Docket No. APHIS-2006-0193
Regulatory Analysis and Development
PPD, APHIS, Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

Re: Tuberculosis; Required Approved Herd Plans Prior to Payment of Indemnity;
Docket No. APHIS-2006-0193

September 22, 2008

To whom it may concern:

The National Milk Producers Federation appreciates the opportunity to provide comment on the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service proposed regulation for Tuberculosis; Required Approved Herd Plans Prior to Payment of Indemnity (Docket No. APHIS-2006-0193). 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 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.

Begun in 1917, the Cooperative State-Federal Tuberculosis Eradication Program, administered by the USDA-APHIS, State animal health agencies, and U.S. livestock producers, has nearly eradicated bovine tuberculosis from the domestic livestock population. This disease's presence in humans has been reduced as a result of the eradication program, advances in sanitation and hygiene, the discovery of effective drugs, and pasteurization of milk. NMPF has been and continues to be a strong supporter of this program and its goal of eliminating bovine tuberculosis in our domestic livestock population.

Since 2000, only 71 newly affected herds have been detected and at the present time bovine tuberculosis remains an isolated occurrence in two distinct areas of the country for separate reasons. Recent outbreaks of bovine tuberculosis in Minnesota and Michigan are related to exposure to infected wildlife, mainly but not limited to whitetail deer. Outbreaks in the Southwestern area of the country including the recent outbreak in...
California usually contain isolates that are typical of strains associated with Mexican-origin cattle.

NMPF understands the intention of USDA to place more responsibility on owners with a previous bovine tuberculosis infection to protect their herds from reinfection. In the proposal, USDA states:

“The proposed changes would only affect those premises that become reinfected with tuberculosis and are found to have not followed a herd plan to prevent reinfection. For owners that do follow a herd plan, the proposed rule would not change the amount of indemnity for which the herd owner would be eligible; it would merely provide that 90 percent of the gross indemnity payment be made after the herd plan has been approved and that 10 percent of the gross indemnity payment be held until the herd plan is implemented.”

NMPF supports efforts to maintain the effectiveness of the tuberculosis program including prevention of the reinfection of tuberculosis into herds previously infected. However, NMPF has reservations about the ambiguity of the proposed regulations that could result in confusion with their practical implementation. This leads NMPF to a series of questions that require further consideration prior to any change in current regulations.

**What constitutes a herd plan?** The Bovine Tuberculosis Eradication Uniform Methods and Rules (APHIS 91-45-0111) currently establishes requirements for a herd plan. Will USDA revise the requirements for a herd plan in light of these proposed regulatory changes?

**How is a herd plan developed?** Currently a herd plan is developed by the herd owner(s) and/or their representative(s), and a State or Federal veterinarian. Will USDA revise the development process for a herd plan in light of these proposed regulatory changes?

**How is a herd plan approved?** Currently the herd plan must be approved by the Chief State Animal Health Official and Area Veterinarian in Charge, and have the concurrence of the Designated Tuberculosis Epidemiologist or Regional Tuberculosis Epidemiologist. Will USDA revise the approval process for a herd plan in light of these proposed regulatory changes?

**What is the timeframe to develop and approve a herd plan?** The proposed rule ties the first 90% of indemnity payments to approval of the herd plan. A prolonged process for developing and approving a herd plan would result in delayed payment and may result in economic hardship for the producer. Will USDA provide for timely development and approval of a herd plan to prevent undue economic hardships on an affected producer?

**How is implementation of a herd plan measured?** The proposed rule ties the remaining 10% of indemnity payments to implementation of a herd plan. Implementation will be
viewed during a site visit by the Veterinarian in Charge or official designee. Without a demonstrable understanding of what constitutes implementation, the remaining 10% of indemnity payments could be withheld indefinitely. Will USDA provide a verifiable assessment to demonstrate a herd plan has been implemented?

**How are violations of a herd plan substantiated?** The proposed rule would not allow claims for indemnity for a producer if the herd or replacement herd has become reinfected due to failure to follow the herd plan. Will USDA provide a verifiable assessment to demonstrate a herd plan has not been followed?

**How are accidental versus willful violations of a herd plan distinguished?** Some items contained in a herd plan may commit the producer to rely on things beyond their immediate control. The producer should not be penalized if the herd or replacement herd has become reinfected due to circumstances that are beyond their control. Will USDA differentiate between willful and accidental violations of a herd plan?

NMPF supports efforts to make the Cooperative State-Federal Tuberculosis Eradication Program more effective particularly as incidence of tuberculosis has dramatically declined through the success of the program. A key to the successful eradication of tuberculosis is improving tuberculosis testing sensitivity and specificity. NMPF believes the current tuberculosis test is no longer adequate to meet the needs of Cooperative State-Federal Tuberculosis Eradication Program given the low level of prevalence that now exists in the U.S.

We appreciate the opportunity to provide these comments to USDA. Please contact me if you have any questions about these comments.

Sincerely,

Jamie S. Jonker  
Director, Regulatory Affairs