculosis is no longer maintained; and dissemination of information to involved stakeholders

regarding risk factors associated with transmission of tuberculosis between wildlife and livestock.

- The finding of TB infection in wild deer has had a significant impact on the tuberculosis eradication efforts in livestock in areas with wildlife infection and on the entire eradication program. Until the exposure of domestic livestock to TB-infected wildlife can be effectively prevented, the outbreak of TB in the white-tail deer and elk will continue to have a significant impact on the eradication of bovine tuberculosis in the U.S.
- The wildlife reservoir is not adequately addressed.

Suggestions from focus groups:

- Zero in on wildlife
- The group agreed that expanded surveillance was necessary to address TB in wildlife.
- Implement a surveillance program to focus on reservoirs of TB in cervids.
- Develop risk assessments and create critical control points/zones.
- Separate heifers from the rest of the cattle population.
- Develop a vaccine.
- Public opinion of the issue of TB in wildlife is significant and should be managed through the dissemination of informative material. In addition, working groups that include hunters should be established to help develop approaches for the implementation of surveillance. If enforcement of these approaches is unsuccessful, the U.S. Secretary of Agriculture and State officials should work to establish enforcement of them.

Suggestions from public and written comments:

- The disease does not recognize borders or certain species, and therefore we need to look at how we can better coordinate and work with our partners in North America to completely eliminate this disease.
- It is proposed that a cooperative State/Federal/industry wildlife/livestock working group be established to identify the actions needed and recommend those actions to APHIS/VS, the State officials, and industry leaders as needed. Those recommendations would then be incorporated into action by the participating stakeholders.
- If the working group recommendations are not followed, it is suggested that the Secretary of Agriculture meet with the respective State Governor and/or Secretary and come to an agreement on how the mandates of both parties can be fulfilled.

Miscellaneous

Comments:

- Continued low incidence of TB in the U.S.: The national TB eradication program has successfully reduced the incidence of the disease in U.S. cattle, but recently the number of newly identified infected herds has increased. USDA needs to address the reason(s) for this increase.
- One person suggested that USDA follow a successfully established model of cooperation between government and industry (such as the Nucleic Acid Testing effort). Another person was quick to raise the point that the Nucleic Acid Testing example included cost recovery and pre-licensing).
- Two people also discussed modeling collaborative approaches/authorities such as the Pasteurized Milk Order, which is used by other agencies. Another concurred that the Pasteurized Milk Order could be modified to encourage biosecurity practices on dairy farms.
- Program had worked well for 75 years but now for 2 decades there have been problems (State). Cows move more now across the U.S..
- All these ideas for what is wrong and some improvements are really no-brainers; why are you (APHIS) coming to us now when you haven't even gotten the regulations out that you promised? Recommendations from 4-5 years ago have not been implemented. Though these listening sessions are a good thing.
- Take steps on known risk factors: Mexican cattle, wildlife, State status and roping cattle.
- End the inertia—move the action items forward.
- Need to be more automated for TB surveillance.

Suggestions:

- Do things incrementally—don't wait until you have it all right to try to implement. Can't wait for everything to be in place.

Roles and Responsibilities

No specific comments about roles and responsibilities

These summaries and points reflect the observations, opinions, and knowledge of listening session participants and other commenters. They are not fact-checked, nor do not they reflect the views of USDA.