



National Milk Producers Federation

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"Connecting Cows, Cooperatives, Capitol Hill, and Consumers"

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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 Milk Producers Federation (NMPF) is pleased to comment on the USDA concept paper *A New Approach for Managing Bovine Tuberculosis: Veterinary Services' Proposed Action Plan* (Docket No. APHIS-2009-0073). The National Milk Producers Federation, based in Arlington, VA, develops and carries out policies that advance the well being of dairy producers and the cooperatives they own. The members of NMPF's 30 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 40,000 dairy producers on Capitol Hill and with government agencies.

The national tuberculosis (TB) eradication program has successfully reduced the incidence of the disease in United States (US) cattle, but there continues to be a low incidence of TB as evidenced by the newly identified infected herds over the past several years. As we struggle to deal with the impacts of the current TB episodes in the near term, we are extremely interested in working with USDA to improve the national TB program to ensure that we meet its long term goal of protecting human and animal health by eradicating zoonotic 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 from our US cattle herd, with no recursions, it has become evident that USDA's program needs to be updated, and the antiquated testing methodologies and surveillance tools improved. USDA's Concept Paper set's a clear pathway for modernizing the TB eradication program. In general, NMPF supports the pathway presented in the Concept Paper to modernize the TB eradication program. Below we present specific comment on each aspect of the Concept Paper to provide USDA a clear direction when proceeding from concept to regulatory proposal.

Jerry Kozak, President/Chief Executive Officer

Randy Mooney, Chairman

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Mitigate Disease Introduction

Efforts to fully eradicate TB in the US are compounded by several known or suspected routes of exposure which require further regulatory enhancements to minimize these risks. Our comments in this area will focus on Mexican imported feeder cattle, Mexican imported event cattle, Canadian imported cattle, wildlife reservoirs, and employee transmission.

Mexican Imported Feeder Cattle – Epidemiological investigations conducted by USDA indicate that most TB-infected cattle detected at slaughter were imported from Mexico. While there has been a significant reduction in the prevalence of TB in Mexico, importation of Mexican cattle remains the highest risk for introduction of TB to domestic cattle. NMPF believes that to mitigate this risk, USDA should take the following measures to reduce the risk of introducing TB to domestic cattle from imported Mexican feeder cattle:

1. Prior to importation
 - Require individual animal traceability to herd of origin;
 - Require annual negative herd-test;
 - Enhance TB testing prior to entry including at the port of entry;
 - Restrict entry of cattle that have been comingled with dairy animals, including dairy steers; and
 - Restrict entry of cattle from herds from which a TB-infected animal identified in the US has previously originated from.
2. After importation
 - Continue individual animal traceability through slaughter or death;
 - Restrict all comingling with breeding animals including housing and transportation including;
 - Buffer zones separated by two fences and a distance of at least 30 feet maintained between feeder cattle of Mexican and breeding animals;
 - Drainage from higher risk areas cannot flow through areas of a lesser risk;
 - No shared watering or feeding troughs between classes of facilities
 - Separate hospital/sick pen facilities;
 - Separate processing/receiving facilities or these facilities must be cleaned and disinfected prior to being used for breeding cattle of US origin.
 - Move animals directly to terminal feedlots without interim grazing or pasturing.
3. Impose penalties for violating requirements.

Mexican Imported Event Cattle – Over 25,000 head of event cattle (particularly Corriente cattle) are imported from Mexico annually for use in rodeos, team penning competitions, cutting horse events, and other exhibitions. These cattle present a unique challenge because of their extensive movement around the US. USDA should conduct a risk analysis of the unique TB risks these cattle pose to determine if their importation should be entirely restricted. In absence of restricting importation, USDA should take the following measures to reduce the risk of introducing TB to domestic cattle from imported Mexican event cattle:

1. Prior to importation
 - Require individual animal traceability to herd of origin;
 - Require annual negative herd-test;

- Enhance TB testing prior to entry including at the port of entry;
 - Restrict entry of cattle that have been comingled with dairy animals, including dairy steers; and
 - Restrict entry of cattle from herds from which a TB-infected animal identified in the US has previously originated from.
2. After importation
 - Continue individual animal traceability through slaughter or death;
 - Restrict all comingling with breeding animals including housing and transportation;
 - Require notification to fence line contact farms of the presence of Mexican event cattle; and
 - Require semiannual TB testing.
 3. Impose penalties for violating requirements.

Canadian Imported Cattle – Cattle of Canadian origin may not represent the same degree of risk as cattle of Mexican origin due to the much lower apparent incidence in their national herd; however Canada has a wildlife TB reservoir in Manitoba and Alberta provinces. Because breeding stock is allowed to be imported from Canada, a TB-infected animal imported could have a long residence time among US cattle. USDA should conduct a risk analysis of the unique TB risks these cattle pose to determine if additional measures should be implemented particularly for cattle from Manitoba and Alberta.

Wildlife Reservoirs – The 1995 discovery of self-sustaining bovine TB in white-tail deer in Michigan was a prelude to the importance of controlling bovine TB at the cattle and wildlife interface. Subsequent discovery of TB in free-ranging white tail deer in Minnesota confirms the need for risk-mitigation efforts in areas with wildlife TB reservoirs. NMPF believes that to mitigate this risk USDA should consider the following measures for areas with a wildlife TB reservoir:

1. Partner with wildlife agencies for increased surveillance;
2. Conduct research to develop strategies (such as vaccinations) to reduce prevalence of TB in wildlife;
3. Make available on-farm best management practices to reduce livestock-wildlife interaction.

Employee Transmission – Traditionally, the human health focus for bovine TB has been to prevent the transmission from cattle to people. However, transmission from employees to cattle is a plausible route for introduction into cattle. A human-to-cow transmission route has been postulated for a recent TB-infected animal in a dairy herd in California where epidemiology has been unable to trace the origin. Working with the Center for Disease Control, USDA should conduct a risk analysis of employee-to-cow transmission and determine if additional measures should be implemented for persons working directly with cattle. This would include an analysis on mandating TB testing for individuals employed by dairy operations and determining the legality of employment decisions based on TB status.

Enhance Diagnostics and Surveillance & Traceability

Diagnostic and surveillance & traceability capabilities have not kept pace with the changing needs of the TB eradication program. Current diagnostics are no longer adequate for the low-level incidence

of TB the US now has. The success of both the TB and brucellosis eradication programs has led to a decline in the use of permanent identification for breeding cattle.

Diagnostics – The current suite of diagnostic tests have many limitations. The caudal fold tuberculin test (CFT), the primary screening test for bovine TB, is unchanged since the TB eradication program began in 1917. This time consuming test requires multiple veterinary visits to administer and has a 15 percent false negative response rate along with a 3 percent false positive rate. NMPF believes that improved diagnostics are necessary and USDA should take the following measures to improve TB diagnostics:

1. Finalize a robust serum and tissue database of known TB-positive and TB-negative cattle;
2. Prioritize current funding or identify alternative funding to expedite validation and approval of new diagnostics;
3. Determine the feasibility of milk tests for dairy cattle populations;
4. Establish minimum standards to approve veterinarians to administer the CFT test including regular review to ensure an adequate response rate.

Surveillance & Traceability – TB surveillance needs to ensure early detection to minimize disease spread. Currently the cornerstone for TB surveillance is slaughter surveillance, which has been hindered by lack of an effective animal ID and traceability program (see **Manage TB Affected Animals & Herds**). Too often a TB-infected animal identified during slaughter surveillance cannot be traced back to its herd of origin. As surveillance and traceability are updated, USDA must ensure their conformity with the World Animal Health Organization (OIE) international guidelines for declaring a country free from bovine TB. NMPF believes that improved surveillance and traceability are necessary and USDA should take the following measures:

1. Implement a mandated national animal identification system;
2. Conduct increased surveillance of imported animals;
3. Partner with wildlife agencies for increased surveillance in wildlife reservoirs;
4. Require a negative TB test within 60-days on all breeding stock 12 months or older prior to moving in interstate commerce; and
5. Require individual animal traceability from herd of origin through slaughter or death.

Manage TB Affected Animals & Herds

Enhancement of the management tools available for producers who have a TB-infected animal identified to their premises is required to advance the TB eradication program. Traditionally, USDA and States have relied on whole herd depopulation as the preferred response to maintain State status. The recent TB experience in California where a single TB-infected animal is identified out of thousands of animals demonstrates the need for a viable test-and-cull strategy. At the same time, whole herd depopulation must remain in the suite of management strategies. A linchpin to these efforts is an effective animal ID system.

Herd Management Strategies – Traditionally when a TB-infected animal was traced to its herd of origin, depopulation was the first choice of action. During the last decade nearly \$250 million (mostly in emergency funding) has been spent to depopulate herds. This allowed a State to maintain its TB-free status (see **Transition to a Zoning Approach**). While depopulation needs to continue to

be a tool in the management of TB-infected herds, a viable test-and-cull procedure is necessary. NMPF believes that USDA should take the following measures to ensure effective herd management strategies include depopulation and test-and-cull procedures are available to producers:

1. Develop a risk-management decision-making tool for depopulation and test-and-cull strategies:
 - Depopulation consideration should not be made on herd size, rather disease transmission risks; and
 - Test-and-cull protocols should expedite return of a herd to commercial status linked to disease transmission risks
2. Indemnity payments
 - Maintain fair market value for individual animals;
 - Maintain current maximum levels;
 - Link indemnity payments to specific risk mitigation practices such as:
 - Participation in animal ID and traceability system;
 - Frequency of whole-herd TB testing;
 - Best management practices to reduce wildlife interfaces in areas with endemic TB wildlife populations; and
 - Provide financial assistance for labor costs/production loss when a producer implements a test-and-cull strategy contingent on risk mitigation practices

Animal Identification & Traceability – Inadequate individual animal ID continues to hamper successful traceback and epidemiological investigations when a TB-infected animal has been identified during slaughter surveillance. A compounding issue in traceback is the growing frequency and complexity of cattle movements during an animal's lifetime. NMPF believes that an effective animal ID and traceability system are necessary and USDA should take the following measures:

1. Mandate individual animal ID with prescribed technology standards; and
2. Require individual animal traceability from herd of origin through slaughter or death.

Modernize Regulatory Framework

NMPF believes that an effective TB eradication program requires modernizing the regulatory framework. Current regulations governing the TB eradication program have not been updated to reflect current farming practices and reduced TB incidence. Attempts to update the regulations in recent years have been stymied due to the Federal rulemaking process. Within certain boundaries, USDA should be given the means to revamp the TB eradication program in a timely manner to reflect changes in the cattle industries, improved diagnostics, and shifting disease introduction risks.

Transition to a Zoning Approach

Currently, USDA classifies States according to a multi-level system based on the number of TB-infected herds identified in a defined time period. Changes in state status lead to additional control requirements for interstate movement of cattle. This approach does not consider true risk of disease transmission as political boundaries do not prohibit disease transmission. Additionally, the state status approach can lead to imposition of additional control requirements even in parts of a state where disease transmission is minimal compared to the area of the state with the disease

outbreak. NMPF believes that state status no longer meets the needs for risk mitigation in the control of TB and recommends USDA move to a zoning approach which should include:

1. Transition period from state status to a zoning approach;
2. Mechanism for zoning across state boundaries;
3. Risk-based approach to determine zoning around an infected herd(s) or wildlife reservoir;
4. Defined testing requirements and movement restrictions within a zone;
5. Criteria to initiate, resize, or eliminate a zone; and
6. Consistent with OIE requirements for animal disease control zones.

Shared Responsibility

NMPF recognizes that to fully complete TB eradication in US cattle, we must have a coordinated effort between Federal animal health authorities, State animal health authorities, and industry. We welcome a renewed joint effort to advance TB disease knowledge to dairy producers. As the dairy industry has modernized, animal movement has increased with dairy animals now being routinely moved through multiple locations during their lifetime. Developing improved animal disease risk management strategies for dairy producers is an important measure to ensure the successful completion of TB eradication from cattle. This educational effort should be jointly undertaken by industry and our government partners.

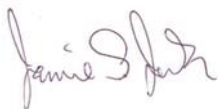
NMPF is concerned about USDA's intentions for industry-funded activities for the TB eradication program. In the Concept Paper, USDA references industry cost-share and industry-funded insurance programs several times in apparent reference to indemnity. As presented, NMPF cannot support the use of limited producer monies in such manners. We strongly believe that indemnification is a governmental process as it is a benefit for the public good (human health). During the past year the dairy industry has experienced the lowest milk prices in a generation combined with historically high input costs (particularly feed and energy) that have led to real losses in income and substantial losses in equity.

Conclusions

NMPF greatly appreciates the opportunity to offer you the above comments in support of modernizing the TB eradication program. We are encouraged by the direction USDA has proposed in the Concept Paper and believe that our comments will help strengthen the TB eradication program in the future. Dairy farmers support a modernization of the Federal program to complete the nearly century long process to eradicate bovine TB from the US. We look forward to working with USDA on this important process to modernize the TB eradication program.

Please contact me if you have any questions about these comments.

Sincerely,



Jamie S. Jonker, Ph.D.
Vice President, Scientific and Regulatory Affairs

Jerry Kozak, President/Chief Executive Officer

Randy Mooney, Chairman