



# National Milk Producers Federation

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May 16, 2016

Docket Clerk, USDA-APHIS  
Docket No. APHIS-2011-0044  
Regulatory Analysis and Development  
PPD, APHIS, Station 3A-03.8  
4700 River Road Unit 118  
Riverdale, Maryland 20737-1238

## **RE: Brucellosis and Bovine Tuberculosis: Update of General Provisions (Docket No. APHIS-2011-0044)**

The National Milk Producers Federation is pleased to provide the U.S. Department of Agriculture Animal and Plant Health Inspection Service's (USDA-APHIS) proposed updates to the bovine tuberculosis (TB) and brucellosis general provisions and program standards (Docket No. APHIS-2011-0044; Proposed Rule and Program Standards). The National Milk Producers Federation (NMPF), 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 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 32,000 dairy producers on Capitol Hill and with government agencies.

NMPF appreciates the open approach taken by USDA-APHIS for stakeholder engagement to arrive at the proposed changes in regulations for bovine TB and brucellosis. Stakeholder input was sought as early as 2008-2009 through comment and review of concept papers. USDA-APHIS held additional public meetings in 2011 and produced a draft regulatory framework document for further public input. However, there has been little stakeholder engagement since then with USDA-APHIS giving no indication that these two regulatory programs would be combined in the Program Standards and that their regulatory programs would be markedly changed in both structure and terminology. **NMPF has identified numerous concerns for the implementation of the Proposed Rule and Program Standards, and we believe that additional revision and stakeholder input are necessary prior to finalization.**

### **Disease Challenges**

While significant progress has been made since 1917 through cooperative, national effort to eradicate bovine TB from cattle, challenges and knowledge gaps still exist for the disease. Bovine TB is a complicated disease with a long incubation period, silent shedders, complex wildlife components, premises biosecurity issues, and import challenges. Prioritization to obtain knowledge for an improved understand and

management of these disease complexities. Additional research in bovine TB is needed to establish improved tools for surveillance, prevention, and response. Knowledge gaps are linked to the lack of adequate long-term federal research for bovine TB in order to advance knowledge of the disease. This issue is not unique to TB or even to animal health issues as Federal funding for animal agricultural research has steadily decreased.

Perhaps the largest impediment to bovine TB eradication is the lack of an accurate, sensitive, specific, and rapid test availability. The caudal fold test (CFT) has worked well when bovine TB incidence was much higher, but it is not good enough for the present low incidence of disease in the United States. Furthermore, the CFT is cumbersome with multiple days and multiple handling of cattle required. **NMPF respectfully requests that USDA make research and development of improved bovine TB diagnostic tests a priority in helping to control and eradicate the disease.** Additionally, we hope new collaborations and partnerships can be formed to find solutions to knowledge gaps that more adequately address the wildlife reservoirs for bovine TB.

*Brucella abortus* is the most common cause of brucellosis in cattle bison, and captive cervids. Outside of the Greater Yellowstone Area (GYA), *Brucella suis* affects more program animals in the U.S. Feral swine routinely come into contact with program animals, and pose a continuing wildlife reservoir risk on their own to the program animals. More research is needed in this area as program animals infected with *Brucella suis* will test positive on *Brucella abortus* diagnostic tests, and subsequently fall under the jurisdiction of the Proposed Rule related to management of test positive animals, costing producers and animal health agencies significant expense. NMPF encourages USDA-APHIS to work with the USDA-Agricultural Research Service (ARS) to study the effects of *Brucella suis* in program animals and to work towards developing more specific diagnostic tests and effective vaccines. Additionally, program animals infected with *Brucella suis* should be addressed in this Proposed Rule to the extent that it is stated that they cannot be moved interstate, and should be removed from herds for slaughter only; but, do not count as reactors for prevalence statistics.

### **Overview of General Provisions**

NMPF's comments in 2009 about the concept papers, and our comments on the *Proposed Bovine Tuberculosis and Brucellosis Draft Regulatory Framework* in 2011 were generally supportive of the need for USDA-APHIS to modernize the regulatory framework to allow greater flexibility and adaptability in disease eradication (2009 and 2011 comments appended). We believe modernization is still necessary and finding answers to existing knowledge gaps necessary. However, NMPF has identified significant concerns for the implementation of the Proposed Rule and believes that additional revision and stakeholder input are necessary prior to finalization.

**NMPF fully supports sustained efforts to eradicate bovine TB and brucellosis from the United States.** The national bovine TB and brucellosis eradication programs have successfully reduced the incidence of the diseases in United States cattle. However, there continues to be a low incidence of TB as evidenced by the newly identified infected herds over the past several years including through a wildlife reservoir in Michigan. Likewise a small but persistent level of brucellosis exists in the Greater Yellowstone Area due to a wildlife reservoir. We interpret from the Proposed Rule that eradication of these two diseases is no longer a primary focus. Changing the definition from free status (zero prevalence) to consistent status (no reference to prevalence) and asserting that the eradication programs based on achieving zero prevalence is no longer feasible due to wildlife reservoirs and Mexican imports, forms the supporting basis for the USDA change in program focus from eradication to control. The apparent abandoning of the long-term eradication goal for these two diseases could result in recurrence of disease and perpetuate the wildlife reservoirs as well as become counterproductive to securing necessary funding for future disease control.

**NMPF has serious reservations and does not support combining the bovine TB and brucellosis Program Standards as suggested in the Proposed Rule.** Brucellosis and bovine TB differ markedly in their reservoir host populations, susceptible populations, geographic distribution, method of transmission, incubation period, test sensitivity and specificity, zoonotic threat, and infection rates. The diagnostic capabilities for these two diseases, which lead to regulatory approaches, are not the same. We believe combining these two diseases into the same Program Standards will be confusing and impede progress on disease eradication. NMPF recommends organizing the information into separate sections for each disease and include separate disease Program Standards for bovine TB and brucellosis. This may require either a re-proposal or interim final rule allowing for additional stakeholder comment prior to full finalization.

As with our 2011 comments, NMPF has organized comments on this Proposed Rule aligning with the eight program elements: 1) Program (State) Requirements; 2) Recognized Management Areas; 3) Surveillance; 4) Affected Herd Management and Epidemiological Investigations; 5) Indemnity; 6) Interstate Movement Controls; 7) Import Requirements; 8) Laboratory and Diagnostic Test Approval.

#### **Element 1 – Program (State) Requirements**

***Animal Health Plans*** – NMPF recognizes the need to modernize the current State status system for both brucellosis and bovine TB. Our review of the specific State requirements in the Proposed Rule has raised questions and concerns about the State animal health plans (AHPs) and the classification system based on consistency with the

AHPs. Historically, bovine TB and brucellosis have been cooperative programs, with logistical, personnel, and financial resources assistance from USDA-APHIS.

The Proposed Rule requires State animal health authorities implement and manage AHP which include a many activities for which they may lack adequate resources such as identify and monitor potential sources of disease transmission, conduct and report surveillance activities, establish prevalence of the two diseases, identify and carry out risk mitigation actions, establish legal authority, infrastructure and resources, and complete disease investigation and response. In our 2011 comments we expressed concern “*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.*” **NMPF remains concerned about technical, workforce, and financial resources available implementation of AHPs by States and Tribes.**

Most States have not dealt directly with these two diseases for over a decade and available financial resources are often linked to current disease risks. We believe that some States will have significant challenges to rebuild the necessary resources to develop and implement AHPs. Many States may lack the infrastructure to assume the additional program work when decades of surveillance have shown negligible risk for disease in their State. For States currently actively managing brucellosis or TB issues, the available funding through cooperative agreements has been decreasing. Without USDA cooperative funding support, many States may not effectively manage large disease outbreaks or complex disease program enforcement and surveillance activities. **NMPF requests that USDA-APHIS commit to support State actions needed to maintain an adequate AHP by utilizing the current cooperative funding agreement concept as well as continuing to provide direct field support.**

Additionally, USDA-APHIS plans to publish notice via *Federal Register* proposing the approval of a State AHP and making the AHP available for public review and comment however the Proposed Rule does not adequately detail timeframe for this process **NMPF requests that USDA-APHIS make public for comment a detailed timeframe for moving each State or Tribe AHP through the notice and approval process in the *Federal Register*.**

***State and Tribal Classifications*** – NMPF has concerns with replacing the current disease prevalence rate-based classification system for bovine TB and brucellosis with a classification system based on the degree of consistency with the AHP. The classification system detailed in the Proposed Rule of “consistent”, “provisionally consistent”, and “inconsistent” may disincentive States to promptly investigate cases of brucellosis or TB and fail to induce mitigation of future disease spread. Perhaps disease prevalence rates should still be linked to State status, as historically has been done.

**We are also concerned about the lack of decisive metrics in the Proposed Rule to identify minimum targets for State and Tribal classification of “provisionally consistent” or “consistent”.** While USDA-APHIS has proposed timelines that states must meet when an infected herd is discovered, there is no corresponding minimum standards for the level of surveillance required by a “consistent” state. Words such as “adequate” and “sufficient” do not provide the precision to understand requirements in the Proposed Rule and Program Standards.

Earlier we stated our concerns about technical, workforce, and financial resources available for implementation of AHPs by States and Tribes. If a State or Tribe status becomes inconsistent due to a non-disease factor such as laboratory certification due to financial resources, NMPF believes that export of dairy products could be impacted. Some dairy export certificates require attestations about disease status which when a State or Tribe status is inconsistent may result in the inability of USDA to make such attestations. **USDA must ensure that State or Tribe status as inconsistent due to non-disease issues still allows for conformity with the World Animal Health Organization (OIE) international guidelines for declaring a country (or zone) free from bovine TB to prevent trade disruption.**

Finally, many commenters on the bovine TB and brucellosis concept papers supported the idea of a control or advisory board of Federal, State, Tribal and industry experts to provide USDA-APHIS with recommendations regarding compliance with regulatory requirements and status classifications. NMPF was silent to this issue in previous comments. The Federal Advisory Committee Act would require that an advisory board with industry representation must follow the extensive protocol of an advisory committee. For this reason, the agency has elected to no longer support this idea and has only proposed to solicit the opinion of technical when circumstances warrant. **NMPF believes, for transparency in the selection process of technical experts, that creation of an expert advisory board composed of Federal, State, Tribe and industry representatives to direct the implementation of modernized bovine TB and brucellosis eradication regulations is warranted.**

#### **Element 2 – Recognized Management Areas**

USDA-APHIS has proposed that recognized management areas with clearly defined and delineated geographical boundaries are to be developed by and incorporated into State or Tribal AHP if eradication of bovine TB or brucellosis cannot be achieved in a short period of time. The practical application for this today would be for brucellosis in the Greater Yellowstone area and for bovine TB in a specific part of Michigan, although these provisions could be applied in the future to other areas should a need arise. As proposed, the regulations do not allow herds in recognized management areas to be

accredited free for bovine TB or brucellosis. Furthermore, owners of currently accredited herds in these areas will not be able to seek reaccreditation once the Proposed Rule is finalized. The option of accredited free herds should be available in order to assist producers wishing to move cattle interstate safely and efficiently. Accredited herd testing provides another layer of surveillance for “at risk” populations of animals and should be allowed if the producer is willing to incur the expense. **NMPF requests that producers in recognized management areas be permitted to achieve accredited free herd status in these areas according to details worked out in the Program Standards for managing movements and any additional mitigation measures necessary to protect against the threat of disease.**

A recognized management area plan denotes the determination of the risk for the transmission of the detected program disease (bovine TB or brucellosis) and establishes measures to control the spread of the disease as well as to eventually eradicate the disease from the area. The plan seeks to quarantine and eradicate the disease from program animals within a reasonable time frame as well as to require disease mitigations in wildlife within the management area. Wildlife authorities in the management area must agree to AHP criteria to manage wildlife disease as state animal health authorities often lack complete authority for wildlife. A long range plan needs to be in place that benchmarks efforts to control and subsequently eradicate bovine TB or brucellosis from all susceptible species in the management area. This may require cooperative agreements or mutual orders of understanding between state animal health officials and wildlife authorities working in the area. **NMPF believes that the role/responsibilities and collaboration of state wildlife authorities with state animal health authorities in recognized management areas must be more clearly defined.**

### **Element 3 – Surveillance**

In many ways, disease surveillance 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. 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 bovine TB the US now has. The success of both the bovine TB and brucellosis eradication programs has led to a decline in the use of permanent identification for breeding cattle.

The national surveillance approach is outlined in the National Surveillance Plans for Bovine TB and Brucellosis Programs and describes the routine surveillance practices. The State and Tribal AHP define the targeted surveillance of “at-risk” animal populations and “source” populations (both domestic animals and wildlife) as well as

other surveillance. The Proposed Rule states that if a State fails to meet the surveillance levels set forth in the National Surveillance Plans or their own AHPs then this could result in a classification change to “provisionally consistent” or “inconsistent” status. **NMPF concurs about the importance of surveillance but we reiterate our concerns expressed in Element 1 about technical, workforce, and financial resources available implementation of AHPs by States and Tribes.**

An 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 more than 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 advance this for the dairy industry.**

#### **Element 4 – Affected Herd Management and Epidemiological Investigations**

In the event that a bovine TB or brucellosis case-animal is identified, USDA-APHIS and the State or Tribal animal health authority in which the animal originated will investigate the disease occurrence. The Proposed Rule states that within 15 days of identifying disease in a case- animal with bovine TB or brucellosis, State animal health authorities must identify the origin and destination of all animals that may have resided with an affected herd and restrict future animal movements. Recent experience with bovine TB infected dairy herds in Texas has demonstrated that such investigations can take months to years to achieve complete disease traceability rather than days. The prescribed disease traceability requirement of 15 days in the Proposed Rule does not seem reasonable or even likely achievable in the majority of cases today due to a lack of an effective animal ID and traceability program (see Element 3 for further discussion). NMPF is concerned about the failure of a State or Tribe to achieve the 15 day requirement for traceability of all involved animals resulting in that State or Tribe status becoming “inconsistent”. **NMPF requests USDA-APHIS work with States, Tribes and industry to develop alternative language for expected epidemiological reporting timelines that meets the requirement for timely reporting without unnecessarily jeopardizing the State’s status.**

Specific to calf raising facilities outlined in part 4.2.7 of the Program Standards, USDA-APHIS restricts movement of exposed animals directly to slaughter until all exposed animals have been removed from the facility. Texas has regulations (Texas Administrative Code 4.2.43.A §43.6 and §43.7) for Dairy Calf Ranches and Authorized Calf Ranches which allow for intrastate movement of animals for the intended use upon completion of a herd plan. **NMPF requests that USDA-APHIS work with Texas to harmonize definitions and standards in this area.**

Finally, NMPF concur with USDA-APHIS on the affected herd management plans outlined in part 4.2.3 of the Program Standards to include options for whole herd depopulation and test-and-remove options. Traditionally, USDA and States have relied on whole herd depopulation as the preferred response to maintain State status. **NMPF believes depopulation consideration should not be made on herd size, rather disease transmission risk; and test-and-cull protocols should expedite return of a herd to commercial status linked to disease transmission risks.**

#### **Element 5—Indemnity**

USDA-APHIS chose not to include indemnity in the rulemaking for the Proposed Rule to consolidate and update bovine TB and brucellosis program regulations. USDA-APHIS plans to develop a separate comprehensive regulation and Program Standards document that addresses indemnity for multiple disease programs and in multiple species. Until these changes are made to indemnity policy, USDA-APHIS will continue to operate using current policies and procedures for indemnity associated with bovine TB and brucellosis.

NMPF supports fair market value for individual animals and as stated in previous comments (comments appended), with the use of an “appraisal calculator” 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). **NMPF requests USDA-APHIS proceed with rulemaking so that review and comment from stakeholders can be provided.**

#### **Element 6—Interstate Movement Controls**

The Proposed Rule lists provisions for interstate movement of cattle and bison from inconsistent States or Tribes as requiring a negative herd test for TB from 4-12 months prior to movement and an individual TB test within 60 days. Situations may exist in which a State is inconsistent for non-disease related reasons and the animals moved present no greater disease risk than a consistent state. **NMPF requests that USDA-APHIS provide alternative accepted methods for movement of animals from inconsistent States, as warranted, upon approval by the USDA-APHIS Administrator and in agreement with the chief State animal health official of the receiving State.**

The Program Standards lack detail for interstate movement for commuter herds – those herds with closed management systems which routinely transit animals across state lines. While not common, some dairy farms near State boundaries may have animal facilities in both States with movement of animals between these facilities. While an approved AHP may include provisions for these commuter herds, more



formalized direction in the Program Standards is warranted. **NMPF requests USDA-APHIS establish Program Standards for interstate movement controls specific to commuter herds including stakeholder input through formalized notice and public comment.**

Specific to quarantine feedlots and quarantine outlined in part 6.10 of the Program Standards, USDA-APHIS restricts movement of animals directly to slaughter. Texas has regulations (Texas Administrative Code 4.2.43.A §43.6 and §43.7) for Dairy Calf Ranches and Authorized Calf Ranches which may allow for interstate movement of animals for the intended use upon completion of a herd plan. **NMPF requests that USDA-APHIS work with Texas to harmonize definitions and standards in this area.**

The interstate movement of rodeo, event, or exhibited cattle or bison present unique risks for the transmission of bovine TB and brucellosis. **NMPF supports the Program Standards for interstate movement controls for rodeo, event, or exhibited cattle or bison as proposed by USDA-APHIS.**

#### **Element 7—Import Requirements**

The Proposed Rule revises the conditions for the importation of cattle and bison that are contained in 9CFR Part 93 Subpart D, which addresses the risk that imported cattle or bison may pose in disseminating bovine TB and/or brucellosis. Contained in the supporting documents for the Proposed Rule is the risk analysis (RA), "*Bovine Tuberculosis and Brucellosis: Evaluation of Import Risk and Mitigation Strategies*," completed by USDA-APHIS in March 2015 to address two possible modifications for the current regulations:

1. Adopting international standards developed by the World Organization for Animal Health (OIE); or
2. Applying the United States prevalence based requirements delineated in Uniform Methods and Rules for Brucellosis and Bovine Tuberculosis in the United States to import cattle from foreign regions.

The risk analysis concluded that USDA-APHIS could substantially mitigate the risk of importing cattle infected with bovine TB or brucellosis by applying U.S. domestic standards to importation requirements. Unlike the domestic status classification system proposed by the new rule, import requirements will be based on the prevalence rates for the two program diseases in the foreign country or region as well as on risk estimation decisions in the USDA-APHIS RA document. Many of the proposed import requirements are inconsistent with previous requirements and in several instances, requirements appear to be less stringent for imported animals than the regulations governing domestic animals in similar situations.

In the Proposed Rule, USDA-APHIS suggests creating an exemption for entry of imported cattle from Level V regions around the world. Level V regions lack a TB program that meets USDA-APHIS requirements for TB classification and possess a TB prevalence of greater than 0.5 % or are unassessed by the agency regarding their TB prevalence. USDA-APHIS stated that certain importers in the United States might wish to import genetically diversified cattle from regions of the world that lack a TB control program. For this reason, USDA-APHIS is presenting a proposed testing scheme to allow such importation to occur. Experience in trying to guarantee that cattle from Level V regions are risk-free for TB by using a series of tuberculin skin tests has demonstrated limitations associated with TB test sensitivity. Under the current or proposed domestic regulations, a State or Tribe in the U.S. with equivalent Level V TB prevalence would have movement restrictions on program animals to protect the health of the national herd. Foreign regions wanting to export cattle to the U.S. should have effective TB control programs in place and functioning for a sustained period of time in order to better guard against the risk of disease transmission.

USDA-APHIS is also proposing in the tuberculosis section 93.439 that cattle imported from Level III regions (TB prevalence between 0.01 and 0.1 percent) and which originate from accredited herds can be imported into the U.S. without further TB testing. By comparison, the Proposed Rule in section 76.15 does not allow U.S. cattle originating from inconsistent states to move without further herd and individual animal testing. Inconsistent states could have a TB herd prevalence of less than 0.01% and most likely have been involved in a U.S. national TB program for nearly 100 years. The test requirements for cattle being moved from certain inconsistent U.S. states are likely being held to a higher and more rigorous standard than what is being proposed for the importation of cattle from TB Level III or less regions in other countries. **NMPF does not support the requirement in the Proposed Rule that permits importation of cattle from accredited TB herds in Level III regions into the U.S. without further testing and requests that these cattle should minimally have a negative TB test 60 days prior to importation into the United States.**

NMPF supports trade that employs movement requirements that maintain appropriate management of disease risk. Protocols need to be in place to determine quarantines, establish export regions and control animal movements. Given their proximity and importance in live cattle trade, implementation of movement controls for imports from Mexico and Canada are a high priority. **NMPF encourages USDA-APHIS to work with Mexico and Canada to ensure that changes in the bovine TB and brucellosis regulations are transparent and readily understood by our trading partners.**

Finally, NMPF believes that imported animals and animal products must present no more than a negligible risk to human and animal health and supports scientific, risk-based decision making concerning the importation of animals and animal products into the United States. As proposed, the updated bovine TB and brucellosis regulations found in element 7 address import requirements for program species. At the same time, concerns exist that the changes in State and Tribe bovine TB and brucellosis classification may work to adversely affect U.S. export access to foreign markets. Several times earlier in these comments we have already expressed our concerns about State or Tribe status becoming inconsistent due to non-disease issues. **NMPF believes an assessment of the Proposed Rule’s potential impact on U.S. dairy product exports needs to be more completely addressed.**

#### **Element 8—Laboratory and Diagnostic Test Approval**

Today there appears to be inconsistency between States in the oversight of the performance of the CFT for bovine TB by accredited veterinarians. **NMPF requests that USDA-APHIS provide a template for States and Tribes to facilitate training for accredited veterinarians performing TB testing.** A template would be preferable to States describing the core and refresher courses for accredited veterinarians currently available in the State, as proposed in the rule, and would function to add consistency to the national surveillance program.

Additionally reiterating our comments from earlier, the current suite of TB diagnostic tests has many limitations. The caudal 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 respectfully requests that USDA make research and development of improved bovine TB diagnostic tests a priority in helping to control and eradicate the disease.**

#### **Conclusions**

In reviewing the USDA-APHIS Proposed Rule and Program Standards for bovine TB and brucellosis, **NMPF has identified numerous concerns for the implementation of the Proposed Rule and Program Standards, and we believe that additional revision and stakeholder input are necessary prior to finalization.** To assist USDA-APHIS, our recommendations and requests for improvement to the Proposed Rule and Program Standards have been indicated throughout these comments in **bold text**. We have also appended our previous comments dating back to 2009 on the bovine TB and brucellosis eradication programs to this document.

NMPF appreciates the opportunity to review and provide our comments for this significant Proposed Rule involving cattle health. We look forward to working with

USDA-APHIS in addressing the many questions and issues raised for consideration in our comments. If you have any questions or concerns, please contact me at 703-243-6111 or at [jjonker@nmpf.org](mailto:jjonker@nmpf.org).

Sincerely,

A handwritten signature in cursive script that reads "Jamie Jonker".

Jamie Jonker, Ph.D.  
Vice President  
Sustainability & Scientific Affairs