Proposal #: Joint Council 301
Committee: Aseptic/MMSR

*New Procedure

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

C. Proposed Solution					
Changes	to be made on page(s):	See at	ttached documents. of the (X - one of the following):		
X	2009 PMO		2009 EML		
X	2009 MMSR		2400 Forms		
X	2009 Procedures		2009 Constitution and Bylaws		

NOTE: Please refer to the attached PMO, MMSR and Procedures documents for the proposed changes.

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

<u>NOTE:</u> This provision shall take immediate effect upon the issuance of the IMS-a, Actions from the 2011 National Conference on Interstate Milk Shipments, following FDA's concurrence with the NCIMS Executive Board.

As part of the NCIMS Aseptic Program addressing aseptically processed and packaged Grade "A" low acid milk and milk products and the Aseptic Pilot Program addressing aseptically processed and packaged Grade "A" acidified and fermented high acid milk and milk products, an NCIMS Aseptic Program Committee (APC) shall be formed in accordance with NCIMS *Procedures*. The APC shall be responsible for the oversight of the NCIMS Aseptic Program addressing aseptically processed and packaged Grade "A" low acid milk and milk products as well as aseptically processed and packaged Grade "A" acidified and fermented high acid milk and milk products in consultation with FDA, including the development of forms, documents

and guidance necessary to implement, evaluate and provide training as well as study current and new aseptic technology and its application. The APC shall provide a report to the 2013 NCIMS.

This Proposal also authorizes FDA to make appropriate editorial changes to the NCIMS documents as needed, in accordance with NCIMS *Procedures*, resulting from Proposals that are passed at the 2011 NCIMS Conference, and concurred with by FDA, related to the wording addressing aseptic processing and packaging systems.

All milk plants producing aseptically processed and packaged Grade "A" acidified and fermented high acid milk and milk products, as defined by the PMO and regulated under the NCIMS program will participate in the Aseptic Pilot Program for those milk and milk products.

Proposal #: 303
Committee: Lab

*Procedures Change

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

C. Proposed Solution						
Changes	to be made on page(s)	:	7, 27	of the (X - one of the following):		
	2009 PMO		2009 EML			
	2009 MMSR		2400 Forms			
X	2009 Procedures		2009 Constitution	and Bylaws		

Page 7:

- a. PHS/FDA shall evaluate and approve the laboratory facilities and procedures of State Laboratory Approval Agencies to assure compliance with FDA 2400 Series Evaluation Forms and, where appropriate, the current edition of *Standard Methods for the Examination of Dairy Products (SMEDP)* and *Official Methods of Analysis of AOAC INTERNATIONAL (OMA)*.
- b. PHS/FDA shall periodically evaluate milk laboratories of participating States to assure compliance with FDA 2400 Series Evaluation Forms, and where appropriate, the current edition of *SMEDP* and *OMA*. Evaluations conducted during recertification of LEOs shall be submitted, but it shall be the option of the LEO as to whether or not the evaluation is submitted for official action regarding laboratory status-, except when the LEO is conditionally approved. All laboratory evaluations conducted by conditionally approved LEOs are official.

Page 27:

I. LABORATORY PROCEDURES

Laboratory procedures used to examine milk and milk products of interstate milk shippers

shall conform to the procedures in the current edition of *SMEDP*, published by the American Public Health Association, revisions of the NCIMS/FDA 2400 Series Forms and the *OMA* using only methods approved by the NCIMS. Vitamin testing shall be performed using test methods acceptable to PHS/FDA and other official methodologies that give statistically equivalent results to the PHS/FDA methods.

Name: Catherine Hall						
Agency/O	rganiz	ation:	NCIMS Labo	rato	ory Committee	000
Address:	1100	West 4	9 th Street			
City/State/Zip: Austin, TX 78756						
Telephone No.: 512-458-7585 E-mail Address: Catherine.hall@dshs.state.tx.us						

Proposal #: 308

Committee: Aseptic

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

C. Proposed Solution						
Changes	to be made on page(s):	121 and 122	of the (X - one of the following):			
X	2009 PMO	2009 EML				
	2009 MMSR	2400 Forms				
	2009 Procedures	2009 Constitution	n and Bylaws			

Strike through text to be deleted and underline text to be added.

Make the following changes to the **2009 PMO**.

Page 121:

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

Milk and milk products, from points beyond the limits of routine inspection of the ... of... or its jurisdiction, shall be sold in..., ¹ or its jurisdiction provided they are produced and pasteurized, ultra-pasteurized, aseptically processed, <u>retort processed after packaging</u>, concentrated (condensed) or dried under regulations which are substantially equivalent to this *Ordinance* and have been awarded acceptable Milk Sanitation Compliance and Enforcement Ratings; or have been awarded a <u>an satisfactory acceptable HACCP</u> listing, under the NCIMS HACCP Program as specified in Appendix K. of this *Ordinance*; or are from a country that PHS/FDA has determined, after conferring with <u>the NCIMS</u>, to have in place a public health regulatory program and government oversight of that program that have an equivalent effect on the safety of regulated milk and/or milk products.

ADMINISTRATIVE PROCEDURES

The Regulatory Agency should accept, without their actual physical inspection, supplies of milk and milk products from an area or an individual shipper not under their routine inspection. Provided, that:

Page 122:

- 2. After receipt, pasteurized, ultra-pasteurized, aseptically processed, <u>retort processed after packaging</u>, concentrated (condensed) or dried milk and milk products shall comply with Sections 2, 4 and 10. ...
- 12. Retort processed after packaging milk and milk products as addressed in Definition X of this Ordinance shall be considered to be Grade "A" milk or milk products if they are used as an ingredient to produce any milk or milk product defined in Definition X of this *Ordinance*; or if they are labeled as Grade "A" as described in Section 4 of this Ordinance. Retort processed after packaging milk and milk products shall be labeled "Grade "A"" and meet Section 4 labeling requirements of this Ordinance whenever they meet the provisions cited within Definition X of this Ordinance. The source(s) of the milk and/or milk products used to produce retort processed after packaging Grade "A" milk and/or milk products shall be IMS listed. The milk plant or portion of the milk plant that is producing retort processed after packaging Grade "A" milk and/or milk products shall be awarded a Milk Sanitation Compliance Rating of at least ninety percent (90%) and an Enforcement Rating equal to the local supply, or equal to ninety percent (90%) or higher; or if the Enforcement Rating is below ninety percent (90%) on a rating, a re-rating must occur within (6) months of this rating. Both the Milk Sanitation Compliance and Enforcement Ratings must be equal to ninety percent (90%) or higher on the re-rating; or the supply is considered in violation of this Section. In the case of HACCP/Retort listings, an acceptable HACCP listing by a SRO is required. For milk plants that produce retort processed after packaging Grade "A" milk and/or milk products and prior to the milk plant participating in the NCIMS Retort Pilot Program, the State's regulatory and rating personnel shall have completed a training course that is acceptable to the NCIMS and FDA addressing the procedures for conducting regulatory inspections and ratings under the NCIMS Retort Pilot Program. The NCIMS Retort Pilot Program addressing retort processed after packaging Grade "A" milk and milk products regulated under 21 CFR Parts 108, 110, and 113 will expire on December 31, 2013, unless extended by future conference action.

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

NOTE: This provision shall take immediate effect upon the issuance of the IMS-a, Actions from the 2011 National Conference on Interstate Milk Shipments, following FDA's concurrence with the NCIMS Executive Board.

This NCIMS Retort Pilot Program shall be assigned as a part of the NCIMS Aseptic Pilot Program Implementation Committee's (APPIC) current charge that addresses aseptically

processed and packaged Grade "A" low acid milk and milk products. The APPIC shall also be responsible for the oversight of the NCIMS Retort Pilot Program addressing retort processed after packaging Grade "A" milk and milk products in consultation with FDA; and shall include the development of required forms, documents and guidance necessary to implement, evaluate and provide training, as well as study current and new retort technology and its application. The APPIC shall provide a report to the 2013 NCIMS.

All milk plants producing retort processed after packaging Grade "A" milk and/or milk products, as defined by the PMO and regulated under the NCIMS program shall participate in the NCIMS Retort Pilot Program for those milk and/or milk products.

Proposal #: 309

Committee: ICPP

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

C. Proposed Solution						
Changes	to be made on page(s):		122	of the (X - one of the following):		
XX	2009 PMO		2009 EML			
	2009 MMSR		2400 Forms			
	2009 Procedures		2009 Constitution	and Bylaws		

Make the following change to the 2009 PMO.

Strike out text to be deleted and <u>underlined</u> text to be added.

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

ADMINISTRATIVE PROCEDURES

Page 122

9. The foreign supplies have been awarded a satisfactory listing, by an NCIMS Certified Third Party Rating Officer standardized by the FDA, under the NCIMS International Certification Pilot Program. This provision will expire December 31, 2011 2013, unless extended by future conference action.

Proposal #:	312
Committee:	ICCP

				Passed as Submitted	Passed as Amended
COUNC	CIL ACTION				X
FINAL A	ACTION				X
-	C. Proposed Solution				
Changes	to be made on page(s)):		of the (X - one of	of the following):
Changes	to be made on page(s,	,·			of the following).
Changes	2009 PMO	,.	2009 EML	_ or the (21 one (or the following).
		/·	2009 EML 2400 Forms		of the following).

No NCIMS Document Referenced.

Change the voluntary NCIMS International Certification Pilot Program (ICPP) as defined in IMS-a-45 and amended by IMS-a-47, that once a Third Party Certifier (TPC) has four (4) plants IMS listed and the completion and issuance of the equivalent of a State Program Evaluation, with a determination that the TPC is in **Compliance** with the PMO, the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments* (Procedures) and other NCIMS related documents, including the ICPP's Policies and Procedures, Letter of Intent (LOI) and Code of Ethics, the TPC may request from the ICPP Committee permission to add two (2) additional plants for a maximum of six (6) IMS listed plants.

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

NOTE: This provision shall take immediate effect upon the issuance of the IMS-a, Actions from the 2011 National Conference on Interstate Milk Shipments, following FDA's concurrence with the NCIMS Executive Board.

Proposal #:	313
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):			of the (X - one of the following):	
X	2009 PMO		2009 EML		
	2009 MMSR		2400 Forms		
	2009 Procedures		2009 Constitution	and Bylaws	

To request that the NCIMS Executive Board request the Liaison Committee to study, provide comments and stakeholder outreach on the implications establish an Ad-HOC committee to align the Pasteurized Milk Ordinance with of the Food Safety Modernization Act on the Interstate Milk Shipments Program. The committee shall report back to the Executive Board with recommendations before the 2013 NCIMS Conference.