



December 4, 2009

John Clifford, DVM
Docket No. APHIS-2009-0073
Regulatory Analysis and Development
PPD, APHIS, Station 3A-03.8
4700 River Road Unit 118,
Riverdale, MD 20737-1238

RE: Comments on the USDA concept paper *A New Approach for Managing Bovine Tuberculosis: Veterinary Services' Proposed Action Plan* (Docket No. APHIS-2009-0073)

Dear Dr. Clifford,

The National Cattlemen's Beef Association (NCBA) welcomes this opportunity to comment on the United States Department of Agriculture Animal and Plant Health Inspection Service's (USDA APHIS) concept paper "*A New Approach for Managing Bovine Tuberculosis: Veterinary Services' Proposed Action Plan*" (Docket No. APHIS-2009-0073). Additionally we greatly appreciate the approach APHIS has taken in soliciting input from stakeholders prior to initiating rulemaking. Undertaking a much needed new approach to a longstanding regulatory program is challenging and as with all change, often disconcerting to affected parties. The ability to have an open dialogue which would not be possible under rulemaking restrictions is appreciated and will be beneficial for all parties as we move towards the future of reaching a common goal of eliminating this disease from the United States.

Producer-directed and consumer-focused, NCBA is the nation's oldest and largest national trade association for cattlemen and represents over 230,000 cattle producers through direct membership and our state and breed affiliates. NCBA's top priority is to produce the safest, highest quality, affordable beef in the world. This has been consistent throughout our industry's history and in our long-term efforts to continually improve our knowledge and ability to raise healthy cattle.

One long-term important area has been the cooperative Federal-State-industry national effort (since 1917) to eradicate bovine tuberculosis (TB) from U.S. cattle. The success of this effort is the result of years of dedication, hard work and cooperation from all involved. Building upon this successful program that has significantly reduced the incidence of bovine TB in U.S. cattle to less than 0.001 percent will require updating now invalid assumptions upon which the old program was based, and focusing efforts on areas of priority that will enable now known glaring gaps in knowledge and tools to detect, prevent and eliminate the disease. As well, re-evaluating how we better deal with geopolitical boundaries and improving coordination among countries, federal agencies, federal and state agencies, and among animal health, wildlife and human health agencies are essential components as we move forward collectively to successfully reach our common goal. NCBA producers understand we have an important role in this successful partnership and look forward to continuing our century old proactive relationship with APHIS.

NCBA is generally pleased with most of the concept paper action plan's outlined areas of reducing the introduction of TB into the U.S. herd from wildlife, enhancing TB surveillance, increasing options for managing TB-affected herds (with some concerns to be discussed below), modernizing the regulatory framework to allow greater flexibility and adaptability, and addressing a State status classification system that isn't working. Additionally encouraging are the items regarding thinking outside of the traditional collaborations and exploring new partnerships to find solutions to knowledge gaps and more adequately addressing the wildlife issues. We do however have some significant concerns in several areas especially regarding imports, managing TB infected herds, resources and roles/responsibilities. Last, unfortunately NCBA will not at this time be able to provide detailed comments on some very important items in the concept paper because we do not currently have policy regarding them. Having the ability to identify these areas that need more industry as well as government discussion is helpful and we will discuss several areas below that would benefit all stakeholders greatly if continued opportunities for open discussion are made available before rulemaking proceeds.

A productive discussion of suggestions to this new approach would not be possible without first addressing the primary challenges and knowledge gaps regarding bovine tuberculosis. 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.

Put quite simply – 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 percent incidence of TB in the U.S. herd and preventing re-introduction, will not be solved by any program.

Most of the gaps outlined above can be directly linked to a long-term 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 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 NCBA 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 taxpayer.

While APHIS does not have direct jurisdiction over research, they can certainly increase their activity and collaboration with other federal government agencies and international entities that do conduct TB research or have authority/programs for research. Can APHIS as part of their budgetary process for animal health programs and specifically the TB program explore adding this component to their annual budget request?

Related to that can APHIS increase their annual budget requests for the TB program? As was stated in the concept paper, “The Federal annual appropriation for the TB line item...reached its plateau at approximately \$15 million since 2003.” And “We expect federally appropriated funds to remain constant or decrease and do not anticipate having emergency funds available.” It remains unclear why the long-term decreasing and/or flat-lining of all of agriculture’s, and especially livestock’s, federally administered programs continue the significant downward trend, especially given that food security concerns for the U.S. and the world are increasing and the current spending level of the Federal Government is the greatest in recent memory. Agriculture has experienced this for far too long and the lack of investment into agriculture and food and fiber production in the U.S. by the federal government is now catching up and overcoming all of the tremendous strides afforded by the advancements previous generations made because of Federal investments. There is certainly justification for increased federal investments/budget improvements as well as historic evidence of how adequate and sustained federal investment into research as well as animal health programs pays off exponentially and for everyone. Therefore NCBA recommends that as part of APHIS’s new approach to the TB program USDA should adequately address the chronic Federal underfunding of the APHIS TB program as well as the chronic inadequate Federal research funding through the Agriculture Research Service (ARS) and the National Institute of Food and Agriculture (NIFA) /formerly Cooperative State Research Education and Extension Service (CSREES) as well as explore other Federal and international research opportunities.

Additionally, 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 methodology. There is an urgent need for the exploration of other diagnostic technologies and innovative applications of epidemiology towards eradication of this disease. Unnecessary hurdles in validating and approving new testing methodologies should be minimized. We are encouraged by the mention of the Veterinary Services 2006 serum bank efforts as well as identifying alternative sources of funding within the Federal Government to support test development and validation as well as exploring new partnerships for such. One of the largest hindrances to TB eradication progress is the lack of an accurate, sensitive, specific, and rapid TB test. The caudal fold test (CFT) currently in use has served its purpose but is not good enough for the current situation of low incidence of the disease in the U.S. As well it is too cumbersome with the multiple days and multiple handling of cattle it requires.

Having a better test to replace the CFT as well as providing a solution to the need for an efficient and accurate pen-side or “field” screening test for accurate initial screening at import or initial preparation for movement would help eliminate some of the current discussions regarding cattle movement, whether interstate or internationally or type of cattle. It would also help quickly eliminate many of the final hurdles to completely eradicate this disease.

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 to explore the possibility of compartmentalization or regionalization in regards to this disease.

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. 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. Additionally we encourage the items within the concept paper that seems to indicate APHIS is contemplating looking outside of the traditional collaborations and exploring new partnerships to find solutions to knowledge gaps and more adequately addressing the wildlife issues. Are there other methods to identify, control or eliminate the disease that are not currently known or being utilized?

Addressing the specific sections in the Concept Paper:

1. Mitigate Disease Introduction:

a) Apply Additional Requirements to Cattle Imports from Mexico

NCBA has concerns that much of the underlying assumptions in this section of the concept paper have not been adequately explained and publicly discussed. For example the statement that “However, epidemiological investigations indicate that the majority of TB-infected cattle detected at slaughter in the United States originated in Mexico.” NCBA is not aware of a recent broadly accessed public discussion of the epidemiological investigations or trend analysis on cattle detected at slaughter to thoroughly understand this statement. Are these epidemiological investigations and slaughter surveillance referenced from the last few years, from the last decade, longer? Also, two charts presented at December 2008’s listening sessions (the dispersal of cattle imported from Mexico Jan 2005 – April 2008 and the distribution of positive TB herds from FY 2004- 2008) seemed to conflict with each other and they relate to the statement quoted. The concept paper also states “Each year, the United States imports approximately 1 million cattle from Mexico. The prevalence of TB-affected herds in virtually all Mexican States and the number of TB cases in imported Mexican cattle have declined substantially from the late 1990s.” NCBA suggests it would be helpful for a comprehensive data presentation and analysis with public discussion prior to rulemaking of all slaughter surveillance and epidemiological investigations since the late 1990s. This would be helpful not only for solutions regarding mitigating risk from imports, it would also be helpful in better targeting what needs to be done to improve slaughter surveillance as well as identifying reasons for epidemiological investigations that were not able to be completed in order to improve both the investigations as well as improve our knowledge of the disease and its transmission.

Additionally we are concerned, based on the listening sessions conducted in December 2008 as well as some comments already submitted on this concept paper that some outside of the border states area have taken an overly simplistic view of cattle imported from Mexico and possibly inaccurately focused the majority of the cause of the continued low incidence of TB in the U.S. solely on these cattle. This is not helpful in the long-term for eradicating this disease from the

entire country as well as the continent. Solutions based on inaccurate assumptions will not achieve the common goal of U.S. eradication. For example, a blanket ban to pasture or graze cattle imported from Mexico to date has not been scientifically justified and could cause very real tremendous economic harm, if not complete restructuring or elimination of, a large part of the U.S. cattle industry. Pasturing of imports is possible with appropriate biosecurity. Solutions should be thoroughly discussed with active industry input prior to decisions and rulemaking. NCBA is not aware of any evidence of exposure, epidemiological evidence, or investigations of positive cases in the U.S. to have shown to be due to fence line contact of imported Mexican cattle at pasture. There has however been evidence that comingling of breeding cattle or other cattle that stay in the U.S. herd for extended time periods such as event cattle with TB infected cattle does contribute to the TB problem. It might be helpful to take a step back and assess what we do know: comingling cattle with exposed or infected TB cattle (especially silent carriers) / comingling animals that stay in the U.S. herd for years with cattle that are intended to be harvested much sooner has been linked to positive TB cases. Appropriately prohibiting the exposure of cattle not destined for processing with cattle that are is a point worthy of more detailed discussion. Later in the concept paper APHIS proposes the need to revise program definitions. It might be useful to have discussions on the value to broaden the terms suggested to be defined and have discussions on the definitions themselves. NCBA cannot offer any detailed suggestions at this time regarding definitions nor sufficient detailed input regarding several of the bulleted alternatives that VS is considering due to current lack of specificity in our existing policies but would strongly encourage APHIS to have further public conversations and input from stakeholders prior to going into the rulemaking process. NCBA is supportive of regulations that would require timed event/sport cattle be tested for TB within twelve months prior to crossing state lines, with the stipulation that U.S. born timed event/sport cattle, that have not been exposed to cattle from another origin, be exempt from TB testing when they move directly from the premises of birth to another premise. 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 (see below caveat).

The current testing for importation has not been adequate to prevent TB infection from Mexican imports. That being said, the challenges with ensuring imports are TB free has a great deal to do with the poor testing tools previously discussed. Until better testing tools are available some of the discussions regarding increasing testing will not help. The results will only be as good as the testing limitations. There are 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, as well as improve the collection and recording of all identification at slaughter to enable proper traceback of infected animals.

Risk evaluations, herd plans and additional testing requirements for exposed herds, as well as conducting supplemental surveillance in geographic areas that have an increased risk for exposure should not be limited only to imported cattle and we will discuss these concepts later in our comments in the broader context of all cattle and wildlife.

In closing on this section, there are challenges to cleaning up the disease in Mexico. Producers on both sides of the border have worked together for many years on cattle health issues. NCBA will continue to work with our producer counterparts in Mexico to find constructive solutions with the ultimate goal of eradicating this disease from the continent. USDA needs to continue working aggressively and collaboratively with Mexico to help decrease the challenges of TB for our neighbors. APHIS should closely monitor and appropriately follow-through with Mexican states who continue to have positive TB cases. Continued and concerted collaboration by all parties – producers, state and federal animal health officials and researchers – is essential.

NCBA is also supportive of adhering to our obligations under WTO. Changes to the TB program as it relates to imports must be consistent with meeting these obligations.

b) Enhance Efforts to Mitigate Risks from Wildlife

The lack of knowledge regarding the TB wildlife reservoir and wildlife/cattle interface has been previously discussed in our comments.

The chronic lack of optimal coordination among federal agencies, federal and state agencies, and among animal health, wildlife and human health agencies is becoming increasingly apparent for many U.S. cattle health issues as well as wildlife health. For bovine TB and brucellosis it is safe to say the U.S. will never be completely free of these diseases or risk of recurrence until we have more investment in knowledge and tools for wildlife and until the agencies with abutting authorities across state and federal jurisdictions drastically improve their coordination and work in concert to eliminate the reservoirs in wildlife. It would be very beneficial for USDA APHIS and the Department of Interior to publicly discuss the individual and collective hurdles preventing true coordination and eliminating these diseases in wildlife.

Also, NCBA promotes the development of new diagnostics within and outside of APHIS for TB infection in other species and include these species under the current national eradication program. Along these lines, the idea of targeted surveillance in wildlife as part of a comprehensive, national surveillance plan seems appropriate. An improved review of the risk factors that contribute to the spread of this disease, including control methods to protect against disease, is also required.

Because of the above long-standing problems, it is concerning that this concept paper says APHIS will be “developing on-farm mitigations to control the risk of disease transmission between wildlife and livestock and evaluate the effectiveness of these mitigations.” Based on our current limitations in knowledge and tools as it pertains to wildlife, how can this be successfully done to truly mitigate transmission and without accidental hardship to cattle producers? And how can the effectiveness of a mitigation step be accurately evaluated given the current gaps? This becomes even more concerning later in the paper when APHIS discusses program standards, biosecurity, herd plans and indemnity. There has already been demonstrable harm to cattle producers doing everything correctly based on current knowledge to prevent TB in their herds in states with a documented wildlife TB reservoir. Therefore NCBA urges increased details and much more discussion before proceeding with rulemaking. Limitations regarding wildlife solutions are equally problematic and should be considered along with our comments regarding concerns due to testing limitations.

2. Enhance Surveillance:

a) Crafting a Comprehensive National Surveillance Plan

NCBA welcomes discussion of a comprehensive national surveillance plan. TB control is dependent on adequate surveillance of appropriate populations of cattle and other species, exhaustive attempts to identify all possible sources of infection and appropriate biosecurity protocols. Surveillance and trace-out capabilities need to be improved.

The possible human component that might sometimes be a factor needs to be further scientifically evaluated. Several aspects of slaughter surveillance inspection issues need to be addressed:

- 1) There needs to be an improved coordination between APHIS and USDA's Food Safety and Inspection Service (FSIS). And APHIS policy regarding FSIS personnel performing their inspection duties needs to be re-evaluated. Even though this is an APHIS concept paper, while APHIS is modernizing the TB program, it would be beneficial as part of this process thoroughly evaluate all aspects of surveillance.
- 2) Suggestions for improvements specific to TB surveillance needs regarding identification at slaughter, including but not limited to: the lack of collection of eartags, and the policy of not noting brands at slaughter (specific to Canadian and Mexican brands) needs to be re-evaluated.

More detailed outlining of APHIS' thinking regarding "other possible novel surveillance streams" would be greatly appreciated. As would clarification/discussion regarding 'perceived risk of exposure resulting from observed herd management and biosecurity practices may be used to "target" cattle, domestic bison, and captive cervid herds for supplemental testing.' There is not enough detail to adequately provide constructive comments. Also current NCBA policy does not cover many of the excellent points in this section of the concept paper and we would need more specifics and more time to adequately evaluate and provide feedback.

b) Accelerating Diagnostic Test Development to Support Surveillance

See comments above regarding improvements to diagnostic test development.

3. Manage TB-affected Animals and Herds:

a) Conducting Epidemiological Investigations and Assessing Individual Herd Risk

In addition to suggestions provided previously in these comments regarding epidemiological investigations and revising definitions, NCBA is interested in the concept of developing a standardized tool to evaluate and classify risk of TB transmission but order to provide constructive comments, we respectfully request more detail on the concept, and especially on the latter half of that bullet point – “associated with individual herds under investigation based on producer-identified risks (e.g. wildlife exposure), management practices, and biosecurity”.

b) Applying Whole Herd Depopulation and Developing Alternative Strategies

NCBA welcomes discussion considering alternatives to whole herd depopulation. It is important to note that successful implementation of alternative strategies will require a built-in flexibility for producers and states and would benefit by APHIS closely coordinating these concepts with changes regarding the state status aspects of the current TB program. NCBA is concerned that producers may be unduly harmed if they are not given choices and flexibility as we transition from the current system to whatever the new program is. The problems and limitations with the current state status classification system need to be addressed concurrently with any move from eliminating herd depopulation as an option if the producer so desires. Until this is addressed it is inappropriate for APHIS to eliminate whole herd depopulation as an option for a producer. Test and quarantine as an option would be more viable for producers to choose and not cause unintended harm to producers in the rest of that state if the state status classification issues are resolved concurrently. Full evaluation of the California herd which is currently under a test and quarantine option – how it is affecting the producer, how it is affecting the rest of the states’ producers and how other states have dealt with interstate commerce requirements of cattle leaving California would be helpful.

Performance standards that are outcome based is an interesting idea. But based on current information (see previous discussion) it may be

premature for performance standards given all of the unknowns about, and limitations regarding, the disease. NCBA believes more discussion of this concept would certainly be beneficial for all stakeholders. More detail regarding performance standards and the outcomes intended would be helpful.

NCBA has significant concerns regarding where APHIS seems to be heading with indemnity to producers. The Animal Health Protection Act currently mandates that APHIS must pay fair market value to a producer when APHIS “takes” an animal. And there is a modest maximum indemnity amount per animal specified in current law. There has long been a problem regardless of the livestock species with the cap on indemnity not providing true value for many breeding animals. There has also often been a problem with efficient determination of “fair market value” for livestock other than breeding animals. APHIS’ proposal to reduce the maximum amount of Federal indemnity paid per individual animal is not a constructive one and raises severe concerns. Indemnity payments do not make a producer whole and even with indemnity payments under current law often producers are not able to overcome the losses resulting from having an occurrence of a mandatory program disease event in on their operation. Also at this time linking Federal indemnity payments to the implementation of specific risk mitigation and biosecurity practices within a herd is very problematic. APHIS has presented this concept previously in a proposed rule published (never finalized) in 2007. NCBA is concerned that the direction APHIS seems to be heading with indemnity will cause more problems than it will possibly improve and it will unduly hurt the majority of producers who are doing everything possible to prevent TB in their herds based on current knowledge and tools available.

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 the previously proposed rule and the items regarding indemnity in this concept paper, while attempting to address what APHIS admits is only a possible problem with a very small number of inadequate biosecurity and herd health plans, will actually cause harm to the majority of producers.

Given the inadequacies of knowledge and tools for this disease, APHIS' ideas on indemnity is of great concern and makes it all the more imperative that adequate information is available regarding other species' (especially wildlife) roles in bovine TB, and better epidemiological, testing and surveillance tools are made available. NCBA is concerned that this approach, 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. USDA should ensure that adequate indemnity funding for herd owners be available so that current legal requirements under the AHPA is fulfilled.

NCBA suggests instead focusing on education and outreach efforts to producers to better deliver the information and tools we do currently have as well as addressing the previously discussed comments regarding prioritization and solving knowledge and tool availability gaps. We would welcome discussions and working with APHIS on how to better collaborate on educational and outreach activities for beef producers. We would also be interested in discussing the underlying issues APHIS is intending to resolve with their concepts on changes to indemnity and collaboratively constructively addressing these. There should be in-depth discussions on the scope of the perceived problems, and causes. There is a difference in how to solve deficiencies in implementation of risk mitigation and biosecurity practices caused by lack of knowledge versus willful intent. NCBA has had a proactive and strong working relationship with APHIS for over 100 years and we look forward to building upon that strong foundation and continuing to actively find solutions that mutually benefit NCBA producers and animal health officials.

c) Applying Animal ID Standards to Meet Animal ID Needs

Please see comments previous in this submission regarding some specific areas of improvement to maintaining and collecting some identification of imports and at slaughter surveillance as well as need for definitions.

Additionally NCBA recognizes and supports the need for a national animal identification system for the purpose of enabling state and federal animal health officials to respond rapidly and effectively to animal health emergencies, such as foreign animal disease outbreaks or emerging domestic diseases. We also support the use of animal identification systems for genetic improvement and marketing arrangements.

NCBA is aware that APHIS has been developing electronic health certificates for several years now. Is this system operational, able to move at the speed of commerce, and interconnected between states and with other countries? Are electronic health certificates the same as electronic movement certificates mentioned in this concept paper?

4. Modernize the Regulatory Framework:

NCBA is supportive of APHIS' goal to modernize the TB regulatory framework. The national tuberculosis eradication program has successfully reduced the incidence of the disease in United States (U.S.) cattle, but there continues to be a low incidence of TB as evidenced by the newly identified infected herds over the past several years. Several of our states and APHIS are dealing with multiple cases of bovine TB in different regions of the country and struggling with issues related to surveillance, control, eradication and prevention of this disease in the nation's cattle population and the wildlife TB reservoir.

The ability to provide more flexibility to industry and animal health officials as more knowledge becomes available, industry changes over time or new challenges are identified is important. NCBA is supportive of science-based decisions and cost/benefit analysis of regulatory programs. Costs cannot outweigh the benefits to the regulated industry if a program is to be successful. Likewise successful animal health programs must be science-based.

5. Transition to a Zoning Approach:

At this time NCBA does not have policy regarding eliminating the current State status system and therefore we cannot directly address the details of the ideas under this part of the concept paper. We have had long-standing concerns with the current system and agree that it is not working for producers or animal health officials. NCBA suggestions for streamlining and improving the State status classification was discussed in-depth in our comments submitted for the December 2008 APHIS TB listening sessions. We will not repeat them here since that is not a question the concept paper outlined.

That being said, the system has not kept up with the disease challenges and limitations of current technology. As well, discussions of transitioning to a zoning or compartmentalization approach in animal health disease programs have been conducted at the international level and most notably at the OIE (World Animal Health Organization). NCBA does have policy supportive of USDA exploring the concepts of compartmentalization, zoning, and/or risk area in regards to TB. Risk-based and science-based decisions should be a component of any state status modification determinations. NCBA wholly supports open access to marketing and movement options while maintaining appropriate disease risk. Precise protocols should be in place to determine quarantines, regionalization, or other movement restrictions in a herd or area. NCBA supports research to develop protocols and determine the economic impact of an internal regionalization of states or area.

As APHIS moves forward on this topic NCBA strongly encourages industry and state input and collaboration as plans are developed and before rulemaking proceeds. Not enough in-depth discussion has transpired in the U.S. across the board on this topic prior to rulemaking. Many questions remain, even with the thoughts outlined in this concept paper. What are the criteria for defining a “zone”, what are the benchmarks and plan for dissolving, expanding or decreasing a “zone” as TB is eliminated from the defined area? What are the requirements for producers who are within the “zone” and how do they continue to be able to operate while in this situation? What steps will be put into place that ensures that the problems with the current State status classification system won’t be replicated with a “zone” system? How will the transition period be handled as APHIS moves from the current State status structure to a new approach? Those details will need to be

thought through and communicated prior to any modifications in order for success and to avoid unnecessary or accidental harm to producers or disruptions in interstate commerce, marketing or state animal health programs.

TB does not recognize state or geopolitical borders. An updated approach when a TB positive animal has been identified is warranted. The pros and cons of eliminating state status classifications should be discussed as well as interim steps as a transition is made. The final result of changes to updating the current system should work for producers as well as state and federal animal health officials.

6. Implementation, Oversight, and Monitoring of the New Approach

a) Resources

Please refer to our comments previously offered in this document.

b) Roles and Responsibilities

NCBA is fully supportive of appropriate producer responsibilities in regards to herd management, disease prevention and control, and risk mitigation. In addition to the concerns provided in our previous discussion regarding indemnity, and the unavoidable problems caused by lack of available tools and knowledge to adequately address the remaining issues, we have significant concerns in the bullet point “Developing industry- and producer-driven components of the TB program and generating the funds necessary to support these activities.” Much more detail prior to initiating rulemaking is needed to adequately understand what APHIS is considering here. The federal government has obligations under its responsibilities for mandatory animal health programs and historically, funding for the mandatory TB program has been APHIS’ responsibility and considered such because of the benefit to the public good. That does not mean that over the last 92 years producers have not contributed nor been affected economically as the TB program has been implemented. Transferring this governmental responsibility to producers for them to pay for mandates the government dictates through regulation is unacceptable.

7. Potential Obstacles to Implementing this New Approach

- a) Replacing the current State status system may reduce or eliminate incentives for States to promptly investigate cases and mitigate the continue spread of TB.**
- b) The described zoning approach may be inappropriate to manage a chronic disease such as TB and cannot be applied consistently across the country.**
- c) It will not be possible to enforce program requirements without specifically including them in the text of the regulations contained within the CFR.**

Potential obstacles to implementing this new approach have been discussed above. As APHIS moves forward and provides more details some of the obstacles may diminish and new ones may come to light. Others will need to be thought and worked through to find mutually beneficial solutions. The ability to continue open discussions and have more details to the new approach is paramount to a successful new Tb program.

In closing, the long-term cooperative Federal-State-industry national effort to eradicate bovine tuberculosis (TB) from U.S. cattle has been successful. This is the result of years of dedication, hard work and cooperation from all involved. In order to have a more concerted effort to achieve the end goal of complete eradication of bovine TB from our U.S. cattle herds, with no recursions, it has become evident that USDA's program needs to be updated, the antiquated testing methodologies and surveillance tools improved, the wildlife component concurrently adequately addressed, and the state status classification system updated.

We sincerely appreciate all of the hard work and efforts APHIS has previously done regarding this disease. 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 this disease from the U.S. cattle herd as well as its eradication from North America, and ensuring no future recursions in our herds.

If you have any questions or concerns, please contact Dr. Elizabeth Parker, NCBA's Chief Veterinarian at (202) 347-0228 or at eparker@beef.org

Sincerely,

A handwritten signature in black ink that reads "Gary Voogt". The signature is written in a cursive, flowing style.

Gary Voogt
President
National Cattlemen's Beef Association