

33rd NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #:	Joint Council 301
Committee:	Aseptic/MMSR

***New Procedure**

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

A. Summary of Proposal

This Proposal contains modifications to the PMO, Methods, and Procedures documents that address the regulation and rating of aseptic milk plants producing Grade "A" low acid aseptic milk and milk products. It will incorporate the Aseptic Pilot Program Implementation Committee's findings and determination for aseptic milk plants that produce Grade "A" low acid aseptic milk and milk products into the NCIMS documents and make this Pilot a permanent part of the Grade "A" Milk Safety Program

This Proposal also requests a two (2) year extension of the NCIMS Aseptic Pilot Program to specifically address aseptically processed and packaged Grade "A" acidified and fermented high acid milk and milk products. The additional two (2) years will be utilized to evaluate the effectiveness of regulating and rating aseptic milk plants producing Grade "A" acidified and/or fermented high acid milk and milk products.

This Proposal addresses the regulation of the aseptic processing and packaging system in accordance with the Low Acid Canned Foods (LACF)/Acidified Foods (AF) regulations contained in 21 CFR 108, 110, 113, and 114, while regulating the areas of the milk plant that are outside the aseptic processing and packaging system in accordance with the PMO. It provides for a separate IMS listing for Grade "A" aseptic milk and milk products.

**B. Reason for the Submission and
Public Health Significance and/or Rationale Supporting the Submission**

The 2003 NCIMS authorized the formation of the initial Aseptic Committee to explore the possibility of better coordinating the regulation of aseptically processed and packaged milk and milk products under the CFRs and the PMO. At the 2005 NCIMS, the delegates voted in

favor of Proposal 319. Proposal 319 instructed the NCIMS Aseptic Committee to continue studying aseptic processing and packaging as it relates to the PMO, CFRs and the NCIMS. As instructed by Proposal 319, the Aseptic Committee expanded its membership to include a larger group of stakeholders involved in producing and regulating aseptic milk and milk products. The Committee also obtained input from stakeholders through a survey and forums.

At the 2007 NCIMS, the delegates voted in favor of Proposal 303 which called for the establishment of the Aseptic Pilot Program Implementation Committee (APPIC) and the implementation of an Aseptic Pilot Program. The APPIC, comprised of 21 members including State Regulatory Agencies, FDA and industry, developed the documents, forms and training necessary to conduct the Aseptic Pilot Program.

At the 2009 NCIMS, the APPIC was granted an extension of the pilot program to allow additional time for conducting an evaluation and to further refine the implementation of the program. The NCIMS Aseptic Pilot Program recognizes that 21 CFR 108, 110, and 113 provide the basis for the safety of aseptically processed and packaged low acid milk and milk products. The program eliminates the areas of conflict and removes much of the duplication of the PMO and CFR requirements while making the best use of available resources and maintaining milk and milk product safety.

The NCIMS Aseptic Pilot Program has fulfilled the objectives as outlined in the original Proposal and has demonstrated that it:

- maintains the most important contributions to milk and milk product safety from both sets of regulations, the PMO and CFR;
- eliminates confusion and costs (in time and dollars) stemming from conflicts between the PMO and the CFR requirements;
- promotes national regulatory uniformity; and
- provides effective utilization of resources.

These elements have demonstrated the continuing effectiveness of the program in assuring milk and milk product safety for Grade "A" aseptic milk and milk products.

In addition, the Committee also recognized the need to evaluate aseptically processed and packaged Grade "A" acidified and fermented high acid milk and milk products in light of new product innovations and the 2009 updates made to Definition X, "Milk Products", in the PMO. In 2009, the Executive Board supported the development of solutions for two (2) additional milk and milk product categories, acidified and fermented high acid milk and milk products.

This Proposal includes a request for a two (2) year extension of the NCIMS Aseptic Pilot Program (APP) to address aseptically processed and packaged Grade "A" acidified and fermented high acid milk and milk products. The two (2) years will allow time to study, develop and evaluate the additional Grade "A" milk and milk product categories under a controlled pilot program and to develop a formal training program.

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) will 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.

C. Proposed Solution

Changes to be made on page(s): See attached documents. of the (X - one of the following):

- | | |
|------------------------------|--|
| <u> X </u> 2009 PMO | <u> </u> 2009 EML |
| <u> X </u> 2009 MMSR | <u> </u> 2400 Forms |
| <u> X </u> 2009 Procedures | <u> </u> 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.

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.

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.

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**ASEPTIC PILOT PROGRAM IMPLEMENTATION COMMITTEE
2011 NCIMS PROPOSAL
1/12/2011**

**PROCEDURES GOVERNING THE COOPERATIVE STATE-PUBLIC
HEALTH SERVICE/FOOD AND DRUG ADMINISTRATION PROGRAM
OF THE NATIONAL CONFERENCE ON INTERSTATE MILK
SHIPMENTS**

2009 REVISION

NOTE: Underlined text is proposed new wording and ~~struck through text~~ is wording that is proposed to be deleted.

Make the following changes to SECTION II. SCOPE on Page 1:

Page 1

A. PRODUCTS COVERED

Agreements adopted by the NCIMS shall apply to Grade "A" raw milk and milk products for pasteurization, heat-treated products, pasteurized, ultra-pasteurized, and aseptically processed and packaged milk and milk products, condensed and dry milk products, and whey and whey products produced under the NCIMS program.

Make the following changes to SECTION III. DEFINITIONS on Pages 2 and 3:

Page 2

SECTION III. DEFINITIONS

C. ASEPTIC PROCESSING AND PACKAGING SYSTEM (APPS): For the purposes of this document, the Aseptic Processing and Packaging System in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade "A" milk or milk products. The APPS shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The APPS shall begin at the constant level tank and end at the discharge of the packaging machine, provided that the Process Authority may provide written documentation which will clearly define additional processes or equipment that are considered critical to the commercial sterility of the product.

D. BULK TANK UNIT (BTU):

Re-letter the remaining Definitions accordingly.

I.J. IMS LISTED SHIPPER: An interstate milk shipper (BTU, receiving station, transfer station, or milk plant), which has been certified by the State Rating Agency as having attained the ~~milk~~ Sanitation Compliance and Enforcement Ratings necessary for inclusion in the *IMS List*. The ratings are based on compliance with the requirements of the *Grade "A" PMO* and were made in accordance with the procedures set forth in the *Methods of Making Sanitation Ratings of Milk Shippers* (MMSR). For milk plants that produce aseptically processed and packaged Grade "A" milk and/or milk products, prior to the milk plant participating in the NCIMS Aseptic Processing and Packaging Program, the State's regulatory and rating personnel shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting regulatory inspections and ratings under the NCIMS Aseptic Processing and Packaging Program.

JK. INDIVIDUAL RATING: An individual rating is the rating of a single producer group, milk plant, receiving station, and/or transfer station under the supervision of a single Regulatory Agency. Milk plants producing Grade "A" condensed or dried milk and milk products and/or Grade "A" condensed or dry whey and whey products may be rated separately from the same milk plant producing other Grade "A" milk or milk products, provided each listing holds a separate permit. Milk plants that produce both aseptically processed and packaged Grade "A" milk and/or milk products and pasteurized and/or ultra-pasteurized Grade "A" milk and/or milk products shall be rated separately. Provided that an NCIMS HACCP milk plant listing that produces aseptically processed and packaged Grade "A" milk and/or milk products shall have only an NCIMS HACCP listing. An individual dairy farm shall only be included in one (1) IMS Listing.

Re-letter the remaining Definitions accordingly.

OP. MILK PLANT: A milk plant is any place, premises, or establishment where milk or milk products are collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed and packaged, condensed, dried, packaged, or prepared for distribution.

Re-letter the remaining Definitions accordingly.

Make the following changes to SECTION IV. OVERSIGHT AND RESPONSIBILITIES on Pages 8, 10, 11 and 16:

A. PHS/FDA RESPONSIBILITIES

5. Electronic Publication of Sanitation Compliance and Enforcement Ratings

- a. PHS/FDA shall provide an electronic publication of the *IMS List* on their web site. The electronic *IMS List* is available at <http://www.fda.gov/Food/FoodSafety/Product->

SpecificInformation/MilkSafety/FederalStatePrograms/InterstateMilkShippersList/default.htm. The Sanitation Compliance and Enforcement Ratings of Regulatory Agencies and the IMS Listed shippers' expiration rating dates contained in the electronic publication are certified by the State Rating Agency to be those established by ratings conducted in accordance with the *MMSR* by certified SROs when the FORM FDA 2359i-INTERSTATE MILK SHIPPER'S REPORT is signed and submitted to the PHS/FDA Regional Office for publication.

~~Transfer stations, receiving stations and milk plants~~ Milk plants, receiving stations and ~~transfer stations~~ must achieve a Sanitation Compliance Rating of 90 percent (90%) or higher, except as cited in Section VIII., C.,5. for HACCP listings, in order to be eligible for a listing in the *IMS List*. Sanitation Compliance Rating scores for transfer and receiving stations and milk plants will not be identified in the *IMS List*.

PHS/FDA shall update the *IMS List* not less than monthly.

Page 10

7. Interpretations and Editorial Updates

b. After each Conference and/or request by the NCIMS Executive Board, PHS/FDA shall incorporate editorial updates into the *Constitution of the National Conference on Interstate Milk Shipment*, *Bylaws of the National Conference on Interstate Milk Shipment*, *Grade "A" PMO*, the *MMSR*, the *Procedures* and the *EML* in accordance with the guidelines ~~to be~~ developed jointly by PHS/FDA and the NCIMS Executive Board.

8. Check Ratings of the Sanitation Compliance Status of Listed Interstate Milk Shippers

a. PHS/FDA shall conduct, each year, check ratings of the Sanitation Compliance status of listed interstate milk shippers. To conduct check ratings of aseptic milk plants, the PHS/FDA Regional Milk Specialist shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting check ratings under the NCIMS Aseptic Processing and Packaging Program. Within a State, check ratings will be made of a representative number of IMS Listed shippers. The selection of shippers for check rating in a given State will be made randomly.

Page 11

g. Enforcement Ratings ~~will~~ shall be ~~made~~ conducted as part of check ratings.

B. STATE RESPONSIBILITIES

Page 16

7. Challenges and Remedies

c. Action to be Taken if the PHS/FDA Check Rating Indicates the Listed Rating is Not Justified:

2.) Milk Plants, Receiving Stations and/or Transfer Stations

C.) Withdrawal of Certification

When check rating data indicates that the Sanitation Compliance Rating of a milk plant, receiving station and/or transfer station requires a withdrawal of certification, the State Rating Agency, upon written recommendation of PHS/FDA, shall immediately withdraw the current certification of the shipper and notify such shipper, PHS/FDA, and all known receiving States thereof, in accordance with Section IV., B., 1.d. In case of withdrawal, a new rating shall be made in not less than thirty (30) days and not to exceed sixty (60) days, unless the State Rating Agency has reason to believe a new rating within a lesser time period would result in an acceptable rating. The effective date for action shall be determined from the date of the letter of notification by the State Rating Agency. Such letter shall be dated within five (5) working days following the date of the official notification. A withdrawal of certification is also required if an aseptic milk plant has any Aseptic Critical Listing Element (ACLE) identified as not being in compliance on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products following the procedures cited above.

Make the following changes to SECTION V. QUALIFICATIONS AND CERTIFICATIONS on Pages 17, 18, 19, 22, 23 and 25:

Page 17

A. SUPERVISION REQUIREMENTS

3. Sampling procedures and laboratory examinations are a fundamental and basic component of supervision. The surveillance of sample collection procedures shall be conducted as prescribed in the *EML Grade "A" PMO*. Samples from each dairy farm and each pasteurization milk plant shall be examined for the prescribed tests at the frequency prescribed in the PHS/FDA recommended *Grade "A" PMO*.

C. SANITATION COMPLIANCE AND ENFORCEMENT RATINGS REQUIRED

D. MILK SANITATION RATING PERSONNEL

2. Have been standardized by PHS/FDA as a SRO and hold a valid certificate of qualification in one (1) or any combination of the following categories: milk pasteurization plants, including HACCP and/or aseptic processing and packaging if appropriate, dairy farms

and transfer/receiving stations, including HACCP if appropriate. The PHS/FDA will issue a certificate, valid for three (3) years, to each individual who meets the criteria listed below, as applicable. Certification of a SRO shall qualify that SRO to perform ratings or HACCP listings, if applicable, in any State, upon the request of that State's Regulatory/Rating Agency as long as the Officer's certification is valid.

Page 18

3. A SRO applicant for initial standardization following number of dairy facilities:
 - b. Five (5) pasteurization milk plants. ~~Milk Plants~~ plants of varying sizes using, vat, HTST, HHST pasteurization and/or aseptic processing and packaging, if applicable, should be included in these evaluations. One (1) transfer or receiving station may also be included as one (1) of the required five (5) pasteurization milk plants. ...
6. To conduct ratings of aseptic processing and packaging milk plants, the applicant shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting the rating and the implementation of the NCIMS Aseptic Processing and Packaging Program.
67. Applicants must demonstrate the ability to conduct and compute ~~Milk~~ Sanitation Compliance and Enforcement Ratings by completing all of the necessary forms.

Re-number all remaining Items accordingly.

Page 19

78. A certified SRO shall be re-standardized once three (3) years number of dairy farms.
 - b. Three (3) pasteurization milk plants. ~~Milk Plants~~ plants of varying sizes using, vat, HTST, HHST pasteurization and/or aseptic processing and packaging, if applicable, should be included in these evaluations.
 - c. One (1) dry milk plant, if applicable. The dry milk plant may be used as one (1) of the required three (3) pasteurization milk plants.
 - d. If HACCP certified for milk plants, receiving or transfer stations, in addition to meeting the requirements listed above for pasteurization milk plants for a SRO, one (1) recertification audit is required. The recertification audit can be done independent as a mock-listing audit or as part of an official HACCP listing audit, at the discretion of the PHS/FDA ~~REGIONAL MILK SPECIALIST~~ Regional Milk Specialist and SRO. (Refer to Section VIII., E.6. for additional HACCP certification procedures.)

Page 22

H. THE HEARING PROCEDURE FOR REVOKING THE CERTIFICATION OF A SRO,

SSO, OR LEO

1. Certification Hearing Panel Members

- c. The Director of the Division of ~~Cooperative Programs~~ Plant and Dairy Food Safety or designee.

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3. Request for a Hearing

The SRO, SSO, or LEO, after being notified of PHS/FDA's intent to revoke his or her certification, may request a hearing. This request must be received by the Director of the Division of ~~Cooperative Programs~~ Plant and Dairy Food Safety within fifteen (15) days of the date the SRO, SSO, or LEO receives written notification of the intent to revoke his or her certification. The hearing request must identify one (1) or more substantial issues of fact for which a hearing is requested.

If the Certification Hearing Panel determines that the material submitted by the SRO, SSO, or LEO does not raise any genuine and substantial issue of fact, the request for the hearing will be denied. The Certification Hearing Panel will notify the SRO, SSO, or LEO of the decision in writing, and the revocation of the certification shall be effective immediately. If the Certification Hearing Panel determine that the material submitted by the SRO, SSO, or LEO raises one (1) or more genuine and substantial issues of fact, the Certification Hearing Panel will notify the SRO, SSO, or LEO and the PHS/FDA Standard in writing that a hearing will be held....

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J. INDIVIDUAL RATINGS

3. If an aseptic milk plant has any ACLE identified by a SRO or PHS/FDA Regional Milk Specialist as not being in compliance on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Milk and/or Milk Products, the listing shall be immediately denied or withdrawn.

34. If an IMS listed shipper receives an Enforcement Rating of less than ninety percent

Make the following changes to SECTION VI. STANDARDS on Page 27:

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, and the *OMA*. Vitamin testing shall be performed in a laboratory which has been accredited by PHS/FDA and which is acceptable to the Regulatory Agency using test methods acceptable to PHS/FDA and other official methodologies that give statistically equivalent results to the PHS/FDA methods.

Make the following changes to SECTION VIII. PROCEDURES GOVERNING THE CERTIFICATION OF MILK PLANT, RECEIVING STATION AND TRANSFER STATION NCIMS HACCP SYSTEMS FOR IMS LISTED SHIPPERS on Pages 28, 29, 32, 33, 37, 39, 40 and 43:

Page 28

A. PURPOSE AND SCOPE

2. Products Covered Under HACCP Listings

Agreements adopted by the NCIMS shall apply to Grade "A" raw milk and milk products for pasteurization, heat-treated products, pasteurized, ultra-pasteurized, and aseptically processed and packaged milk and milk products, condensed and dry milk products, and whey and whey products produced under the NCIMS program. Listings made under the voluntary HACCP listing system described in this Section, may be made for milk plants, receiving stations and transfer stations.

B. HACCP DEFINITIONS:

1. **AUDIT:** An evaluation of the entire milk plant, receiving station, or transfer station facility, and HACCP System to ensure compliance with the HACCP System and other NCIMS regulatory requirements, with the exception of the APPS for aseptic processing and packaging milk plants.

Page 29

4. **PHS/FDA AUDIT:** An evaluation conducted by PHS/FDA of the entire milk plant, receiving station, or transfer station facility to ensure compliance with the HACCP System and other NCIMS regulatory requirements, with the exception of the APPS for aseptic processing and packaging milk plants.
7. **LISTING AUDIT:** An evaluation conducted by a SRO of the entire milk plant, receiving station or transfer station facility to ensure compliance with the NCIMS HACCP Program and other NCIMS regulatory requirements, with the exception of the APPS for aseptic processing and packaging milk plants.
8. **STATE PROGRAM EVALUATION:** Definition ST. in Section III shall apply as

written, except that for purposes of this Section the words "check ratings of IMS Listed Shippers" shall include "PHS/FDA audits of IMS Listed Shippers".

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C. PHS/FDA RESPONSIBILITIES

8. PHS/FDA Audits of HACCP Listing

a. PHS/FDA shall conduct, each year, PHS/FDA audits of HACCP listed shippers. To conduct audits of HACCP/aseptic processing and packaging milk plants, the PHS/FDA Regional Milk Specialist shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting the audit and the implementation of the NCIMS Aseptic Processing and Packaging Program. Within a State conducting the NCIMS HACCP Program, PHS/FDA audits will be made of a representative number of IMS HACCP listed shippers. The selection of shippers for auditing in a given State will be made randomly.

h. PHS/FDA shall conduct on-site milk plant, receiving station and transfer station audits of the HACCP compliance status of listed interstate milk shippers. These PHS/FDA HACCP audits shall be conducted using the procedures for State HACCP listing audits as described in the MMSR. These audits will be used in the overall State Program Evaluation. Provided, that for NCIMS HACCP listed milk plants producing aseptically processed and packaged Grade "A" milk and milk products, PHS/FDA HACCP audits shall be conducted using the procedures identified in the NCIMS Aseptic Processing and Packaging Program related to the inspection/auditing and regulation of the APPS, as described in the Grade "A" PMO and MMSR, along with the completion of FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Milk and Milk Products.

i. PHS/FDA shall review the Regulatory Agency records for the milk plant, receiving station or transfer station being audited. In the event that there is reason to doubt the safety of any State's milk or milk products that are HACCP listed, PHS/FDA shall immediately investigate the State's Milk Safety Program and may evaluate/audit the milk plants, receiving stations or transfer stations affected. This applies even if the HACCP listing of the milk plant, receiving station or transfer station being audited is sustained.

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Based on this investigation, if there are substantial milk or milk product safety program weaknesses, PHS/FDA shall send a written notice requiring corrections to the State Regulatory Agency with a copy to the Rating Agency. If after thirty (30) days, PHS/FDA determines that the corrections were not made, PHS/FDA shall notify the affected industry and receiving States.

If after this investigation of HACCP listings in the State, PHS/FDA determines that the State is not able to fulfill its obligations under the NCIMS HACCP Program and milk or milk products safety remains in doubt, PHS/FDA shall provide written notification to the State specifying the reasons this determination was made.

This written notification will specify that the State has 180 days from the date of the written notification to show to PHS/FDA's satisfaction that the State has made appropriate corrections and is once again able to fulfill its obligations under the NCIMS HACCP Program. ...

D. STATE HACCP RESPONSIBILITIES

1. State HACCP Listings for Milk Plants, Receiving Stations and Transfer Stations

c. When the Sanitation Compliance status of a listed shipper's supply changes as a result of a new listing made within the twenty-four (24) month eligibility period, the most recent listing and FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT and the FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT, shall apply and shall be submitted to PHS/FDA. Provided that for NCIMS HACCP listed milk plants producing aseptically processed and packaged Grade "A" milk and milk products, FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM MILK PLANT CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products shall also be completed and submitted to PHS/FDA.

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C.) Withdrawal of Certification

1.) A HACCP listing shall be requested to be withdrawn when CLE's have been noted on FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT indicating that the milk plant, receiving station or transfer station has failed to recognize or correct a deficiency(ies) or nonconformity(ies) indicating:

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8. HACCP SYSTEM AUDIT FOLLOW-UP ACTIONS: ...

3.) A HACCP/aseptic listing that includes aseptically processed and packaged Grade "A" milk and/or milk products shall be requested to be withdrawn when any ACLE is identified as not being in compliance on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products.

34.) When PHS/FDA audit data indicates that the milk plant, receiving station and/or transfer station requires a withdrawal of certification, the Rating Agency, upon written recommendation of the PHS/FDA, shall immediately withdraw the current certification of the shipper and notify such shipper, PHS/FDA, and all known receiving States thereof. In case of withdrawal, a new listing shall be made in not less than thirty (30) days and not to exceed sixty (60) days, unless the Rating Agency has reason to believe a new listing within a lesser time period would result in an acceptable listing. The effective date for action shall be determined from the date of the letter of notification by the Rating Agency. Such letter shall be dated within five (5) working days following the date of the official notification.

Re-number remaining Items accordingly.

Page 40

E. QUALIFICATIONS AND CERTIFICATIONS

3. HACCP Listing

a. An acceptable HACCP listing shall be substituted for an acceptable Sanitation Compliance and Enforcement Rating for a milk plant, receiving station or transfer station participating in the NCIMS HACCP Program. FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT and FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT shall be completed as a part of all milk plant, receiving station or transfer station HACCP listing audits. Provided that for NCIMS HACCP listed milk plants producing aseptically processed and packaged Grade "A" milk and/or milk products, FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM MILK PLANT CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products shall be completed as a part of all HACCP/aseptic listing audits.

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6. Certification Procedure for SROs Who Will Conduct HACCP Listing Audits

d. Paperwork Review

FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT, with attachments, FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT, and FORM FDA 2359o-PERMISSION FOR PUBLICATION (*Interstate Milk Shipper's Listing*) shall be submitted with FORM FDA 2359i for each NCIMS HACCP Listing Audit to the PHS/FDA Regional Office for quality assurance review. Provided that for NCIMS HACCP listed milk plants producing aseptically processed and packaged Grade

“A” milk and/or milk products, FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM MILK PLANT CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products shall also be completed and submitted for quality assurance review.

These reviews will be used to enhance uniformity and strengthen each individual’s skills and will be used to assist in identifying needs for future training.

**ASEPTIC PILOT PROGRAM IMPLEMENTATION COMMITTEE
2011 NCIMS PROPOSAL
1/11/2011**

**GRADE “A” PASTEURIZED MILK ORDINANCE
2009 REVISION**

NOTE: Underlined text is proposed new wording and ~~struck through text~~ is wording that is proposed to be deleted.

*Make the following changes to the **TABLE OF CONTENTS** on Pages viii, ix and xiii:*

Page viii

STANDARDS FOR GRADE “A” RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING AND PACKAGING

Page ix

STANDARDS FOR GRADE “A” PASTEURIZED, ULTRA-PASTEURIZED AND ASEPTICALLY PROCESSED AND PACKAGED MILK AND MILK PRODUCTS ...

ITEM 16p. PASTEURIZATION AND ASEPTIC PROCESSING AND PACKAGING ...

~~ITEM 16p.(C). ASEPTIC PROCESSING SYSTEMS~~

ITEM 16p.(~~DC~~). PASTEURIZERS AND ASEPTIC PROCESSING SYTEMS

EMPLOYING REGENERATIVE HEATING

MILK OR MILK PRODUCT-TO-MILK OR MILK PRODUCT REGENERATIVE HEATING

MILK OR MILK PRODUCT-TO-WATER-TO-MILK OR MILK PRODUCT REGENERATIVE HEATING

ITEM 16p.(~~ED~~). PASTEURIZATION AND ASEPTIC PROCESSING RECORDS, EQUIPMENT TESTS AND EXAMINATIONS

Page xiii

APPENDIX Q. OPERATION OF AUTOMATIC MILKING INSTALLATIONS FOR THE PRODUCTION OF GRADE “A” RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING AND PACKAGING

APPENDIX S. ASEPTIC PROCESSING AND PACKAGING PROGRAM

*Make the following changes to **TABLES** on Page xv:*

Table 4. Equipment Tests – Batch Pasteurizers, and HTST; and HHST ~~and~~ Aseptic Processing Pasteurization Systems

Make the following changes to SECTION 1. DEFINITIONS on Pages 1-11:

B. ASEPTIC PROCESSING AND PACKAGING: The term “Aseptic Processing and Packaging”, when used to describe a milk or milk product, means that the milk or milk product has been subjected to sufficient heat processing and packaged in a hermetically sealed container, to conform to the applicable requirements of 21 CFR Parts 108, 110 and 113 (~~Refer to the Reference in Appendix L.~~) ~~and the provisions of Section 7, Item 16p of this Ordinance,~~ and to maintain the commercial sterility of the product under normal non-refrigerated conditions.

C. ASEPTIC PROCESSING AND PACKAGING SYSTEM (APPS): For the purposes of this Ordinance, the Aseptic Processing and Packaging System in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade "A" milk or milk products. The APPS shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The APPS shall begin at the constant level tank and end at the discharge of the packaging machine, provided that the Process Authority may provide written documentation which will clearly define additional processes or equipment that are considered critical to the commercial sterility of the product.

CD. AUTOMATIC MILKING INSTALLATION (AMI):

Re-letter remaining definitions accordingly.

V. LOW-ACID ASEPTIC MILK AND MILK PRODUCTS: Milk or milk products having a water activity (a_w) greater than 0.85 and a finished equilibrium pH greater than 4.6 and are regulated under 21 CFR Parts 108, 110 and 113. Aseptically processed and packaged low-acid milk and milk products are stored under normal non-refrigerated conditions. Excluded from this definition are low-acid milk and milk products that are labeled for storage under refrigerated conditions.

Re-letter remaining definitions accordingly.

VX. MILK PLANT: A milk plant is any place, premises, or establishment where milk or milk products are collected, handled, processed, stored, pasteurized, ultra-pasteurized,

aseptically processed and packaged, condensed, dried, packaged, or prepared for distribution.

*Re-letter remaining Definitions accordingly and make specific Definition re-lettering citations throughout the **PMO** on Pages 6 (QQ to SS), 79, 81, 89-93, 100 (all FF to HH), 127 (II to KK), 176 and 359 (FF to HH and MM to OO).*

*Make the following changes to **SECTION 4. LABELING** on Pages 15 and 16:*

Page 15

All bottles, containers and packages containing milk or milk products, except milk tank trucks, storage tanks and cans of raw milk from individual dairy farms, shall be conspicuously marked with:

1. The identity of the milk plant where pasteurized, ultra-pasteurized, aseptically processed and packaged, condensed and/or dried.
2. The words "keep refrigerated after opening" in the case of aseptically processed and packaged milk and milk products.....

Page 16

ADMINISTRATIVE PROCEDURES

IDENTITY LABELING: "Identity", as used in this Section, is defined as the name and address or permit number of the milk plant at which the pasteurization, ultra-pasteurization, aseptic processing and packaging, condensing and/or drying takes place. It is recommended that the voluntary national uniform coding system for the identification of milk plants, at which milk and milk products are packaged, be adopted in order to provide a uniform system of codes throughout the country.

In cases where several milk plants are operated by one firm, the common firm name may be utilized on milk bottles, containers and packages. Provided, that the location of the milk plant at which the contents were pasteurized, ultra-pasteurized, aseptically processed and packaged, condensed and/or dried is also shown, either directly or by a code. This requirement is necessary in order to enable the Regulatory Agency to identify the source of the pasteurized, ultra-pasteurized, aseptically processed and packaged, condensed and/or dried milk or milk products. The street address of the milk plant need not be shown when only one (1) milk plant of a given name is located within the municipality.....

MISLEADING LABELS: The Regulatory Agency shall not permit the use of any misleading marks, words or endorsements upon the label. They may permit the use of registered trade designs or similar terms on the bottle cap or label, when in their opinion, they are not misleading and are not so used as to obscure the labeling required by this *Ordinance*. For dry milk products, the outer bag must be preprinted "Grade "A" before

filling. The use of super grade designations shall not be permitted. However, this should not be construed as prohibiting the use of official grade designations awarded to dry milk products by the United States Department of Agriculture (USDA). Grade designations such as "Grade "AA" Pasteurized", "Selected Grade "A" Pasteurized", "Special Grade "A" Pasteurized", etc., give the consumer the impression that such a grade is significantly safer than Grade "A". Such an implication is false, because the *Ordinance* requirements for Grade "A" pasteurized, ultra-pasteurized, or aseptically processed and packaged milk and milk products when properly enforced, will ensure that this grade of milk and milk products will be as safe as ~~milk~~ they can practically be made. Descriptive labeling terms must not be used in conjunction with the Grade "A" designation or name of the milk or milk product and must not be false or misleading.

Make the following changes to SECTION 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS on Pages 17-20:

Page 17

3. Inspect each milk plant and receiving station at least once every three (3) months, ~~except~~ provided that, for those milk plants and receiving stations that have HACCP Systems, which are regulated under the NCIMS HACCP Program, regulatory audits shall replace the regulatory inspections described in this Section. The requirements and minimum frequencies for these regulatory audits are specified in Appendix K. Provided further, that regulatory inspections of a milk plant or portion of a milk plant that is IMS listed to produce aseptically processed and packaged milk or milk products shall be conducted by the State Regulatory Agency in accordance with this Ordinance at least once every six (6) months. (Refer to Appendix S.) The milk plant's APPS shall be inspected by FDA, or the State Regulatory Agency when designated by FDA, in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113 at a frequency determined by FDA.

Page 18

The Regulatory Agency shall take immediate action to prevent further movement of such milk or milk product until such violations of critical processing element(s) have been corrected. Should correction of such critical processing element(s) not be accomplished immediately, the Regulatory Agency shall take prompt action to suspend the permit as provided for in Section 3 of this *Ordinance*. ~~Provided, that in the case of milk plants producing aseptically processed milk and milk products, when an inspection of the milk plant and its records reveal that the process used has been less than the required scheduled process, it shall be considered an imminent hazard to public health and the Regulatory Agency shall take immediate action to suspend the permit of the milk plant for the sale of aseptically processed milk and milk products in conformance with Section 3 of this Ordinance.~~

Page 19

ADMINISTRATIVE PROCEDURES

INSPECTION FREQUENCY: For the purposes of determining the inspection frequency for dairy farms, ~~and transfer stations~~ and milk plants or the portion of a milk plant that is IMS listed to produce aseptically processed and packaged milk or milk products, the interval shall include the designated six (6) month period plus the remaining days of the month in which the inspection is due.

For the purposes of determining the inspection frequency for all other milk plants and receiving stations the interval shall include the designated three (3) month period plus the remaining days of the month in which the inspection is due.

One (1) milk tank truck inspection every twelve (12) months; or bulk milk hauler/sampler's or industry plant sampler's pickup and sampling procedures inspection each twenty-four (24) months; or one (1) producer, transfer station, milk plant or portion of a milk plant that is IMS listed to produce aseptically processed and packaged milk or milk products or milk tank truck cleaning facility inspection every six (6) months; or one (1) milk plant producing pasteurized, ultra-pasteurized, condensed or dried milk and milk products or receiving station inspection every three (3) months is not a desirable frequency, it is instead a legal minimum.

ENFORCEMENT PROCEDURES: This Section provides that a dairy farm, bulk milk hauler/sampler, milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor, ~~except those processing aseptically processed milk and milk products~~ shall be subject to suspension of permit and/or court action if two (2) successive inspections disclose a violation of the same requirement.

Page 20

ENFORCEMENT PROCEDURES - ASEPTIC PROCESSING AND PACKAGING MILK PLANTS: ~~Because aseptically processed milk and milk products are stored at room temperature and are not refrigerated after processing they must be considered an imminent hazard to public health whenever it is revealed by an inspection or a review of the processing records that the process is less than the required scheduled process and the products produced have not maintained their commercial sterility. Prompt action by the Regulatory Agency to suspend the permit must be initiated in order to protect the public health. The Regulatory Agency shall stop the sale of all under processed milk or milk product and follow at least the minimum requirements of 21 CFR 113.89 before releasing any product. (Refer to Appendix L.)~~ The State Regulatory Agency shall take appropriate regulatory action, in coordination with FDA when applicable, to assure that the Grade "A" aseptic milk plant and the Grade "A" aseptic milk and milk products meet the applicable requirements of this Ordinance.

Make the following changes to SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS on Pages 23-26:

Page 23

1. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization, or aseptic processing and packaging shall be collected from each producer, in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained under the direction of the Regulatory Agency or shall be taken from each producer under the direction of the Regulatory Agency and delivered in accordance with this Section.

2. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization or aseptic processing and packaging, shall be collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained by the Regulatory Agency, from each milk plant after receipt of the milk by the milk plant and prior to pasteurization, ultra-pasteurization or aseptic processing and packaging.

4. During any consecutive six (6) months, at least four (4) samples of pasteurized milk, ultra-pasteurized milk, flavored milk, flavored reduced fat or low fat milk, flavored nonfat (skim) milk, each fat level of reduced fat or low fat milk and each milk product defined in this *Ordinance*, shall be collected by the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days from every milk plant. All pasteurized and (including Aseptically Processed and Ultra-Pasteurized) ultra-pasteurized milk and milk products required sampling and testing is to be done only when there are test methods available that are validated by FDA and accepted by the NCIMS. Products with no validated and accepted methods are not required to be tested. Aseptically processed and packaged milk and milk products shall be exempt from the sampling and testing requirements of this Item

Required bacterial counts, somatic cell counts and cooling temperature checks shall be performed on raw milk for pasteurization, ultra-pasteurization or aseptic processing and packaging. In addition, drug tests on each producer's milk shall be conducted at least four (4) times during any consecutive six (6) months.

Page 24

All pasteurized (including Aseptically Processed and Ultra-Pasteurized) ultra-pasteurized milk and milk products required sampling and testing to be done only when there are test methods available that are validated by FDA and accepted by the NCIMS, otherwise there would be no requirement for sampling. Required bacterial counts, coliform counts, drug tests, phosphatase and cooling temperature determinations shall be performed on Grade "A" pasteurized and ultra-pasteurized milk and milk products defined in this *Ordinance* only when there are validated and accepted test methodology.

NOTE: When multiple samples of the same milk or milk products, except for aseptically processed and packaged milk and milk products, are collected from the same producer or processor from multiple tanks or silos on the same day, the laboratory results are

averaged arithmetically by the Regulatory Agency and recorded as the official results for that day. This is applicable for bacterial (standard plate count and coliform), somatic cell count and temperature determinations only.

Whenever two (2) of the last four (4) consecutive bacterial counts (~~except those for aseptically processed milk and milk products~~), somatic cell count, coliform determinations, or cooling temperatures, taken on separate days, exceed the standard for the milk and/or milk products as defined in this *Ordinance*, the Regulatory Agency shall send a written notice thereof to the person concerned. This notice shall be in effect as long as two (2) of the last four (4) consecutive samples exceed the standard. An additional sample shall be taken within twenty-one (21) days of the sending of such notice, but not before the lapse of three (3) days. Immediate suspension of permit, in accordance with Section 3, and/or court action shall be instituted whenever the standard is violated by three (3) of the last five (5) bacterial counts (~~except those for aseptically processed milk and milk products~~), somatic cell counts, coliform determinations or cooling temperatures.

~~Whenever a container or containers of aseptically processed milk or milk product is found to be non-sterile, due to under processing, the Regulatory Agency shall consider this to be an imminent hazard to public health and shall suspend the permit of the milk plant for the sale of aseptically processed milk and milk products. No aseptically processed milk and milk product shall be sold until it can be shown that the processes, equipment and procedures used are suitable for consistent production of a sterile product. All products from the lot that were found to contain one (1) or more non-sterile units shall be recalled and disposed of as directed by the Regulatory Agency.~~

Samples shall be analyzed at an appropriate official or officially designated laboratory. All sampling procedures, including the use of approved in-line samplers and aseptic samplers for milk tank trucks, and required laboratory examinations shall be in substantial compliance with the most current edition of *Standard Methods for the Examination of Dairy Products* (SMEDP) of the American Public Health Association, and the most current edition of *Official Methods of Analysis of AOAC INTERNATIONAL* (OMA). Such procedures, including the certification of sample collectors and examinations shall be evaluated in accordance with the *Procedures*. ~~Aseptically processed milk and milk products packaged in hermetically sealed containers shall be tested in accordance with FDA's *Bacteriological Analytical Manual* (BAM).~~

Page 25

Assays of milk and milk products as defined in this *Ordinance*, including aseptically processed and packaged milk and milk products, to which vitamin(s) A and/or D have been added for fortification purposes, shall be made at least annually in a laboratory, which has been accredited by FDA and which is acceptable to the Regulatory Agency, using test methods acceptable to FDA or other official methodologies, which gives statistically equivalent results to the FDA methods. Vitamin testing laboratories are accredited if they have one (1) or more certified analysts and meet the quality control

requirements of the program established by FDA. Laboratory accreditation and analyst certification parameters are specified in the Evaluation of Milk Laboratories (EML) manual.

ADMINISTRATIVE PROCEDURES

ENFORCEMENT PROCEDURES: All violations of bacteria, coliform, confirmed somatic cell counts and cooling temperature standards should be followed promptly by inspection to determine and correct the cause. (Refer to Appendix E. Examples of Three (3)-out-of-Five (5) Compliance Enforcement Procedures)

~~Aseptically processed milk and milk products packaged in hermetically sealed containers are exempt from the refrigerated storage requirements of this Ordinance. Therefore, whenever a breakdown in the processing or packaging of these products occurs an imminent hazard to public health exists. Prompt action is needed by the Regulatory Agency. Milk plants aseptically processing milk and milk products in hermetically sealed containers should be encouraged to perform bacterial and other quality tests on each lot of aseptically processed milk and milk product produced in order to ascertain that these products have been properly processed and have not been rendered non-sterile after aseptic processing and packaging. The Regulatory Agency may utilize industry records, of each lot of aseptically processed milk and milk products, to determine when lots can be released for sale after a violation of the bacterial standards has existed.~~

Make the following changes to SECTION 7. STANDARDS FOR GRADE "A" MILK AND MILK PRODUCTS on Pages 28-31:

Page 28

All Grade "A" raw milk or milk products for pasteurization, or ultra-pasteurization, or aseptic processing and packaging and all Grade "A" pasteurized, ultra-pasteurized or aseptically processed and packaged milk and milk products, shall be produced, processed, manufactured and pasteurized, ultra-pasteurized, or aseptically processed and packaged to conform to the following chemical, physical, bacteriological and temperature standards and the sanitation requirements of this Section.

No process or manipulation other than pasteurization, ultra-pasteurization or aseptic processing and packaging; processing methods integral therewith; and appropriate refrigeration shall be applied to milk and milk products for the purpose of removing or deactivating microorganisms, provided that filtration and/or bactofugation processes are performed in the milk plant in which the milk or milk product is pasteurized, ultra-pasteurized or aseptically processed and packaged. Provided, that in the bulk shipment of cream, nonfat (skim) milk or reduced fat or lowfat milk, the heating of the raw milk, one time, to temperatures greater than 52°C (125°F) but less than 72°C (161°F), for separation purposes, is permitted when the resulting bulk shipment(s) of cream, nonfat (skim) milk or reduced fat or lowfat milk are labeled heat-treated. In the case of heat-treated cream, the cream may be further heated to less than 75°C (166°F) in a continuing heating process and immediately cooled to 7°C (45°F) or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason.

Table 1. Chemical, Physical, Bacteriological, and Temperature Standards

<p>GRADE "A" RAW MILK AND MILK PRODUCTS FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING AND PACKAGING</p>	<p>Temperature.....</p>	<p>Cooled to 10°C (50°F) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C (45°F) or less within two (2) hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F). NOTE: Milk sample submitted for testing cooled and maintained at 0°C (32°F) to 4.4°C (40°F), where sample temperature is >4.4°C (40°F), but ≤7.0°C (45°F) and less than three (3) hours after collection has not increased in temperature.</p>
	<p>Bacterial Limits.....</p>	<p>Individual producer milk not to exceed 100,000 per mL prior to commingling with other producer milk. Not to exceed 300,000 per mL as commingled milk prior to pasteurization. NOTE: Tested in conjunction with the drug residue/inhibitory substance test.</p>
	<p>Drugs.....</p>	<p>No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques.</p>
	<p>Somatic Cell Count*..</p>	<p>Individual producer milk not to exceed 750,000 per mL.</p>
<p>GRADE "A" PASTEURIZED MILK AND MILK PRODUCTS AND BULK SHIPPED HEAT-TREATED MILK PRODUCTS</p>	<p>Temperature.....</p>	<p>Cooled to 7°C (45°F) or less and maintained thereat. NOTE: Milk sample submitted for testing cooled and maintained at 0°C (32°F) to 4.4°C (40°F), where sample temperature is >4.4°C (40°F), but ≤7.0°C (45°F) and less than three (3) hours after collection has not increased in temperature.</p>
	<p>Bacterial Limits**.....</p>	<p>Not to exceed 20,000 per mL, or gm.*** NOTE: Tested in conjunction with the drug residue/inhibitory substance test.</p>

	Coliform****	Not to exceed 10 per mL. Provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per mL. NOTE: Tested in conjunction with the drug residue/inhibitory substance test.
	Phosphatase*****	Less than 350 milliunits/L for fluid products and other milk products by approved electronic phosphatase procedures.
	Drugs* *.....	No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques which have been found to be acceptable for use with pasteurized and heat-treated milk and milk products.
GRADE "A" PASTEURIZED CONCENTRATED (CONDENSED) MILK AND MILK PRODUCTS	Temperature.....	Cooled to 7°C (45°F) or less and maintained thereat unless drying is commenced immediately after condensing.
	Coliform.....	Not to exceed 10 per gram. <i>Provided</i> , that in the case of bulk milk transport tank shipments shall not exceed 100 per gram.
GRADE "A" ULTRA-PASTEURIZED MILK AND MILK PRODUCTS	Temperature.....	Cooled to 7°C (45°F) or less and maintained thereat.
	Bacterial Limits**	Not to exceed 20,000 per mL, or gm.***
	Coliform****	Not to exceed 10 per mL. Provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per mL.
	Phosphatase*****	Phosphatase testing of Ultra-Pasteurized milks is not required.
	Drugs**	There are no validated and accepted drug residue tests for Ultra-Pasteurized Milk and Milk Products
GRADE "A" ASEPTICALLY PROCESSED AND PACKAGED MILK AND MILK PRODUCTS	Temperature.....	None.
	Bacterial Limits.....	Refer to 21 CFR 113.3(e)(1)*****
	Drugs**	There are no validated and accepted drug residue tests for Aseptically Processed Milk and Milk Products.

GRADE "A" NONFAT DRY MILK	Butterfat..... Moisture..... Titratable Acidity.... Solubility Index..... Bacterial Estimate... Coliform..... Scorched Particles disc B.....	No More Than: 1.25% 4.00% 0.15% 1.25mL. 30,000 per gram 10 per gram 15.0 per gram
GRADE "A" WHEY FOR CONDENSING AND/OR DRYING	Temperature.....	Maintained at a temperature of 45°F (7°C) or less, or 57°C (135°F) or greater, except for acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below.
GRADE "A" PASTEURIZED CONDENSED WHEY AND WHEY PRODUCTS	Temperature.....	Cooled to 10°C (50°F) or less during crystallization, within 72 hours of condensing.
	Coliform Limit.....	Not to exceed 10 per gram.
GRADE "A" DRY WHEY, GRADE "A" DRY WHEY PRODUCTS, GRADE "A" DRY BUTTERMILK, AND GRADE "A" DRY BUTTERMILK PRODUCTS	Coliform Limit.....	Not to exceed 10 per gram.

* Goat Milk 1,500,000/mL

** Not applicable to acidified or cultured products, eggnog and flavored (non-chocolate) milk and milk products.

Page 31

*** Results of the analysis of dairy products which are weighed in order to be analyzed will be reported in # per gm. (Refer to the current edition of the *SMEDP*)

**** Not applicable to bulk shipped heat-treated milk products.

***** Not applicable to bulk shipped heat-treated milk products; UP products that have been thermally processed at or above 138°C (280°F) for at least two (2) seconds to produce a product which has an extended shelf life (ESL) under refrigerated conditions; and condensed products.

***** 21 CFR 113.3(e)(1) contains the definition of "COMMERCIAL STERILITY".

STANDARDS FOR GRADE “A” RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING AND PACKAGING

Make the following changes to SECTION 7. STANDARDS FOR GRADE “A” PASTEURIZED, ULTRA-PASTEURIZED AND ASEPTICALLY PROCESSED MILK AND MILK PRODUCTS on Page 55:

Page 55

STANDARDS FOR GRADE “A” PASTEURIZED, ULTRA-PASTEURIZED AND ASEPTICALLY PROCESSED AND PACKAGED MILK AND MILK PRODUCTS

Milk plants shall comply with all Items of this Section. Provided, in the case of milk plants or portions of milk plants that are IMS Listed to produce aseptically processed and packaged milk or milk products, the APPS, as defined by this Ordinance, shall be exempt from Items 7p, 10p, 11p, 12p, 13p, 15p, 16p, 17p, 18p, and 19p of this Ordinance and shall comply with the applicable portions of 21 CFR Parts 108, 110 and 113. Those Items, contained within the APPS, shall be inspected by FDA or a State Regulatory Agency, when designated by FDA.

Milk plants that have HACCP Systems, which are regulated under the NCIMS HACCP Program, shall comply with all of the requirements of Item 16p. Pasteurization and Aseptic Processing and Packaging of this Ordinance, and pasteurization shall be managed as a CCP as described in Appendix H. VIII- MILK AND MILK PRODUCT CONTINUOUS-FLOW (HTST AND HHST) PASTEURIZATION---CCP MODEL HACCP PLAN SUMMARY; and MILK AND MILK PRODUCT VAT (BATCH) PASTEURIZATION---CCP MODEL HACCP PLAN SUMMARY.

Make the following changes to ITEM 1p. FLOORS - CONSTRUCTION on Page 56:

Page 56

ADMINISTRATIVE PROCEDURES

3. The floors are provided with trapped drains. Cold-storage rooms used for storing milk and milk products need not be provided with floor drains when the floors are sloped to drain to one or more exits. Storage rooms for dry ingredients, dry packaged milk or milk products, aseptically processed and packaged milk or milk products and/or packaging materials need not be provided with drains.

Make the following changes to ITEM 2p. WALLS AND CEILINGS - CONSTRUCTION on Page 57:

Page 57

NOTE: Refer to Item 11p for requirements for walls for drying chambers. Storage rooms used for the storage of packaged dry milk or milk products and aseptically processed and packaged milk or milk products are exempt from the ceiling requirements of this Item.

Make the following changes to ITEM 5p. SEPARATE ROOMS on Page 58:

Page 58

4. The fabrication of containers and closures for milk and milk products, except for aseptically processed and packaged milk and milk products that are fabricated within the APPS.

Make the following changes to ITEM 11p. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT on Page 66:

Page 66

ADMINISTRATIVE PROCEDURES

12. Provided that all paper, plastics, foil, adhesives, and other components of containers and closures used in the packaging of milk or milk products that have been aseptically processed are governed under the applicable provisions of 21 CFR Parts 110 and 113 and shall not be subject to this Section.

Make the following changes to ITEM 12p. CLEANING AND SANITIZATION OF CONTAINERS AND EQUIPMENT on Pages 66 and 70:

Page 66

The product-contact surfaces of all multi-use containers, utensils and equipment used in the transportation, processing, condensing, drying, packaging, handling, and storage of milk or milk products shall be effectively cleaned and shall be sanitized before each use. Provided, that cloth-collector systems used on dryers shall be cleaned and sanitized or purged at intervals and by methods recommended by the manufacturer and approved by the Regulatory Agency. ~~Provided further, that piping, equipment and containers used to process, conduct or package aseptically processed milk and milk products, beyond the final heat treatment process, shall be sterilized before any aseptically processed milk or milk product is packaged and shall be re-sterilized whenever any non-sterile product has contaminated it.~~

ADMINISTRATIVE PROCEDURES

5. All multi-use containers, utensils and equipment are sanitized before use, employing one or a combination of the methods prescribed under Item 11r. Additionally, for milk plants that condense or dry milk or milk products the following methods are acceptable, or any other method, which has been demonstrated to be equally efficient:

- a. Exposure to an enclosed jet of steam for not less than 1 minute.
- b. Exposure to hot air at a temperature of at least 83°C (180°F) for at least twenty (20) minutes as measured by an acceptable indicating thermometer located in the coldest zone. Assembled equipment must be sanitized prior to each day's run, unless FDA and the Regulatory Agency have reviewed and accepted information supporting the sanitizing of multi-use containers, utensils and equipment at frequencies extending beyond one (1) day. Tests to determine the efficiency of sanitization should be made by the Regulatory Agency at intervals sufficient to satisfy the Regulatory Agency that the sanitization process is effective. ~~Provided, that all piping, equipment and containers used to conduct, process or package aseptically processed milk and milk products, beyond the final heat treatment process, shall be sterilized by heat, chemical sterilant(s) or other appropriate treatment before use and re-sterilized whenever it has been contaminated by nonsterile product.~~

Make the following changes to ITEM 15p. PROTECTION FROM CONTAMINATION on Pages 78 and 79:

15p.(B)

Page 78

c. In the case of ~~aseptically processed and~~ higher-heat-shorter-time (HHST) pasteurized milk and milk products that are processed and the equipment cleaned and/or chemically sanitized above the atmospheric boiling point of the milk or milk product or cleaning and/or sanitizing solutions, the required separation between pipe lines and equipment, used to contain or conduct milk and milk products, and tanks or circuits containing cleaning and/or chemical sanitizing solutions, may be accomplished using an alarmed steam block(s), located between the milk and milk product and cleaning and/or chemical sanitizing solutions if:

(4) The temperature sensor is integrated with automatic controls, such that when there is milk or milk products on one (1) side of the steam block and cleaning and/or chemical sanitizing solutions on the other side of the steam block, and the temperature sensor in the steam trace detects a temperature that indicates that liquid, rather than steam, is present in the steam trace, the cleaning pump will be de-energized, and when needed to prevent solution pressure on the steam block, the cleaning and/or chemical sanitizing solution are automatically drained away from the steam block. Except that:

i) ~~In~~ in systems where the cleaning and/or sanitizing solution is circulated by the timing pump, that pump may continue to operate during an alarmed condition, provided a legal flow-diversion device (FDD) is used to divert the cleaning and/or chemical sanitizing solution flow away from the steam block.

ii) ~~In aseptic processing systems that are not equipped with a legal FDD and where the cleaning and/or sanitizing solution is circulated by the timing pump of the aseptic processing system, that pump may continue to operate during an alarmed condition, provided there are at least two (2) instrumented steam blocks between the milk and milk product and the cleaning and/or chemical sanitizing solutions and at least one (1) of the blocks remains uncompromised.~~

NOTE: The valve arrangement(s) described in this Section shall not be used to separate raw products, dairy, non-dairy or water, from pasteurized milk or milk products. Provided that, nothing in this Section shall be construed as barring any other means to separate milk and milk product from cleaning/sanitizing solution in systems, which have been recognized by FDA ~~and in the case of aseptic processing equipment, by the Processing Authority,~~ to be equally effective and which are approved by the Regulatory Agency.

*Make the following changes to **ITEM 16p. PASTEURIZATION AND ASEPTIC PROCESSING** on Page 81:*

ITEM 16p. PASTEURIZATION AND ASEPTIC PROCESSING AND PACKAGING

Pasteurization shall be performed as defined in Section 1, Definition ~~FF~~ HH and Item 16p of this *Ordinance*. Aseptic processing and packaging shall be performed in accordance with the applicable requirements of 21 CFR Parts ~~113~~, 108, 110 and 113 the ADMINISTRATIVE PROCEDURES of Item 16p, sub-items (C), (D) and (E) of this Section. (Refer to Appendix L.)

A note of caution is in order. Although pasteurization destroys the organisms, it does not destroy the toxins that may be formed in milk and milk products when certain staphylococci are present, as from udder infections, and when the milk or milk product is not properly refrigerated before pasteurization. Such toxins may cause severe illness. Aseptic processing and packaging has also been conclusively demonstrated to be effective in preventing outbreaks from milkborne pathogens. Numerous studies and observations clearly prove that the food value of milk is not significantly impaired by pasteurization.

*Make the following changes to **ITEM 16p. PASTEURIZATION AND ASEPTIC PROCESSING** on Page 84:*

ADMINISTRATIVE PROCEDURES

Page 84

6. The design and operation of pasteurization equipment and all appurtenances thereto shall comply with the applicable specifications and operational procedures of Subitems (A), (B), (~~DC~~) and (~~ED~~).

Make the following changes to ITEM 16p.(A) BATCH PASTEURIZATION on Page 88:

ADMINISTRATIVE PROCEDURES

Page 88

5. RECORDING CHARTS:

All recording thermometer charts shall comply with all the applicable requirements of Item 16p(~~ED~~)1.a.

Make the following changes to ITEM 16p.(B) HIGH-TEMPERATURE-SHORT-TIME (HTST) CONTINUOUS-FLOW PASTEURIZATION on Page 92:

ADMINISTRATIVE PROCEDURES

Page 92

e. Indicating and Recording Thermometers:

(3) The recorder/controller charts shall comply with the applicable provisions of Item 16p(~~ED~~)1.a.

Make the following changes to ITEM 16p.(C) ASEPTIC PROCESSING SYSTEMS on Pages 95-98:

Pages 95-98

ITEM 16p.(C) ASEPTIC PROCESSING SYSTEMS PUBLIC HEALTH REASON

~~Aseptically processed milk and milk products are being packaged in hermetically sealed containers and stored for long periods of time under non-refrigerated conditions. These conditions are favorable to the growth of many types of bacteria, including pathogenic, toxin producing and spoilage organisms. Because of this, every precaution must be taken~~

to ensure that the chosen heat process, for the particular milk or milk product, destroys all viable organisms and their spores. The subsequent handling, packaging and storage processes do not provide an opportunity for recontamination of the milk or milk product. The selected process must conform to the acceptable requirements for low acid canned foods.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

The design and operation of aseptic processing systems comply with the applicable specifications and operational procedures of Item 16p, sub items (C), (D) and (E). Provided, that nothing shall be construed as barring any other aseptic processing system which have been recognized by FDA to be equally effective and which is approved by the Regulatory Agency.

1. INDICATING THERMOMETERS AND RECORDER/CONTROLLER INSTRUMENTS:

All indicating thermometers, recorder/controller instruments and devices, used in connection with aseptic processing systems, used for the aseptic processing of milk or milk products shall comply with the applicable specifications set forth in Appendix H.

2. ASEPTIC PROCESSING EQUIPMENT:

a. **Temperature Indicating Device:** Each aseptic processing system shall be equipped with at least one (1) mercury in glass thermometer or an equivalent temperature indicating device.

b. **Temperature Recorder/Controller:** An accurate temperature recorder/controller shall be installed in the milk or milk product at the holding tube outlet and before the inlet to the cooler or regenerator. The following requirements shall be met with respect to the instrumentation of the temperature recorder/controller:

(1) The temperature recorder/controller shall be set and sealed so that during milk or milk product processing the forward flow of milk or milk product cannot start unless the temperature at the controller sensor is above the required temperature for the milk or milk product and the process used, nor continue during descending temperatures when the temperature is below the required temperature.

The seal shall be applied by the Regulatory Agency after testing and shall not be removed without immediately notifying the Regulatory Agency. The system shall be so designed that no milk or milk product can be bypassed around the controller sensor, which shall not be removed from its proper position during the processing of aseptic milk and milk products.

(2) Additional temperature controllers and timers shall be interwired with the thermal limit controller, and the control system shall be set and sealed so that forward flow of milk or milk product cannot start until all product contact surfaces between the holding tube and FDD have been held at or above the required sterilization temperature, continuously and simultaneously for at least the required sterilization time. The control system shall also be set and sealed so that forward flow cannot continue when the temperature of the milk or milk product in

~~the holding tube is below the required temperature. The seal shall be applied by the Regulatory Agency after being tested and shall not be removed without immediately notifying the Regulatory Agency. The system shall be so designed that no milk or milk product can be bypassed around the control sensors, which shall not be removed from their proper position during the processing of aseptic milk and milk products.~~

~~(3) Manual switches for the control of pumps, homogenizers or other devices that produce flow through the holding tube, shall be wired so that the circuit is completed only when the milk or milk product is above the required temperature for the milk or milk product and the process used, or when the FDD is in the fully diverted position.~~

~~e. **Timing Pump:**~~

~~(1) A positive displacement type timing pump located upstream from the holding tube, or a magnetic flow meter based timing system, which complies with the specifications as outlined in Appendix H, shall be operated to maintain the required rate of milk or milk product flow. The motor of the timing pump shall be connected by means of a common drive shaft, or by means of gears, pulleys or a variable speed drive, with the gear box, the pulley box or the setting of the variable speed protected in such a manner that the hold time cannot be shortened without detection by the Regulatory Agency. This shall be accomplished by the application of a suitable seal(s) after being tested by the Regulatory Agency and such seal(s) shall not be broken without immediately notifying the Regulatory Agency. This provision shall apply to all homogenizers used as timing pumps. Variable speed drives, used in connection with the timing pump, shall be so constructed that wearing or stretching of the belt results in a slowdown, rather than a speedup, of the pump. The timing pump shall be of the positive-displacement type or shall comply with the specifications for magnetic flow meter based timing systems.~~

~~(2) The holding time shall be taken to mean the flow time of the fastest particle of milk or milk product throughout the holding tube section, i.e., that portion of the system that is outside of the influence of the heating medium; and slopes continuously upward in the downstream direction; and is located upstream from the FDD.~~

~~d. **Milk or Milk Product Holding Tube:**~~

~~(1) The milk or milk product holding tube shall be designed to give continuous holding of every particle of milk or milk product for at least the minimum holding time specified in the scheduled process. The holding tube shall be designed, so that no portion of the holding tube between the milk or milk product inlet and the milk or milk product outlet can be heated. In addition, it must be sloped upward at least 2.1 centimeters per meter (0.25 of an inch per foot). Supports for holding tubes shall be provided to maintain all parts of the holding tubes in a fixed position, free from any lateral or vertical movement.~~

~~(2) No device shall be permitted for short circuiting a portion of the holding tube to compensate for changes in rate of milk or milk product flow. Holding tubes shall be installed so that sections of pipe cannot be left out, resulting in a~~

shortened holding time. The holding time for the processes must be determined from the pumping rate, rather than by the salt conductivity test.

(3) The holding tube length must be such that the fastest flowing particle of any milk or milk product will not traverse the holding tube in less than the required holding time.

NOTE: With the direct addition of steam, the holding time is reduced because the milk or milk product volume increases as the steam condenses to water during heating. This surplus water is evaporated as the aseptically processed milk or milk product is cooled in the vacuum chamber. For example, with a 66°C (120°F) increase by steam injection, which is probably the maximum temperature rise that will be used, a volume increase of twelve percent (12%) will occur in the holding tube. The measurement of the average flow rate at the discharge of the aseptic processor does not reflect this volume increase in the holding tube. However, this volume increase, i.e., holding time decrease, must be considered in the calculations.

(4) An aseptic processing system which can operate with milk or milk product in forward flow mode, with less than 518 kPa (75 psig) pressure in the holding tube shall be equipped with a pressure limit indicator/pressure switch in the holding tube to assure that the heated milk or milk product remains in the liquid phase. In systems that do not have a vacuum chamber between the holding tube and the aseptic milk or milk product side of the regenerator, this can be established by verifying that the aseptic processing equipment cannot operate in forward flow with less than 518 kPa (75 psig) pressure on the aseptically processed side of the regenerator. (Refer to Appendix I, Test 9). The pressure limit indicator/pressure switch must be interwired so that the FDD, milk or milk product divert system, milk or milk product divert valve or other acceptable control system will move to the divert position, if the milk or milk product pressure falls below a prescribed value. The instrument must be set at a pressure 69 kPa (10 psi) above the boiling pressure of the milk or milk product at its maximum temperature in the holding tube. If this pressure is too low, the resultant vaporization in the holding tube will substantially reduce residence times.

(5) With the steam injection process, a differential pressure limit indicator, across the injector, is needed to ensure adequate isolation of the injection chamber. The instrument must have a differential pressure switch so that the FDD will move to the divert position if the pressure drop across the injector falls below 69 kPa (10 psi).

e. **Heating by Direct Addition of Steam:** Steam injection is an inherently unstable process; accordingly, when steam is injected into a fluid, condensation of the steam may not be completed inside the injector unless the proper design criteria are used. Lack of complete condensation inside the injector would cause temperature variations in the holding tube, which could lead to some milk or milk product particles being processed below filed process temperature. When culinary steam is injected directly into milk or milk products, as the means of terminal heating to achieve aseptic processing temperature, the steam injector shall be designed, installed and operated to comply with the following or equally satisfactory specifications:

~~(1) The milk or milk product and steam flows must be isolated from pressure fluctuations inside the injection chamber. One (1) method of isolation is to insert supplementary orifices on the milk or milk product inlet and the heated milk or milk product outlet of each injector. The two (2) supplementary orifices must be sized for at least a 69 kPa (10 psi) milk or milk product pressure drop across the injector during a simulation of normal operations. Excessive vibrations, pressure fluctuations or erratic noise levels indicate an unstable steam injection system and a need to check the isolation of the injection chamber.~~

~~(2) The process should be as free as possible of non-condensable gases that may evolve from the milk or milk product or be carried in the steam supply. Any two (2) phase flow, caused by the non-condensable gases, would displace the milk or milk product in the holding tube, resulting in reduced residence times. In addition, these gases in the steam supply may also markedly alter the condensation mechanism at the point of injection. Accordingly, the steam boiler shall be supplied with a de-aerator. The de-aerator will aid in keeping the milk or milk product in the holding tube as free as possible of non-condensable gases.~~

~~f. **Prevention of Milk or Milk Product Adulteration with Added Water:**~~

~~(1) When culinary steam is introduced directly into the milk or milk product, automatic means, i.e., stand-alone and/or PLC-based ratio control system, shall be provided to maintain a proper temperature differential between incoming and outgoing milk or milk products to preclude dilution with water.~~

~~(2) Where a water feed line is connected to a vacuum condenser and the vacuum condenser is not separated from the vacuum chamber by a physical barrier, means shall be provided to preclude the back-up and overflow of water from the vacuum condenser into the vacuum chamber. This provision may be satisfied by the use of a safety shutoff valve, located on the water feed line to the vacuum condenser that is automatically actuated by a control that shuts off the in-flowing water. This valve may be actuated by water, air or electricity and shall be so designed that failure of the primary motivating power will automatically stop the flow of water into the vacuum condenser.~~

~~g. **FDD:** All FDDs used in continuous aseptic process systems shall comply with Item 16p(B)2.b. or equally satisfactory specifications.~~

*Make the following changes to **ITEM 16p.(D) PASTEURIZERS AND ASEPTIC PROCESSING SYSTEMS EMPLOYING REGENERATIVE HEATING** on Pages 98-102:*

Page 98

**ITEM 16p.(D) PASTEURIZERS AND ASEPTIC PROCESSING SYSTEMS
EMPLOYING REGENERATIVE HEATING**

ADMINISTRATIVE PROCEDURES

This Item is deemed satisfied when:

MILK OR MILK PRODUCT-TO-MILK OR MILK PRODUCT REGENERATIVE HEATING

Pasteurizers and ~~aseptic processing systems~~ employing milk or milk product-to-milk or milk product regenerative heating with both sides closed to the atmosphere shall comply with the following or equally satisfactory specifications:

1. Regenerators shall be constructed, installed and operated so that pasteurized ~~or aseptic~~ milk or milk product in the regenerator will automatically be under greater pressure than raw milk or milk product in the regenerator at all times.
2. The pasteurized ~~or aseptic~~ milk or milk product, between its outlet from the regenerator and the nearest point downstream open to the atmosphere, shall rise to a vertical elevation of 30.5 centimeters (12 inches) above the highest raw milk or milk product level, downstream from the constant-level tank, and shall be open to the atmosphere at this or a higher elevation.
4. No pump or flow-promoting device which can affect the proper pressure relationships within the regenerator shall be located between the pasteurized ~~or aseptic~~ milk or milk product outlet from the regenerator and the nearest downstream point open to the atmosphere.
5. No pump shall be located between the raw milk or milk product inlet to the regenerator and the constant-level tank, unless it is designed and installed to operate only when milk or milk product is flowing through the pasteurized ~~or aseptic~~ milk or milk product side of the regenerator and when the pressure of the pasteurized ~~or aseptic~~ milk or milk product is higher than the maximum pressure produced by the pump. This may be accomplished by wiring the booster pump so that it cannot operate unless:
 - a. The timing pump is in operation;
 - b. The FDD is in forward-flow position; and
 - c. The pasteurized ~~or aseptic~~ milk or milk product pressure exceeds, by at least 6.9 kPa (1 psi), the maximum pressure developed by the booster pump. Pressure gauges shall be installed at the raw milk or milk product inlet to the regenerator and the pasteurized ~~or aseptic~~ milk or milk product outlet of the regenerator or the outlet of the cooler. The accuracy of these required pressure gauges shall be checked, by the Regulatory Agency, on installation; quarterly thereafter; and following repair or adjustment.
9. When vacuum equipment is located downstream from the FDD, means shall be provided to prevent the lowering of the pasteurized ~~or aseptic~~ milk or milk product level in the regenerator during periods of diverted-flow or shutdown. An effective vacuum breaker, plus an automatic means of preventing a negative pressure, shall be installed in the line between the vacuum chamber and the pasteurized ~~or aseptic~~ milk or milk product inlet to the regenerator.

10. In the case of pasteurization systems, with the FDD located downstream from the regenerator and/or cooler section, the requirements of paragraphs (2), (3), (5), (7) and (8) of this Section may be eliminated. Provided, that a differential pressure controller is used to monitor the highest pressure in the raw milk or milk product side of the regenerator and the lowest pressure in the pasteurized side of the regenerator, and the controller is interlocked with the FDD and is set and sealed so that whenever improper pressures occur in the regenerator, forward-flow of milk or milk product is automatically prevented and will not start again until all milk or milk product-contact surfaces between the holding tube and FDD have been held at or above the required pasteurization temperature, continuously and simultaneously for at least the required pasteurization time as defined in Definition FF of this *Ordinance*.

~~In the case of aseptic processing systems used for producing aseptic milk and milk products, there shall be an accurate differential pressure recorder controller installed on the regenerator. The scale divisions shall not exceed 13.8 kPa (2 psi) on the working scale of not more than 138 kPa (20 psi) per 2.54 centimeters (1 inch). The controller shall be tested for accuracy against a known accurate standard pressure indicator upon installation; at least once every three (3) months of operation thereafter; or more frequently if necessary, to ensure its accuracy. One (1) pressure sensor shall be installed at the aseptic milk or milk product regenerator outlet and the other pressure sensor shall be installed at the raw milk or milk product regenerator inlet.~~

11. When culinary steam is introduced directly into milk or milk product to achieve pasteurization ~~or aseptic processing~~ temperature, and vacuum equipment is located downstream from the holding tube, the requirement that a vacuum breaker be installed at the inlet to the pasteurized ~~or aseptic~~ side of the regenerator may be eliminated. Provided, that the differential pressure controller is installed and wired to control the FDD as described in paragraph 10 of this Section.

MILK OR MILK PRODUCT-TO-WATER-TO-MILK OR MILK PRODUCT REGENERATIVE HEATING

Page 101

OPTION II. Milk or milk product-to-water-to-milk or milk product regenerators may also be constructed, installed and operated such that the pasteurized ~~or aseptic~~ milk or milk product in the regenerator will be under greater pressure than the heat-transfer-medium in the pasteurized ~~or aseptic~~ milk or milk product side of the regenerator:

1. A differential pressure controller shall be used to monitor pressures of the pasteurized milk or milk product and the heat-transfer-medium.

~~2. In the case of aseptic processing systems, a differential pressure recorder shall be used to monitor pressures of the aseptic milk or milk product and the heat transfer-medium.~~

~~3. In either case, one~~ One (1) pressure sensor shall be installed at the pasteurized ~~or aseptic~~ milk or milk product outlet of the regenerator and the other pressure sensor shall be installed at the heat-transfer-medium inlet of the pasteurized ~~or aseptic~~ milk or milk product side of the regenerator. This controller or recorder-controller shall divert the

FDD whenever the lowest pressure of pasteurized ~~or aseptic~~ milk or milk product in the regenerator fails to exceed the highest pressure of the heat-transfer-medium in the pasteurized ~~or aseptic~~ milk or milk product side of the regenerator by at least 6.9 kPa (1 psi). Forward-flow of milk or milk product shall be automatically prevented until all milk or milk product-contact surfaces between the holding tube and the FDD have been held at or above the required pasteurization ~~or sterilization~~ temperature continuously and simultaneously for at least the pasteurization ~~or sterilization~~ time.

42. The heat-transfer-medium pump shall be wired so that it cannot operate unless the timing pump is in operation.

Make the following changes to ITEM 16p.(E) PASTEURIZATION AND ASEPTIC PROCESSING RECORDS, EQUIPMENT TESTS AND EXAMINATIONS on Pages 102-105:

Page 102

**ITEM 16p.(E) PASTEURIZATION AND ASEPTIC PROCESSING RECORDS,
EQUIPMENT TESTS AND EXAMINATIONS**

1. PASTEURIZATION AND ASEPTIC PROCESSING RECORDS:

All temperature and flow rate pasteurization recording charts or alternative records, acceptable to FDA, in place of charts shall be preserved for a period of three (3) months. ~~Provided, that all records and recording charts for aseptic milk and milk product systems shall be retained for a period of three (3) years.~~ The use of such charts shall not exceed the time limit for which they are designed. Overlapping of recorded data shall be a violation of this Item. The following information shall be entered on the charts or other records acceptable to FDA in place of charts as applicable:

Page 103

c. Continuous-Flow Pasteurizers ~~or Aseptic Processing Equipment~~ with Magnetic Flow Meter Based Timing Systems: Flow rate recording charts shall be capable of continuously recording flow at the flow alarm set point and at least 19 liters (5 gallons) per minute higher than the high flow alarm setting. Flow rate recording charts shall contain all the information specified in Subitem a. above, except (3), (4), (5), ~~and (6), and (7)~~ and in addition, shall include the following:

~~**d. Aseptic Processing Systems:** Recording thermometer charts shall contain all the information specified in Subitem a. above, except (4) and (5). In addition these records shall include Subitem c. above, if applicable, and the following:~~

- ~~(1) A continuous record of the time during which the FDD, valve or system is in the forward flow position;~~
- ~~(2) A continuous record of applicable regenerator pressures;~~
- ~~(3) Not later than one (1) working day after the actual process, and before shipment or release for distribution, a representative of the milk plant management,~~

~~who is qualified by suitable training or experience, shall review all processing and production records for completeness and to ensure that the milk or milk product received the schedule process. The records, including the recording thermometer chart(s), shall be signed or initialed and dated by the reviewer; and (4) Number (6) from above shall also be recorded immediately after a chart has been changed.~~

ed. Electronic Data Collection, Storage and Reporting: Electronic collection, storage and reporting of required pasteurization ~~and aseptic processing~~ records, with or without hard copy printouts, may be acceptable, provided, the electronically generated records are readily available at the milk plant for review by the Regulatory Agency and meet the criteria of this Section and Appendix H., V.

2. EQUIPMENT TESTS AND EXAMINATIONS:

Page 104

In the case of milk plants with HACCP Plans regulated under the NCIMS HACCP Program, pasteurization ~~and aseptic processing~~ equipment may be tested and sealed by industry personnel acceptable to the Regulatory Agency, if the following conditions are met:

- a. Test results for Pasteurization ~~and Aseptic Processing~~ Equipment Testing shall be recorded on a similar document for all milk plants. (Refer to the reference in Appendix M. for an example.)
- b. Industry personnel conducting the Pasteurization ~~and Aseptic Processing~~ Equipment Testing must be adequately trained and must be able to demonstrate an acceptable understanding and ability to conduct these tests to the Regulatory Agency.

.....

c. Pasteurization ~~and Aseptic Processing~~ Equipment Tests shall be conducted at a frequency not less than the requirements of this *Ordinance*. Industry shall have responsibility for the performance of all required tests. At least each six (6) months the Regulatory Agency shall physically supervise these tests. Regulatory supervised tests shall include the semi-annual HTST and HHST tests. These six (6) month tests should be performed at a time that is mutually convenient to all parties. Because these tests are required to support a CCP, the industry is responsible for conducting these tests even in the absence of the regulatory official.

Page 105

d. Upon initial installation or extensive modification of any pasteurization ~~and aseptic processing~~ equipment, tests shall be physically supervised or conducted by the Regulatory Agency.

f. During an audit, the auditor may conduct any or all of the Pasteurization ~~or Aseptic Processing~~ Equipment Tests. The auditor should, through a combination of

physical examination of the equipment and a records review, satisfy themselves that the equipment is properly installed and operated.

*Make the following changes to **TABLE 4. EQUIPMENT TESTS – BATCH, HTST, HHST and ASEPTIC PROCESSING SYSTEMS** on Page 106:*

1.	Vat, HTST, and HHST, Aseptic indicating and airspace thermometers	Temperature accuracy
2.	Vat, HTST, and HHST, Aseptic recording thermometer	Temperature accuracy
3.	Vat, HTST, and HHST, Aseptic recording thermometer	Time accuracy
4.	Vat, HTST, and HHST, Aseptic indicating and recording thermometer	Recording vs. Indicating thermometer
5.1	HTST, and HHST FDD	Leakage pass FDD
5.2	HTST, and HHST FDD	FDD freedom of movement
5.3	HTST, and HHST FDD	Device assembly (single stem)
5.4	HTST, and HHST FDD	Device assembly (dual stem)
5.5	HTST FDD	Manual diversion
5.6	HTST, and HHST FDD	Response time
5.7	HTST, and HHST FDD	Time delay (inspect)
5.8	HTST, and HHST FDD	Time delay (CIP)
5.9	HTST FDD	Time delay (leak-detect flush)
6.	Vat leak-protector valve(s)	Leakage
7.	HTST indicating thermometers	Response time
8.	HTST recording thermometers	Response time
9.1	HTST pressure switches	Regenerator pressures
9.2.1	HTST, and HHST, Aseptic differential pressure controllers	Calibration
9.2.2	HTST differential pressure controllers	Regenerator pressure
9.2.3	HTST*, and HHST and Aseptic differential pressure controllers	Regenerator pressure
9.3.1	HTST booster pump/FDD	Inter-wiring check
9.3.2	HTST booster pump/timing pump	Inter-wiring check
10.1	HTST FDD	Temperature cut-in/cut-out
10.2	HTST*, and HHST FDD, Aseptic divert system (indirect heat)	Temperature cut-in/cut-out
10.3	HTST*, and HHST FDD, Aseptic divert system (direct heat)	Temperature cut-in/cut-out
11.1	HTST holding tubes/timing pumps (except magnetic flow meter based timing systems-MFMBTS)	Holding time
11.2.a	HTST holding tubes/ MFMBTS	Holding time
11.2.b	HTST, and HHST, Aseptic MFMBTS	Flow alarm
11.2.c	HTST, and HHST, Aseptic MFMBTS	Loss of signal/low flow
11.2.d	HTST magnetic flow meter based timing systems	Flow rate cut-in/cut-out
11.2.e	HTST magnetic flow meter based timing systems	Time delay
11.2.f	All magnetic flow meter based timing systems	High flow alarm response time
11.3	HHST holding tubes (indirect heat)	Holding time
11.4	HHST holding tubes (direct injection heat)	Holding time
11.5	HHST holding tubes (direct infusion heat)	Holding time
12.1	HTST*, and HHST, Aseptic systems (indirect heating)	Sequence logic
12.2	HTST*, and HHST, Aseptic systems (direct heating)	Sequence logic

13.	HHST, Aseptic systems	Pressure in the holding tube
14.	HTST*, <u>and</u> HHST, Aseptic systems using (direct injection heating)	Pressure differential across injector
15.	HTST, <u>and</u> HHST, Aseptic (all electronic controls)	Electro-Magnetic Interference

* For HTST systems with the FDD located downstream of the regenerator and/or cooler section.

Make the following changes to ITEM 17p. COOLING OF MILK AND MILK PRODUCTS on Page 109:

ADMINISTRATIVE PROCEDURES

Page 109

6. Each refrigerated room in which pasteurized milk and milk products are stored, ~~except aseptically processed milk and milk products,~~ is equipped with an indicating thermometer that complies with the applicable specifications of Appendix H. Such thermometer shall be located in the warmest zone of the refrigerated room.

Make the following changes to ITEM 18p. BOTTLING, PACKAGING AND CONTAINER FILLING on Page 113:

ADMINISTRATIVE PROCEDURES

Page 113

~~12. In the case of aseptic processing systems, the milk and milk product shall be aseptically filled into sterilized containers and hermetically sealed in conformance with the applicable requirements of 21 CFR Part 113.~~

Make the following changes to SECTION 8. ANIMAL HEALTH on Pages 117-118:

Page 117

1. All milk for pasteurization, ultra-pasteurization or aseptic processing and packaging shall be from herds in Areas which have a Modified Accredited Advanced Tuberculosis (TB) status or higher as determined by the USDA. Provided, that in an Area which fails to maintain such status, any herd shall have been accredited by said Department as tuberculosis free, or shall have passed an annual tuberculosis test, or the Area shall have established a tuberculosis testing protocol for livestock that assures tuberculosis protection and surveillance of the dairy industry within the Area and that it is approved by FDA, USDA and the Regulatory Agency.

2. All milk for pasteurization, ultra-pasteurization or aseptic processing and packaging shall be from herds under a brucellosis eradication program, which meets one (1) of the following conditions:

Page 118

3. Goat, sheep, water buffalo, or any other hooved mammal milk for pasteurization, ultra-pasteurization or aseptic processing and packaging, defined under this *Ordinance*, shall be from a herd or flock that:

Make the following changes to SECTION 9. MILK AND MILK PRODUCTS WHICH MAY BE SOLD on Page 120:

Page 120

From and after twelve (12) months from the date on which this *Ordinance* is adopted, only Grade "A" pasteurized, ultra-pasteurized, or aseptically processed and packaged milk and milk products shall be sold to the final consumer, to restaurants, soda fountains, grocery stores or similar establishments. Provided, only Grade "A" milk and milk products shall be sold to milk plants for use in the commercial preparation of Grade "A" milk and milk products. Provided further, that in an emergency, the sale of pasteurized, ultra-pasteurization or aseptic processed and packaged milk and milk products, which have not been graded, or the grade of which is unknown, may be authorized by the Regulatory Agency, in which case, such milk and milk products shall be labeled "un-graded".

Make the following changes to SECTION 11. MILK AND MILK PRODUCTS FROM POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION on Pages 121-123:

Page 121

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 and packaged, 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 satisfactory acceptable HACCP listing, under the NCIMS HACCP Program as specified in Appendix K. of this *Ordinance*;² or are from a country that PHS/FDA has determined, after conferring with NCIMS, 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 and packaged, concentrated (condensed) or dried milk and milk products shall comply with Sections 2, 4 and 10.

NOTE: Raw, and-pasteurized and ultra-pasteurized milk and milk products beyond the limits of routine inspection shall be sampled as the Regulatory Agency requires.

11. Aseptically processed and packaged milk and milk products in Definition X of this *Ordinance* shall be considered to be Grade "A" milk or milk products. ~~The source~~ sources(s) of the milk and milk products used to produce aseptically processed and packaged 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. Aseptically processed and packaged milk and milk products shall be labeled "Grade "A"" and meet Section 4 labeling requirements of the PMO. The milk plant or portion of the milk plant that is producing aseptically processed and packaged milk and milk products shall be awarded a Milk Sanitation Compliance Rating of a at least ninety percent (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 as "Grade "A"". 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/Aseptic listings, an acceptable HACCP listing by a SRO is required. For milk plants that produce aseptically processed and packaged Grade "A" milk and/or milk products, prior to the milk plant participating in the NCIMS Aseptic Processing and Packaging Program, or the Aseptic 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 Aseptic Processing and Packaging Program or Aseptic Pilot Program. The NCIMS Aseptic Pilot Program addressing aseptically processed and packaged acidified and fermented high acid milk and milk products regulated under 21 CFR Parts 108, 110, and/or 114 will expire on December 31, 2014 2013, unless extended by future conference action.

Make the following changes to SECTION 13. PERSONNEL HEALTH on Page 123:

Page 123

No persons affected with any disease capable of being transmitted to others through the contamination of food shall work at a milk plant in any capacity which brings them into direct contact with pasteurized, ultra-pasteurized or aseptically processed and packaged milk or milk products or which brings them into direct contact with associated pasteurized or aseptically processed and packaged milk or milk product-contact surfaces.

*Make the following changes to **SECTION 14. PROCEDURE WHEN INFECTION OR HIGH RISK OF INFECTION IS DISCOVERED** on Pages 124 and 125:*

Page 124

When a person who may have handled pasteurized, ultra-pasteurized or aseptically processed and packaged milk or milk products or pasteurized, ultra-pasteurized or aseptically processed and packaged milk or milk product-contact surfaces meets one (1) or more of the conditions specified in the ADMINISTRATIVE PROCEDURES of Section 13, the Milk Regulatory Agency is authorized to require any or all of the following measures:

Page 125

NOTE: Persons at risk who decline to be examined may be reassigned to duties where they will not be required to handle pasteurized, ultra-pasteurized or aseptically processed and packaged milk or milk products and associated milk or milk product-contact surfaces.

*Make the following changes to **APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT** on Pages 216 and 217:*

I. HTST PASTEURIZATION

Page 216

HTST PASTEURIZERS EMPLOYING MILK OR MILK PRODUCT-TO-MILK OR MILK PRODUCT REGENERATORS WITH BOTH SIDES CLOSED TO THE ATMOSPHERE

Item 16p(~~D~~C), of Section 7 establishes standards for regenerators. These standards insure that the raw milk or milk product will always be under less pressure than pasteurized milk or milk product in order to prevent contamination of the pasteurized milk or milk product in the event flaws should develop in the metal or joints separating it from the raw milk or milk product. An explanation of regenerator specifications is given below.

During normal operation, i.e., while the timing pump is operating, raw milk or milk product will be drawn through the regenerator at sub-atmospheric pressure. The pasteurized milk or milk product in the milk or milk product-to-milk or milk product re-

generator will be above atmospheric pressure. The required pressure differential will be assured when there is no flow-promoting device downstream from the pasteurized milk or milk product side of the regenerator to draw the pasteurized milk or milk product through the regenerator, and the pasteurized milk or milk product downstream from the regenerator rises to at least 30.5 centimeters (12 inches) elevation above the highest raw milk or milk product level downstream from the constant-level tank, and is open to the atmosphere at this or a higher elevation, as required in Item 16p(ĐC), ADMINISTRATIVE PROCEDURES #2.

During a shutdown, i.e., when the timing pump stops, the raw milk or milk product in the regenerator will be retained under suction, except this suction may be gradually relieved by possible entrance of air drawn through the regenerator plate gaskets from the higher outside atmospheric pressure. With a free draining regenerator, as required under Item 16p(ĐC), ADMINISTRATIVE PROCEDURES #8, the raw milk or milk product level in the regenerator may drop slowly, depending on the tightness of the gaskets, ultimately falling below the level of the plates to the milk or milk product level in the constant-level tank. However, under these conditions, as long as any raw milk or milk product remains in the regenerator, it will be at sub-atmospheric pressure.

During shutdown, the pasteurized milk or milk product in the regenerator is maintained at atmospheric pressure or above by meeting the elevation requirement of Item 16p(ĐC), ADMINISTRATIVE PROCEDURES #2. Pressure greater than atmospheric is maintained when the level of pasteurized milk or milk product is at or above the required elevation and loss of pressure, due to suction, is prevented by prohibiting a downstream pump.

Any backflow of milk or milk product through the FDD would lower the pasteurized milk or milk product level, during pump shutdowns, thus tending to reduce the pressure on the pasteurized milk or milk product side of the regenerator. A FDD cannot be relied upon to prevent backflow in such instances, because during the first few minutes following a pump shutdown, the milk or milk product is still at a sufficiently high temperature to keep the FDD in the forward-flow position. Compliance with the provisions of Item 16p(ĐC), ADMINISTRATIVE PROCEDURES #2 and #3; however, will insure a proper pressure differential in the regenerator.

Page 217

At the beginning of a run, from the time raw milk or milk product or water is drawn through the regenerator, until the pasteurized milk or milk product or water has risen to the elevation specified in Item 16p(ĐC), ADMINISTRATIVE PROCEDURES #2, the pasteurized milk or milk product side of the regenerator is at atmospheric pressure or higher. Even if the timing pump should stop during this period, the pressure on the pasteurized milk or milk product side of the regenerator will be greater than the sub-atmospheric pressure on the raw milk or milk product side. This will be assured by compliance with Item 16p(ĐC), ADMINISTRATIVE PROCEDURES #2 and #3, as long as any raw milk or milk product remains in the regenerator.

When a raw milk or milk product booster pump is incorporated into the HTST pasteurization system, Item 16p(ĐC), ADMINISTRATIVE PROCEDURES #5 requires, in part, that automatic means shall be provided to assure, at all times, the required

pressure differential between raw and pasteurized milk or milk product in the regenerator, before the booster pump can operate.

*Make the following changes to **APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT** on Pages 219 and 220:*

I. HTST PASTEURIZATION

Page 219

PRESSURE RELIEF VALVES LOCATED WITHIN HTST PASTEURIZATION SYSTEMS

OPTION I:

c. The system is designed and operated so that loss of pressure from the pasteurized side of the regenerator cannot occur if the system flow-promoting devices stop while the FDD is in the forward-flow position. A system not protected against this potential pressure loss is considered a violation of Item 16p(DC) of this *Ordinance*

Page 220

OPTION II. The pressure relief valve is spring-loaded and plumbed so that it cannot be opened or forced open in any mode, "Product", "CIP" or "Inspect", without the assistance of pressure from the liquid flowing through the system. In this case, a leaking pressure relief valve can cause an unacceptable loss of pressure in the pasteurized side of the regenerator if the system flow-promoting devices stop while the FDD is in the forward-flow position. This is considered a violation of Item 16p(DC) of this *Ordinance*. Any leakage from this pressure relief valve must be readily visible. This may be accomplished by opening the pressure relief valve vent directly to the floor or by providing sanitary piping from the pressure relief valve vent to the constant-level tank. If the later option is utilized, the piping shall be properly sloped to assure drainage to the constant-level tank and shall be provided with a properly located and installed sight-glass.

2. **Downstream from the Holding Tube:** The pressures in the pasteurized side of the regenerator must be protected from falling within 6.9 kPa (1 psi) of the pressures in the raw side of the regenerator at all times, including during shut down. A relief valve and line on the pasteurized side of the FDD can meet this criterion if:

c. The pressure relief valve is spring-loaded and plumbed so that it cannot be opened or forced open in any mode, "Product", "CIP" or "Inspect", without the assistance of pressure from the liquid flowing through the system. In this case, a leaking pressure relief valve can cause an unacceptable loss of pressure in the pasteurized side of the regenerator during a shut down and is considered a violation of Item 16p(DC) of this

Ordinance. Any leakage from this pressure relief valve must be readily visible. This may be accomplished by opening the pressure relief valve vent directly to the floor or by providing sanitary piping from the pressure relief valve vent to the constant-level tank. If the later option is utilized, the piping shall be properly sloped to assure drainage to the constant-level tank and shall be provided with a properly located and installed sight-glass.

Make the following changes to APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT on Page 222:

MAGNETIC FLOW METER BASED TIMING SYSTEMS FOR WITHIN HTST CONTINUOUS FLOW PASTEURIZERS SYSTEMS

Components:

Page 222

10. All systems shall be designed, installed and operated so that all applicable tests required by Section 7, Item 16p(~~ED~~) can be performed by the Regulatory Agency, at the frequency specified. (Refer to Appendix I.) Where adjustment or changes can be made to these devices or controls, appropriate seals shall be applied by the Regulatory Agency after testing, so that changes cannot be made without detection.

Make the following changes to APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES AND OTHER EQUIPMENT on Pages 251-253:

V. CRITERIA FOR THE EVALUATION OF ELECTRONIC DATA COLLECTION, STORAGE AND REPORTING

Page 251

CRITERIA

The following criteria are to be used for the evaluation of electronic collection, storage and recording or reporting of any information required within Items 12p and 16p(~~ED~~). of Section 7 of this *Ordinance*.

Page 252

5. In the case of pasteurization and ~~aseptic processing~~ records, data shall be stored no less than every five (5) seconds for each required variable. Any event required to be recorded in manual reporting, such as a divert condition; will be recorded no matter how short the duration. Provisions will be made to allow operators to report additional events electronically, such as a record of unusual occurrences. The data for the reporting system

shall be backed up at least once every twenty-four (24) hours. Alternatively, the final reports may be stored and backed up at least once every twenty-four (24) hours.

Page 253

NOTE: While electronic and computerized systems can furnish a wide range of process validation and anomaly reporting, these criteria only require appended reporting of data loss that affects the reports that are required to comply with this Appendix and Items 12p and 16p(ED) or other required reporting contained in this *Ordinance*.

Make the following changes to APPENDIX I. PASTEURIZATION EQUIPMENT AND CONTROLS - TEST on Pages 273-276, 281-291, 296, 297, 299, and 305-311:

Page 273

II. TEST PROCEDURES

TEST 1.

INDICATING THERMOMETERS - TEMPERATURE ACCURACY

Reference: Item 16p (A), (B), ~~(C)~~ and (ED)

Application: To all indicating thermometers used for the measurement of milk or milk product temperature during pasteurization ~~or aseptic processing~~, including airspace thermometers.

Criteria: Within $\pm 0.25^{\circ}\text{C}$ ($\pm 0.5^{\circ}\text{F}$) for pasteurization and ~~aseptic processing~~ ultra-pasteurization thermometers and $\pm 0.5^{\circ}\text{C}$ ($\pm 1^{\circ}\text{F}$) for airspace thermometers, in a specified scale range. Provided, that on batch pasteurizers used solely for thirty (30) minute pasteurization of milk or milk products at temperatures above 71°C (160°F), indicating thermometers shall be accurate to within $\pm 0.5^{\circ}\text{C}$ ($\pm 1^{\circ}\text{F}$).

Procedure:

1. Prepare a quantity of water, oil or other suitable media in a bath, by raising the temperature of the media to within 2°C (3°F) of the appropriate pasteurization, or airspace temperature, ~~or aseptic processing temperature~~.

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TEST 2.

RECORDING THERMOMETERS - TEMPERATURE ACCURACY

Reference: Item 16p (A), (B), ~~(C)~~ and (ED)

Application: To all mercury-actuated recording and recorder-controller thermometers controllers used to record milk or milk product temperatures during pasteurization ~~or aseptic processing~~.

NOTE: When this Test is performed on mercury-actuated recorder-controllers used with HHST pasteurization ~~or aseptic processing~~ systems that operate at or above the boiling point of water, an oil or other suitable media bath shall be substituted for the processing (operating) temperature water mentioned in **Procedures** 1, 4, 5, 6, and 7 as well as the boiling water mentioned in **Procedures** 2, 3 and 5. The temperature of the oil bath that is used in place of the boiling water shall be above the normal operating range but below the highest temperature division on the chart.

Procedure:

2. Prepare a second media bath by heating to the boiling point, or in the case of HHST ~~or aseptic~~ pasteurization systems, to a temperature above the normal operating range but below the highest temperature division on the chart, and maintain temperature. Prepare a third container with melting ice. Place all media baths within working distance of the temperature-sensing element(s).
3. Immerse the recording thermometer sensing element into the boiling water, or in the case of HHST ~~or aseptic processing~~ pasteurization systems into the media bath described above, for not less than five (5) minutes.

Page 275

**TEST 3.
RECORDING THERMOMETERS - TIME ACCURACY**

Reference: Item 16p (A), (B), ~~(C)~~ and (E)

Application: To all recording and recorder-controller thermometers used to record the time of pasteurization ~~or aseptic processing~~.

Criteria: The recorded time of pasteurization ~~or aseptic processing~~ shall not exceed the true elapsed time.

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**TEST 4.
RECORDING THERMOMETERS - CHECK AGAINST
INDICATING THERMOMETERS**

Reference: Item 16p (A), (B), ~~(C)~~ and (E)

Application: To all recording and recorder-controller thermometers used to record milk or milk product temperatures during pasteurization ~~or aseptic processing~~.

Frequency: Upon installation and at least once each three (3) months by the Regulatory Agency, or HACCP qualified industry person, acceptable to the Regulatory Agency, qualified under Item 16p(E)2; and daily by the milk plant operator.

Method: This test requires only that the reading of the recording thermometer or the recorder-controller thermometer be compared with the indicating thermometer at a time

when both are exposed to milk or milk product at a stabilized pasteurization or aseptic processing temperature.

Procedure:

1. While the indicating and recording temperatures are stabilized at or above the minimum legal pasteurization or aseptic processing temperature, read the indicating thermometer.

TEST 5.

FDD - PROPER ASSEMBLY AND FUNCTION

Reference: Item 16p (B), (C) and (ED)

Application: Test 5 (parts 1 through 9) does not apply to aseptic processing divert systems, valves or other acceptable controls which may be used in place of a FDD. Parts 1 to 4 and 6 to 8 apply to all FDDs used with continuous-flow pasteurizers. Parts 5 and 9 apply only to FDDs used with HTST pasteurizers.

Page 281

TEST 6.

LEAK-PROTECTOR VALVE

Reference: Item 16p (A) and (ED)

Page 282

TEST 7.

**INDICATING THERMOMETERS ON PIPELINES -
THERMOMETRIC RESPONSE**

Reference: Item 16p (B) and (ED)

Page 283

TEST 8.

RECORDER/CONTROLLER - THERMOMETRIC RESPONSE

Reference: Item 16p (B) and (ED)

Page 284

TEST 9.

REGENERATOR PRESSURE CONTROLS

Reference: Item 16p (~~DC~~) and (~~ED~~)

Page 285

9.2 DIFFERENTIAL PRESSURE CONTROLLER

Application: Test 9.2.1 applies to all differential pressure controllers used to control the operation of booster pumps on HTST pasteurization systems or used to control the operation of FDDs on HHST and HTST ~~Pasteurization~~ pasteurization systems with the FDD located downstream of the pasteurized regenerator and/or final cooler ~~and aseptic processing systems~~.

Test 9.2.3 applies to the testing of continuous flow pasteurization systems in which the differential pressure controller is used to control the operation of the FDD. ~~Test 9.2.3 also applies to aseptic processing systems in which the differential pressure controller is used to control the FDD, milk or milk product divert system, milk or milk product divert valve or other acceptable control system.~~

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Criteria: The booster pump shall not operate, or the pasteurizer shall not operate in forward-flow, unless the milk or milk product pressure in the pasteurized side of the regenerator is at least 6.9 kPa (1 psi) greater than the milk or milk product pressure in the raw side of the regenerator. When the differential pressure controller is used to control the FDD on HHST ~~or aseptic processing~~ pasteurization systems, and improper pressure occurs in the regenerator, the FDD shall move to the diverted-flow position and remain in diverted-flow until the proper pressures are re-established in the regenerator and all milk or milk product-contact surfaces between the holding tube and FDD have been held at or above the required pasteurization ~~or aseptic processing~~ temperature, continuously and simultaneously for at least the required time.

Method: The differential pressure switch is checked and adjusted to prevent the operation of the booster pump, or prevent forward-flow, unless the milk or milk product pressure in the pasteurized, ~~or aseptic,~~ side of the regenerator is at least 6.9 kPa (1 psi) greater than the pressure in the raw side of the regenerator.

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9.2.3 INTERWIRING OF THE PRESSURE DIFFERENTIAL CONTROLLER WITH THE FDD IN AN HHST CONTINUOUS FLOW PASTEURIZATION SYSTEM; ~~OR AN ACCEPTABLE ALTERNATIVE DEVICE, OR SYSTEM IN ASEPTIC PROCESSING EQUIPMENT~~

Application:

2. To all differential pressure controllers used to control the operation of FDDs, milk or milk product divert systems, or milk or milk product divert valve(s) ~~or other acceptable control systems used in aseptic processing equipment.~~

Method: The differential pressure switch is checked and adjusted to prevent forward-flow, unless the milk or milk product pressure in the pasteurized side of the regenerator is at least 6.9 kPa (1 psi) greater than the pressure in the raw milk or milk product side of the regenerator. In the case of milk or milk product-to-water-to-milk or milk product regenerators, protected on the pasteurized ~~or aseptic~~ side, the "water side" of the regenerator shall be considered to be the "raw product side" for purposes of this Test.

Procedure:

3. Adjust the pressure on the pressure switch sensors to their normal operating pressures, with the pasteurized ~~or aseptic~~ pressure at least 14 kPa (2 psi) higher than the raw product pressure.

- a. The test lamp should be lit. If not, increase the pasteurized ~~or aseptic~~ pressure, or lower the raw product pressure, until the test light is lit.
- b. Gradually lower the pasteurized ~~or aseptic~~ side, or raise the raw product pressure until the test light turns off.
- c. The test light should turn off when the pasteurized ~~or aseptic~~ pressure is at least 14 kPa (2 psi) higher than the raw product pressure.
- d. Note the differential pressure at the point the light turns off.
- e. Gradually raise the pasteurized ~~or aseptic~~ pressure, or lower the raw product pressure, until the test light turns on.

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- f. The test light should not turn on until the pasteurized ~~or aseptic~~ pressure is at least 14 kPa (2 psi) higher than the raw product pressure. Note the differential pressure at the point the light turns off.

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TEST 10.

MILK OR MILK PRODUCT-FLOW CONTROLS AND MILK OR MILK PRODUCT TEMPERATURE AT CUT-IN AND CUT-OUT

References: Item 16p (B), ~~(C)~~ and ~~(ED)~~

10.1 HTST PASTEURIZERS

Frequency: Upon installation; at least once each three (3) months thereafter by the Regulatory Agency, or HACCP qualified industry person, acceptable to the Regulatory Agency, qualified under Item 16p~~(ED)~~2; daily by the milk plant operator; or when a regulatory seal has been broken.

10.2 PASTEURIZERS AND ASEPTIC PROCESSING SYSTEMS USING INDIRECT HEATING

Application: All HHST and HTST ~~pasteurizers~~ pasteurization systems with the FDD located downstream of the regenerator and/or final cooler and ~~aseptic processing systems~~ using indirect heating. ~~When testing aseptic processing systems, the "milk or milk product divert system", or "milk or milk product divert valve" or "acceptable control system" may be substituted for the "FDD" when it is referenced in this Test.~~

Criteria: The pasteurizer ~~or aseptic processor~~ shall not operate in forward-flow unless the pasteurization ~~or aseptic processing~~ temperature has been achieved. The milk or milk product flow shall be diverted at a temperature lower than the chosen pasteurization ~~or aseptic processing~~ standard.

Procedure:

2. After the cut-in temperature has been determined and while the bath is above the cut-in temperature, allow the bath to cool slowly at a rate not exceeding 0.5°C (1°F) per thirty (30) seconds. Observe the temperature reading on the thermal-limit-controller when the test lamp goes out, cut-out temperature. Determine that the cut-out temperature, on the thermal-limit-controller is equivalent to or greater than the chosen pasteurization ~~or aseptic processing~~ standard. Where adjustment is necessary, refer to the manufacturer's instructions. After adjustment, repeat the procedure above, and when the results are satisfactory, record the results for the office records.

10.3 PASTEURIZERS AND ASEPTIC PROCESSING SYSTEMS USING DIRECT HEATING

Application: All HHST and HTST ~~pasteurizers~~ pasteurization systems with the FDD located downstream of the regenerator and/or final cooler and ~~aseptic processing systems~~ using direct heating. ~~When testing aseptic processing systems, the "milk or milk product divert system" or "milk or milk product divert valve" or "acceptable control system" may be substituted for the "FDD" when it is referenced in this Test.~~

Criteria: The pasteurizer ~~or aseptic processor~~ shall not operate in forward-flow unless the pasteurization ~~or aseptic processing~~ temperature has been achieved. The milk or milk product flow shall be diverted at a temperature lower than the chosen pasteurization ~~or aseptic processing~~ standard.

Procedure:

2. After the cut-in temperature has been determined and while the bath is above the cut-in temperature, allow the bath to cool slowly at a rate not exceeding 0.5°C (1°F) per thirty

(30) seconds. Observe the temperature reading on the thermal-limit-controller when the test lamp goes out, cut-out temperature. Determine that the cut-out temperature, on the thermal-limit-controller, is equivalent to or greater than the chosen pasteurization or aseptic processing standard. Where adjustment is necessary, refer to the manufacturer's instructions. After adjustment, repeat the procedure above and when the results are satisfactory, record the results for the office record.

TEST 11.

CONTINUOUS-FLOW HOLDING TUBES - HOLDING TIME

Reference: Item 16p (B), (C) and (D)

Page 295

11.2A MAGNETIC FLOW METER BASED TIMING SYSTEMS CONTINUOUS-FLOW- HOLDING TIME

TEST OPTION I

NOTE: The appropriate temperature elements may be placed in a water or oil bath to simulate the normal pasteurization or aseptic processing temperature of the holding tube as an alternative to heating the water in the system above the pasteurization or aseptic processing temperature.

Page 296

11.2B CONTINUOUS-FLOW HOLDING TUBES - FLOW ALARM

Application: To all continuous-flow pasteurization and aseptic processing systems using a magnetic flow meter based timing system to replace a timing pump. ~~When testing aseptic processing systems, the "milk or milk product divert system" or "milk or milk product divert valve" or "acceptable control system" may be substituted for the "FDD" when it is referenced in this Test.~~

Criteria: When flow rate equals or exceeds the value at which the holding time was measured, the flow alarm shall cause the FDD to assume the diverted position, even though the temperature of the milk or milk product in the holding tube is above the pasteurization or aseptic processing temperature.

Procedure:

1. Operate the pasteurizer or aseptic processing equipment in forward-flow, below the high flow alarm, using water above the pasteurization or aseptic processing temperature.

NOTE: The appropriate temperature elements may be placed in a water or oil bath to simulate the normal pasteurization or aseptic processing temperature of the holding tube

as an alternative to heating the water in the system above the pasteurization or aseptic processing temperature. Observation and recording of this temperature should be done as described in **Procedures 3 and 4** below.

Page 297

11.2C CONTINUOUS-FLOW HOLDING TUBES - LOW FLOW/LOSS-OF-SIGNAL ALARM

Application: To all continuous-flow pasteurization and aseptic processing systems using a magnetic flow meter based timing system to replace a timing pump. ~~When testing aseptic processing systems, the "milk or milk product divert system" or "milk or milk product divert valve" or "acceptable control system" may be substituted for the "FDD" when it is referenced in this Test.~~

Procedure:

1. Operate the pasteurizer or aseptic processing equipment in forward-flow, at a flow rate below the flow alarm set point and above the low flow/loss-of-signal alarm set point, using water.

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11.2F HIGH FLOW ALARM RESPONSE TIME

Application: To all continuous-flow pasteurization and aseptic processing systems using a magnetic flow meter based timing system to replace a timing pump. ~~When testing aseptic processing systems, the "milk or milk product divert system" or "milk or milk product divert valve" or "acceptable control system" may be substituted for the "FDD" when it is referenced in this Test.~~

Procedure:

1. Operate the pasteurizer or aseptic processing equipment in forward-flow, at a flow rate 25% below the high flow alarm as determined in Test 11.2B (Procedure 2).
2. Mark the recorder chart with the high flow alarm set point.

NOTE: The appropriate temperature elements may be placed in a water or oil bath to simulate the normal pasteurization or aseptic processing temperature of the holding tube as an alternative to heating the water in the system above the pasteurization or aseptic processing temperature. Observation and recording of this temperature should be done as described in **Procedures 3 and 4** below.

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TEST 12.

THERMAL-LIMIT-CONTROLLER FOR CONTROL - SEQUENCE LOGIC

References: Items 16p(B) and (E)

Thermal-limit-controllers used with HHST and HTST pasteurizers pasteurization systems that have the FDD located downstream from the regenerator and/or cooler and ~~aseptic processing systems~~ shall be tested by one (1) of the following applicable Tests at the frequency prescribed:

Page 306

12.1 PASTEURIZATION AND ASEPTIC PROCESSING - INDIRECT HEATING

Application: To all HHST and HTST pasteurizers pasteurization systems that have the FDD located downstream from the regenerator and/or cooler and ~~aseptic processing systems~~ using indirect heating. ~~When testing aseptic processing systems, the "milk or milk product divert system" or "milk or milk product divert valve" or "acceptable control system" may be substituted for the "FDD" when it is referenced in this Test.~~

Criteria: The pasteurizer, ~~or aseptic processing equipment,~~ shall not operate in forward-flow until the milk or milk product surfaces downstream from the holding tube have been sanitized, ~~or in the case of aseptic processing equipment, sterilized.~~ Upon start-up, surfaces shall be exposed to fluid at pasteurization temperature, ~~or in the case of aseptic processing equipment, sterilizing temperature,~~ for at least the required pasteurization ~~or sterilization~~ time. If any public health control causes the FDD to assume the diverted flow position due to incorrect temperature, pressure or flow, forward-flow shall not be re-achieved until the milk or milk product-contact surfaces downstream from the holding tube have been re-sanitized, ~~or in the case of aseptic processing equipment, re-sterilized.~~
.....

Procedure:

3. Immerse the sensing element from the holding tube in the bath. The test lamp should light up, i.e., forward-flow after a minimum time delay of one (1) second for continuous-flow pasteurization systems. ~~For aseptic processing systems no delay is required if the filed process includes a documented sterilization period.~~

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12.2 PASTEURIZATION AND ASEPTIC PROCESSING - DIRECT HEATING

Application: To all HHST and HTST pasteurizers pasteurization systems that have the FDD located downstream from the regenerator and/or cooler and ~~aseptic processing systems~~ using direct contact heating. ~~When testing aseptic processing systems, the "milk or milk product divert system" or "milk or milk product divert valve" or "acceptable control system" may be substituted for the "FDD" when it is referenced in this Test.~~

Criteria: The pasteurizer, ~~or aseptic processing equipment,~~ shall not operate in forward-flow until the milk or milk product surfaces downstream from the holding tube have been sanitized, ~~or in the case of aseptic processing equipment, sterilized.~~ Upon start-up,

surfaces shall be exposed to fluid at pasteurization temperature, ~~or in the case of aseptic processing equipment, sterilizing temperature~~ for at least the required pasteurization ~~or sterilization~~ time. If the milk or milk product temperature falls below the pasteurization ~~or sterilization~~ standard in the holding tube, forward-flow shall not be re-achieved until the milk or milk product-contact surfaces downstream from the holding tube have been re-sanitized, ~~or in the case of aseptic processing equipment, re-sterilized.~~

Procedure:

5. Immerse the third sensing element located at the holding tube, into the bath. The test lamp should light up, i.e., forward-flow, after a minimum time delay of one (1) second for continuous-flow pasteurization systems. ~~For aseptic processing systems no delay is required if the filed process includes a documented sterilization period.~~

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TEST 13.

SETTING OF CONTROL SWITCHES FOR MILK OR MILK PRODUCT PRESSURE IN THE HOLDING TUBE

Reference: Item 16p(B) and (ED)

Application: To all HHST ~~pasteurizers and aseptic processing~~ pasteurization systems, which are capable of operating with product in forward-flow mode, with less than 518 kPa (75 psig) pressure in the holding tube. ~~When testing aseptic processing systems, the "milk or milk product divert system" or "milk or milk product divert valve" or "acceptable control system" may be substituted for the "FDD" when it is referenced in this Test.~~

Criteria: The pasteurizer ~~or aseptic processor~~ shall not operate in forward-flow unless the product pressure in the holding tube is at least 69 kPa (10 psi) above the boiling pressure of the product.

Procedure:

Page 309

For each HHST pasteurizer ~~or aseptic processing system~~ temperature, the milk or milk product pressure switch setting is as follows:

TEST 14.

SETTING OF CONTROL SWITCHES FOR DIFFERENTIAL PRESSURE ACROSS THE INJECTOR

Reference: Item 16p(B) and (ED)

Application: To all continuous flow ~~pasteurizers~~ pasteurization systems and ~~aseptic processing systems~~ using direct injection heating. ~~When testing aseptic processing systems, the "milk or milk product divert system" or "milk or milk product divert valve" or "acceptable control system" may be substituted for the "FDD" when it is referenced in this Test.~~

Criteria: The pasteurizer ~~or aseptic processor~~ shall not operate in forward-flow unless the milk or milk product pressure drop across the injector is at least 69 kPa (10 psi).

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TEST 15.

ELECTRO-MAGNETIC INTERFERENCE FROM HAND-HELD COMMUNICATION DEVICES

Application: To all electronic controls devices used to assure compliance with public health safeguards on continuous flow pasteurization and ~~aseptic processing~~ equipment that are installed in milk plants.

Page 311

Procedure:

5. Repeat the Test for each electronic control device used to regulate a pasteurization ~~or aseptic processing~~ system's public health safeguard(s).

For Example: For the temperature set point, operate the pasteurization ~~or aseptic processing~~ equipment on water in diverted-flow in the "Product" mode, at a steady temperature within 3°C (5°F) of the lowest cut-in temperature. In this example, an adverse effect is defined as the forward-flow movement of the FDD or any artificial increase in temperature.

Make the following changes to APPENDIX K. HACCP PROGRAM on Page 328:

II. IMPLEMENTATION OF A HACCP SYSTEM

Page 328

VERIFICATION AND VALIDATION:

1. **Verification:** Every milk plant, receiving station or transfer station shall verify that the HACCP System is being implemented according to design, except that ~~critical factors for aseptically processed Grade "A" milk and milk products, as determined by the process authority and listed on the scheduled process under 21 CFR Part 113~~ the APPS, as defined by this Ordinance, shall be managed separately from the NCIMS HACCP

System, even if identified as a CCP in the hazard analysis. ~~Critical factors shall be monitored under the operating supervision of an individual who has successfully completed an approved course of instruction in low acid canned foods as required under 21 CFR 108.35. Compliance with the provisions of 21 CFR Part 113 shall satisfy the requirements of this Section, regardless of whether a critical factor has also been designated as a CCP.~~ The milk plant's APPS shall be inspected by FDA, or the State Regulatory Agency when designated by FDA, in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113 at a frequency determined by FDA.

*Make the following change to **APPENDIX L. APPLICABLE REGULATIONS, STANDARDS OF IDENTITY FOR MILK AND MILK PRODUCTS AND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT** on Page 335:*

Page 335

21 CFR PART 113 - THERMALLY PROCESSED LOW-ACID FOODS PACKAGED
IN HERMETICALLY SEALED CONTAINERS

21 CFR PART 114 – ACIDIFIED FOODS

21 CFR 130.10 - Requirements for foods named by use of a nutrient content claim and a standardized term

Page 337

Within the Forms cited in APPENDIX M-REPORTS AND RECORDS on page 337, the following changes to FORM FDA 2359-MILK PLANT INSPECTION REPORT and FORM FDA 2359b-MILK PLANT EQUIPMENT TEST REPORT shall be made.

NAME AND LOCATION OF PLANT _____	Pounds Sold Daily _____	Milk _____ Other Milk Products _____ Total _____ Permit No. _____
---	-------------------------	--

Inspection of your plant today showed violations existing in the items checked below. You are further notified that this inspection report serves as notification of the intent to suspend your permit if the violations noted are not in compliance at the time of the next inspection. (Refer to Sections 3 and 5 of the *Grade "A" Pasteurized Milk Ordinance*.)

<p>1. FLOORS: Smooth; impervious; no pools; good repair; trapped drains (a) <input type="checkbox"/></p> <p>2. WALLS AND CEILINGS: Smooth; washable; light-colored; good repair (a) <input type="checkbox"/></p> <p>3. DOORS AND WINDOWS: All outer openings effectively protected against entry of flies and rodents (a) <input type="checkbox"/> Outer doors self-closing; screen doors open outward (b) <input type="checkbox"/></p> <p>4. LIGHTING AND VENTILATION: Adequate light in all rooms (a) <input type="checkbox"/> Well ventilated to preclude odors and condensation; filtered air with pressure systems (b) <input type="checkbox"/></p> <p>5. SEPARATE ROOMS: Separate rooms as required; adequate size (a) <input type="checkbox"/> No direct opening to barn or living quarters (b) <input type="checkbox"/> Storage tanks properly vented (c) <input type="checkbox"/></p> <p>6. TOILET FACILITIES: Complies with local Ordinances (a) <input type="checkbox"/> No direct opening to processing rooms; self-closing doors (b) <input type="checkbox"/> Clean; well-lighted and ventilated; proper facilities (c) <input type="checkbox"/> Sewage and other liquid wastes disposed of in sanitary manner (d) <input type="checkbox"/></p> <p>7. WATER SUPPLY: Constructed and operated in accordance with Ordinance (a) <input type="checkbox"/> No direct or indirect connection between safe and unsafe water (b) <input type="checkbox"/> Condensing water and vacuum water in compliance with Ordinance requirements (c) <input type="checkbox"/> Reclaim water complies with Ordinance (d) <input type="checkbox"/> Complies with bacteriological standards (e) <input type="checkbox"/></p> <p>8. HANDWASHING FACILITIES: Located and equipped as required; clean and in good repair; improper facilities not used (a) <input type="checkbox"/></p> <p>9. MILK PLANT CLEANLINESS: Neat; clean; no evidence of insects or rodents; trash properly handled (a) <input type="checkbox"/> No unnecessary equipment (b) <input type="checkbox"/></p> <p>10. SANITARY PIPING: Smooth; impervious; corrosion-resistant, non-toxic, easily cleanable materials; good repair; accessible for inspection (a) <input type="checkbox"/> Mechanically cleaned lines meet Ordinance specs (b) <input type="checkbox"/> Pasteurized products conducted in sanitary piping, except as permitted by Ordinance (c) <input type="checkbox"/></p> <p>11. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT: Smooth, impervious, corrosion-resistant, non-toxic, easily cleanable materials; good repair; accessible for inspection (a) <input type="checkbox"/> Self-draining; strainers of approved design (b) <input type="checkbox"/> Approved single-service articles; not reused (c) <input type="checkbox"/></p> <p>12. CLEANING AND SANITIZING OF CONTAINERS/EQUIPMENT: Containers, utensils, and equipment effectively cleaned (a) <input type="checkbox"/> Mechanical cleaning requirements of Ordinance in Compliance; records complete (b) <input type="checkbox"/> Approved sanitization process applied prior to use of product-contact surfaces (c) <input type="checkbox"/> Required efficiency tests in compliance (d) <input type="checkbox"/> Multi-use plastic containers in compliance (e) <input type="checkbox"/></p>	<p>Aseptic system sterilized (f) <input type="checkbox"/></p> <p>13. STORAGE OF CLEANED CONTAINERS AND EQUIPMENT: Stored to assure drainage and protected from contamination ... (a) <input type="checkbox"/></p> <p>14. STORAGE OF SINGLE-SERVICE ARTICLES: Received, stored and handled in a sanitary manner; paperboard containers not reused except as permitted by the Ordinance (a) <input type="checkbox"/></p> <p>15a. PROTECTION FROM CONTAMINATION: Operations conducted and located so as to preclude contamination of milk, milk products, ingredients, containers, equipment, and utensils (a) <input type="checkbox"/> Air and steam used to process products in compliance with Ordinance (b) <input type="checkbox"/> Approved pesticides, safely used (c) <input type="checkbox"/></p> <p>15b. CROSS CONNECTIONS: No direct connections between pasteurized and raw milk or milk products (a) <input type="checkbox"/> Overflow, spilled and leaked products or ingredients discarded (b) <input type="checkbox"/> No direct connections between milk or milk products and cleaning and/or sanitizing solutions (c) <input type="checkbox"/></p> <p>16a. PASTEURIZATION-BATCH: (1) INDICATING AND RECORDING THERMOMETERS: Comply with Ordinance Specifications (a) <input type="checkbox"/> (2) TIME AND TEMPERATURE CONTROLS: Adequate agitation throughout holding; agitator sufficiently submerged (a) <input type="checkbox"/> Each pasteurizer equipped with indicating and recording thermometer; bulb submerged (b) <input type="checkbox"/> Recording thermometer reads no higher than indicating thermometer(c) <input type="checkbox"/> Product held minimum pasteurization temperature continuously for 30 minutes, plus filling time if product preheated before entering vat, plus emptying time, if cooling is begun after opening outlet (d) <input type="checkbox"/> No product added after holding begun (e) <input type="checkbox"/> Airspace above product maintained at not less than 5.0° F higher than minimum required pasteurization temperature during holding (f) <input type="checkbox"/> Approved airspace thermometer; bulb not less than 1 inch above product level (g) <input type="checkbox"/> Inlet and outlet valves and connections in compliance with Ordinance (h) <input type="checkbox"/></p> <p>16b. PASTEURIZATION-HIGH TEMPERATURE: (1) INDICATING AND RECORDING THERMOMETERS: Comply with Ordinance specifications (a) <input type="checkbox"/> (2) TIME AND TEMPERATURE CONTROLS: Flow-diversion device complies with Ordinance requirements (a) <input type="checkbox"/> Recorder controller complies with Ordinance requirements (b) <input type="checkbox"/> Holding tube complies with Ordinance requirements (c) <input type="checkbox"/> Flow promoting devices comply with Ordinance requirements (d) <input type="checkbox"/> (3) ADULTERATION CONTROLS: Satisfactory means to prevent adulteration with added water (a) <input type="checkbox"/></p> <p>16c. ASEPTIC PROCESSING: (1) INDICATING AND RECORDING THERMOMETERS: Comply with Ordinance Specifications (a) <input type="checkbox"/></p>	<p>(2) TIME AND TEMPERATURE CONTROLS: Flow diversion device complies with Ordinance requirements (a) <input type="checkbox"/> Recorder controller complies with Ordinance requirements (b) <input type="checkbox"/> Holding tube complies with Ordinance requirements (c) <input type="checkbox"/> Flow promoting devices comply with Ordinance requirements (d) <input type="checkbox"/></p> <p>(3) ADULTERATION CONTROLS: Satisfactory means to prevent adulteration with added water (a) <input type="checkbox"/></p> <p>16d. REGENERATIVE HEATING: Pasteurized or-aseptic product in regenerator automatically under greater pressure than raw product in regenerator at all times (a) <input type="checkbox"/> Accurate pressure gauges installed as required; booster pump properly identified and installed (b) <input type="checkbox"/> Regenerator pressures meet Ordinance Requirements (c) <input type="checkbox"/></p> <p>16e. RECORDING CHARTS: Batch pasteurizer charts comply with applicable Ordinance Requirements (a) <input type="checkbox"/> HTST and HHST pasteurizer charts comply with applicable Ordinance Requirements (b) <input type="checkbox"/> Aseptic charts comply with applicable Ordinance Requirements (c) <input type="checkbox"/></p> <p>17. COOLING OF MILK: Raw milk maintained at 45° F or less until processed (a) <input type="checkbox"/> Pasteurized milk and milk products, except those to be cultured, cooled immediately to 45° F or less in approved equipment; all milk and milk products stored there until delivered (b) <input type="checkbox"/> Approved thermometer properly located in all refrigeration rooms and storage tanks (c) <input type="checkbox"/> Recirculated cooling water from safe source and properly protected; complies with bacteriological standards (d) <input type="checkbox"/></p> <p>18. BOTTLING AND PACKAGING: Performed in a plant where contents finally pasteurized (a) <input type="checkbox"/> Performed in a sanitary manner by approved mechanical equipment (b) <input type="checkbox"/> Aseptic filling in compliance (c) <input type="checkbox"/></p> <p>19. CAPPING: Capping and/or closing performed in sanitary manner by approved mechanical Equipment (a) <input type="checkbox"/> Imperfectly capped/closed products properly handled (b) <input type="checkbox"/> Caps and/or closures comply with Ordinance (c) <input type="checkbox"/></p> <p>20. PERSONNEL CLEANLINESS: Hands washed clean before performing plant functions; rewashed when contaminated (a) <input type="checkbox"/> Clean outer garments and hair covering worn (b) <input type="checkbox"/> No use of tobacco in processing areas (c) <input type="checkbox"/></p> <p>21. VEHICLES: Vehicles clean; constructed to protect milk (a) <input type="checkbox"/> No contaminating substances transported (b) <input type="checkbox"/></p> <p>22. SURROUNDINGS: Neat and clean; free of pooled water, harborages, and breeding areas (a) <input type="checkbox"/> Tank unloading areas properly constructed (b) <input type="checkbox"/> Approved pesticides, used properly (c) <input type="checkbox"/></p>
REMARKS 1. A receiving station shall comply with Items 1 to 15, inclusive, and 17, 20, and 22. Separation requirements of Item 5 do not apply. 2. A transfer station shall comply with Items 1, 4, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 20, 22 and as climatic and operating conditions require, applicable provisions of Items 2 and 3. In every case, overhead protection shall be required. 3. Facilities for the cleaning and sanitizing of milk tank trucks shall comply with the same requirements for transfer stations. 4. In areas of the milk plant where Items 7, 10, 11, 12, 13, 15, 17, 18 and 19 are dedicated only to the Aseptic Processing and Packaging System, as defined by the PMO, these items shall be inspected and regulated in accordance with the applicable requirements of 21 CFR Parts 108.110 and 113.		
DATE _____	SANITARIAN _____	

NOTE – Item numbers correspond to required sanitation Items for Grade "A" pasteurized milk in the *Grade "A" Pasteurized Milk Ordinance*.

FORM FDA 2359 (10/08 10/12)

**MILK PLANT EQUIPMENT
TEST REPORT**

TEST NO.	TEST	TEST FREQUENCY	TESTED (X or NA)	RESULTS OF TEST (See Reverse for Working Notes)
1.	Indicating Thermometers (including air space): Temperature Accuracy	3 months		
2.	Recording Thermometers: Temperature Accuracy	3 months		
3.	Recording Thermometers: Time Accuracy	3 months		
4.	Recording Thermometers: Checked against Indicating Thermometer	3 months		Daily by operator
5.	Flow-Diversion Device (FDD): Proper Assembly and Function (HTST and HHST)			
5.1	Leakage Past Valve Seat(s)	3 months		
5.2	Operation of Valve Stem(s)	3 months		
5.3	Device Assembly (micro-switch) Single Stem	3 months		
5.4	Device Assembly (micro-switches) Dual Stem	3 months		
5.5	Manual Diversion - Parts (A, B, and C) (HTST only)	3 months		
5.6	Response Time	3 months		
5.7	Time Delay Interlock (dual stem devices) (Inspect)	3 months		
5.8	Time Delay Interlock (dual stem devices) (CIP)	3 months		
5.9	Leak Detect Flush Time Delay (HTST only as applicable)	3 months		
6.	Leak-Protect Valves: Leakage (Vats only)	3 months		
7.	Indicating Thermometers on Pipelines: Thermometric Response (HTST only)	3 months		
8.	Recorder-Controller: Thermometric Response (HTST only)	3 months		
9.	Regenerator Pressure Controls			
9.1	Pressure Switches (HTST only)	3 months		
9.2	Differential Pressure Controllers			
9.2.1	Calibration	3 months		
9.2.2	Interwiring Booster Pump (HTST only)	3 months		
9.2.3	Interwiring FDD (HTST ₊ and HHST and Aseptic)	3 months		
9.3	Additional Booster Pump Interwiring (HTST only)			
9.3.1	With FDD	3 months		
9.3.2	With Metering Pump	3 months		
10.	Milk-Flow Controls: Cut-in and Cut-out Temperatures (10.1, 10.2* or 10.3*)	3 months		Daily by operator (HTST)
11.	Timing System Controls			
11.1	Holding time (HTST, except Magnetic Flow Meters)	6 months		Adjusted product holding time if applicable
11.2.a	Magnetic Flow Meters (HTST only)	6 months		
11.2.b	Flow Alarm (HTST ₊ and HHST and Aseptic)	6 months		
11.2.c	Loss of Signal Alarm (HTST ₊ and HHST and Aseptic)	6 months		
11.2.d	Flow Cut-in/Cut-out (HTST only)	6 months		
11.2.e	Time Delay (after divert) (HTST with a FDD located at the end of the holding tube)	6 months		
11.2.f	High Flow Alarm Response Time (All Magnetic Flow Meter Systems)	6 months		
11.3	HHST Indirect Heating	6 months		
11.4	HHST Direct Injection Heating	6 months		
11.5	HHST Direct Infusion Heating	6 months		
12.	Controller: Sequence Logic (HHST and Aseptic) (12.1* or 12.2*)	3 months		
13.	Product Pressure-Control Switch Setting (HHST and Aseptic)	3 months		
14.	Injector Differential Pressure Injection Heating (HTST ₊ and HHST and Aseptic)	3 months		
15.	Electro-Magnetic Interference from Hand-Held Communication Devices (HTST ₊ and HHST and Aseptic)	3 months		
*For HTST systems with the FDD located downstream of the regenerator and/or cooler section.				
REMARKS (If additional space is required please place information on the back of this form or on a separate page.)				
PLANT	IDENTITY OF EQUIPMENT	LOCATION	DATE	SANITARIAN
NOTE: This Form is a supplement to the Milk Plant Inspection Report, FORM FDA 2359, and these tests are in addition to the equipment requirements for which compliance is determined by inspection. (Refer to Appendix I of the Grade "A" Pasteurized Milk Ordinance.)				

FORM FDA 2359b (10/08 10/12) (PREVIOUS EDITIONS ARE OBSOLETE)

Make the following change to APPENDIX Q. OPERATION OF AUTOMATIC MILKING INSTALLATIONS FOR THE PRODUCTION OF GRADE "A" RAW MILK FOR PASTEURIZATION on Page 356:

Page 356

**APPENDIX Q. OPERATION OF AUTOMATIC MILKING
INSTALLATIONS FOR THE PRODUCTION OF GRADE
"A" RAW MILK FOR PASTEURIZATION, ULTRA-
PASTEURIZATION OR ASEPTIC PROCESSING AND
PACKAGING**

This Appendix is intended to clarify how AMIs are to perform to be considered in compliance with the *Grade "A" PMO*. It is formatted to follow the Items as outlined in Section 7. STANDARDS FOR GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING AND PACKAGING. Both requirements and recommendations are discussed.

Make the following change to APPENDIX R. DETERMINATION OF TIME/TEMPERATURE CONTROL FOR SAFETY MILK AND MILK PRODUCTS on Page 359:

Page 359

5. Is the milk or milk product processed and packaged so that it no longer requires TCS; such as, Grade "A" aseptically processed and packaged milk and milk products?

Add a new APPENDIX S. ASEPTIC PROCESSING AND PACKAGING PROGRAM on Page 362:

**APPENDIX S. ASEPTIC PROCESSING AND PACKAGING
PROGRAM**

The Aseptic Processing and Packaging Program is designed to include all low-acid (21 CFR Part 113) Grade "A" aseptic processed and packaged milk and milk products.

Inspections of a milk plant or portion of a milk plant that is IMS listed to produce aseptically processed and packaged milk or milk products shall be conducted by the Regulatory Agency in accordance with this Ordinance and the information provided below at least once every six (6) months. The APPS, as defined by this Ordinance, shall be exempt from Items 7p, 10p, 11p, 12p, 13p, 15p, 16p, 17p, 18p, and 19p of this Ordinance and shall comply with the applicable portions of 21 CFR Parts 108, 110 and

113. The milk plant's APPS shall be inspected by FDA, or the State Regulatory Agency when designated by FDA, in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113 at a frequency determined by FDA.

When the APPS, as defined by this Ordinance, is utilized to produce aseptically processed and packaged milk or milk products and pasteurized and/or ultra-pasteurized milk and milk products, the APPS shall be inspected and tested by the Regulatory Agency in accordance with the requirements cited in Section 7 of this Ordinance.

**ASEPTIC PROCESSING AND PACKAGING PROGRAM CFR/PMO
COMPARISON SUMMARY REFERENCE**

<u>PMO, Section 7 Items</u>	<u>Aseptic Program</u>	<u>Authority</u>
<u>1p. Floors – Construction</u>	<u>Floor drains are not required in storage rooms for aseptic processed and packaged milk or milk products.</u>	<u>PMO</u>
<u>2p. Walls and Ceiling – Construction</u>	<u>Ceiling requirements are exempt in aseptically processed and packaged milk or milk products dry storage rooms. (Same as for dry milk or milk products.)</u>	<u>PMO</u>
<u>3p. Doors and Windows</u>	<u>None</u>	<u>PMO</u>
<u>4p. Lighting and Ventilation</u>	<u>None</u>	<u>PMO</u>
<u>5p. Separate Rooms</u>	<u>Fabrication of containers and closures for aseptic processed and packaged milk and milk products within the APPS is exempt.</u>	<u>PMO</u>
<u>6p. Toilet – Sewage Disposal Facilities</u>	<u>None</u>	<u>PMO</u>
<u>7p. Water Supply*</u>	<u>The APPS is exempt, but shall comply with the CFR.</u>	<u>PMO/CFR</u>
<u>8p. Handwashing Facilities</u>	<u>None</u>	<u>PMO</u>
<u>9p. Milk Plant Cleanliness</u>	<u>None</u>	<u>PMO</u>
<u>10p. Sanitary Piping*</u>	<u>The APPS is exempt, but shall comply with the CFR.</u>	<u>PMO/CFR</u>
<u>11p. Construction and Repair of Containers and Equipment*</u>	<u>The APPS is exempt, but shall comply with the CFR. Paper, plastics, foil, adhesives and other components of containers and closures used in the packaging of milk or milk products that have been aseptically processed and packaged are not required to comply with Appendix J of the PMO;; originate from an IMS Listed Source;; and are subject to the requirements of the CFR.</u>	<u>PMO/CFR</u>
<u>12p. Cleaning and Sanitizing of Containers and Equipment*</u>	<u>The APPS is exempt, but shall comply with the CFR.</u>	<u>PMO/CFR</u>
<u>13p. Storage of Cleaned Containers and Equipment*</u>	<u>The APPS is exempt, but shall comply with the CFR.</u>	<u>PMO/CFR</u>

<u>PMO, Section 7 Items</u>	<u>Aseptic Program</u>	<u>Authority</u>
<u>14p. Storage of Single- Service Containers, Utensils and Materials</u>	<u>None</u>	<u>PMO</u>
<u>15p.(A) Protection from Contamination*</u>	<u>The APPS is exempt, but shall comply with the CFR.</u>	<u>PMO/CFR</u>
<u>15p.(B) Protection from Contamination - Cross Connections*</u>	<u>The APPS is exempt, but shall comply with the CFR. APPS equipment is exempt from the separation requirements of the PMO in relationship to instrumented steam blocks between milk and milk products and cleaning and/or chemical sanitizing solutions.</u>	<u>PMO/CFR</u>
<u>16p. Pasteurization and Aseptic Processing and Packaging (A) through (D)*</u>	<u>The APPS is exempt, but shall comply with the CFR. The State Regulatory Agency is not required to conduct the quarterly equipment testing and sealing of aseptic processing equipment. Records and recording charts are not required to be reviewed during routine inspections, State ratings or check ratings.</u>	<u>CFR</u>
<u>17p. Cooling of Milk and Milk Products*</u>	<u>The APPS and aseptic processed and packaged product storage is exempt, but shall comply with the CFR.</u>	<u>PMO/CFR</u>
<u>18p. Bottling, Packaging and Container Filling*</u>	<u>The APPS is exempt, but shall comply with the CFR.</u>	<u>CFR</u>
<u>19p. Capping, Container Closure and Sealing and Dry Milk Product Storage*</u>	<u>The APPS is exempt, but shall comply with the CFR.</u>	<u>CFR</u>
<u>20p. Personnel -Cleanliness</u>	<u>None</u>	<u>PMO</u>
<u>21p. Vehicles</u>	<u>None</u>	<u>PMO</u>
<u>22p. Surroundings</u>	<u>None</u>	<u>PMO</u>

*** NOTE:** In areas of the milk plant where these Items are dedicated only to the APPS, as defined by this Ordinance, these Items shall be inspected and regulated in accordance with the applicable FDA regulations (21 CFR Parts 108, 110 and 113).

Make the following change to the INDEX on Pages 362-379:

Page 362

Aseptic

~~aseptically processed processing and packaging, definition~~
~~aseptic processing and packaging systems system, definition~~.....

controlling added water.....
cooling exemption.....
examination of.....
imminent hazard.....
labeling.....
process authority.....
resterilized after contamination.....
sampler-milk tank truck.....

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Flow diversion device.....
 aseptic systems.....
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Indicating thermometer

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 records for aseptically packaged products.....
 records, drug residue testing.....

Low-acid aseptic milk and milk products, definition.....

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Milk

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 aseptically processed processing and packaging, definition.....

 flavored.....

 low-acid aseptic, definition.....
 lowfat.....

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Packaging

aseptic.....
equipment.....

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Pasteurization, definition.....

milk or milk product-to-water-to-milk or milk product regenerative heating
pasteurization and aseptic processing records, equipment tests and examination.....
pressure relief valves.....

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Recording thermometer.....
aseptic system
~~aseptic system, chart reviewed by management~~.....
batch pasteurizer.....

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Records
access to industry
~~aseptic processing~~.....
batch pasteurization.....

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Storage
aseptically processed and packaged milk

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Temperature
aseptic milk storage.....
charts.....

Tests

airspace thermometer
~~aseptic processing equipment~~.....
~~aseptically packaged milk and milk products~~.....
booster pump.....

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Thermometer

airspace

aseptic system

batch pasteurization.....

**ASEPTIC PILOT PROGRAM IMPLEMENTATION COMMITTEE
2011 NCIMS PROPOSAL
1/13/2011**

**METHODS OF MAKING SANITATION RATINGS OF
MILK SHIPPERS**

2009 REVISION

NOTE: Underlined text is proposed new wording and ~~struck-through text~~ is wording that is proposed to be deleted.

*Make the following changes to the **TABLE OF CONTENTS** on Pages ii through iv:*

Page ii

C. RATING METHODS FOR MILK PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS.....
....

2. COLLECTION OF DATA

 d. Recording of Data for Milk Plants and Receiving Stations Being Listed Under the NCIMS Aseptic Processing and Packaging Program.....

3. COMPUTATION OF SANITATION COMPLIANCE RATINGS.....

D. COMPUTATION OF ENFORCEMENT RATINGS.....
.....

4. MILK PLANTS.....

 a. Aseptic Milk Plant.....

 ab. Milk Plant with an Unattached Supply of Raw Milk.....

 bc. Milk Plant with an Attached Supply of Raw Milk.....

E. PREPARATION OF THE SROs REPORT.....
.....

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F. PUBLICATION OF THE “INTERSTATE MILK SHIPPER’s REPORT”
.....

4. PREPARATION OF THE “INTERSTATE MILK SHIPPER’s REPORT” FOR ASEPTIC PROCESSING AND PACKAGING PROGRAM LISTINGS.....

G. EXAMPLES OF RATING, AND NCIMS HACCP LISTING, AND ASEPTIC PROCESSING AND PACKAGING PROGRAM LISTING FORMS

.....

13. FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products.....

H. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING, AND NCIMS HACCP LISTING, AND ASEPTIC PROCESSING AND PACKAGING PROGRAM LISTING FORMS.....

.....

Page iv

23. FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products

24. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (EXAMPLE: ASEPTIC MILK PLANT).....

Make the following changes to A. DEFINITIONS on Pages 1 and 2:

Page 1

2. ASEPTIC CRITICAL LISTING ELEMENT (ACLE): An item on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products. The identification of any ACLE element by a SRO or FDA Regional Milk Specialist as not being in compliance, whereby a listing shall be immediately denied or withdrawn.

3. ASEPTIC MILK PLANT RATING: A rating of a milk plant or portion of a milk plant that produces aseptically processed and packaged Grade "A" milk and/or milk products that is rated separately from the rating of pasteurized and/or ultra-pasteurized Grade "A" milk and milk products produced in the milk plant. This rating shall be made for all milk plants producing aseptically processed and packaged milk and/or milk products as defined in the *Grade "A" PMO*. An NCIMS HACCP milk plant listing that produces aseptically processed and packaged Grade "A" milk and/or milk products shall have only an NCIMS HACCP listing. **NOTE:** The raw milk receiving area may be rated with the aseptic milk plant, or with a separately-listed pasteurization and/or ultra-pasteurized milk plant, or separately as a receiving station.

4. ASEPTIC PROCESSING AND PACKAGING SYSTEM (APPS): For the purposes of this document, the Aseptic Processing and Packaging System in a milk plant

is comprised of the processes and equipment used to process and package aseptic Grade "A" milk or milk products. The APPS shall be regulated in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. The APPS shall begin at the constant level tank and end at the discharge of the packaging machine, provided that the Process Authority may provide written documentation which will clearly define additional processes or equipment that are considered critical to the commercial sterility of the product.

25. AUDIT: An evaluation of the entire milk plant, receiving station, or transfer station facility, and HACCP System to ensure compliance with the HACCP System and other NCIMS regulatory requirements, with the exception of the APPS for aseptic processing and packaging milk plants.

Renumber remaining Definitions accordingly.

Page 2

§11. FDA AUDIT: An evaluation conducted by FDA of the entire milk plant, receiving station, or transfer station facility to ensure compliance with the HACCP System and other NCIMS regulatory requirements, with the exception of the APPS for aseptic processing and packaging milk plants.

Renumber remaining Definitions accordingly.

1013. INDIVIDUAL RATING: An individual rating is the rating of a single producer group, milk plant, receiving station, and/or transfer station under the supervision of a single Regulatory Agency. Milk plants producing Grade "A" condensed or dried milk and milk products and/or Grade "A" condensed or dry whey and whey products may be rated separately from the same milk plant producing other Grade "A" milk or milk products, provided each listing holds a separate permit. Milk plants that produce both aseptically processed and packaged Grade "A" milk and/or milk products and pasteurized and/or ultra-pasteurized Grade "A" milk and/or milk products shall be rated separately. Provided, that an NCIMS HACCP milk plant listing that produces aseptically processed and packaged Grade "A" milk and/or milk products shall have only an NCIMS HACCP listing. An individual dairy farm shall only be included in one (1) IMS Listing.

114. LISTING AUDIT: An evaluation conducted by a SRO of the entire milk plant, receiving station or transfer station facility to ensure compliance with the NCIMS HACCP Program and other NCIMS regulatory requirements, with the exception of the APPS for aseptic processing and packaging milk plants.

1215. MILK PLANT: A milk plant is any place, premises, or establishment where milk or milk products are collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed and packaged, condensed, dried, packaged, or prepared for distribution.

1316. RECEIVING STATION:
Renumber remaining Definitions accordingly.

Make the following changes to C. RATING METHODS FOR MILK PLANTS, RECEIVING STATIONS AND TRANSFER STATIONS on Pages 9, 10 and 13:

Page 9

2. COLLECTION OF DATA

a. Recording of Inspection Data

3.) The average number of pounds of milk and milk products processed daily is needed for computing the rating and is entered in the appropriate place at the top of FORM FDA 2359-MILK PLANT INSPECTION REPORT. When a deficiency in a milk plant affects only one (1) type of packaging, i.e., paper, glass, single-service plastics, multi-use plastics, dispenser, cottage cheese, sour cream or yogurt containers; or the capping of these containers; or an individual pasteurization unit used, i.e., vat, HTST, or HHST, ~~or aseptic processing~~; or product(s) that have not been pasteurized at minimum pasteurization times and temperatures; only the quantity of all products affected by the deficiency, rather than the entire plant's production, is recorded for use in the computation of the plant's Sanitation Compliance Rating. Only violations of Items 16p, 18p and 19p of the *Grade "A" PMO* are to receive partial debits. Provided, that bacterial count, coliform count and cooling temperature may be partially debited for the particular product involved. All other violations should be considered as affecting the entire production of the milk plant.....

Page 10

b. Recording of Laboratory and Other Test Data

(3) The SRO may utilize Regulatory Agency's records in*Grade "A" PMO*.

NOTE: The sampling and testing of aseptically processed and packaged Grade "A" milk and/or milk products is not required, with the exception of the annual vitamin assay analysis to which vitamin(s) A and/or D have been added for fortification purposes. The sampling and testing requirements of Section 6 of the Grade "A" PMO for raw milk for aseptic processing and packaging is required.

Page 13

c. Recording of Data for Milk Plants, Receiving Stations and Transfer Stations Being Listed Under the NCIMS HACCP Listing Procedure

B.) Significant deficiencies involving one (1) or more CLE's constitute grounds for denial or withdrawal of a plant's, receiving station's or transfer station's NCIMS HACCP Listing.

(viii) **HACCP SYSTEM AUDIT FOLLOW-UP ACTION:** A series of observations that lead to a finding of a potential HACCP System failure that is likely to result in a compromise to milk or milk product safety.

NOTE: In the case of a HACCP/aseptic listed milk plant, the identification of any ACLE element on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products by a SRO or FDA Regional Milk Specialist as not being in compliance shall also constitute an ACLE deficiency under the NCIMS HACCP System, whereby a listing shall be immediately denied or withdrawn.

d. Recording of Data for Milk Plants and Receiving Stations Being Listed Under the NCIMS Aseptic Processing and Packaging Program

1.) Inspection Criteria

(A.) The NCIMS Aseptic Processing and Packaging Program includes all low-acid aseptically processed and packaged Grade "A" milk and/or milk products as defined in the *Grade "A" PMO*.

(B.) State Regulatory inspections of a milk plant or portion of a milk plant that is listed to produce aseptically processed and packaged Grade "A" milk and/or milk products shall be conducted in accordance with the *Grade "A" PMO* at least once every six (6) months. The milk plant's APPS, as defined by the *Grade "A" PMO*, shall be inspected by FDA, or the State Regulatory Agency when designated by FDA, in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113 at a frequency determined by FDA.

(C.) For milk plants or portions of milk plants that are listed to produce aseptically processed and packaged Grade "A" milk and/or milk products, the APPS, as defined by the *Grade "A" PMO*, shall be exempt from Items 7p, 10p, 11p, 12p, 13p, 15p, 16p, 17p, 18p, and 19p of the *Grade "A" PMO*. These items which are dedicated only to the APPS shall comply with the applicable portions of 21 CFR Parts 108, 110 and 113. The rest of the milk plant, including the receiving area, shall be inspected in accordance with the *Grade "A" PMO* and rated and listed in accordance with the current NCIMS requirements. (Refer to Appendix S. Aseptic Processing and Packaging Program of the *Grade "A" PMO*).

(D.) When the APPS is utilized to produce aseptically processed and packaged Grade "A" milk and/or milk products and pasteurized and/or ultra-pasteurized Grade "A" milk and/or milk products, the APPS shall be inspected and tested by the Regulatory Agency in accordance with the requirements cited in Section 7 of the *Grade "A" PMO*.

(E.) NCIMS HACCP listed aseptic milk plants shall be inspected/audited and regulated under the NCIMS HACCP Program with the exception of the APPS which shall be inspected and regulated under the NCIMS Aseptic Processing and Packaging Program. Provided that FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM MILK PLANT CRITICAL

LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products shall also be completed and submitted.

2.) Criteria and Procedures for Denial or Withdrawal of a Listing

In addition to the current NCIMS requirements for a listing, the identification of any ACLE element on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products by a SRO or FDA Regional Milk Specialist as not being in compliance, requires that a listing shall be immediately denied or withdrawn.

3. COMPUTATION OF SANITATION COMPLIANCE RATINGS

*Make the following changes to **D. COMPUTATION OF ENFORCEMENT RATINGS** on Pages 15 and 18:*

Page 15

D. COMPUTATION OF ENFORCEMENT RATINGS

For all NCIMS HACCP listings, including aseptic milk plants, complete FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT. (Refer to Section H, # 19 for an example.) Enforcement ratings shall be made for dairy farms that are listed with milk plants, receiving stations, or transfer stations that are listed under the NCIMS HACCP listing procedure. These enforcement ratings shall be made using the procedures for raw milk for pasteurization addressed in 2. of this Section.

Page 18

4. MILK PLANTS

a. For NCIMS aseptic milk plants, all Items in Part II-MILK PLANTS, except Number 5, and all Items on Part III-INDIVIDUAL SHIPPER RATING on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), shall be evaluated. The total weight, which can be earned in Part II, is eighty-five (85). Therefore, the sum of the total credits earned in Part II should be divided by eighty-five (85) and multiplied by 100.

ab. Milk Plant with an Unattached Supply of Milk

Note: Re-letter remaining sub items.

*Make the following changes to **E. PREPARATION OF THE SROs REPORT** on Page 21:*

4. RECOMMENDATIONS OF THE SRO

.....

For all NCIMS HACCP listings, including aseptic milk plants, complete FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT, which includes an evaluation of the following: (Refer to Section H, #19 for an example.)

Make the following changes to F. PUBLICATION OF THE "INTERSTATE MILK SHIPPER's REPORT on Page 25:

b. FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT and FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT shall be submitted with all FORM FDA 2359i's.

4. PREPARATION OF THE "INTERSTATE MILK SHIPPER's REPORT" FOR ASEPTIC PROCESSING AND PACKAGING PROGRAM LISTINGS

The provisions of this Section apply to milk plants and receiving stations listed under the NCIMS Aseptic Processing and Packaging Program listing procedure, except that FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products shall be submitted with FORM FDA 2359i for each NCIMS aseptic milk plant listing to the PHS/FDA Regional Office for quality assurance review.

Make the following changes to G. EXAMPLES OF RATING AND NCIMS HACCP LISTING FORMS on Page 26:

G. EXAMPLES OF RATING, AND NCIMS HACCP LISTING, AND ASEPTIC PROCESSING AND PACKAGING PROGRAM LISTING FORMS

2. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2).....

Note: Update this FORM as indicated below:

**MILK PLANT
PART II**

- 2 Milk plant and receiving station(s) inspected ~~at least~~ once every three (3) months;
aseptic milk plant and transfer station(s) once every six (6) months
- 5 Pasteurization equipment tested at required frequency (Not required for aseptic milk plants.)

**INDIVIDUAL SHIPPER RATING
PART III**

INDIVIDUAL SHIPPER ENFORCEMENT RATINGS

Individual Shipper of Raw Milk for Pasteurization:

- Without Milk Plant, Receiving Station, or Transfer Station or Plant:

Individual Shipper of Pasteurized Milk and Milk Products:

- Aseptic Milk Plants:
 - Evaluate all Items PART II., except Number 5. Divide by 85.
- With Attached Raw Supply:

.....

FORM FDA 2359j (~~10/08~~ 10/11) (PAGE 2)

*Refer to FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B.
REPORT OF ENFORCEMENT METHODS (PAGE 2) on the next page.*

NOTE: Also make these same changes on Pages 28, 46, 49, 53, and 55.

SECTION B. REPORT OF ENFORCEMENT METHODS

MILK SANITATION KAJING KEPUKI

SHIPPER _____

DATE OF RATING _____

ENFORCEMENT RATING _____

DAIRY FARMS PART I						MILK PLANT PART II						INDIVIDUAL SHIPPER RATING PART III											
Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit
1	3	All dairy farmers hold a valid permit				5		1	3	All milk plant, receiving station and transfer station operators hold a valid permit				5		1	1	Enter TOTAL CREDIT from PART I under Percent Complying				47	
2	5	All dairy farms inspected at least once every six (6) months or as required in Appendix "P"				15		2	5	Milk plant and receiving station(s) inspected at least once every three (3) months; aseptic milk plant and transfer station(s) once every six (6) months				15		2	2	Enter TOTAL CREDIT from PART II under Percent Complying				47 / 94	
3	5	Inspection sheet posted or available				5		3	5	Inspection sheet posted or available				5		3	4	All milk and milk products properly labeled				6	
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10		4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10		TOTAL CREDIT, PART III ➔							
5	8	TB & Brucellosis Certification on file as required				10		5	7	Pasteurization equipment tested at required frequency (Not required for aseptic milk plants.)				15	INDIVIDUAL SHIPPER ENFORCEMENT RATINGS								
6	7	Water samples tested and reports on file as required				5		6	7	Individual and cooling water samples tested and reports on file as required				5	INDIVIDUAL SHIPPER OF RAW MILK FOR PASTEURIZATION:								
7	5	Milking time inspection program established				5		7	6	Samples of each plant's milk and milk products collected at required frequency and all necessary laboratory examinations made				10	<ul style="list-style-type: none"> Without Milk Plant, Receiving Station, or Transfer Station or Plant: <ul style="list-style-type: none"> Evaluate all items PART I. and record. With Receiving Station(s) or Transfer Station(s): <ul style="list-style-type: none"> Evaluate all items PART I. Evaluate all items PART II., except Numbers 5 and 7. Divide by 75. Evaluate all items PART III. 								
8	6	At least four (4) samples collected from each dairy farm's supply every six (6) months and all necessary laboratory examinations made				10		8	6	Sampling procedures approved by PHS/FDA evaluation methods				10	INDIVIDUAL SHIPPER OF PASTEURIZED MILK AND MILK PRODUCTS:								
9	6	Sampling procedures approved by PHS/FDA evaluation methods				10		9	3, 5, 6, 16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15	<ul style="list-style-type: none"> Aseptic Milk Plants: <ul style="list-style-type: none"> Evaluate all items PART II., except Number 5. Divide by 85. With Attached Raw Supply: <ul style="list-style-type: none"> Evaluate all items PART I. Evaluate all items PART II., use 47 Weight. With Unattached Raw Supply: <ul style="list-style-type: none"> Evaluate all items PART II., use 94 Weight. Evaluate all items PART III., except Number 1. 								
10	3, 5, 6, 16	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15		10	10	Records systematically maintained and current				10	TOTAL CREDIT, PART II ➔								
11		Records systematically maintained and current				10		TOTAL CREDIT, PART I ➔															
TOTAL CREDIT, PART I						TOTAL CREDIT, PART II						TOTAL CREDIT, PART III											
REMARKS						REMARKS						REMARKS											

FORM FDA 2359j (40/08 10/11) (PAGE 10) (PREVIOUS EDITIONS ARE OBSOLETE)

11. FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY
REVIEW REPORT.....

Note: Update this FORM as indicated below:

A narrative description shall be provided as a part of all NCIMS HACCP Listings and FDA Audits, including aseptic milk plants with NCIMS HACCP Listings. This report shall include an evaluation of the following requirements:

4. Pasteurization equipment tested as required frequency. (Not applicable to receiving and transfer stations and aseptic milk plants.)

FORM FDA 2359n (~~10/10~~ 10/11)

Refer to FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT on the next page.

NOTE: Also make these same changes on Pages 41 and 67.

Department of Health and Human Services Food and Drug Administration		NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT (To be included with all NCIMS HACCP Listings and FDA Audits)	
STATE REGULATORY AGENCY		DATE OF EVALUATION	
FIRM NAME	LICENSE/PERMIT NO.	IMS PLANT NO.	
ADDRESS			
EXPLANATION OF CONCERNS NOTED REGARDING REGULATORY AGENCY OBLIGATIONS UNDER THE NCIMS HACCP SYSTEM (Use additional sheets if necessary.)			
A narrative description shall be provided as a part of all NCIMS HACCP Listings and FDA Audits, <u>including aseptic milk plants with NCIMS HACCP Listings</u> . This report shall include an evaluation of the following requirements:			
1. Milk plant, receiving station or transfer station holds a valid permit.			
2. Milk plant, receiving station or transfer station audited by the Regulatory Agency at the minimum required frequency.			
3. Requirements interpreted in accordance with the <i>Grade "A" PMO</i> as indicated by past audits.			
4. Pasteurization equipment tested at required frequency. (Not applicable to receiving and transfer stations <u>and aseptic milk plants</u> .)			
5. Individual and cooling water samples tested and reports on file as required.			
6. Samples of milk plant's milk and milk products collected at the required frequency and all necessary laboratory examinations made. (Not applicable to receiving and transfer stations.)			
7. Sampling procedures approved by PHS/FDA evaluation methods.			
8. Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required.			
9. Records systematically maintained and current.			

13. FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products

Note: Add this new FORM after Page 42 of this Section.

**NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM
CRITICAL LISTING ELEMENTS**
(Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products)

(To be included with all NCIMS Aseptic Processing and Packaging Program State Ratings/HACCP Listings and FDA Check Ratings/HACCP Audits.)

MILK PLANT _____ **DATE OF RATING** _____

ADDRESS _____ **LICENSE PERMIT NUMBER** _____

RATING AGENCY _____

**EXPLANATION OF CONCERNS NOTED REGARDING CRITICAL LISTING ELEMENTS
UNDER THE NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM**
(Use additional sheets as necessary.)

A narrative description shall be provided as a part of all NCIMS Aseptic Processing and Packaging Program State Ratings/HACCP Listings and FDA Check Ratings/HACCP Audits. This report shall include an evaluation of the following requirements:

1. Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic Grade "A" milk and milk products covered by a filing with the FDA LACF using Form FDA 2541c or equivalent electronic filing?

2. Are the milk plant's filed scheduled processes for all of its low-acid aseptic Grade "A" milk and milk products developed by a recognized Process Authority qualified as having expert knowledge of thermal processing requirements?

3. Are the operators of the milk plant's aseptic processing and packaging systems under the supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent)?

4. Is the milk plant currently under an "Order of Determination of Need" for an Emergency Permit?

FORM FDA 2359p (10/11)

Make the following changes to H. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING AND NCIMS HACCP LISTING FORMS on Pages 43 and 44:

Page 43

H. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING, AND NCIMS HACCP LISTING, AND ASEPTIC PROCESSING AND PACKAGING PROGRAM LISTING FORMS

Page 44

23. FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM CRITICAL LISTING ELEMENTS for Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products
24. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (EXAMPLE: ASEPTIC MILK PLANT).....

Add the following two (2) new completed FORMS after Page 71 of this Section.

**NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM
MILK PLANT CRITICAL LISTING ELEMENTS**

(Low-Acid (pH greater than 4.6) Aseptic Milk and Milk Products)

(To be included with all NCIMS Aseptic Processing and Packaging Program State Ratings/HACCP Listings and FDA Check Ratings/HACCP Audits.)

MILK PLANT ASEPTIC DAIRY **DATE OF RATING** 10/8-9/2012

ADDRESS 1000 PLANT DRIVE **LICENSE PERMIT NUMBER** 80-001

RATING AGENCY USA MILK CONTROL AGENCY

**EXPLANATION OF CONCERNS NOTED REGARDING CRITICAL LISTING ELEMENTS
UNDER THE NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM**

(Use additional sheets as necessary.)

A narrative description shall be provided as a part of all NCIMS Aseptic Processing and Packaging Program State Ratings/HACCP Listings and FDA Check Ratings/HACCP Audits. This report shall include an evaluation of the following requirements:

1. Is the milk plant registered with FDA LACF and are all of the milk plant's low-acid aseptic Grade "A" milk and milk products covered by a filing with the FDA LACF using Form FDA 2541c or equivalent electronic filing?

Yes – FCE number 000000; Grade "A" Products: White Milks (Whole, 2%, 1% and Skim), Flavored Milk, including chocolate (Whole, 2% and Skim) SID 2005-01-12/001 indirect UHT processor. SUP SID 2005-01-12/003 Tetra Pak A3/Flex. (Or refer to attached list of additional SIDs and SUP SIDs.)

2. Are the milk plant's filed scheduled processes for all of its low-acid aseptic Grade "A" milk and milk products developed by a recognized Process Authority qualified as having expert knowledge of thermal processing requirements?

YES-Sterilization Processing System #1 and 2: Processing Authorities, Inc., 400 SE 1st Aseptic, State 00000 (George reviewer); Aseptic Fillers #3 and 4: Good Packaging, LLC, 1111 Filler Lane, Bottle, State 00000 (Johnny B. Sterile)

3. Are the operators of the milk plant's aseptic processing and packaging systems under the supervision of a person who has attended a school approved by the FDA (such as Better Process Control School or recognized equivalent)?

YES-Supervisors on site are: Jeff Plant-Better Processing Control School-Purdue University (10/2011); Robert Fixer-Better Processing Control School-WA State University (6/2005); and Jamie Boss-Better Processing Control School-University of Arkansas (8/2010).

4. Is the milk plant currently under an "Order of Determination of Need" for an Emergency Permit?

No.

FORM FDA 2359p (10/11)

SECTION B. REPORT OF ENFORCEMENT METHODS

MILK SANITIZATION KAIING KEPUKI (Example: Aseptic Milk Plant)

MILK SANITIZATION KAIING KEPUKI (Example: Aseptic Milk Plant)

SHIPPER ASEPTIC DAIRY

DATE OF RATING 10/8-9/2012

ENFORCEMENT RATING 91

DAIRY FARMS PART I						MILK PLANT PART II						INDIVIDUAL SHIPPER RATING PART III												
Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	Number	Ordinance Section	Item	Number Inspected	Number Complying	Percent Complying	Weight	Credit	
1	3	All dairy farmers hold a valid permit				5		1	3	All milk plant, receiving station and transfer station operators hold a valid permit				5	5	1	1	Enter TOTAL CREDIT from PART I under Percent Complying				NA	47	NA
2	5	All dairy farms inspected at least once every six (6) months or as required in Appendix "P"				15		2	5	Milk plant and receiving station(s) inspected once every three (3) months, aseptic milk plant and transfer station(s) once every six (6) months	4	3	75	15	11.25	2	2	Enter TOTAL CREDIT from PART II under Percent Complying				92.06	86.54	
3	5	Inspection sheet posted or available				5		3	5	Inspection sheet posted or available				10		3	4	All milk and milk products properly labeled				80	6	4.80
4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections				10		4	7	Requirements interpreted in accordance with PHS/FDA PMO as indicated by past inspections	1	90	90	10	9.00									
5	8	TB & Brucellosis Certification on file as required				10		5	7	Pasteurization equipment tested at required frequency (Not required for aseptic milk plants.)	NA	NA	NA	15	NA									
6	7	Water samples tested and reports on file as required				5		6	7	Individual and cooling water samples tested and reports on file as required	6	6	100	5	5									
7	5	Milking time inspection program established				5		7	6	Samples of each plant's milk and milk products collected at required frequency and all necessary laboratory examinations made	5	4	80	10	8.00									
8	6	At least four (4) samples collected from each dairy farm's supply every six (6) months and all necessary laboratory examinations made				10		8	6	Sampling procedures approved by PHS/FDA evaluation methods	1	1	1	10	10									
9	App B	Sampling procedures approved by PHS/FDA evaluation methods				10		9	3.5	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required	1	1	100	15	15									
10	3.5	Permit issuance, suspension, revocation, reinstatement, hearings, and/or court actions taken as required				15		10	10	Records systematically maintained and current	1	1	100	10	10									
11		Records systematically maintained and current				10																		
TOTAL CREDIT, PART I						TOTAL CREDIT, PART II						TOTAL CREDIT, PART III												
92.06						92.06						91.34												

REMARKS
#2-One (1) of the required six (6) month inspections was missed (12/2011).
#4-Violation of Item 7(b) (4 pts)-Submerged water inlet in the CIP make-up tank; Item 15b(c) (5 pts)-Cross connection between the raw milk storage silo #2 and the CIP system in the receiving area, and Item 1(a) (1 pt)-The flooring in the APPS room was in very poor condition, existed but were not debited on the last inspection.
#7-Aseptic 2% chocolate milk, with vitamins A & D added, did not have a vitamin assay conducted during 2011.
78.25/85 = 92.06
#3-Aseptic nonfat milk was not labeled as Grade "A" and "Keep Refrigerated After Opening".

Make the following changes to **APPENDIX A. GUIDELINES FOR COMPUTING ENFORCEMENT RATINGS** on Pages 79, 80 and 82:

Page 79

PART II. MILK PLANTS

2. Milk plants and receiving stations inspected at least once every three (3) months (transfer stations and aseptic milk plants once every six (6) months) (*Grade "A" PMO*, Section 5 - INSPECTION OF MILK PLANTS). Prorate by number of inspections in compliance with the required frequency.

For Example:

$$= \frac{\text{\# of three (3) or six (6) month periods with an inspection conducted}}{\text{Total \# of three (3) or six (6) month periods in rating period}}$$

- a. Milk plants and receiving stations inspected at least once every three (3) months.
- b. Transfer stations and aseptic milk plants inspected at least once every six (6) months.

NOTE: Use *Methods*, Section D., 1., e. as a guide: "...the interval shall include the designated period plus the remaining days of the month in which the inspection is due."

Page 80

5. Pasteurization equipment tested at required frequency (*Grade "A" PMO*, Section 7 - STANDARDS FOR MILK AND MILK PRODUCTS and APPENDIX I. - PASTEURIZATION EQUIPMENT AND CONTROLS-TESTS). Prorate by number of units per quarter that were correctly tested within the required testing frequency vs. total number of units.

NOTE: Not required for aseptic milk plants, except when the APPS is utilized to produce aseptically processed and packaged Grade "A" milk and/or milk products and pasteurized and/or ultra-pasteurized Grade "A" milk and/or milk products. The APPS shall then be tested by the Regulatory Agency in accordance with the requirements cited in Section 7 of the *Grade "A" PMO*.

- a. Total required tests performed based on pasteurization system(s): equals the (# number of Vat Past. Pasteurizers-, + # plus the number of HTST Past. Pasteurizers-, + # plus the number of HHST Past. Pasteurizers-, + # plus the number of Aseptic Systems APPS, if applicable as cited above, at the milk plant.

For Example:

Page 82

7. Samples of each milk plant's milk and milk products collected at the required frequency and all necessary laboratory examinations made (*Grade "A" PMO*, Section 6 - THE EXAMINATION OF MILK AND MILK PRODUCTS). Prorate by number of products in compliance.

a. During any consecutive six (6) months, at least four (4) samples of raw milk, after receipt by the milk plant, including aseptic milk plants, shall be collected, prior to pasteurization, ultra pasteurization, or aseptic processing and packaging, in four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days.

e. Assays of Vitamin A, D, and/or A and D fortified milk and milk products, including aseptically processed and packaged milk and milk products, made at least annually in an IMS Listed Laboratory. Credit for vitamin-fortified products is not given unless vitamin analysis is completed and records are available. Each fortified product is evaluated separately.

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	302
Committee:	Lab/SSCC

***Procedures Change**

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

A. Summary of Proposal

To remove the requirement for the sampling and testing of single service containers from the PMO and related documents.

To update the 2400 series forms for the container testing to reflect that testing only be done on re-usable glass containers.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Single service containers are processed in such a manner that it is not possible for bacteria (including coliforms) survive. From the period of June 1, 2010 through December 31, 2010 there were 1,469 samples collected in a state which included single service containers, closures and paper. During that time 1,469 SPC and 1,468 coliform tests were performed. There were no violative counts for coliform. Of the 45 violative counts for the SPC test none counted against the facility as the containers were sampled in groups and the average count was not in violation. No facilities in this state have been de-listed due to this testing.

C. Proposed Solution

Changes to be made on page(s): Procedures – 20, 21
PMO – 71, 71, 314, 315 of the (X - one of the following):

- | | |
|--|---|
| <input checked="" type="checkbox"/> 2009 PMO

<input type="checkbox"/> 2009 MMSR | <input type="checkbox"/> 2009 EML

<input checked="" type="checkbox"/> 2400 Forms |
|--|---|

Remove the following text from the Procedures document and the PMO.

Procedures page 20

b. One (1) plant sampler that collects raw and finished product samples and single service containers/closures at one (1) pasteurization plant, if applicable.

Procedures page 21 middle

2.) One (1) plant sampler that collects raw and finished product samples and single service containers/closures at one (1) pasteurization plant, if applicable.

Procedures page 21 bottom

2.) One (1) plant sampler that collects raw and finished product samples and single service containers/closures at one (1) pasteurization plant, if applicable.

PMO page 70 – item 12p

b. ~~The residual bacteria count of single service containers and closures, used for packaging pasteurized milk and milk products, shall not exceed fifty (50) colonies per container, or in the case of dry product packaging, shall not exceed one (1) colony per milliliter (1/mL) of capacity when the rinse test is used, except that in containers less than 100 mL the count shall not exceed ten (10) colonies or fifty (50) colonies per eight (8) square inches (one (1) colony per square centimeter) of product contact surface, when the swab test is used, in three (3) out of four (4) samples taken at random on a given day. Coliform organisms shall be undetectable in all single service containers.~~

PMO page 71 – item 12p

e. ~~When single service containers or closures are fabricated in another plant that conforms to the Standards of Appendix J and the Regulatory Agency has information that they do comply, the Regulatory Agency may accept the containers as being in conformance without additional testing. If there is reason to believe that containers do not conform to the bacteriological standards, additional testing may be required. If containers are fabricated in the milk plant, the Regulatory Agency shall collect, during any consecutive six (6) months, at least four (4) sample sets of containers, as defined in Appendix J., from each manufacturing line, as defined in Appendix J., in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days, and analyze the sample sets at an Official, Commercial or Industry Laboratory, approved by the State Milk Laboratory Certifying Agency specifically for the examinations required under Appendix J.~~

PMO page 71 – Appendix J

e. ~~When single service containers or closures are fabricated in another plant that conforms to the Standards of Appendix J and the Regulatory Agency has information that they do comply, the Regulatory Agency may accept the containers as being in conformance without additional testing. If there is reason to believe that containers do not conform to the bacteriological standards, additional testing may be required. If containers are fabricated in the milk plant, the Regulatory Agency shall collect, during any consecutive six (6) months, at least four (4) sample sets of containers, as defined in Appendix J., from each manufacturing line, as defined in Appendix J., in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days, and analyze the sample sets at an Official, Commercial or Industry Laboratory, approved by the State Milk Laboratory Certifying Agency specifically for the examinations required under Appendix J.~~

PMO page 314 – Appendix J

~~15. "Sample Set" shall mean: a. For the rinse test, a minimum of four (4) containers shall be tested. b. For the swab test, a minimum of four (4), 50 square centimeter areas of surface from separate containers shall be tested. In the case of containers or closures with a product contact surface area smaller than 50 square centimeters, more than four (4) containers or closures to equal at least 50 square centimeters times four (4) will be required to be swabbed.~~

~~16.15 "Sanitization" shall mean the application of any effective method or substance to properly cleaned surfaces for the destruction of pathogens and other microorganisms as far as is practicable. Such treatment shall not adversely affect the equipment, the milk and/or milk product, or the health of consumers, and shall be acceptable to the Regulatory Agency. Methods of sanitization shall meet the requirements contained in Appendix F. of this Ordinance.~~

~~1716. "Single-Service Articles" shall mean articles that are constructed wholly, in part, or in combination from paper, paperboard, molded pulp, plastic, metals, coatings or similar materials and intended by the manufacturer for one (1) usage only.~~

~~1817. "Single-Service Container" shall mean any container having a milk or milk product-contact surface and used in the packaging, handling or storage of Grade "A" milk and milk products which is intended for one (1) use only.~~

PMO pages 314 -315, Appendix J

~~C. BACTERIAL STANDARDS AND EXAMINATION OF SINGLE-SERVICE CONTAINERS AND CLOSURES~~

~~1. Paper stock shall meet the bacteriological standard of not more than two hundred fifty (250) colonies per gram as determined by the disintegration test. The paper stock supplier shall certify that their paper stock was manufactured in compliance with this Standard. This applies only to the paper stock prior to lamination.~~

~~2. Where a rinse test can be used, the residual microbial count shall not exceed fifty (50) per container, except that in containers less than 100 mL, the count shall not exceed ten (10), or when using the swab test, not over fifty (50) colonies per 8 square inches (1 per square centimeter) of product contact surface in three (3) out of four (4) samples taken at random on a given day. All single-service containers and closures shall be free of coliform organisms.~~

~~3. During any consecutive six (6) months, at least four (4) sample sets shall be collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days, and analyzed at an Official, Commercial or Industry Laboratory approved by the State Milk Laboratory Certifying Agency specifically for the examinations required under these Standards. (Refer to Item 12p of this Ordinance for sampling of containers and closures in milk plants.) 315~~

~~4. When a single-service container or closure is made from one (1) or more component parts as defined in this document, only those final assembled products that may have product contact surface(s), must be sampled and tested for compliance with Section C.~~

~~5. A sample set from each manufacturing line, as defined in these Standards, shall consist of a minimum of four (4) containers or closures, when the rinse test is used, or a minimum of four (4) 50 square centimeters (cm²) areas of surface, when the swab test is used.~~

~~6. The following criteria pertain to manufacturers of pre-forms and bottles preformed at one (1) plant and molded at a second plant: a. The pre-forming plant must be IMS Listed but sampling of the pre-forms is not required at this plant. b. If the first pre-forming plant is also molding the containers into their final form, this plant must be listed and the containers must be sampled at this plant. c. If the second plant, where containers are molded into their final form, is a single-service manufacturer, this plant must be listed and the containers must be sampled at this plant. d. If the second plant is a milk plant where containers are molded into their final form, for use only in that~~

~~milk plant, the milk plant listing is sufficient, but the containers must be sampled at this plant. Procedures for obtaining samples and for the laboratory examination of these products are contained in the latest edition of SMEDP and shall be in substantial compliance with these methods. Such procedures and examinations shall be evaluated in accordance with the current revision of the EML. A list of approved laboratories may be found in the current IMS List, which is published by FDA and available on the Internet at www.fda.gov.~~

2400 Series forms language would be worked out with the NCIMS Laboratory Committee.

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33rd NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 303

Committee: Lab

***Procedures Change**

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

A. Summary of Proposal

Update items in the Procedures document to the same as the EML.

**B. Reason for the Submission and
Public Health Significance and/or Rationale Supporting the Submission**

There are items in the Procedures document that are incorrect and need to be changed to reflect the correct items in the EML.

There is no public health significance.

C. Proposed Solution

Changes to be made on page(s): 7, 27 of the (X - one of the following):

- | | |
|---|---|
| <input type="checkbox"/> 2009 PMO | <input type="checkbox"/> 2009 EML |
| <input type="checkbox"/> 2009 MMSR | <input type="checkbox"/> 2400 Forms |
| <input checked="" type="checkbox"/> 2009 Procedures | <input type="checkbox"/> 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 evaluation 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.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	304
Committee:	MMSR

***Procedures Change**

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

A. Summary of Proposal

To provide the competent regulatory authority discretion to allow for shipment of milk when a Sanitation Compliance Rating score is below 90% prior to a re-rating when such activity does not present a human health hazard. Upon the initial re-rating, failure would result in de-listing.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The penalty for having a milk supply not being able to ship milk is becoming increasingly significant to the industry. Survey data indicate that an IMS listed shipper failing (receiving a sanitation compliance rating score less than 90%) is infrequent – less than 5% of compliance ratings. Typically when a BTU has been delisted, milk is allowed to be redirected to non-grade A manufacturing purposes, thus suggesting that a compliance rating score less than 90% in itself does not represent a human health hazard. Additionally with the increasing number of plants that previously took non-grade A milk now requiring grade A to meet customer requirements milk from delisted BTUs cannot economically be transported to a grade A plant and must be dumped.

Additionally with the consolidation in both production and processing across the dairy industry, the impact of these BTU delisting on the producer has increased. Based on an analysis of data on BTU failures provided by States, a BTU failure results in a minimum of 160,000 pounds of milk per day for an average of more than 16 days to either be redirected to non-grade A manufacturing purposes or to be disposed of on-farm when this option is not available.

When a human health hazard does not exist, redirecting of milk to non-grade A manufacturing

purposes increases costs to the industry through increased transportation costs, decreased value of the milk (compared to Grade A uses), and in some cases replacement costs to secure additional milk supplies for contracted Grade A manufacturing purposes – estimated to cost more than \$100,000 per BTU delisted. When a human health hazard does not exist and milk cannot be redirected to non-grade A manufacturing purposes, the milk does not enter the commercial marketplace with costs to the industry from lost milk marketings and in some cases replacement costs to secure additional milk supplies for contracted Grade A manufacturing purposes – estimated to cost more than \$430,000 per BTU delisted.

When an IMS listed shipper fails a sanitation compliance rating, it is with a score just below 90% and often a subjective matter (approximately one-third of the time, the failing score is $\geq 88\%$). This proposal provides the competent regulatory authority discretion to allow for shipment of milk when a Sanitation Compliance Rating score is below 90% prior to a re-rating when such activity does not present a human health hazard. Upon the initial re-rating, failure would result in de-listing.

C. Proposed Solution

Changes to be made on page(s): Procedures 11, 24, 33-34, 38; MMSR 11, 13, 18, 19, 23,24,25; Form 2359a of the (X - one of the following):

- | | |
|---|--|
| 2009 PMO | 2009 EML |
| <input checked="" type="checkbox"/> 2009 MMSR | <input checked="" type="checkbox"/> 2400 Forms |
| <input checked="" type="checkbox"/> 2009 Procedures | 2009 Constitution and Bylaws |

Make the following change to the 2009 Procedures.

~~Strike out~~ text to be deleted and underlined text to be added.

Page 11

J. STATE RESPONSIBILITIES

1. State Ratings

d. When a certified interstate milk shipper's supply, raw or pasteurized, changes status because of degrading, permit revocation, significant change in number of producers, ~~or~~ change in the Sanitation Compliance Rating that results in revocation of the BTU IMS listing, or change in the Enforcement Rating to less than ninety percent (90%), the shipping State shall immediately notify all known receiving States and the appropriate PHS/FDA Regional Office.

Page 24

J. INDIVIDUAL RATINGS

2. If an IMS listed shipper receives a Sanitation Compliance Rating of less than ninety percent (90%), a re-rating shall be conducted after written notification from an authorized representative of the IMS listed shipper to the Rating Agency that the IMS listed shipper is in substantial compliance. The Rating Agency has discretion to allow for shipment of milk when a Sanitation Compliance Rating score is below 90% prior to a re-rating when such

activity does not present a human health hazard. If written notification for a re-rating is not received within fifteen (15) days or if the initial Sanitation Compliance re-rating is less than ninety percent (90%), the IMS listing will be revoked. A re-rating shall be completed in no more than fifteen (15) days, from the date of receipt of the notification, unless the Rating Agency has a reason to believe a new rating within a lesser time would result in an acceptable rating.

Page 33-34

1. State HACCP Listings for Milk Plants, Receiving Stations and Transfer Stations

d. When a certified interstate milk shipper's supply, raw or pasteurized, changes status because of degrading, permit revocation, significant change in number of producers, change in the Sanitation Compliance Rating that results in revocation of the BTU IMS listing, change in the Enforcement Rating to less than ninety percent (90%), or a change in HACCP listing status, the shipping State shall immediately notify all known receiving States and the appropriate PHS/FDA Regional Office.

Page 38

C. Withdrawal of Certification

iv. Milk is received from a supply other than a NCIMS listed source or from a listed source with a Sanitation Compliance Rating resulting in revocation of the BTU IMS listing. ~~below ninety percent (90%).~~

Page 38

7. OTHER NCIMS REQUIREMENTS: Including a milk supply from a NCIMS listed source(s) with a Sanitation Compliance Rating(s) which results in a successful BTU IMS listing ~~of 90 percent (90%) or above~~ and a drug residue control program implemented.

Make the following change to the 2009 MMSR.

~~Strike-out~~ text to be deleted and underlined text to be added.

Page 11

(iv) Milk is received from a supply other than a NCIMS listed source or from a listed source with a Sanitation Compliance Rating resulting in revocation of the BTU IMS listing. ~~below 90 percent (90%).~~

Page 13

(vii) **OTHER NCIMS REQUIREMENTS:** Incoming milk supply from a NCIMS listed source(s) with a Sanitation Compliance Rating(s) which results in a successful BTU IMS listing ~~of 90 percent (90%) or above~~ and a drug residue control program implemented.

Page 18

3.) The utilization of milk from a separately rated source, which has a Milk Sanitation Compliance Rating, which results in revocation of the BTU IMS listing ~~is not equal to ninety percent (90%) or greater,~~ or is from an unlisted source, would initiate an immediate withdrawal of the shipper from the *IMS List*.

Page 19

3.) The utilization of milk from a separately rated source, which has a Milk Sanitation Compliance Rating, which results in revocation of the BTU IMS listing ~~is not equal to ninety percent (90%) or greater~~, or is from an unlisted source, would initiate an immediate withdrawal of the shipper from the *IMS List*.

Page 23

All unattached supplies shall have a Sanitation Compliance Rating which results in a successful BTU IMS listing ~~of ninety percent (90%) or greater~~. The Sanitation Compliance Rating of the attached supply shall be reported as the Raw Milk Sanitation Compliance Rating for the plant. The earliest rating date shall be reported on FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. In addition, the name of each unattached shipper, during the thirty (30) days preceding the rating, along with the Sanitation Compliance Rating and Date of Rating of each shipper shall be listed on the reverse side of FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. If milk is received from an unlisted source or from a source having a Raw Milk Sanitation Compliance Rating which results in revocation of the BTU IMS listing ~~of less than ninety percent (90%)~~, the PHS/FDA Regional Office shall be notified and the plant shall be immediately withdrawn from the *IMS List*.

Page 24

A.) **Option 1:** If all raw milk sources have a published, or submitted for publication, Sanitation Compliance Rating of ninety percent (90%) or greater and the plant desires to be listed with the plant rating date, the raw milk will be reported as ninety percent (90%) or listed with an asterisk (*), which denotes all supplies are ninety percent (90%) or greater. This will eliminate the need for frequent updating of FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT by the State Milk Sanitation Rating Agency. Certain precautions must be taken to ensure that the raw supply remains at or above the listed ninety percent (90%) Sanitation Compliance Rating. The name of each shipper of raw milk for the thirty (30) days preceding the rating must be listed on the reverse side of FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT, along with their Sanitation Compliance Rating and the Date of Rating. The plant shall be immediately withdrawn from the *IMS List* when milk is received from an unlisted source or from a source having a Raw Milk Sanitation Compliance Rating which results in revocation of the BTU IMS listing ~~of less than ninety percent (90%)~~. The appropriate PHS/FDA Regional Office shall be immediately notified should either of the above events occur.

Page 25

NOTE: The acceptance of milk, which has a Sanitation Compliance Rating which results in revocation of the BTU IMS listing ~~score of less than ninety percent (90%)~~, or is from an unlisted source, is a violation of the agreed upon provisions of **Options 1 and 2** and would initiate an immediate withdrawal of the shipper from the *IMS List*.

Make the following change to the Form 2059o.

~~Strike out~~ text to be deleted and underlined text to be added.

It is further agreed that plants, receiving stations or transfer stations, which receive milk or milk products for processing into milk or milk products for which that milk plant, receiving station or transfer station is listed, are from a non-listed source or a source having a Milk Sanitation Compliance

Rating which results in revocation of the BTU IMS listing of less than ninety percent (90%), shall be immediately withdrawn from the Interstate Milk Shipper's List.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	305
Committee:	

*** Procedures Change**

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

A. Summary of Proposal

This proposal seeks to increase the maximum inspection frequency for State Ratings of farms, plants, receiving stations, transfer stations and single service facilities from twenty – four (24) months to thirty six (36) months.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

Farms, plants, receiving stations, transfer stations and single service facilities currently receive a State Rating once every twenty four (24) months at a minimum. With the twenty four (24) month frequency many States are actually rating these facilities at intervals of eighteen (18) months. The current low level of re-ratings and re-inspections by States and the very low adverse action levels as the result of FDA check rating demonstrate a high level of industry compliance with NCIMS requirements. With significant tightening of available State resources to maintain the NCIMS program, increasing State Ratings from once every two (2) years to once every three (3) years should be implemented.

As with the current system, nothing would prohibit States from rating facilities more frequently based on a state's preference or if a situation warranted more frequent ratings. However, this extension would also allow States to focus their limited resources toward the areas of the program and the facilities that need more attention.

The extension of the State Rating frequency for farms, plants, receiving stations, transfer stations and single service facilities by one year will not reduce public health safety of dairy products since the major tool to insure compliance with the NCIMS requirements is the quarterly inspection requirements. The 36 month rating requirement could actually improve

public health by allowing state inspectors' time to be spent on the areas of greatest need.

NCIMS requirements to conduct state ratings have been in place for many years. With the extensive changes in the dairy industry, its high level of compliance with NCIMS requirements and knowledgeable, educated and well trained personnel, there is no need to conduct ratings of farms, plants, receiving stations, transfer stations and single service facilities at two (2) year intervals or less. Therefore, three (3) year intervals will support the NCIMS need for compliance, uniformity, and reciprocity.

C. Proposed Solution

Changes to be made on page(s): 24 and 44 of the (X - one of the following):

- | | |
|------------------------------|--|
| <u> </u> 2009 PMO | <u> </u> 2009 EML |
| <u> </u> 2009 MMSR | <u> </u> 2400 Forms |
| <u> X </u> 2009 Procedures | <u> </u> 2009 Constitution and Bylaws |

Make the following changes to the 2009 Procedures Governing the Cooperative State – Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments.

~~Strike out~~ text to be deleted and underlined text to be added.

I. AREA RATINGS

1. Area ratings shall be made at a frequency of not less than once every thirty-six (36) months. ~~twenty-four (24)~~

J. INDIVIDUAL RATINGS

1. Individual ratings shall be made at a frequency of not less than once every thirty-six (36) months. ~~twenty-four (24) months.~~

E. QUALIFICATIONS AND CERTIFICATIONS

9. Milk Plant, Receiving Station and Transfer Station HACCP Listings

a. Individual milk plants, receiving stations or transfer stations participating in the NCIMS HACCP listing process shall be audited for listing at a frequency of not less than once every thirty-six (36) months. ~~twenty-four (24) months.~~

Name: Milk Industry Foundation (MIF)

Agency/Organization: IFDA

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City/State/Zip: Washington, DC

Telephone No.: 202-220-3544

E-mail Address: Jgardner@idfa.org

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	306
Committee:	MMSR

***Procedure Change**

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

A. Summary of Proposal

To modify the current State Enforcement Rating for NCIMS Grade "A" plants to be uniform throughout the NCIMS Grade "A" Program.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The traditional NCIMS Enforcement Rating that evaluates the performance of State Dairy Regulatory Programs in complying with the NCIMS requirements results in a numerical score. A numerical Enforcement score of less than 90% indicates a State Regulatory Program is not meeting the minimum requirements for enforcing the NCIMS requirements. However, an enforcement score below 90% places the Grade "A" milk plant's ability to ship milk and milk products via interstate commerce in jeopardy. An enforcement score below 90% is not an indication of the plants ability to maintain compliance with the NCIMS requirements, its ability to produce safe wholesome products, or does it affect the Public's Health.

The NCIMS voluntary HACCP program has been successful by modifying the traditional NCIMS-scored Enforcement Program to evaluate State program compliance with NCIMS requirements on the NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT. This form allows for the recording of State Regulatory oversights; which are utilized by the FDA Regional Milk Specialists to prepare state program evaluations.

C. Proposed Solution

Changes to be made on page(s): _____ of the (X - one of the following):

	2009 PMO	2009 EML
XX	2009 MMSR	2400 Forms
XX	2009 Procedures	2009 Constitution and Bylaws

Request FDA to make the necessary changes to the wording in the 2009 Methods of Making Sanitation Ratings of Milk Shippers, the 2009 Procedures Governing The Cooperative State – Public Health Service/Food and Drug Administration Program of The National Conference on Interstate Milk Shipments, and the associated forms as required. So that all Grade “A” dairy plant Enforcement Ratings are uniform and are utilized to prepare a State Program Evaluation.

Example: Replace the use of the Form FDA 2359J, Milk Sanitation Rating Report (Page 2) Section B. Report of Enforcement Methods with *Form FDA 2359n NCIMS HACCP System Regulatory Agency Review Report*, retitled as the *Form FDA 2359n NCIMS Regulatory Agency Review Report*

Name:	Milk Industry Foundation (MIF)	
Agency/Organization:	IDFA	
Address:	1250 H Street NW	
City/State/Zip:	Washington, DC	
Telephone No.:	202-220-3544	E-mail Address: jgardner@idfa.org

33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #: 307

Committee:

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

A. Summary of Proposal

This proposal asks for development of appropriate processes/procedures to be followed prior to future regulatory activities being enacted that overlap with existing NCIMS programs or place in jeopardy Grade "A" status of milk or milk products established by conformance with NCIMS programs.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

From time to time regulatory initiatives arise that impact and/or overlap with various activities of the dairy industry included under the voluntary Cooperative State-USPHS/FDA Program for the Certification of Interstate Milk Shippers, a program participated in by all Fifty (50) States, the District of Columbia and U.S. Trust Territories.

The successful track record of the NCIMS Program combined with the ongoing commitment and cooperation of state and federal regulators working with industry representatives to safeguard our product(s) and the entire industry provides the rationale for establishing processes that involve the NCIMS in the background, development, and implementation of such future regulatory initiatives.

C. Proposed Solution

Changes to be made on page(s): _____ of the (X - one of the following):

2009 PMO

2009 EML

2009 MMSR	2400 Forms
2009 Procedures	2009 Constitution and Bylaws

The NCIMS Chair will assign an NCIMS standing committee, special committee, or ad hoc committee as approved by the NCIMS Executive Board to develop processes/procedures to be followed prior to future regulatory activities being enacted that overlap with existing NCIMS programs or place in jeopardy Grade "A" status of milk or milk products established by conformance with NCIMS programs.

The objective of this request would be the submission of a proposal to the 2013 NCIMS to resolve this concern.

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33rd NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #: 308

Committee: Aseptic

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

A. Summary of Proposal

FDA requests the Chair to assign this Proposal to the NCIMS Aseptic Pilot Program Implementation Committee (APPIC) as approved by the NCIMS Executive Board.

This Proposal request that the regulatory oversight, rating, IMS Listing and check rating of milk plants that choose the option of labeling their retort processed after packaging milk and/or milk products as Grade "A", as provided for in Definition X. Milk Products of the PMO, be specifically assigned to the charge of the NCIMS APPIC to develop, implement, oversee and evaluate a NCIMS Retort Pilot Program as it relates to the PMO, CFR and the NCIMS. This NCIMS Retort Pilot Program under the APPIC will expire on December 31, 2013, unless extended by future conference action.

**B. Reason for the Submission and
Public Health Significance and/or Rationale Supporting the Submission**

Recently, FDA has been made aware of milk plants that, by their choice, wish to label their retort processed after packaging milk and/or milk products as Grade "A" in accordance with the Definition X. option provided for in the PMO. To our memory, this is one of the first such requests that FDA has ever received for this Grade "A" labeling option.

Definition X. Milk Products of the PMO provides that milk or milk products, which have been retort processed after packaging are only included in this Definition of Grade "A" Milk and Milk Products if they are used as an ingredient to produce any milk or milk product defined in this Definition or if they are labeled as Grade "A" as described in Section 4 of the PMO.

This Proposal specifically addresses the clarification needed as to the regulation, rating, IMS listing and check rating of Grade "A" labeled milk and/or milk products that are retort processed after packaging relative to FDA's Low Acid Canned Foods (LACF) regulations contained in 21 CFR 108, 110, and 113 and the requirements of the PMO.

FDA believes that the most logical assignment for this NCIMS Retort Pilot Program addressing Grade "A" retort processed after packaging milk and/or milk products is to be added to the charge of the existing NCIMS APPIC. The APPIC has the vast depth of knowledge, expertise and history of working with the issues, concerns, and regulations in relationship between the PMO and the CFR Parts 108, 110 and 113 as they relate to LACFs.

The APPIC shall 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. This 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 processing technology and its application. The APPIC shall provide a report to the 2013 NCIMS.

C. Proposed Solution

Changes to be made on page(s): 121 and 122 of the (X - one of the following):

- | | | | |
|-----------------|-----------------|-----------------|------------------------------|
| <u>X</u> | 2009 PMO | <u> </u> | 2009 EML |
| <u> </u> | 2009 MMSR | <u> </u> | 2400 Forms |
| <u> </u> | 2009 Procedures | <u> </u> | 2009 Constitution 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, retort processed after packaging, 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 an satisfactory acceptable HACCP 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 the NCIMS, 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, retort processed after packaging, 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.

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33rd NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #:	309
Committee:	ICPP

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

A. Summary of Proposal

This Proposal contains the provisions for extending the voluntary International Certification Pilot Program (ICPP) for the regulatory oversight, rating and IMS listing of milk shippers and milk laboratories located outside the geographic boundaries of the National Conference on Interstate Milk Shipments (NCIMS) member states.

**B. Reason for the Submission and
Public Health Significance and/or Rationale Supporting the Submission**

The ICPP was established in Proposal #316 by the 2005 NCIMS Conference delegates and extended under Proposal #304 at the 2007 NCIMS. This pilot program provides an additional option to M-I-00-4 and addresses the issue of imported Grade "A" milk and milk products by establishing a third party regulatory and rating program designed to follow and comply with all of the applicable NCIMS Grade "A" Milk Safety Program requirements. The ICPP is limited to 3 Third Party Certifiers (TPC), and was expanded to a maximum of 12 foreign milk companies – 4 per TPC during the 2009 Conference.

The NCIMS International Certification Pilot Program Committee was charged, under Proposal #316, to implement, evaluate, monitor and enforce the ICPP. Foreign milk companies have taken longer than anticipated to achieve listing on the IMS List-FDA has performed check ratings of all of the plants (4) and farms (4) that are currently listed and the equivalent of a State Program Evaluation of the two (2) TPCs that have IMS Listings. Initial compliance of these foreign listed firms has adequately met the PMO. The International Certification Pilot Program Committee does not have enough ongoing data at this time to adequately evaluate the pilot program to determine how a final ICPP could be fully implemented and sustainable within the structure of the NCIMS Program. Therefore, the Committee is requesting that this voluntary

pilot program be extended until December 31, 2013.

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 underlined 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.

Name:	NCIMS International Certification Pilot Program Committee Tom Ford (Indiana) & Claudia Coles (Washington) Co-Chairs		
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33rd NATIONAL CONFERENCE ON
INTERSTATE MILK SHIPMENTS

Proposal #:	310
Committee:	ICPP

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

A. Summary of Proposal

This Proposal contains the provisions for expanding and extending the voluntary International Certification Pilot Program (ICPP) for the regulatory oversight, rating and IMS listing of milk shippers and milk laboratories located outside the geographic boundaries of the National Conference on Interstate Milk Shipments (NCIMS) member states to include options for domestic participation.

**B. Reason for the Submission and
Public Health Significance and/or Rationale Supporting the Submission**

The ICPP was established in Proposal #316 by the 2005 NCIMS Conference delegates and extended under Proposal #304 at the 2007 NCIMS. This pilot program provides an additional option to M-I-00-4 and addresses the issue of imported Grade "A" milk and milk products by establishing a third party regulatory and rating program designed to follow and comply with all of the applicable NCIMS Grade "A" Milk Safety Program requirements. The ICPP is limited to 3 Third Party Certifiers (TPC), and was expanded to a maximum of 12 foreign milk companies – 4 per TPC during the 2009 Conference.

The NCIMS International Certification Pilot Program Committee was charged, under Proposal #316, to implement, evaluate, monitor and enforce the ICPP. While foreign milk companies have taken longer than anticipated to achieve listing on the IMS List, FDA has performed check ratings of all of the plants (4) and farms (4) that are currently listed and the equivalent of a State Program Evaluation of the two (2) TPCs that have IMS Listings. The ICPP does not have experience with implementing the procedures with domestic milk companies. If the ICPP is to be fully implemented within the structure of the NCIMS Program in the future, the domestic industry will be required to have access to the same opportunity as foreign participants.

Additionally many States are facing broad budgetary constraints which raise the possibility for marketplace disruption due to a State's compromised ability to maintain a fully staffed regulatory program. Allowing domestic participation will allow states an opportunity to examine how third-party certification may augment their regulatory programs.

Therefore, the National Milk Producers Federation is requesting that this voluntary pilot program be extended until December 31, 2013 for a maximum 12 foreign and domestic milk companies.

C. Proposed Solution			
Changes to be made on page(s):		122	of the (X - one of the following):
X	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 underlined 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.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	311
Committee:	ICPP

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

A. Summary of Proposal

Direct the International Certification Pilot Program Committee to expand the International Certification Pilot Program (ICPP) to allow up to five (5) Third Party Certifiers (TPCs).

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The International Certification Pilot Program (ICPP) has successfully establish criteria to evaluate “third party certifiers (TPC)” and the result has been a few international dairy plants making Grade “A” product inspected and listed as meeting the minimum requirements of the Pasteurized Milk Ordinance (PMO) and associated documents. This pilot program has been running for four (4) years as the result of significant contributions of time and creativity by the members of the ICPP Committee and TPC participants. As interest in exporting Grade “A” milk products to the United States continues and the threat of a World Trade Organization or other international trade challenge continues, it is important that the NCIMS position itself to provide defensible avenues for internationally-based processors of Grade “A” milk products to export while ensuring that the stringent food safety and quality requirements of the PMO are met. This effort needs to be developed carefully so it does not disadvantage U.S.-based Grade “A” processors.

The number of foreign dairy companies showing interest in participating in the pilot program continues to grow. As the ICPP program has matured, the success of using TPCs has been demonstrated and the critieria and oversight for TPC operation has been established and tested by the ICPP. There is strong interest by qualified private companies with long-term experience in the NCIMS to participate as third party certifiers (TPCs). Yet, the current ICPP restriction on allowing only three (3) TPCs creates a monopolistic environment that

commercially benefits these three (3) TPCs to the disadvantage of other qualified private companies. With the ICPP operating for four (4) years, it is time to expand the number of TPCs in a measured way, i.e. from three (3) to a total of five (5).

C. Proposed Solution

Changes to be made on page(s): _____ of the (X - one of the following):

2009 PMO	2009 EML
2009 MMSR	2400 Forms
2009 Procedures	2009 Constitution and Bylaws

The NCIMS International Certification Pilot Program (ICPP) Committee shall modify the International Certification Pilot Program as defined in IMS-a 45 to accept applications and certify two (2) additional Third Party Certifiers (TPCs) for a total of five (5).

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	312
Committee:	ICCP

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

A. Summary of Proposal

Expand the ICCP to allow each TPC to Certify up to 6 plants.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The International Certification Pilot Program (ICPP) was established during the 2005 NCIMS Conference. The ICPP is intended to provide an additional certification option for milk companies located outside the United States seeking participation in the NCIMS Grade A milk safety program and a listing in the Interstate Milk Shippers (IMS) List. The main goal of the ICPP is to evaluate whether or not Third Party Certifiers (TPCs) can administer all aspects of the Grade A PMO and related documents in the same manner as State Regulatory Agencies. In order to accomplish this, foreign milk plants must be certified and listed so that records can be generated for the committee to review. The more data that is generated the better the committee will be able to determine the viability of this program. This will allow the Conference to better determine the effectiveness of the ICPP.

As there is increased interest in importing Grade A Milk and Milk Product to the US there needs to be additional opportunities to allow for this importation. A number of foreign dairy companies have shown an interest in participating in the pilot program but cannot due to the current limitation. To avoid restraint of trade issues, the pilot program should be expanded.

C. Proposed Solution

Changes to be made on page(s): _____ of the (X - one of the following):

2009 PMO	2009 EML
2009 MMSR	2400 Forms
2009 Procedures	2009 Constitution and Bylaws

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.

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33rd NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

Proposal #:	313
Committee:	

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

A. Summary of Proposal

To request the NCIMS Executive Board establish an Ad HOC committee to align the Pasteurized Milk Ordinance with the FDA Food Safety Modernization Act.

B. Reason for the Submission and Public Health Significance and/or Rationale Supporting the Submission

The FDA Food Safety Modernization Act mandates new responsibilities for food companies impacting daily operations, food safety plans, preventive controls, supply chain management, records maintenance and access, environmental monitoring programs, and food allergen control program recall plans. The Food Safety Modernization Act also requires Food Safety Plans and Hazard Analysis for all food products produced in the permitted facility. Currently the NCIMS Hazard Analysis Critical Control Point program is voluntary and the traditional Grade "A" Pasteurized Milk Ordinance program may not be adequate under the Food Safety Modernization Act.

C. Proposed Solution

Changes to be made on page(s): _____ of the (X - one of the following):

- | | |
|-----------------------|------------------------------------|
| <u> X </u> 2009 PMO | _____ 2009 EML |
| _____ 2009 MMSR | _____ 2400 Forms |
| _____ 2009 Procedures | _____ 2009 Constitution and Bylaws |

To request that the NCIMS Executive Board establish an Ad HOC committee to align the Pasteurized Milk Ordinance with the Food Safety Modernization Act. The committee shall report back to the Executive Board with recommendations before the 2013 NCIMS Conference.

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