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M-I-08-3

January 17, 2008

TO: All Regional Food and Drug Directors

FROM: Dairy and Egg Branch (HFS-316)

SUBJECT: Mandatory NCIMS Aseptic Pilot Program Implementation Committee (APPIC) Training for State Regulatory Personnel, State Rating Officers (SROs) and FDA Regional Milk Specialists (RMSs)

Proposal 303 (attached) passed by the 2007 NCIMS Conference states: "All milk plants producing aseptically processed and packaged milk or milk products as defined by the PMO and regulated under the NCIMS program **will** participate in the Aseptic Pilot Program (APP)."

At the September 2007 meeting between FDA and the NCIMS Executive Board, an agreement was reached regarding the implementation of the APP as follows: "This provision shall take immediate effect upon each participating State's regulatory and rating personnel being trained in the implementation of the Aseptic Pilot Program. Until such time, aseptic plants will be inspected and rated using the current system."

The APPIC has developed the training required for State regulatory person, SROs and FDA RMSs that have inspectional or rating responsibilities for Grade "A" aseptic milk plants. The APPIC has established the following schedule for this required training.

March 3-4, 2008, (Dairy Management Inc. near O'Hare Airport, Chicago, IL)
April 3-4, 2008 (Silver Legacy Hotel, Pacific Regional Milk Seminar, Reno, NV)
May 5-6, 2008 (NY State Fairgrounds, Syracuse, NY)

All State Regulatory and/or Rating Agencies are strongly encourage to register at least one (1) State milk plant inspector and one (1) SRO with responsibility for a Grade "A" aseptic milk plant(s) for a training session listed above as soon as possible. While the APPIC has not anticipated any space restrictions, priority will be given to State Regulatory and Rating personnel from States with a Grade "A" aseptic milk plant. Registration is being handled by Mr. Brian Fields at (202)

220-3566 or bfields@idfa.org. Confirmation of registration will be emailed once the registration fee of \$50 has been received or arrangements have been made for on-site payment. Information related to the training, including nearby hotels, shuttles from the airport to the training location, etc. may be obtained from Mr. Fields for the Chicago training, Ms. Gena Reich (509) 546-2977 for the Reno training and Ms. Becca Durant (315) 264-3045 for the Syracuse training.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, State Milk Regulatory Agencies, State Laboratory Evaluation Officers and State Milk Sanitation Rating Officers in your region. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and also will be available on the CFSAN Web Site at <http://www.cfsan.fda.gov> at a later date.

If you would like an electronic version of this document prior to it being available on the CFSAN Web Site, please e-mail your request to robert.hennes@fda.hhs.gov.

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Ms. Susan K. Esser
Chair, NCIMS Aseptic Pilot Program
Implementation Committee
Michigan State Department of Agriculture

CAPT Robert F. Hennes, RS, MPH

31st NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #:	303
Committee:	

	No Action	Passed as Submitted	Passed as Amended
COUNCIL ACTION			X
FINAL ACTION			X

C. Proposed Solution

Changes to be made on page(s):		PMO page 117	of the (X - one of the following):
<input checked="" type="checkbox"/>	2005 PMO	<input type="checkbox"/>	2005 EML
<input type="checkbox"/>	2005 MMSR	<input type="checkbox"/>	2400 Forms
<input type="checkbox"/>	2005 Procedures	<input type="checkbox"/>	2005 Constitution and Bylaws

SECTION 11. MILK AND MILK PRODUCTS FROM POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION

10. Aseptically processed and packaged milk and milk products in Definition W of this Ordinance shall be considered to be Grade “A” milk or milk products. The source of the milk and milk products shall be IMS-listed and the aseptic raw milk receiving area/aseptic raw milk receiving station of the milk plant where the aseptic milk and milk products are processed and packaged shall be IMS-listed. The milk plant shall be awarded a Milk Sanitation Compliance Rating of at least ninety (90) and a satisfactory Aseptic Milk Plant Regulatory Agency Review Report or a satisfactory HACCP listing by a SRO trained under the NCIMS Aseptic Pilot Program and label its milk and milk products “Grade “A”.

The NCIMS Aseptic Pilot Program will expire on December 31, 2009 unless extended by future conference action. This provision shall take immediate effect.

The following text is a mandatory part of this solution but will not be placed in an NCIMS document:

As part of the NCIMS Aseptic Pilot Program, an NCIMS Aseptic Pilot Program Implementation Committee (APPIC) shall be formed in accordance with NCIMS *Procedures*. The APPIC shall be responsible for oversight of the NCIMS Aseptic Pilot Program in consultation with FDA, including development of the forms, documents and guidance necessary to implement, evaluate and provide training for the NCIMS Aseptic Pilot Program as well as study current and new aseptic technology and its application. The APPIC shall provide a report to the 2009 NCIMS.

The NCIMS Aseptic Pilot Program document attached to this proposal will be used as the basis for the Pilot Program.

All milk plants producing aseptically processed and packaged milk or milk products as defined by the PMO and regulated under the NCIMS program will participate in the Aseptic Pilot Program.