DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

SEP 3 2013

Dr. Stephen Beam, Chair
National Conference on Interstate
Milk Shipments
California Department of Food
and Agriculture
1220 "N" Street
Sacramento, California 95814

Dear Dr. Beam:

I am very pleased to have heard from several sources that this year's conference continued the successful consensus building process that was begun at the 2001 conference. I extend my appreciation for the important role that the National Conference on Interstate Milk Shipments (NCIMS) plays in that process.

In accordance with the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments,* we have evaluated each of the proposals passed at the 2013 NCIMS. The Food and Drug Administration (FDA) concurs with all of the passed proposals with the exception of proposal 231. I would like to point out that having only one non-concurrence, which is addressed in this letter, is evidence of our continuing success at collaboration and mutual professional trust.

The proposal which FDA does not concur with is as follows:

NOTE: The text that is ~~struck through~~ was to be deleted from the current text in the 2011

Pasteurized Milk Ordinance (PMO) as indicated in proposal 231 as passed at the conference.

Proposal: 231
Document: FDA 2400 Forms

*Make the following changes to the **FDA 2400 Form**:*

2400m Dairy Waters

1. Laboratory Requirements

   e. Transit time does not exceed ~~30~~ 48 hours

   f. Samples examined within ~~30~~ 48 hours of collection or within 2 hours of receipt (item 1d)

FDA's rationale for non-concurrence is outlined below:

- There are no recent scientific data on the investigation of coliform density which support the 48 hour holding time recommended by the author of this proposal. From the discussions or conclusions of the scientific studies provided by the author, the results obtained by extending the holding time were inconsistent and/or inconclusive.

- Scientific studies showed that the initial 24 hour holding time is when the most decrease in coliform recovery occurs irrespective of holding temperature. There are significant decreases in coliform recovery with a 30 hour holding time and further significant decrease with a 48 hour holding time even at refrigerated temperatures (e.g., 5°C). Hsu and Williams in 1982 (cited below) did not show that sample held for 48 hours provided the same analytical result as those analyzed at 30 hour holding time. Due to the inconsistent results obtained, these researchers suggested that factors such as pH, chemical content and coliform strains may affect the outcome of the holding times on coliform densities in water samples.

- McDaniels, *et al* in 1983 and1985 also highlighted the inconsistencies that may occur as a result of increased holding time. There was a decrease in refrigerated sample coliform recovery of 23% and 33 % at 24 hours and 30 hours, respectively. Also the studies indicated that the coliform recovery decreased further at 48 hour hold time. The authors recommended that the water samples be analyzed as soon as possible on the day of collection so as to minimize changes in the concentration of bacteria. These researchers again suggested that bacterial densities and holding time effects are influenced by the sample matrix (chemical composition, pH, electrolyte concentration, protein nitrogen, bacterial flora, and other undetermined factors associated with specific water sources). The literature showed that increase in pH, bacterial load and heterotrophic plate count (i.e., nutrient competition) are correlated with coliform die off.

- Standridge and Delfino (1983) called for caution on increasing the holding time based on their inconsistent findings. They suggested that health officials must weigh the advantage of longer holding time (48 hour) over the consequences of the inability to detect smaller amount of coliforms in samples.

- The 20th edition of the Standard Methods for the Examination of Water and Wastewater stated that 30 hour holding time should not be exceeded i.e. from collection to analysis for coliform bacteria in drinking water. It should be noted that water types other than potable water have much shorter holding times.

Based on all the inconsistencies and lack of appropriate science to support this proposal, FDA does not concur that an increase in holding time from 30 to 48 hours will not have a significant effect on the bacterial densities of the samples. Allowing this increase may result into false or inaccurate data which may pose a health risk to consumers.

Literature Cited

a. A.E. McDaniels, R.H. Bordner, P.S. Gartside, J.R Haines, K.P Brenner, C.C. Rankin, Holding Effects on Coliform Enumeration in Drinking Water Samples, Applied and Environmental Microbiology, Oct. 1985
b. S.C. Hsu, T.J. Williams, Mich. Dept. of Public Health, Evaluation of Factors Affecting the Membrane Filter Technique for Testing Drinking Water, Applied and Environmental Microbiology, Aug. 1982
c. A.E. McDaniel, R.H. Bordner, Effects of Holding Time and Temperature on Coliform Numbers in Drinking Water, Research and Technology, Journal AWWA, Sept. 1983
d. J.H. Standridge, J.J. Delfino, Effect of Ambient Temperature Storage on Potable Water Coliform Population Estimations, Applied and Environmental Microbiology, Nov. 1983

If you think that it would be helpful, the Center for Food Safety and Applied Nutrition personnel are available to review the contents of this letter with you in advance of the October 9-10, 2013 NCIMS Executive Board meeting. If you would like to arrange for such discussions, please contact Mr. John Sheehan, Director, Division of Plant and Dairy Food Safety at (240) 402-1488 or John.Sheehan@fda.hhs.gov. FDA representatives look forward to meeting with the full Executive Board on October 9-10, 2013 and I join them in looking forward to continuing a cooperative and productive process.

Sincerely yours,

Michael M. Landa
Director
Center for Food Safety
and Applied Nutrition

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