

National Milk Producers Federation

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July 5, 2011

John Clifford, DVM
Docket No. APHIS–2011–0044
Regulatory Analysis and Development
PPD, APHIS, Station 3A–03.8
4700 River Road Unit 118,
Riverdale, MD 20737–1238

Re: Bovine Tuberculosis and Brucellosis; Program Framework [Docket No. APHIS–2011–0044]

Dear Dr. Clifford,

The National Milk Producers Federation (NMPF) is pleased to comment on the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) draft Regulatory Framework for Bovine Tuberculosis and Brucellosis (Docket No. APHIS–2011–0044). 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 31 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. Visit www.nmpf.org for more information.

The national tuberculosis (TB) and brucellosis eradication programs have successfully reduced the incidence of the diseases in United States (US) cattle. There continues to be a low incidence of TB as evidenced by the newly identified infected herds over the past several years. Likewise a small but persistent level of brucellosis exists in the Greater Yellowstone Area (GYA). As we struggle to deal with the impacts of the current TB and brucellosis episodes in the near term, we are extremely interested in working with USDA to improve the national TB and brucellosis eradication 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 and brucellosis from our US cattle herd, with no recursions, it has become evident that USDA's programs need to be updated, and the antiquated testing methodologies and surveillance tools improved. USDA's draft Framework set's a pathway for modernizing these eradication programs. In general, NMPF supports the pathway presented in the draft Framework to modernize the TB and Brucellosis eradication programs. Below we present specific comment on each of the eight aspects outlined in the draft Framework 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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Element 1: Program (State) Requirements

While NMPF expects States to have the most significant comments on **Element 1**, we believe State requirements will have the most dramatic impact on disease eradication and interstate commerce. While agreeing with the **Regulatory Objectives** with the ultimate goal of eradication, we believe there should be reference to surveillance, monitoring, and containment as they relate to program requirements. These could be elaborated in **Regulatory Objective 3**.

NMPF is intrigued by the three-tiered State status concept presented as part of the **Regulatory Components**, but believes that moving from the draft Framework to proposed regulations will require significant explanation and concrete provisions as to how States move from one Tier to another (Consistent to Provisionally Consistent to Inconsistent). For example, will a State status be impacted if it is within a zone created by an outbreak in an adjoining State for which appropriate actions have not been taken? NMPF is also concerned about halting industry commerce as a result of requirements placed on States that cannot be fulfilled due to insufficient federal funding to accomplish a federal mandate.

On a similar note for the **Regulatory Components** on State compliance and accountability, we caution USDA on the approach of “reduction of cooperative agreement funding, increased surveillance requirements, State quarantine, or increased reporting frequency” outlined in Point 7. At a point when a State has been found deficient, reduction in cooperative agreement funding tied with increased surveillance and/or State quarantine would penalize industry when federal funding has been removed to meet the necessary federal requirements.

A final consideration for the **Regulatory Components** on scope of the program, should consider human to animal 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. 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.

Element 2: Zoning (As a Component of Response and Containment)

NMPF strongly supports the concept of regionalization and zoning and is reassured about USDA’s commitment to zoning with its inclusion as **Element 2**. The current State status approach does not consider true risk of disease transmission as political boundaries do not prohibit disease transmission. Additionally, the current 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 brucellosis 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.

For an affected herd, NMPF believes an important element is missing from the **Regulatory Components**. The goal of eradication from the affected herd must be tied to the goal of protecting non-affected livestock from exposure to the disease as well.

The wildlife-livestock interface is an extremely important aspect for zoning for both brucellosis in the GYA and TB in Michigan. USDA recognizes this importance by including wildlife infection within the **Regulatory Components** of zoning. NMPF believes that to mitigate this risk USDA should consider the following additional measures for areas with a wildlife TB or brucellosis reservoir:

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

Element 3: Surveillance

In many ways, disease surveillance (**Element 3**) is the linchpin to successful disease control and eradication. Indeed, many comments that NMPF will make in this section have been expanded upon in other sections. We find the **Regulatory Objectives** to be consistent with longstanding NMPF policy on disease eradication. However, diagnostic, surveillance, and traceability capabilities have not kept pace with the changing needs of the TB and brucellosis eradication programs. 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.

In a number of the **Regulatory Components** for surveillance, NMPF strongly believes that specific emphasis should be placed on surveillance at the borders and the subsequent imported animals (addressed in greater detail in **Element 7**). National surveillance should place an emphasis at the Canadian and Mexican border. For target surveillance, emphasis should be placed on imported animals which do not go directly to slaughter (event cattle for example).

NMPF again concurs with USDA that *“effective surveillance will require unique and official individual animal identification.”* We are very concerned about the lack of progress on an effective disease traceability system with individual animal ID despite a decade of work by USDA. NMPF believes USDA has current authority to implement an effective disease traceability system with individual animal ID and request the Agency take steps to initiate this for the dairy industry.

Currently the cornerstone for TB surveillance is slaughter surveillance, which has been hindered by lack of an effective animal ID and traceability program. 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 (or zone) free from bovine TB. NMPF believes that improved surveillance and traceability are necessary and USDA should take the following measures:

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Randy Mooney, Chairman

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.

Element 4: Affected Herd Management and Epidemiological Investigations

It would be easy to concentrate comments on **Element 4** about the limitations of current diagnostics; however majority of that discussion is reserved for **Element 8**. Suffice to say, NMPF believes limitations that must be addressed in diagnostics will make affected herd management and epidemiological investigations easier for USDA, States, and industry.

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. NMPF believes USDA should develop a risk-management decision-making tool for depopulation and test-and-cull strategies:

1. Depopulation consideration should not be made on herd size, rather disease transmission risk; and
2. Test-and-cull protocols should expedite return of a herd to commercial status linked to disease transmission risks

For the **Regulatory Components**, NMPF suggests that USDA explore the needs for separate definitions and management considerations for dairy, heifer growing, feedlot, and cow-calf operations. We believe the distinct management systems including animal ID, animal movement, and other risk factors will suggest different approaches for these (and perhaps other) management systems.

Element 5: Indemnity

When considering indemnity under the draft Framework, it may be helpful to consider recent experience in indemnity for TB identified herds. 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. 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 with effective herd management strategies (see **Element 4**) including depopulation and test-and-cull procedures available to producers; USDA should explore the following measures for indemnity:

1. Maintain fair market value for individual animals;
2. Maintain current maximum levels;
3. 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

NMPF believes that with the ability to quickly change the indemnity process through program standards and the use of an “appraisal calculator” (**Regulatory Components**) there is a need for an appeals process for indemnity valuations. An appeal process is necessary to provide the producer an opportunity to discuss the indemnity process and receive justifications as to why circumstances in their instance results in the indemnity proposed. We strongly believe that indemnification is a governmental process as it is a benefit for the public good (human health).

Element 6: Interstate Movement Controls

Interstate movement controls must consider not only the animal ID process associated with the TB and brucellosis eradication programs but the traceability for animals moving to and from a control zone (see **Element 3**). NMPF believes a vital element is missing from the **Regulatory Components** for interstate movement controls. The use of electronic veterinary certificates should be highly encouraged by USDA.

Element 7: Import requirements

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, and Canadian imported cattle.

Mexican Imported Feeder Cattle – Epidemiological investigations conducted by USDA indicate that a significant number of 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.

Element 8: Approval Procedures Related to Official Tests and Laboratories

The current suite of TB diagnostic tests has 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;

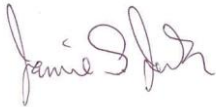
2. Prioritize current funding or identify alternative funding to expedite validation and approval of new diagnostics;
3. Determine the feasibility of milk tests for dairy cattle populations;
4. Establish minimum standards to approve veterinarians to administer the CFT test including regular review to ensure an adequate response rate.

Conclusions

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

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

Sincerely,



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