

July 5, 2011



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Ms. Lee Ann Thomas  
Docket No. APHIS-2011-0044  
Ruminant Health Programs  
National Center for Animal Health Programs  
VS, APHIS  
4700 River Road Unit 43  
Riverdale, MD 20737

**RE: Comments on the United States Department of Agriculture Animal and Plant Health Inspection Service's (USDA APHIS) Proposed Bovine Tuberculosis and Brucellosis Draft Regulatory Framework (Docket Number APHIS-2011-0044)**

Dear Ms. Thomas:

Texas Cattle Feeders Association (TCFA) welcomes this opportunity to comment on the USDA APHIS' framework document "*Proposed Bovine Tuberculosis and Brucellosis Draft Regulatory Framework*" (Docket No. APHIS-2011-0044).

TCFA represents cattle feeders and feedyards in Texas, New Mexico and Oklahoma—an area that markets almost 30% of the nation's fed beef, or 6.5 million head annually. TCFA appreciates the tremendous amount of effort that USDA has put into carefully evaluating the current federal tuberculosis (TB) regulations and the willingness to advance meaningful suggestions to revise the existing program to reflect the current status of the disease in the United States (U.S.) today.

The national bovine TB eradication program and brucellosis program have successfully reduced the incidence of the diseases in U.S. cattle, but we are extremely interested in working with USDA to improve these programs to ensure that we meet our long-term goal of protecting human and animal health by eradicating the diseases from our nation's cattle herd.

In order to have a more concerted effort to achieve the end goal of complete eradication of bovine TB and brucellosis from our U.S. cattle herds, it has become evident that USDA's program needs to be updated, and the antiquated testing methodologies and surveillance tools be improved. TCFA supports efforts to make the federal rule more effective, more flexible and better adaptable to changes in disease research, diagnostics and the cattle industry by focusing on areas of risk rather than detailed standards and requirements that are the norm today.

TCFA appreciates current and previous attempts by APHIS to solicit input from stakeholders prior to initiating formal rulemaking. The public meetings, listening sessions and concept papers have been helpful in facilitating a better understanding between regulators and industry for what is needed to successfully eradicate these two diseases from the U.S. cattle herd. However, we are concerned that the recent framework documents lack details and were developed without industry participation on the working group. Additionally, the framework seems to shift a significant amount of responsibility to the States and Tribes without clearly articulating the federal role in the programs.

General Framework Comments/Questions:

*Element 1: Program (State) Requirements, Component 1: State status*

- More information would be greatly appreciated. The current state status methodology for both TB and brucellosis needs to be streamlined and updated, but given the lack of detail in the framework document it is unclear if this will be accomplished. For example, what are the details of the “key criteria” that will be used to determine status? Also, a control or advisory board is mentioned that *may be* formed to evaluate States and Tribes for compliance with program requirements and to give Veterinary Services (VS) status recommendations. Will producers, private veterinarians and university experts be allowed to serve on this advisory board?
- *Component 3, Number 5 and Number 6.* Under this element VS will make review results available to Federal, State and Tribal animal health and wildlife officials. What information will be provided to industry? This is especially pertinent when one of the stated penalties to States and Tribes for not meeting APHIS’ requirements is more requirements. This directly affects producers in those States and those who market in interstate commerce.
- *Element 1 Component 5: Scope of program regulations Number 4.* More details would be beneficial for transparency and understanding.

*Element 2: Zoning (As a Component of Response and Containment); Regulatory Components for the Element*

- *Component 1: Short-term containment actions, Number 5* - Will producers be allowed to serve on the advisory board?
- *Component 2: Long-term containment actions (>1 year)*
  - *Number 3* – Is a risk assessment part of the initial short term plan or just long-term plans?
  - *Number 8* – It is important for the plans to include methodical elimination of the zone as the disease is eradicated.

*Element 5: Indemnity*

- Much more discussion with industry needs to occur regarding APHIS’ mindset on indemnity.
- The objectives of *Element 5*, besides being inconsistent with the Animal Health Protection Act (AHPA), miss two major goals—encouraging producer cooperation and eradication of the two diseases.
- Additionally, TCFA has significant concerns that APHIS’ brief description of biosecurity and indemnity is inconsistent with the AHPA mandates of paying producers when the federal government depopulates their livestock for any reason, including TB and brucellosis. Also, how is the statement the “indemnity payments are contingent upon the availability of Federal funds” consistent with APHIS’ obligations under the AHPA? We can state with certainty that there will be no indemnity funds from state sources. Since these are federal animal health programs, the federal government should provide indemnity as provided for in AHPA.
- The use of an appraisal calculator is an idea that merits discussion, especially for certain sectors and business models of the industry, but it certainly will not work for all sectors and definitely will not work if APHIS continues with the stance that there is no opportunity for appeal or an independent appraisal. TCFA believes this is contrary to the AHPA and certainly is not conducive for positive cooperation from industry partners. In addition, APHIS states “VS will monitor market prices to ensure that the appraisal calculators remain current.” Given USDA’s historic lack of state of the art technology and lack of a common computing environment, as well as the rapid pace of markets, we

have concerns regarding APHIS' ability to accomplish this in a realistic, timely and accurate manner. APHIS mentions that key objective parameters such as age, weight and milk production (for dairy) will be used to determine fair market value. What about breeding animals or those with genetic value? Also, APHIS mentions some limited regionalization values might be utilized. Will the regions be based on a physical region and/or marketing channels/regions for beef cattle? How does APHIS plan to update the calculator when markets change constantly? How will APHIS calculate the value of "partially" fed cattle? Since there is not a well established market for these animals, will it be on a cost basis considering cost of the animal and cost of feed, medicine, etc.?

*Element 7-B: At Import*

- *Regulatory Objectives of Element Number 1* – Should not this objective be to ensure that animals are healthy at the time of import to the U.S. rather than "appear healthy"?
- *Regulatory Components for the Element General Requirements*
  - *Number 3* – What is the definition of "high-risk" imported livestock, and what are the details of the term "separated"?
- *Post-entry restricted movements and long-term follow-up testing*
  - *Number 2* – What is the frequency of testing before events and exhibitions?
  - *Number 3* – What is meant by "be kept separate from domestic breeding cattle during pasturing"? We are not aware of scientific data identifying any disease transmission from casual fence-line contact in pasture settings. We recommend that "kept separate" prohibit commingling Mexican origin animals with domestic breeding stock.

*Definitions*

- We respectfully request that APHIS work with industry regarding the many terms they plan on defining in the framework/TB and brucellosis programs. It is important to have clear, workable, real-world applicable definitions that also do not conflict with other USDA livestock related definitions.

Without further detail to the Framework, it is difficult to provide more in-depth comments. Therefore we submit the following overarching concerns regarding updating the TB and brucellosis programs.

Primary Program Challenges:

A productive discussion of suggestions to this new approach would not be possible without first addressing the primary challenges and knowledge gaps regarding bovine TB. TB is a complicated disease. Aspects such as the long incubation period, silent carriers, the incompletely understood or managed wildlife component, subsequent biosecurity challenges, import challenges and the many unknowns all add up to a need for prioritization, a targeted focus and quickly obtaining knowledge to some of these outstanding TB complexities.

If we do not first have improved tools for surveillance, prevention, and response for TB, as well as significant advances in reducing the knowledge gaps of this disease (e.g. significantly improved testing capabilities, improved knowledge regarding epidemiology, improved knowledge of and tools to manage the disease in wildlife, how to better mitigate the problems of the wildlife/livestock interface, improved prevention tools, and sustained increased funding for research to find answers and effectively manage the program) the majority of the roadblocks both government and industry have encountered in eliminating the last 0.001% incidence of TB in the U.S. herd and preventing re-introduction, will not be solved by any program.

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Most of the gaps outlined above can be directly linked to a long-term lack of adequate federal research of TB in order to enhance knowledge of the disease and improve testing, surveillance, diagnosis and treatment (none exists), and decrease the need for depopulation of positive cases. This is not unique to TB or even to animal health issues. Federal funding for agriculture research across the board has steadily decreased for many years. For most of the cattle diseases remaining to be eradicated in the U.S., the most significant hurdle is a lack of research to provide final answers and tools. This is especially true in diseases that share a wildlife component. For TB specifically, the lack of research and investment into providing updated tools will continue to stymie the last step to full eradication. Therefore TCFA suggests that as APHIS looks to updating this successful program, a priority should be made on these areas. The sooner we have better tools the sooner the outstanding hurdles regarding eradication are eliminated and many of the regulatory items APHIS is contemplating will not be necessary. This will not only eliminate a disease from the U.S. cattle herd more quickly and further elimination in wildlife, it will also cause less economic harm to producers (and allied industries and rural communities), as well as cost less for the federal government and American taxpayers. Greater knowledge and tools to prevent wildlife brucellosis also would be beneficial.

While APHIS does not have direct jurisdiction over research, the agency should increase collaboration with other federal government agencies and international entities that do conduct TB and brucellosis research or have authority/programs for research?

The impact of wildlife has not been adequately addressed for either disease. Specifically, there remains a need for optimal coordination between federal and state animal health, wildlife and human health agencies. The wildlife component has not been adequately understood or addressed in TB and is the weak link in completely eradicating brucellosis. Further, completion of current national livestock disease eradication programs are jeopardized by the presence of disease in wild and free ranging species not covered by the national programs. Therefore, APHIS VS should have disease control and eradication authority to address disease causing agents regardless of the species in which the agent or organism is found.

TCFA requests a complete APHIS evaluation of the epidemiology process for bovine TB and brucellosis as well as exploration of other diagnostic technologies and innovative applications of epidemiology towards eradication of the diseases. Testing and depopulation strategies need to be updated in a manner that encourages producer cooperation and positive partnership on these two diseases. There must be adequate United States government funding and support of the development and approval of serologic or other tests that would improve specificity and sensitivity over the current testing methodologies. 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 allow removal of infected animals without depopulation of entire herds and/or to enable APHIS, States and Tribes, and industry to explore the possibility of compartmentalization or regionalization.

TCFA respectfully requests that USDA make research and development of improved TB diagnostic tests a priority in helping to combat this disease and eradicate it from the U.S. cattle herd. 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. Improved TB diagnostic tests will actually save tax dollars, as well as minimize cattle losses 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.

The TB caudal fold test requires too much time and multiple handling of cattle:

- 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 tests.
- Need “field” test—pen side test for accurate initial screening at import or initial in preparation for movement.
- Test and hold/quarantine program would require more timely and accurate tests than we currently have.
- 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 program is not adequate for entire herd depopulation.
- Heifers under six months of age should not require testing.
- Are there other methods to control the disease that are not currently being utilized?

Surveillance should be updated:

- Control is dependent on adequate surveillance of appropriate populations of cattle and other species, and exhaustive attempts to identify all possible sources of infection and appropriate biosecurity protocols. Surveillance and trace-out capabilities need to be improved.
- It is known that wildlife is a contributing factor to TB and brucellosis incidence, and this is becoming more problematic in several states. To date, there has not been enough coordinated attention paid to the extra complications this requires.
- The possible human TB component that might sometimes be a factor needs to be further scientifically evaluated.
- TCFA encourages the development of new diagnostics within and outside of APHIS for TB and brucellosis infection in other species and to include these species under the current national eradication program.
- An improved review of the risk factors that contribute to the spread of these diseases, including control methods to protect against the diseases, is required.
- Several aspects of slaughter surveillance inspection issues need to be addressed.
  - There needs to be an improved coordination between APHIS and FSIS. Also, APHIS policy regarding FSIS personnel performing their inspection duties needs to be re-evaluated.
  - Suggestions for improvements specific for TB surveillance needs regarding identification at slaughter, including but not limited to: the lack of collection and recording of ear tags, and the policy of not noting brands at slaughter (specific to Mexican and Canadian brands) needs to be re-evaluated.
  - What is APHIS’ plan regarding brucellosis surveillance both for undefined “at-risk” populations as well as national surveillance?

Prevention methodologies need to be updated:

- Steps should be taken to more fully examine each of the risk factors that have the potential to propagate and spread the diseases now and in the future and help develop program changes to address them.
- Approach and management of risks imposed by cattle imported from Mexico and Canada need to be reassessed. 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.
- USDA needs to continue working aggressively and collaboratively with Mexico in this regard. APHIS should closely monitor and appropriately follow-through with Mexican

states who continue to have positive TB cases.

- Challenges with biosecurity of imports—mixing of Mexican feeder cattle with breeding stock, challenges with event cattle (testing, biosecurity, mixing with breeding and other stock; this is true for imports as well as domestic origin event cattle). Pasturing of imports is possible with appropriate biosecurity. Confined feeding of imports and sexually intact cattle is possible at the same facility with appropriate biosecurity. All solutions should be thoroughly discussed with active industry input prior to decisions.
- Challenges with tracking of Mexican origin cattle. For example, under current practice, often the origin does not follow the individual once it leaves the original U.S. state of import. This hinders biosecurity as well as traceback capability.
- USDA should ensure the unique identification of Mexican cattle by “M” brand and Mexican ear tag is implemented and not tampered with, and improve the collection and recording of all identification at slaughter to enable proper traceback of infected animals.

Approach and management of event cattle should be re-evaluated:

- Domestic 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. However, they should 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 address the lack of adequate funding for the APHIS TB Program as well as inadequate Federal research funding through the Agriculture Research Service (ARS) and the Cooperative State Research, Education 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.

- The U.S. needs more funding for the APHIS program and adequate, sustained funding for research to provide more answers and better solutions.
- TCFA 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.

TCFA is fully supportive of appropriate producer responsibilities in regard to herd management, disease prevention and control, and risk mitigation. That being said, we have significant concerns that the direction APHIS seems to be heading in this framework document regarding indemnity will actually cause harm to the majority of producers and discourage what has been a long successful history of teamwork and collaboration between federal and state animal health officials and cattle producers. Given the inadequacies of knowledge and tools for these diseases and the complicating wildlife and political components, this framework document is of concern and makes it all the more imperative that adequate information is available regarding other species' (especially wildlife) roles in bovine TB, better control of brucellosis in wildlife and improved epidemiological, testing and surveillance tools are made available.

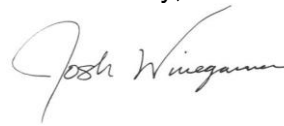
TCFA is concerned that this new approach to indemnity, combined with the lack of adequate knowledge, epidemiology, testing capabilities, surveillance and control; including no treatment options; will create severe financial consequences for affected producers, put increased pressures on states and allow the federal government to abdicate their responsibilities under the AHPA. The El Paso, Texas, area history is an example of how difficult these diseases can

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be to control when wildlife or unknown factors are involved 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. USDA should ensure that adequate indemnity funding for herd owners be available so that mandatory depopulation of U.S. TB or brucellosis infected herds is economically feasible.

We sincerely appreciate all of the hard work and effort APHIS has previously done regarding both these diseases. Thank you for the opportunity to provide input prior to rulemaking and listening to our concerns and suggestions. We look forward to actively working with USDA to obtain the ultimate goal of expedient eradication of both TB and brucellosis from the U.S. cattle herd.

Sincerely,

A handwritten signature in cursive script that reads "Josh Winegarner". The signature is written in black ink and is positioned above the printed name and title.

Josh Winegarner  
Government Relations Director