HHS:PHS:FDA:CFSAN:OFS:DDEMP:MMPB

5001 Campus Drive
College Park, MD 20740-3835

January 29, 2020

IMS-a-52
(Revised)

To: Director, Office of State Cooperative Programs
Attn: All Staff, Division of Milk Safety

From: Milk and Milk Products Branch (HFS-316)

Subject: Actions of the 2019 National Conference on Interstate Milk Shipments

The 37th National Conference on Interstate Milk Shipments (NCIMS) was held in Saint Louis, Missouri, April 26-May 1, 2019. A total of seven-five (75) Proposals were submitted and deliberated at the Conference. During the Conference, the State delegates approved several changes to the *Grade "A" Pasteurized Milk Ordinance* (PMO) and related NCIMS documents. Following is a table showing the Actions taken by the voting delegates:

COUNCIL	# OF PROPOSALS	NO ACTION	PASSED AS SUBMITTED	PASSED AS AMENDED	TABLED
I	23	12	6	5	0
II	42	23	6 3-Sent to 2400 Forms Protocol	13 2-Sent to 2400 Forms Protocol	0
III	8	1	2	5	0
JOINT COUNCIL	2	0	0	2	0
TOTAL	75	36	14 3-Sent to 2400 Forms Protocol	25 2-Sent to 2400 Forms Protocol	0

The following Proposals were passed and addressed changes to the *PMO*: 106, 108, 109, 111, 113, 117, 118, 120, 122, 203, 205, 206 (FDA originally non-concurred), 207, 208, 210 (FDA originally non-concurred), 211 (FDA originally non-concurred), 215, 216, 301, 308, JC-1(FDA originally non-concurred) and JC-2.

The following Proposals were passed and addressed changes to the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments* (Procedures): 303, 304, 305, 306, 307, 308 (Identified as *Procedures* changes). JC-1 and JC-2 (Identified as a new *Procedure*).

The following Proposals were passed and addressed changes to the *Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers* (MMSR): 215, JC-1, and JC-2.

The following Proposals were passed and addressed changes to the *Constitution* and/or the *Bylaws of the National Conference on Interstate Milk Shipments* (Constitution and Bylaws): 304.

The following Proposals were passed and addressed changes to the *Evaluation of Milk Laboratories* (EML): 223, 306, and JC-2.

The following Proposals were identified as FDA/NCIMS 2400 Forms and were voted on as a block to be handled by FDA and the NCIMS Laboratory Committee following the procedures for issuing and updating FDA/NCIMS 2400 Forms: 230, 234, 238, 239, and 241.

The following Proposals identified the development of new FDA/NCIMS 2400 Forms or changes to FDA/NCIMS 2400 Forms and were not voted on as a block to be handled by FDA and the NCIMS Laboratory Committee following the procedures for issuing and updating FDA 2400 Forms: 228, 229 and 240.

The following Proposals were passed and addressed changes to the inspection forms utilized in the Program and a new form introducing critical listing element for fermented high-acid milk and or milk products: 301 and JC-2

- FORM FDA 2359m-MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT (10/13) Proposal 301
- FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE-CRITICAL LISTING ELEMENTS Proposal JC-2

The following Proposals were passed and will be assigned to a Standing Committee, ad hoc Committee, Special Assignment Committee or the development of a Pilot Program:

Joint Council (JC) Proposal-1: The Liaison Committee requests the Chair to assign this proposal to an NCIMS standing committee, special committee, or ad hoc committee as approved by the NCIMS Executive Board.

The assigned committee is charged to work cooperatively with FDA to develop a pilot program which will establish a regulatory framework to find efficiencies in inspection activities for facilities that manufacture both Grade “A” and non-Grade “A” products and be implemented by FDA and the participating States.

In developing the details of the inspectional model(s) to pilot, the assigned committee will, at least, consider: the regulatory authorities of state regulatory agencies, the eligibility criteria for pilot consideration, the types of non-Grade “A” products manufactured in dual-grade facilities, the resource needs and potential hurdles likely to be encountered, and the metrics for evaluating success.

When implemented, the pilot program will meet the Agency's commitment to the NCIMS of identifying additional ways to maximize state and federal resources and to create greater efficiencies through its obligations under the FDA Food Safety Modernization Act while maintaining the high safety of the U.S. milk supply.

FDA shall inform and confer with the assigned committee to answer questions and address concerns to provide clarity and transparency at a frequency determined by the NCIMS Executive Board. A complete report of the pilot program will be shared at the 2021 Conference.

In recognition that FDA is strongly committed to developing and implementing the dairy inspection pilot program and stands ready to work in a collaborative spirit on the framework for this pilot program immediately with the assigned committee, the Liaison Committee requests an effective date of the receipt and acceptance of FDA concurrence at the next NCIMS Executive Board meeting after the Conference.

Proposal 112: The NCIMS Chairman shall assign to either a standing committee or an ad hoc committee, with input from affected stakeholders, the responsibility of reviewing the NCIMS role in regulating the repackaging of yogurt, sour cream, acidified sour cream and cultured milk and/or milk products and report to the 2021 NCIMS Conference.

Note: *This proposal was passed as amended as a substitute solution.*

Proposal 114: This proposal requests the NCIMS Chair assign an NCIMS standing committee, special committee, or ad hoc committee as approved by the NCIMS Executive Board to study the safety of water used in the dairy industry, including technologies to produce disinfected and/or Pasteurized Equivalent Water as prescribed in Section VII, Appendix D. and Appendix H. and report back to the 2021 NCIMS conference.

Note: *This proposal was passed as amended substitute solution.*

Proposal 212: This proposal directs the NCIMS Hauling Procedures Committee to conduct a comprehensive review of FDA Form 2399a and report back to the 2021 Conference.

The following Proposals were passed and are of significance to the Grade "A" Milk Safety Program:

Joint Council (JC) Proposal 2: Contains modifications to the PMO, Methods, Procedures, Bylaws and EML documents that address the regulation and rating of milk plants producing Grade "A" fermented high-acid, shelf-stable milk and/or milk products. These products are produced by fermentation using live and active cultures and then processed and packaged on equipment that is utilized to produce aseptic low-acid food products which have a Low Acid Canned Foods (LACF) filing as required by 21 CFR 113 or which are processed and packaged in accordance with all applicable provisions of the PMO to achieve shelf stability and then stored and distributed under normal non-refrigerated conditions.

Proposal 118: This proposal incorporated Appendix Q. requirements for the operation of automatic milking installations (AMIs) into Section 7, STANDARDS FOR GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSING AFTER PACKAGING. Revised Appendix Q. GENERAL REQUIREMENTS FOR AMI COMPUTER SYSTEMS and incorporated the AMI computer control requirements into Appendix H. As a result, Appendix Q. requirements were deleted in its entirety.

FDA responded in writing to the NCIMS Conference Chair on August 20, 2019 and met with the NCIMS Executive Board on October 23-24, 2019 concerning the Proposals passed during the 2019 Conference. Within FDA's letter dated August 20, 2019, FDA concurred with all the passed Proposals except for Proposals 206, JC-1, 210, and 211.

206: FDA originally non-concurred with this Proposal because the Proposal is fundamentally flawed and cannot be fixed with minor editorial corrections. FDA understands this proposal was well-intentioned to resolve confusion created by inconsistencies between the FDA/NCIMS 2400 form and other conference documents. However, as written the text on page 29 and 30 can be interpreted to mean that all sampling procedures, including the use of approved in-line samplers and approved aseptic samplers for milk tank trucks or for farm bulk milk tanks and/or silos shall be in substantial compliance with FDA/NCIMS 2400 Forms. It would be further interpreted that if there was a discrepancy between SMEDP and the FDA/NCIMS 2400 Forms, the FDA/NCIMS Forms would have primacy in resolving issues related to sampling procedures, including the use of approved in-line samplers and approved aseptic samplers for milk tank trucks or for farm bulk milk tanks and/or silos.

FDA/NCIMS 2400 Forms are specific to sample analysis and laboratory techniques, not sampling procedures. The PMO, Appendix B. and the SMEDP establish sampling procedure requirements. In addition, FDA Forms 2399 and 2399a are used when evaluating sampling procedures, not the FDA/NCIMS 2400 Forms.

During the October 23-24, 2019 NCIMS Executive Board meeting, FDA and the Executive Board did not reach mutual concurrence with Proposal 206; therefore Proposal 206 in accordance with Section X-Application of Conference Agreements, A-Implementation of Changes 4, of the *Procedures* will be referred to the next Conference for discussion

JC-1: FDA originally non-concurred with this Proposal because as written Appendix T. compliance would have to be determined once every thirty-six (36) months by a federal check rating or by a state rating. FDA Compliance Program 18003 states that milk plant check ratings should be conducted once every 3 years and if a milk plant is withdrawn from the IMS list the milk plant should be re-checked rated twelve (12) to eighteen (18) months after the milk plant is re-listed. A specific thirty-six (36) month requirement is too prescriptive and could create a conflict with FDA CP 18003. In addition, state ratings are to be conducted within a twenty-four (24) month period and stipulating that Appendix T. compliance shall be determined once every thirty-six (36) months is not clear on how or when Appendix T. compliance is to be determined on state ratings.

During the October 23-24, 2019 NCIMS Executive Board meeting, FDA and the Executive Board reached mutual concurrence with Proposal JC-1. This provides for the words "at least" to be inserted prior to the statement "once every thirty-six (36) months…" in *Procedures*.

210 and 211: FDA originally non-concurred with these proposals because they did not give clear direction to FDA of how the text in the Proposals shall be added to the PMO. Proposal 210 inserted a new Section V into Appendix B. of the PMO titled "REQUIREMENTS FOR USING AN APPROVED ON-TANKER FARM BULK TANK ASEPTIC SAMPLER FOR MULTIPLE AND/OR SINGLE FARM PICKUPS." Proposal 211 inserted a new Section VI into Appendix B. of the PMO titled "REQUIREMENTS FOR USING AN APPROVED ON-TANKER FARM BULK TANK ASEPTIC SAMPLER FOR MULTIPLE AND/OR SINGLE FARM PICKUPS" and changed the existing Section VI to Section VII. The result of the two proposals as passed is that there are two sections titled "Section V" in Appendix B.

During the October 23-24, 2019 Executive Board meeting, FDA and the Executive Board reached mutual concurrence with Proposals 210 and 211. This provides for the renumbering of Appendix B., Section VI – VIII as follows, and make the corresponding changes to the PMO TABLE OF CONTENTS:

> V. REQUIREMENTS FOR USING AN APPROVED ON-TANKER FARM BULK MILK TANK ASEPTIC SAMPLER FOR MULTIPLE AND/OR SINGLE FARM PICKUPS
>
> VI. REQUIREMENTS FOR SANITIZING SAMPLING COCKS AND IN-LINE SAMPLE POINTS
>
> VII. REQUIREMENTS FOR THE SAMPLING OF RAW SHEEP MILK THAT HAS BEEN FROZEN PRIOR TO BEING TESTED FOR APPENDIX N. DRUG RESIDUE.
>
> VIII. MILK TANK TRUCK PERMITTING AND INSPECTION

All Proposals that were passed and concurred with by FDA and the NCIMS Executive Board will become effective within one (1) year of the electronic publication of the affected document(s); or by the official notification to the States through the transmittal of this IMS-a, as applicable, following the Conference at which the changes were passed. For States that can legally enforce the new regulations based on the issuance of this IMS-a, the effective date will be January 24, 2021.

The following Proposals are exceptions to the effective dates cited above:

Joint Council (JC) Proposal 1: The Liaison Committee requests the Chair to assign this proposal to an NCIMS standing committee, special committee, or ad hoc committee as approved by the NCIMS Executive Board.

The assigned committee is charged to work cooperatively with FDA to develop a pilot program which will establish a regulatory framework to find efficiencies in inspection activities for facilities

that manufacture both Grade "A" and non-Grade "A" products and be implemented by FDA and the participating States.

Note: *This proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2019 National Conference on Interstate Milk Shipments, following FDA concurrence with the NCIMS Executive Board.*

Proposal 112: The NCIMS Chairman shall assign to either a Standing Committee or an Ad hoc committee, with input from affected stakeholders, the responsibility of reviewing the NCIMS role in regulating the repackaging of yogurt, sour cream, acidified sour cream and cultured milk and/or milk products and report to the 2021 NCIMS Conference.

Note: *This proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2019 National Conference on Interstate Milk Shipments, following FDA concurrence with the NCIMS Executive Board.*

Proposal 114: This proposal requests the NCIMS Chair assign an NCIMS standing committee, special committee, or ad hoc committee as approved by the NCIMS Executive Board to study the safety of water used in the dairy industry, including technologies to produce disinfected and/or Pasteurized Equivalent Water as prescribed in Section VII, Appendix D. and Appendix H. and report back to the 2021 NCIMS conference.

Note: *This proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2019 National Conference on Interstate Milk Shipments, following FDA concurrence with the NCIMS Executive Board.*

Proposal 212: This proposal directs the NCIMS Hauling Procedures Committee to conduct a comprehensive review of FDA Form 2399 and report back to the 2021 Conference.

Note: *This proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2019 National Conference on Interstate Milk Shipments, following FDA concurrence with the NCIMS Executive Board.*

Proposal 304: This proposal would allow States and TPCs the option of having their State Program Evaluations (SPEs) conducted once every five (5) years instead of every three (3) years. The option to extend the SPEs out to a 5-year timeframe would be dependent upon the following two minimum requirements being satisfied. The State or TPC had two (2) consecutive triennial written Regulatory/Rating Agency Program Evaluations conducted and completed within the established 3-year time frames, and both of these SPEs are classified as being "in compliance" with the requirements of the Grade "A" PMO and the NCIMS Procedures document.

Note: *Amendments to the Procedures and Bylaws.*

Proposal 308: The utilization of the training from the PHS/FDA Milk Specialist on Appendix T. coupled with the abbreviated training course approved by the HACCP Implementation Committee constitutes sufficient and adequate training for original certification of the SRO. The

abbreviated training course approved by the HACCP Implementation Committee meets the training requirements for recertification of the SRO.

The HACCP Implementation Committee requests an effective date of the receipt and acceptance of FDA concurrence at the next NCIMS Executive Board meeting after the Conference.

Note: *This proposal shall take immediate effect upon the issuance of the IMS-a, Actions from the 2017 National Conference on Interstate Milk Shipments, following FDA concurrence with the NCIMS Executive Board.*

Some of the language as adopted by the delegates was editorialized in order to maintain continuity with the present language and to ensure compatibility with existing sections of the affected NCIMS document(s). The edits have not changed the intent of the voted actions. Deletions to the current document's language are identified by ~~strikeout~~ and additions are identified by underlined text, unless otherwise noted.

Proposal: JC-1
Document: 2017 PMO
Pages: 21, 33

Make the following changes to the 2017 PMO:

PMO (Page 21)

SECTION 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS
3. ….
….c. Inspections of a milk plant for compliance with Appendix T. of this *Ordinance* may be conducted by the Regulatory Agency at least once every thirty-six (36) months. Inspection for compliance by the Regulatory Agency can only occur after the completion of either the Grade "A" PMO Preventive Controls Training for Regulatory/Rating Agencies or the Preventive Controls for Human Food Regulators Course (FD254).

PMO (Page 33)

SECTION 7. STANDARDS FOR GRADE "A" MILK AND/OR MILK PRODUCTS

….. Buttermilk and whey used in the manufacture of Grade "A" milk and milk products shall be produced in a milk/cheese plant that complies with Items 1p, 2p, 3p, 4p, 5p, 6p, 7p, 8p, 9p, 10p, 11p, 12p, 13p, 14p, 15p, 17p, 20p, 21p and 22p as provided in this *Ordinance*. Whey shall be from:

1. Cheese made from Grade "A" raw milk for pasteurization, which has been pasteurized prior to use, in accordance with Item 16p of this *Ordinance*, or
2. Cheese made from Grade "A" raw milk for pasteurization, which has been heat-treated to a temperature of at least 64°C (147°F) and held continuously at that temperature for at least twenty-one (21) seconds or to at least 68°C (153°F) and held continuously at that temperature for at least

fifteen (15) seconds, in equipment meeting the pasteurization requirements provided for in this O*rdinance*. Provided, that this requirement shall not be construed as barring any other heat treatment process which has been recognized by the FDA to be equally efficient in the destruction of staphylococcal organisms and which is approved by the Regulatory Agency.

Document: 2017 PROCEDURES
Pages: 26

Make the following changes to the 2017 PROCEDURES:

PROCEDURES (Page 26)

F. **FOOD SAFETY PLAN COMPLIANCE**

An IMS listed milk plant shall comply with the applicable Food Safety Plan requirements cited in Appendix T. of the *Grade "A" PMO* as determined once every thirty-six (36) months ~~on~~ by a PHS/FDA check rating or, upon agreement between a State Rating Agency and FDA, by a state rating. Check ratings, state ratings, and any required re-inspection to determine compliance with Appendix T. shall be conducted only by personnel who have completed either the PHS/FDA *Grade "A" PMO* Preventive Controls training for Regulatory/Rating Agencies or the Preventive Controls for Human Food Regulators Course (FD254).

NOTE: If a re-inspection is required following a PHS/FDA check rating or state rating because of the milk plant not being in substantial compliance with Appendix T. of the *Grade "A" PMO*, then the milk plant shall upon re-inspection ~~initially~~ be determined to be in substantial compliance with Appendix T. of the *Grade "A" PMO* and ~~upon re-inspection then~~ shall achieve a Sanitation Compliance Rating of ninety percent (90%) or higher on the re-inspection in order to be eligible for a listing on the *IMS List*.

Document: 2017 MMSR
Pages:13, 14

Make the following changes to the 2017 MMSR:

MMSR

(Page 13)

2. FOOD SAFETY PLAN COMPLIANCE – PROCEDURES FOR DETERMINING MILK PLANT COMPLIANCE

During a PHS/FDA check rating/audit, or a state rating/audit upon agreement between a State Rating agency and FDA, it is necessary to determine compliance of the milk plant with the requirements of Appendix T. Preventive Controls for Human Food Requirements for Grade "A" Milk and Milk Products of the *Grade "A" PMO* related to the requirement that the milk plant shall have a written food safety plan. The following criteria are to be used in making that determination:

(Page 14)

If the milk plant is determined not to be in substantial compliance with Appendix T. of the *Grade "A" PMO* by a check rating, the milk plant shall not be immediately removed from the *IMS List* and PHS/FDA shall formally notify the Rating Agency that a re-inspection/re-audit of the milk plant shall be required within sixty (60) days. If the milk plant is determined not to be in substantial compliance with Appendix T. of the Grade "A" PMO as determined by a state rating, the milk plant shall not be immediately removed from the *IMS List* and the Rating Agency shall conduct a re-inspection/re-audit of the milk plant within sixty (60) days of the initial rating.

NOTE: If a re-inspection/re-audit is required following a PHS/FDA check rating/audit or a state rating/audit because of the milk plant not being in substantial compliance with Appendix T. of the *Grade "A" PMO*, then the milk plant upon re-inspection shall ~~initially~~ be determined to be in substantial compliance with Appendix T. of the *Grade "A" PMO* and ~~then~~ shall achieve a Sanitation Compliance Rating of ninety percent (90%) or higher on the re-inspection or shall receive an acceptable listing audit for NCIMS HACCP milk plants on a re-audit in order to be eligible for a listing on the *IMS List*.

The Liaison Committee requests the Chair to assign this proposal to an NCIMS standing committee, special committee, or ad hoc committee as approved by the NCIMS Executive Board.

The assigned committee is charged to work cooperatively with FDA to develop a pilot program which will establish a regulatory framework to find efficiencies in inspection activities for facilities that manufacture both Grade "A" and non-Grade "A" products and be implemented by FDA and the participating States.

In developing the details of the inspectional model(s) to pilot, the assigned committee will, at least, consider: the regulatory authorities of state regulatory agencies, the eligibility criteria for pilot consideration, the types of non-Grade "A" products manufactured in dual-grade facilities, the resource needs and potential hurdles likely to be encountered, and the metrics for evaluating success.

When implemented, the pilot program will meet the Agency's commitment to the NCIMS of identifying additional ways to maximize state and federal resources and to create greater efficiencies through its obligations under the FDA Food Safety Modernization Act while maintaining the high safety of the U.S. milk supply.

FDA shall inform and confer with the assigned committee to answer questions and address concerns to provide clarity and transparency at a frequency determined by the NCIMS Executive Board. A complete report of the pilot program will be shared at the 2021 Conference.

In recognition that FDA is strongly committed to developing and implementing the dairy inspection pilot program and stands ready to work in a collaborative spirit on the framework for this pilot program immediately with the assigned committee, the Liaison Committee requests an effective date of the receipt and acceptance of FDA concurrence at the next NCIMS Executive Board meeting after the Conference**.**

FDA DID NOT CONCUR WITH THIS PROPOSAL AS CITED IN THEIR LETTER TO THE NCIMS CHAIR DATED AUGUST 20, 2019

The FDA non-concurred with this Proposal because Appendix T. compliance would have to be determined once every thirty-six (36) months by a federal check rating or by a state rating. FDA Compliance Program 18003 states that milk plant check ratings should be conducted once every 3 years and if a milk plant is withdrawn from the IMS List the milk plant should be re-checked rated twelve (12) to eighteen (18) months after the milk plant is re-listed. A specific thirty-six (36) month requirement is prescriptive and creates a conflict with FDA CP 18003. In addition, state ratings are to be conducted within a twenty-four (24) month period and stipulating that Appendix T. compliance shall be determined once every thirty-six (36) months is not clear on how or when Appendix T. compliance is to be determined on state ratings.

FDA met with the NCIMS Executive Board on October 23-24, 2019 concerning this Proposal as passed during the 2019 Conference. During this NCIMS Executive Board meeting, FDA and the Executive Board reached mutual concurrence with Proposal JC-1 as follows:

NOTE: The text that is double underlined is text that is to be added to the PMO and/or text of the passed Proposal as mutually concurred with by the NCIMS Executive Board and FDA.

PROCEDURES (Page 26)

F. **FOOD SAFETY PLAN COMPLIANCE**

An IMS listed milk plant shall comply with the applicable Food Safety Plan requirements cited in Appendix T. of the *Grade "A" PMO* as determined at least once every thirty-six (36) months ~~on~~ by a PHS/FDA check rating or, upon agreement between a State Rating Agency and FDA, by a state rating. Check ratings, state ratings, and any required re-inspection to determine compliance with Appendix T. shall be conducted only by personnel who have completed either the PHS/FDA *Grade "A" PMO* Preventive Controls training for Regulatory/Rating Agencies or the Preventive Controls for Human Food Regulators Course (FD254).

NOTE: If a re-inspection is required following a PHS/FDA check rating or state rating because of the milk plant not being in substantial compliance with Appendix T. of the *Grade "A" PMO*, then the milk plant shall upon re-inspection ~~initially~~ be determined to be in substantial compliance with Appendix T. of the *Grade "A" PMO* and ~~upon re-inspection then~~ shall achieve a Sanitation Compliance Rating of ninety percent (90%) or higher on the re-inspection in order to be eligible for a listing on the *IMS List*.

Proposal: JC-2
Document: 2017 PMO
Pages: vi, ix, x, xiv, xvii, 2, 4, 7, 8, 10, 18, 19, 20, 21, 23, 24, 27, 28, 29, 32, 33, 34, 36, 59, 62, 64, 65, 73, 90, 114, 124, 125, 128, 129, 130, 131, 132, 133, 349, 388, 390, 393, 394, 395, 403, 410, 412, 413, 421

Make the following changes to the 2017 PMO:

Page vi:

INTRODUCTION

This edition of the *Ordinance* contains sanitary standards for Grade "A" raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging and Grade "A" milk and/or milk products defined in Section 1.

Page ix:

STANDARDS FOR GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~OR~~ RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING

Page x:

STANDARDS FOR GRADE "A" PASTEURIZED, ULTRA-PASTEURIZED, ASEPTICALLY PROCESSED AND PACKAGED LOW-ACID MILK AND/OR MILK PRODUCTS, ~~AND~~ RETORT PROCESSED AFTER PACKAGED LOW-ACID MILK AND/OR MILK PRODUCTS AND FERMENTED HIGH-ACID, SHELF-STABLE MILK AND/OR MILK PRODUCTS ……..

ITEM 16p. PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~AND~~ RETORT PROCESSED AFTER PACKAGING AND FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING ……

Page xiv:

APPENDIX Q. OPERATION OF AUTOMATIC MILKING INSTALLATIONS FOR THE PRODUCTION OF GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~OR~~ RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING

APPENDIX S. ASEPTIC PROCESSING AND PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM AND FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING PROGRAM

Page xvii:

AQFPSS (Aseptic-Qualified Filler and Product Sterilizer System)
FHA (Fermented High-Acid)

Page 1:

An *Ordinance* defining "milk" and certain "milk products", "milk producer", "pasteurization", etc.; prohibiting the sale of adulterated and misbranded milk and/or milk products; requiring permits for the sale of milk and/or milk products; regulating the inspection of dairy farms and milk plants; the examination, labeling, pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging, fermented high-acid, shelf-stable processing and packaging and distribution and sale of milk and/or milk products; providing for the construction of future dairy farms and milk plants; the enforcement of this *Ordinance*; and the fixing of penalties.

Be it ordained by the ... of ...[1] as follows:

SECTION 1 DEFINITIONS

B. **ASEPTIC-QUALIFIED FILLER AND PRODUCT STERILIZER SYSTEM (AQFPSS):** A filler and product sterilizer and associated equipment which are used for aseptic processing and packaging as defined in 21 CFR 113.3(a). This system will be described within filings for aseptic low acid products that have been filed with and reviewed by the Food Processing Evaluation Team in FDA/CFSAN's Office of Food Safety. The aseptic-qualified filler (which includes the package sterilizer) is operated as described within the Form FDA 2541g filing submission. The aseptic-qualified product sterilizer is operated in a manner that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of non-health significance capable of reproducing in the food under conditions of ambient storage. The scope of the AQFPSS includes the filler and product sterilizer described within the Form FDA 2541g filing submission and any other equipment or processes which will be defined in written documentation provided by the Process Authority that are critical to maintain the safety of the product.

Re-letter remaining DEFINITIONS accordingly.

Page 2:

F. **BULK MILK PICKUP TANKER:** A bulk milk pickup tanker is a vehicle, including the truck, tank and those appurtenances necessary for its use, used by a bulk milk hauler/sampler to transport bulk raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging from a dairy farm to a milk plant, receiving station, or transfer station.

Page 4:

R. FERMENTED ~~(CULTURED)~~ HIGH ACID SHELF STABLE MILK AND/OR MILK PRODUCTS: Grade "A" Fermented High-Acid (FHA), shelf-stable milk and/or milk products are Grade "A" milk and/or milk products that have been pasteurized and fermented ~~(cultured)~~ to pH 4.6 or lower, which may contain safe and suitable ingredients, and

R-1. which are thermally processed and packaged in accordance with the Process Authority's recommendations using an Aseptic-Qualified Filler and Product Sterilizer System (AQFPSS) to achieve shelf-stability and then stored and distributed under normal non-refrigerated conditions and subject to all requirements of Appendix S. of the PMO, or R-2. which are processed and packaged in accordance with all applicable provisions of the PMO to achieve shelf stability and then stored and distributed under normal non-refrigerated conditions.

Note: This does not include acidified milk and/or milk products, such as acidified milk and acidified sour cream.

S. FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING: For the purpose of this *Ordinance* Fermented High-Acid, Shelf-Stable Processing and Packaging is the processing and packaging of Grade "A" fermented high-acid, shelf-stable milk and/or milk products on an AQFPSS. The Grade "A" fermented high-acid, shelf-stable milk and/or milk products shall be subjected to a process that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of non-health significance capable of reproducing in the food under conditions of ambient storage. Fermented High-Acid, Shelf-Stable Processing and Packaging shall conform to the applicable requirements of 21 CFR Part 117.

Re-letter remaining DEFINITIONS accordingly.

T. **HACCP DEFINITIONS**: **(FOR USE IN CONJUNCTION WITH APPENDIX K. OF THIS *ORDINANCE*.)**

T-1. **AUDIT:** An evaluation of the entire milk plant, receiving station or transfer station facility and NCIMS HACCP System to ensure compliance with the NCIMS HACCP System and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants and Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants, and Aseptic-Qualified Filler and Product Sterilizer System (AQFPSS) for fermented high-acid, shelf-stable processing and packaging milk plants, respectively.

Page 7:

EE. **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, retort processed after packaged, fermented high-acid, shelf-stable processed and packaged, condensed, dried, packaged, or prepared for distribution.

Page 8:

This definition shall include those milk and milk products, as defined above, which have been aseptically processed and then packaged, or in the case of fermented high-acid, shelf-stable products, processed and packaged on an AQFPSS.

Page 10:

NN. **OFFICIALLY DESIGNATED LABORATORY:** An officially designated laboratory is a commercial laboratory authorized to do official work by the Regulatory Agency, or a milk industry laboratory officially designated by the Regulatory Agency or Milk Laboratory Control Agency for the examination of producer samples of Grade "A" raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging; and bulk milk pickup tanker samples of raw milk and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for drug residues.

Page 18-19:

SECTION 4. LABELING

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, retort processed after packaging, fermented high-acid, shelf-stable processed and packaged, condensed and/or dried.
2. The words "keep refrigerated after opening" in the case of aseptically processed and packaged low-acid milk and/or milk products, ~~and~~ retort processed after packaging low-acid milk and/or milk products and fermented high-acid, shelf-stable milk and/or milk products.

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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, retort processed after packaging, fermented high-acid, shelf-stable 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/or 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 (1) 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, retort processed after packaging, fermented high-acid, shelf-stable 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, retort processed after packaging, fermented high-acid, shelf-stable processed and packaged, condensed and/or dried milk and/or milk products. The street address of the milk plant does not need to be shown when only one (1) milk plant of a given name is located within the municipality.

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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 shall 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," etc., give the consumer the impression that such a grade is significantly safer than Grade "A." Such an implication is false, because the *Ordinance* requirement for Grade "A" pasteurized, ultra-pasteurized, aseptically processed and packaged low-acid milk and/or milk products, ~~or~~ retort processed after packaged milk and/or milk products or fermented high-acid, shelf-stable milk and/or milk products …

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SECTION 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS

Each dairy farm, milk plant, receiving station, transfer station, milk tank truck cleaning facility whose milk and/or milk products are intended for consumption within ...of...[1] or its jurisdiction, and each bulk milk hauler/sampler who collects samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging, for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station and each milk tank truck and its appurtenances shall be inspected/audited by the Regulatory Agency prior to the issuance of a permit. Following the issuance of a permit, the Regulatory Agency shall:

1. Inspect each milk tank truck and its appurtenances used by a bulk milk hauler/sampler who collects samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging, or fermented high-acid, shelf-stable processing and packaging for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station, at least once every twenty-four (24) months.

…

3. Inspect each milk plant and receiving station at least once every three (3) months, provided:

…

b. Regulatory inspections of a milk plant or portion of a milk plant that is IMS listed to produce aseptically processed and packaged low-acid milk and/or milk products, ~~and/or~~ retort processed after packaging low-acid milk and/or milk products and/or fermented high-acid, shelf-stable milk and/or milk products shall be conducted by the Regulatory Agency in accordance with this *Ordinance* at least once every six (6) months. (Refer to Appendix S. of this *Ordinance*.) The milk plant's Aseptic Processing and Packaging System (APPS), ~~and~~ Retort Processed after Packaging System (RPPS), and/or Aseptic Qualified Filler and Product Sterilizer System (AQFPSS) respectively, shall be inspected by FDA, or a Regulatory Agency designated by FDA under the FDA Low Acid Canned Foods (LACF) Program, in accordance with the applicable requirements of 21 CFR Parts 108, 113 and 117 at a frequency determined by FDA.

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ADMINISTRATIVE PROCEDURES

INSPECTION FREQUENCY: For the purposes of determining the inspection frequency for dairy farms, transfer stations and milk plants or the portion of a milk plant that is IMS listed to produce aseptically processed and packaged low-acid milk and/or milk products and/or retort processed after packaged low-acid milk and/or milk products and/or fermented high-acid, shelf-stable milk and/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.…

One (1) milk tank truck inspection every twenty-four (24) 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) dairy farm, transfer station, milk plants or the portion of a milk plant that is IMS listed to produce aseptically processed and packaged low-acid milk and/or milk products and/or retort processed after packaged low-acid milk and/or milk products and/or fermented high-acid, shelf-stable milk and/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/or milk products or receiving station inspection every three (3) months is not a desirable frequency, it is instead a legal minimum. Bulk milk hauler/samplers, industry plant samplers, milk tank trucks, milk tank truck cleaning facilities, dairy farms, milk plants, receiving stations and transfer stations experiencing difficulty meeting requirements should be visited more frequently. Milk plants that condense and/or dry milk and/or milk products and which operate for a short duration of time or intermittent periods of time should also be inspected more frequently. Inspections of dairy farms shall be made at milking time as often as possible and of milk plants at different times of the day in order to ascertain if the processes of equipment assembly, sanitizing, pasteurization, ultra-pasteurization, cleaning and other procedures comply with the requirements of this *Ordinance*. …

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ENFORCEMENT PROCEDURES - ASEPTIC PROCESSING AND PACKAGING MILK PLANTS AND/OR RETORT PROCESSED AFTER PACKAGING MILK PLANTS AND/OR FERMENTED HIGH-ACID, SHELF-STABLE MILK PLANTS: 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/or Grade "A" retort milk plant and/or Grade "A" fermented high-acid, shelf-stable milk plant, and the aseptic Grade "A" low-acid milk and/or milk products and/or the retort processed Grade "A" low-acid milk and/or milk products and/or Grade "A" fermented high-acid, shelf-stable milk and/or milk products, respectively, meet the applicable requirements of this *Ordinance*.

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SECTION 6. THE EXAMINATION OF MILK AND/OR MILK PRODUCTS

……..

During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging, or fermented high-acid, shelf-stable 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.
During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging, or fermented high-acid, shelf-stable 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, aseptic processing and packaging, ~~or~~ retort processed after packaging, or fermented high-acid, shelf-stable processing and packaging.
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 ultra-pasteurized milk and/or milk products required sampling and testing is to be conducted only when there are test methods available that are validated by FDA and accepted by the NCIMS. Milk and/or milk products that do not have validated and accepted methods are not required to be tested. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.) Aseptically processed and packaged low-acid milk and/or milk products, ~~and~~ retort processed after packaged low-acid milk and/or milk products and fermented high-acid, shelf-stable milk and/or 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-pasteurized, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging. In addition, drug tests for Beta lactams on each producer's milk shall be conducted at least four (4) times during any consecutive six (6) months.
All pasteurized and ultra-pasteurized milk and/or 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 not be a requirement for sampling. Required bacterial counts, coliform counts, drug tests for Beta lactams, phosphatase and cooling temperature determinations shall be performed on Grade "A" pasteurized and ultra-pasteurized milk and/or milk products defined in this *Ordinance* only when there are validated and accepted test methodology. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.)

NOTE: When multiple samples of the same milk and/or milk products, except for aseptically processed and packaged low-acid milk and/or milk products, ~~and~~ retort processed after packaged low-acid milk and/or milk products~~,~~ and fermented high-acid, shelf-stable milk and/or 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 or by personnel approved by the Milk Laboratory Control Agency at an Official or Officially Designated Laboratory, with industry consent where applicable, 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.

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…

Assays of milk and/or milk products as defined in this *Ordinance*, including aseptically processed and packaged low-acid milk and/or milk products, ~~and~~ retort processed after packaged low-acid milk and/or milk products~~,~~ and fermented high-acid, shelf-stable milk and/or milk products, to which vitamin(s) A and/or D have been added for fortification purposes, shall be conducted 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. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods for vitamins.) 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.

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SAMPLING PROCEDURES: *SMEDP* contains guidance for the sampling of milk and milk products. Optionally, sample collection time may be identified in military time (24 hour clock). (Refer to Appendix G. of this *Ordinance* for a reference to drug residues in milk and/or milk products and the conditions under which a positive phosphatase reaction may be encountered in properly pasteurized milk or cream. Refer to Appendix B. of this *Ordinance* for reference to farm bulk milk hauling programs regarding training, licensing/permitting, routine inspection and the evaluation of sampling procedures.)

When samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging are taken at a milk plant prior to pasteurization, ultra-pasteurization, aseptic processing, ~~and/or~~ retort processing or fermented high-acid, shelf-stable processing and packaging, respectively, they shall be drawn following adequate agitation from randomly selected storage tanks/silos. All counts and temperatures shall be recorded on a milk-ledger form as soon as reported by the laboratory. A computer or other information retrieval system may be used.

…

SECTION 7. STANDARDS FOR GRADE "A" MILK AND/OR MILK PRODUCTS

All Grade "A" raw milk and/or milk products for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging and all Grade "A" pasteurized, ultra-pasteurized, aseptically processed and packaged low-acid milk and/or milk products, ~~or~~ retort processed after packaged low-acid milk and/or milk products or fermented high-acid, shelf-stable milk and/or milk products, shall be produced, processed, manufactured and pasteurized, ultra-pasteurized, aseptically processed and packaged, ~~or~~ retort processed after packaged or fermented high-acid, shelf-stable 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, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging; processing methods integral therewith; and appropriate refrigeration shall be applied to milk and/or 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 and/or milk product is pasteurized, ultra- pasteurized, aseptically processed and packaged, ~~or~~ retort processed after packaged or fermented high-acid, shelf-stable processed and packaged. Provided, that in the bulk shipment of cream, nonfat (skim) milk, reduced fat or lowfat milk, the heating of the raw milk, one (1) time, to temperatures greater than 52ºC (125ºF) but less than 72ºC (161ºF), for separation purposes, is permitted when the resulting bulk shipment(s) of cream, nonfat (skim) milk, 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 75ºC (166ºF) in a continuing heating process and immediately cooled to 7ºC (45ºF) or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason.

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Whey shall be from cheese made from Grade "A" raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging as provided in this *Ordinance*….

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

GRADE "A" RAW MILK AND MILK PRODUCTS FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~OR~~ RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH ACID SHELF STABLE PROCESSING AND PACKAGING

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STANDARDS FOR GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~OR~~ RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING

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ITEM 18r. RAW MILK COOLING

Raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging shall be cooled to 10ºC (50ºF) or less within four (4) hours or less, of the commencement of the first milking, and to 7ºC (45ºF) 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 10ºC (50ºF).

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

Raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging shall be cooled to 10ºC (50ºF) or less within four (4) hours or less, of the commencement of the first milking, and to 7ºC (45ºF) 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 10ºC (50ºF).

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STANDARDS FOR GRADE "A" PASTEURIZED, ULTRA- PASTEURIZED, ASEPTICALLY PROCESSED AND PACKAGED LOW-ACID MILK AND/OR MILK PRODUCTS, ~~AND~~ RETORT PROCESSED AFTER PACKAGED LOW-ACID MILK AND/OR MILK PRODUCTS AND FERMENTED HIGH-ACID, SHELF-STABLE PROCESSED AND PACKAGED MILK AND/OR 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 low-acid milk and/or milk products and/or retort processed after packaging low-acid milk and/or milk products and/or fermented high-acid, shelf-stable milk and/or milk products, the APPS or RPPS or AQFPSS, respectively, 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, 113 and 117. Those Items, contained within the APPS, ~~and~~ RPPS and/or AQFPSS, shall be inspected by FDA or a State Regulatory Agency, when designated by FDA. The overall sanitation of a milk plant shall be under the supervision of one (1) or more qualified individuals (QIs) assigned responsibility for this function.

Milk plants that have HACCP Systems, which are regulated under the NCIMS voluntary HACCP Program, shall comply with all of the requirements of Item 16p. Pasteurization, Aseptic Processing and Packaging, ~~and~~ Retort Processed after Packaging and Fermented High-Acid, Shelf-Stable Processing and Packaging of this *Ordinance*, and pasteurization shall be managed as a critical control point (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 of this *Ordinance*

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ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

3. The floors are provided with trapped drains. Cold-storage rooms used for storing milk and/or milk products need not be provided with floor drains when the floors are sloped to drain to one (1) or more exits. Storage rooms for dry ingredients, dry packaged milk and/or milk products, aseptically processed and packaged low-acid milk and/or milk products and/or packaging

materials, ~~and~~ retort processed after packaged low-acid milk and/or milk products and/or packaging materials and fermented high-acid, shelf-stable milk and/or milk products and/or packaging materials are not required to be provided with drains.

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ITEM 2p. WALLS AND CEILINGS – CONSTRUCTION …

ADMINISTRATIVE PROCEDURES…

This Item is deemed to be satisfied when: …

NOTE: Refer to Item 11p for requirements for walls for drying chambers. Storage rooms used for the storage of packaged dry milk and/or milk products, aseptically processed and packaged low-acid milk and/or milk products, ~~and~~ retort processed after packaged low-acid milk and/or milk products and fermented high-acid, shelf-stable milk and/or milk products are exempt from the ceiling requirements of this Item.

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ITEM 5p. SEPARATE ROOMS

There shall be separate rooms for: …

4. The fabrication of containers and closures for milk and/or milk products, except for aseptically processed and packaged low-acid milk and/or milk products and/or retort processed after packaging low-acid milk and/or milk products and/or fermented high-acid, shelf-stable milk and/or milk products in which the containers and closures are fabricated within the APPS, ~~or~~ RPPS or AQFPSS, respectively.

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12. Provided that all paper, plastics, foil, adhesives, and other components of containers and closures used in the packaging of milk and/or milk products that have been aseptically processed and packaged, ~~or~~ retort processed after packaged or fermented high-acid, shelf-stable processed and packaged are governed under the applicable provisions of 21 CFR Parts 113 and 117 and shall not be subject to this Item.

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ITEM 16p. PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~AND~~ RETORT PROCESSED AFTER PACKAGING, AND FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING

Pasteurization shall be performed as defined in Section 1., Pasteurization and Item 16p of this *Ordinance*. Aseptic processing and packaging, ~~and~~ retort processed after packaging and fermented high-acid, shelf-stable processing and packaging shall be performed in accordance with the

applicable requirements of 21 CFR Parts 108, 113 and 117. (Refer to Appendices L. and S. of this *Ordinance*.)

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PUBLIC HEALTH REASON

……..

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/or milk products when certain staphylococci are present, as from udder infections, and when the milk and/or milk product is not properly refrigerated before pasteurization. Such toxins may cause severe illness. Aseptic processing and packaging, ~~and~~ retort processed after packaging and fermented high-acid, shelf-stable processing and packaging have 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.

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ITEM 17p. COOLING OF MILK AND/OR MILK PRODUCTS …

……

On delivery vehicles, the temperature of milk and milk products shall not exceed 7ºC (45ºF). Aseptically processed and packaged low-acid milk and/or milk products, ~~and~~ retort processed after packaged low-acid milk and/or milk products and fermented high-acid, shelf-stable milk and/or milk products to be packaged in hermetically sealed containers shall be exempt from the cooling requirements of this Item.

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SECTION 8. ANIMAL HEALTH

1. All milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging shall be from herds under a tuberculosis eradication program, which meets one (1) of the following conditions:…

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2. All milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging shall be from herds under a brucellosis eradication program, which meets one (1) of the following conditions:…

3. Goat, sheep, water buffalo, camel, or any other hooved mammal milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging, defined under this *Ordinance*, shall be from a herd or flock that:…

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SECTION 9. MILK AND/OR MILK PRODUCTS WHICH MAY BE SOLD

From and after twelve (12) months from the date on which this *Ordinance* is adopted, only Grade "A" pasteurized, ultra-pasteurized, aseptically processed and packaged low-acid milk and/or milk products, ~~or~~ retort processed after packaged low-acid milk and/or milk products or fermented high-acid, shelf-stable milk and/or milk products shall be sold to the final consumer, to restaurants, soda fountains, grocery stores or similar establishments. Provided, only Grade "A" milk and/or milk products shall be sold to milk plants for use in the commercial preparation of Grade "A' milk and/or milk products. Provided further, that in an emergency, the sale of pasteurized, ultra-pasteurized, aseptically processed and packaged low-acid milk and/or milk products, ~~or~~ retort processed after packaged low-acid milk and/or milk products or fermented high-acid, shelf-stable milk and/or 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/or milk products shall be labeled "ungraded".

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

Milk and/or 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, retort processed after packaging, fermented high-acid, shelf-stable 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 an acceptable HACCP listing, under the NCIMS voluntary HACCP Program as specified in Appendix K. of this *Ordinance*; or are from a country that USPHS/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…

2. After receipt, pasteurized, ultra-pasteurized, aseptically processed and packaged, retort processed after packaging, fermented high-acid, shelf-stable processed and packaged, concentrated (condensed) or dried milk and milk products shall comply with Sections 2., 4. and 10. of this *Ordinance*.

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11. Aseptically processed and packaged low-acid or fermented high-acid, shelf-stable milk and/or milk products in the definition of Milk Products of this *Ordinance* shall be considered to be Grade "A" milk and/or milk products. The sources(s) of the milk and/or milk products used to produce aseptically processed and packaged low-acid or fermented high-acid, shelf-stable milk and/or milk products shall be IMS listed. Aseptically processed and packaged low-acid and fermented high-

acid, shelf-stable milk and/or milk products shall be labeled "Grade "A" and meet Section 4. labeling requirements of this *Ordinance*. The milk plant or portion of the milk plant that is producing aseptically processed and packaged low-acid and/or fermented high-acid, shelf-stable 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 shall occur within (6) months of this rating. Both the Milk Sanitation Compliance and Enforcement Ratings shall 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" low-acid or fermented high-acid, shelf-stable 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 Regulatory Agency's and Rating Agency's 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 the NCIMS Fermented High-Acid, Shelf-Stable Processing and Packaging Program. ~~or Aseptic Pilot Program. The NCIMS Aseptic Pilot Program addressing aseptically processed and packaged fermented high-acid milk and/or milk products regulated under 21 CFR Parts 108 and/or 110 shall expire on December 31, 2017, unless extended by future conference action.~~ …

SECTION 13. PERSONNEL HEALTH

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Persons affected with any disease capable of being transmitted to others through the contamination of food shall not work at a milk plant in any capacity which brings them into direct contact with pasteurized, ultra-pasteurized, aseptically processed and packaged low- acid milk and/or milk products, ~~or~~ retort processed after packaged low-acid milk and/or milk products or fermented high-acid milk and/or milk products or which brings them into direct contact with associated milk and/or milk product- contact surfaces.

In the case of milk plants, receiving stations, or transfer stations that have HACCP Systems, which are regulated under the NCIMS voluntary HACCP Program, the HACCP System shall address the public health concerns described in this Section in a manner that provides protection equivalent to the requirements in this Section.

ADMINISTRATIVE PROCEDURES

Milk plant operators who have received reports, under this Section, from employees who have handled pasteurized, ultra-pasteurized, aseptically processed and packaged low-acid milk and/or milk products, ~~or~~ retort processed after packaged low-acid milk and/or milk products or fermented high-acid, shelf-stable milk and/or milk products or associated milk and/or milk product-contact surfaces shall immediately report these facts to the appropriate Regulatory Agency. …

SECTION 14. PROCEDURE WHEN INFECTION OR HIGH RISK OF INFECTION IS DISCOVERED

When a person who may have handled pasteurized, ultra-pasteurized, aseptically processed and packaged low-acid milk and/or milk products, ~~or~~ retort processed after packaged low-acid milk and/or milk products or fermented high-acid, shelf-stable milk and/or milk products or associated milk and/or milk product-contact surfaces meets one (1) or more of the conditions specified in the **ADMINISTRATIVE PROCEDURES** of Section 13. of this *Ordinance*, the Regulatory Agency is authorized to require any or all of the following measures:…

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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, aseptically processed and packaged low-acid milk and/or milk products, ~~or~~ retort processed after packaged low-acid milk and/or milk products or fermented high-acid, shelf-stable milk and/or milk products and associated milk and/or milk product-contact surfaces.

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APPENDIX K. HACCP PROGRAM…

II. IMPLEMENTATION OF A HACCP SYSTEM …

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 the milk plant's APPS, ~~or~~ RPPS, or AQFPSS, respectively, as defined by this *Ordinance*, shall be managed separately from the NCIMS HACCP System, even if identified as a CCP in the hazard analysis. The milk plant's APPS, ~~or~~ RPPS, or AQFPSS, respectively, 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, 113 and 117 at a frequency determined by FDA.

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APPENDIX Q. OPERATION OF AUTOMATIC MILKING INSTALLATIONS FOR THE PRODUCTION OF GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~OR~~ RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING

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ITEM 18r. RAW MILK COOLING

For AMIs the raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging shall be cooled to 10ºC (50ºF) within four (4) hours or less after starting the milking operation and the milk shall be cooled within two (2) more hours to 7ºC (45ºF). The milk in the farm bulk milk tank/silo shall not exceed 7ºC (45ºF) after that time. Farm bulk milk tank/silo recording thermometers are recommended if not already required by this *Ordinance*.

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APPENDIX R. DETERMINATION OF TIME/TEMPERATURE CONTROL FOR SAFETY MILK AND/OR MILK PRODUCTS …

Before using Tables A and B, which are included in the definition of Time/Temperature Control for Safety of Milk and/or Milk Products of this *Ordinance*, in determining whether a milk or milk product requires TCS, answers to the following questions should be considered:…

5. Is the milk and/or milk product processed and packaged so that it does not require TCS; such as, aseptically processed and packaged Grade "A" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products and/or fermented high-acid, shelf-stable milk and/or milk products?

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APPENDIX S. ASEPTIC PROCESSING AND PACKAGING PROGRAM, ~~AND~~ RETORT PROCESSED AFTER PACKAGING PROGRAM AND FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING PROGRAM

The Aseptic Processing and Packaging Program is designed to include all Grade "A" low-acid (21 CFR Part 113) aseptically processed and packaged milk and/or milk products.
The Retort Processed after Packaging Program is designed to include all Grade "A" low-acid (21 CFR Part 113) retort processed after packaged milk and/or milk products.
The Fermented High-Acid, Shelf-Stable Processing and Packaging Program is designed to include all Grade "A" fermented high-acid, shelf stable processed and packaged milk and/or milk products.

NOTE: Retort processed after packaging low-acid milk and/or milk products as addressed in the definition of Milk Products of this *Ordinance* shall be considered to be Grade "A" milk and/or milk products if they are used as an ingredient to produce any milk and/or milk product defined in the definition of Milk Products of this *Ordinance*; or if they are labeled as Grade "A" as described in Section 4. of this *Ordinance*.

Inspections of a milk plant or portion of a milk plant that is IMS listed to produce aseptically processed and packaged low-acid milk and/or milk products and/or retort processed after packaged low-acid milk and/or milk products and/or fermented high-acid, shelf-stable milk and/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 milk plant's APPS, ~~or~~ RPPS, or AQFPSS, respectively, 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, 113 and 117. The milk plant's APPS, ~~and/or~~ RPPS, or AQFPSS, respectively, 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, 113 and 117 at a frequency determined by FDA.

When the APPS and/or AQFPSS, as defined by this *Ordinance*, is utilized to produce aseptically processed and packaged low-acid milk and/or milk products or fermented high-acid, shelf-stable milk and/or milk products, and pasteurized and/or ultra-pasteurized milk and/or milk products, the APPS and/or AQFPSS, 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, ~~AND~~ RETORT PROCESSED AFTER PACKAGING PROGRAM AND FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING PROGRAM GRADE "A" PMO/CFR COMPARISON SUMMARY REFERENCE

PMO, Section 7. Items	Aseptic Program/Retort Program/ Fermented High-Acid, Shelf-Stable Program	Authority
1p. Floors – Construction	Floor drains are not required in storage rooms for aseptic processed and packaged low-acid milk and/or milk products, ~~and~~ retort processed after packaged low-acid milk and/or milk products and fermented high-acid, shelf-stable milk and/or milk products.	PMO
2p. Walls and Ceiling – Construction	Ceiling requirements are exempt in aseptically processed and packaged low-acid milk and/or milk products, ~~and~~ retort processed after packaged low-acid milk and/or milk products and fermented high-acid, milk and/or shelf-stable milk products dry storage rooms. (Same as for dry milk or milk products.)	PMO
3p. Doors and Windows	None	PMO
4p. Lighting and Ventilation	None	PMO
5p. Separate Rooms	Fabrication of containers and closures for aseptic processed and packaged low-acid milk and/or milk products, ~~and~~ retort processed after packaged low-acid milk and/or milk products and fermented high-acid, shelf-stable milk and/or milk products within the APPS, ~~and/or~~ RPPS, or AQFPSS, respectively, is exempt.	PMO
6p. Toilet – Sewage Disposal Facilities	None	PMO
7p. Water Supply*	The APPS, ~~and/or~~ RPPS, or AQFPSS**, respectively, is exempt, but shall comply with the CFR.	PMO/CFR
8p. Handwashing Facilities	None	PMO
9p. Milk Plant Cleanliness	None	PMO
10p. Sanitary Piping*	The APPS, ~~and/or~~ RPPS, and/or**, ~~respectively~~, is exempt, but shall comply with the CFR.	PMO/CFR
11p. Construction and Repair of Containers and Equipment*	The APPS, ~~and/or~~ RPPS, or AQFPSS, respectively, 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 and/or milk products that have been aseptically processed	PMO/CFR

PMO, Section 7. Items	Aseptic Program/Retort Program/ Fermented High-Acid, Shelf-Stable Program	Authority
	and packaged, ~~or~~ retort processed after packaged or fermented high-acid, shelf-stable processed and packaged are not required to comply with Appendix J. of this Ordinance; are not required to originate from an IMS Listed Source; and are subject to the requirements of the CFR.	
12p. Cleaning and Sanitizing of Containers and Equipment*	The APPS, ~~and/or~~ RPPS, or AQFPSS**, respectively, is exempt, but shall comply with the CFR.	PMO/CFR
13p. Storage of Cleaned Containers and Equipment*	The APPS, ~~and/or~~ RPPS, or AQFPSS**, respectively, is exempt, but shall comply with the CFR.	PMO/CFR
14p. Storage of Single-Service Containers, Utensils and Materials	None	PMO
15p.(A) Protection from Contamination*	The APPS, ~~and/or~~ RPPS, or AQFPSS**, respectively, is exempt, but shall comply with the CFR.	PMO/CFR
15p.(B) Protection from Contamination - Cross Connections*	The APPS, ~~and/or~~ RPPS, or AQFPSS **, respectively, is exempt, but shall comply with the CFR. APPS, ~~and/or~~ RPPS and/or AQFPSS 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.	PMO/CFR
16p. Pasteurization and Aseptic Processing and Packaging (A) through (D)*	The APPS, ~~and/or~~ RPPS, or AQFPSS, respectively, is exempt, but shall comply with the CFR. The Regulatory Agency is not required to conduct the quarterly equipment testing and sealing of aseptic and/or processing equipment. Records and recording charts are not required to be reviewed during routine inspections, ratings or check ratings. Provided that records and recording charts of the AQFPSS shall be evaluated in accordance with FHA CLE #5.	CFR
17p. Cooling of Milk and Milk Products*	The APPS, ~~and/or~~ RPPS, or AQFPSS, respectively; aseptic processed and packaged low-acid milk and/or milk product storage; ~~and~~ retort processed after packed low-acid milk and/or milk product storage; fermented high-acid, shelf-stable milk and/or milk product storage; are exempt but shall comply with the CFR.	PMO/CFR
18p. Bottling, Packaging and Container Filling*	The APPS, ~~and/or~~ RPPS, or AQFPSS, respectively, is exempt, but shall comply with the CFR.	CFR
19p. Capping, Container Closure and Sealing and Dry Milk Product Storage*	The APPS, ~~and/or~~ RPPS, or AQFPSS, respectively, is exempt, but shall comply with the CFR.	CFR
20p. Personnel – Cleanliness	None	PMO
21p. Vehicles	None	PMO
22p. Surroundings	None	PMO

*__NOTE:__ In areas of the milk plant where these Items are dedicated only to the APPS, ~~and/or~~ RPPS, or AQFPSS, respectively, as defined by this *Ordinance*, these Items shall be inspected and regulated in accordance with the applicable FDA regulations (21 CFR Parts 108, 113 and 117).

**__NOTE:__ Only portions of the AQFPSS that are included in the FDA Form 2541g filing will be exempt from this requirement. Any additional equipment not included in the Form FDA 2541g filing submission will be inspected per the PMO.

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Make the following changes to the 2017 MMSR:

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PREFACE

…….
The rating method for evaluating the sanitary quality of milk and/or milk products measures the extent to which a shipper complies with the standards contained in the *Grade "A" PMO*. These

nationally recognized standards, rather than local requirements, are used as a yardstick in order that ratings of individual Bulk Tank Units (BTUs) or attached shippers and milk plants, receiving stations and/or transfer stations may be comparable to each other, both interstate and intrastate. Ratings are expressed in terms of percentage compliance. For example, if the milk plant, receiving station, transfer station and/or dairy farms comply with all of the requirements of the *Grade "A" PMO*, the Sanitation Compliance Rating of the pasteurized milk supply and/or raw milk supply, respectively, would one hundred percent (100%); whereas, if the milk plant, receiving station, transfer station or some of the dairy farms fail to satisfy one (1) or more of these requirements, the Sanitation Compliance Rating would be reduced in proportion to the amount of milk and/or milk products involved in the violation and to the relative public health significance of the violated Item(s). Procedures for the collection of data, the computation of Sanitation Compliance Ratings for raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging and pasteurized milk, and the computation of the Enforcement Rating of the Regulatory Agency, responsible for administering milk sanitation regulations, are described in the following Sections.

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3. **ASEPTIC, ~~OR~~ RETORT OR FERMENTED HIGH-ACID, SHELF-STABLE MILK PLANT RATING:** A rating of a milk plant or portion of a milk plant that produces aseptically processed and packaged Grade "A" low-acid milk and/or milk products, ~~and/or~~ retort processed after packaged Grade "A" low-acid milk and/or milk products and/or Grade "A" fermented high-acid, shelf-stable milk and/or milk products that is rated separately from the rating of pasteurized and/or ultra-pasteurized Grade "A" milk and/or milk products produced in the milk plant. This rating shall be made for all milk plants producing aseptically processed and packaged Grade "A" low-acid milk and/or milk products, ~~and/or~~ retort processed after packaged Grade "A" low-acid milk and/or milk products and/or Grade "A" fermented high-acid, shelf-stable 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" low-acid milk and/or milk products, ~~and/or~~ retort processed after packaged Grade "A" low-acid milk and/or milk products and/or Grade "A" fermented high-acid, shelf-stable milk and/or milk products shall have only an NCIMS HACCP listing.

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4. **ASEPTIC-QUALIFIED FILLER AND PRODUCT STERILIZER SYSTEM (AQFPSS):** A filler and product sterilizer and associated equipment which are used for aseptic processing and packaging as defined in 21 CFR 113.3(a). This system will be described within filings for aseptic low acid products that have been filed with and reviewed by the Food Processing Evaluation Team in FDA/CFSAN's Office of Food Safety. The aseptic-qualified filler (which includes the package sterilizer) is operated as described within the Form FDA 2541g filing submission. The aseptic-qualified product sterilizer is operated in a manner that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of non-health significance capable of reproducing in the food under conditions of ambient storage. The scope of the AQFPSS includes the filler and product sterilizer described within the Form FDA 2541g filing submission and any other equipment or processes which will be defined in written documentation provided by the Process Authority that are critical to maintain the safety of the product.

Re-number remaining DEFINITIONS accordingly.

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14. **FDA AUDIT:** An evaluation conducted by FDA of the entire milk plant, receiving station, or transfer station facility to ensure compliance with the NCIMS HACCP System and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants, ~~and~~ the Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants and the Aseptic-Qualified Filler and Product Sterilizer System (AQFPSS) for Fermented High-Acid, Shelf-Stable plants, respectively.

15. **FERMENTED HIGH-ACID, SHELF-STABLE CRITICAL LISTING ELEMENT:** An Item on FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL

LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures. The identification of any Fermented High-Acid, Shelf-Stable Critical Listing Element by a Milk Sanitation Rating Officer (SRO) or PHS/FDA Milk Specialist as not being in compliance, shall cause a listing to be immediately denied or withdrawn.

~~16.~~ 17. **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 and/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 and/or milk products, provided each listing holds a separate permit. Milk plants that produce aseptically processed and packaged Grade "A" low-acid milk and/or milk products, ~~and/or~~ retort processed after packaged Grade "A" low-acid milk and/or milk products, and/or Grade "A" fermented high-acid, shelf-stable 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" low-acid milk and/or milk products, ~~and/or~~ retort processed after packaged Grade "A" low-acid milk and/or milk products and/or Grade "A" fermented high-acid, shelf-stable 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-number remaining DEFINITIONS accordingly.

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~~23~~ 25. **MILK PLANT:** A milk plant is any place, premises, or establishment where milk and/or milk products are collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed and packaged, retort processed after packaged, fermented high-acid, shelf-stable processed and packaged, condensed, dried, packaged, or prepared for distribution.

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B. RATING METHODS FOR RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~OR~~ RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSSING AND PACKAGING

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3. COMPUTATION OF SANITATION COMPLIANCE RATINGS

a. Rating results are transferred to FORM FDA 2359k- STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~OR~~ RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING This Form may be obtained from a PHS/FDA Milk Specialist or at the following FDA website:

http://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm. The Form is sufficiently flexible to permit various combinations of pages to be used for reporting ratings of area or individual shippers.

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3. COMPUTATION OF SANITATION COMPLIANCE RATINGS

a. Rating results are transferred to FORM FDA 2359k- STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~OR~~ RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING. This Form may be obtained from a PHS/FDA Milk Specialist or at the following FDA website: http://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm. The Form is sufficiently flexible to permit various combinations of pages to be used for reporting ratings of area or individual shippers.

b. The identity of each dairy farm, included in the rating, and the total pounds of milk sold daily, expressed to the nearest 100 pound unit (cwt.), are entered in the first, “Name of Dairy Farm”, and second, "Pounds Sold Daily (100# Units)", columns, respectively, of FORM FDA 2359k- STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~OR~~ RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING.

……

NOTE: Item 8-Water Supply on FORM FDA 2359a-DAIRY FARM INSPECTION REPORT has been divided into two (2) point and five (5) point violations/debits. The maximum point value for the entire Item 8r cannot exceed five (5) points on FORM FDA 2359k- STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~OR~~ RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING. (Refer to APPENDIX B. TABLE OF DAIRY FARM WATER SUPPLY VIOLATIONS, which provides guidance, which may be used to differentiate between two (2) point (minor) and five (5) point (major) violations of Section 7., Item 8r of the *Grade “A” PMO* during Ratings and FDA Check Ratings.)

Non-compliance with Item 15r-DRUG AND CHEMICAL CONTROL, Administrative Procedures #s 5, 6 and 7 of the *Grade “A” PMO* (debited under Item 15r(d) and (e) on FORM FDA 2359a-DAIRY FARM INSPECTION REPORT), would constitute a five (5) point debit, not to exceed a total of seven (7) points for the entire Item 15-Drugs on FORM FDA 2359k- STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~OR~~ RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING.

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Non-compliance with Item 18r-RAW MILK COOLING, Administrative Procedure #3 of the *Grade "A" PMO*, would constitute a one (1) point debit, not to exceed a total of five (5) points for the entire Item 18-Cooling on FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~OR~~ RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING.

…….

This rating figure is entered in the appropriate space in the upper right-hand corner of FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~OR~~ RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING. It is also entered on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION A. REPORT OF THE MILK SANITATION RATING (PAGE 1), in the appropriate location.

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2.) Compliance with bacterial, coliform and cooling temperature requirements is based on whether, at the time of the rating, a milk plant's Grade "A" milk and/or milk products meet the standards of Section 7. of the *Grade "A" PMO*. Each milk and/or milk product, including commingled raw milk prior to pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~and~~ retort processed after packaging and fermented high-acid, shelf-stable processing and packaging for each of the above applicable requirements, shall be debited if two (2) of the last four (4) sample results exceed the limit(s), and the last sample result is in violation. ……

The sampling and testing of aseptically processed and packaged Grade "A" low-acid milk and/or milk products, ~~and~~ retort processed after packaged Grade "A" low-acid milk and/or milk products, and Grade "A" fermented high-acid 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 and retort processed after packaging is required.

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NOTE: In the case of a HACCP aseptic listed milk plant, ~~and/or~~ HACCP retort listed milk plant, and/or HACCP fermented high-acid, shelf-stable milk plant, the identification of any ~~A~~CLE ~~element~~ on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND/OR PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) or FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products

- pH of 4.6 or below obtained by fermentation using live and active cultures by a SRO or PHS/FDA Milk Specialist as not being in compliance shall also constitute an ~~A~~CLE deficiency under the NCIMS HACCP System, whereby a listing shall be immediately denied or withdrawn.

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d. Recording of Data for Milk Plants and Receiving Stations Being Listed Under the NCIMS Aseptic Processing and Packaging Program and/or the NCIMS Retort Processed after Packaging Program and/or the Fermented High-Acid, Shelf-Stable 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.) The NCIMS Retort Processed after Packaging Program includes all low-acid retort processed after packaging Grade "A" milk and/or milk products as defined in the Grade "A" PMO.

C.) The NCIMS Fermented High-Acid, Shelf-Stable Processing and Packaging Program includes all Grade "A" high-acid fermented shelf-stable milk and/or milk products as defined in the Grade "A" PMO.

……..

C.) Regulatory Agency inspections of a milk plant or portion of a milk plant that is listed to produce aseptically processed and packaged Grade "A" low-acid milk and/or milk products, ~~and/or~~ retort processed after packaged Grade "A" low-acid milk and/or milk products and/or fermented high-acid, shelf-stable 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, ~~and/or~~ RPPS and/or AQFPSS, respectively, as defined by the *Grade "A" PMO,* shall be inspected by FDA, or a Regulatory Agency designated by FDA under the FDA LACF, in accordance with the applicable requirements of 21 CFR Parts 108, 113 and 117 at a frequency determined by FDA.

D.) For milk plants or portions of milk plants that are listed to produce aseptically processed and packaged Grade "A" low-acid milk and/or milk products, ~~and/or~~ retort processed after packaged Grade "A" low-acid milk and/or milk products and/or fermented high-acid, shelf-stable processed and packaged Grade "A" milk and/or milk products, the APPS, ~~and/or~~ RPPS and/or AQFPSS, respectively, 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 or RPPS, respectively, shall comply with the applicable portions of 21 CFR Parts 108, 113 and 117.

….

……

F.) NCIMS HACCP listed aseptic and/or retort and/or fermented high-acid, shelf-stable milk plants shall be inspected/audited and regulated under the NCIMS voluntary HACCP Program with the exception of the APPS, ~~or~~ RPPS~~,~~ or AQFPSS respectively, which shall be inspected and regulated under the NCIMS Aseptic Processing and Packaging Program

and/or Retort Processed after Packaging Program, and or Fermented High-Acid, Shelf-Stable Processing and Packaging Program respectively. Provided that FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND/OR PACKAGING PROGRAM AND RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) and or FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures shall also be completed and submitted.

Page 20:

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~~ critical listing element on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) or FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures by a SRO or PHS/FDA Milk Specialist as not being in compliance, requires that a listing shall be immediately denied or withdrawn.

Page 22:

f. If, upon receipt, one (1) or more shipper(s) of unattached raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid processing and packaging violates the bacterial and/or cooling temperature standards, the violations are debited against the rating of the receiving station(s) and/or transfer station(s) shipping the milk, prior to combining the ratings in accordance with the methods described above.

Page 24:

E. COMPUTATION OF ENFORCEMENT RATINGS

For all NCIMS HACCP listings, including aseptic, ~~and/or~~ retort and/or fermented high-acid, fermented shelf-stable milk plants, complete FORM FDA 2359n-NCIMS HACCP SYSTEM REGULATORY AGENCY REVIEW REPORT. (Refer to Section K. #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 voluntary HACCP listing procedure. These Enforcement Ratings shall be made using the procedures for raw milk for pasteurization, ultra-pasteurization, aseptic processed and packaging, ~~and~~ retort processed after packaging and fermented high-acid processing and packaging addressed in 2. of this Section.

Page 25:

2. RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~OR~~ RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING ONLY

a. When an individual shipper offers for sale only raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging directly from dairy farms, known as a BTU, and there are not any milk plant(s), receiving and/or transfer station(s) involved, all Items in Part I-DAIRY FARMS, FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) shall be evaluated. The total of the credit column of Part I shall be the Enforcement Rating and shall be recorded on Page 1 of this Form, in the appropriate location. (Refer to Section K. #s 1, 9 and 11 for examples.)

Page 26:

3. RECEIVING STATION OR TRANSFER STATION

a. When an individual shipper offers for sale raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging, which is shipped from a receiving station or transfer station, with one (1) or more dairy farms rated with it, all Items in Part II-MILK PLANTS, except Numbers 5 and 7, 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. When a receiving station and/or transfer station receives and trans-ships raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging from one (1) or more rated and listed BTUs and wishes a separate listing for its facilities, all Items in Part II, except Numbers 5 and 7, and all Items in Part III, except Number 1 shall be evaluated. The procedures outlined in E., 3., b and E., 4., b.3.), 4.) and 5.) shall be followed in computing the Enforcement Rating of the receiving station and/or transfer station.

Page 27:

4. MILK PLANTS

a. For NCIMS aseptic milk plants, ~~and~~ retort milk plants and fermented high-acid, shelf-stable 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 shall be divided by eighty-five (85) and multiplied by 100.

b. Milk Plant with an Unattached Supply of Raw Milk

1.) When an individual shipper of pasteurized milk and/or milk products imports all raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging from outside the jurisdiction of the Regulatory Agency in which the milk plant is located, only Parts II and III of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), shall be evaluated. ……

Page 28:

c. Milk Plant with an Attached Supply of Raw Milk

1.) When an individual shipper of pasteurized milk and/or milk products receives raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging from an attached supply(ies) within the jurisdiction of the Regulatory Agency in which the milk plant is located, Parts I, II, and III, on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) shall be evaluated. If raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging is received from both attached and unattached supplies, only those sources from attached supplies shall be evaluated in Part I. If an Item requires more than one (1) test or determination, i.e., Part II, Numbers 2, 4, 5, 6, 7, 8, 9, and 10, then compliance is also based on the proportion of tests or determinations, which according to the Regulatory Agency's records, were made at the required frequency.

Page 29:

2. SUMMARY OF RATING RESULTS

Sanitation Compliance Ratings computed in accordance with procedures previously described and other data pertinent to the shipper are entered in the SUMMARY OF RATING RESULTS on FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION A. REPORT OF MILK SANITATION RATING (PAGE 1). When the Sanitation Compliance Rating of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging has been combined with the rating(s) of unattached supplies in accordance with the conditions and procedures found under H. PUBLICATION OF THE "INTERSTATE MILK SHIPPER's REPORTS", Sections 2., c., 2.) or 2., c., 3.)B.); the combined rating, rather than the rating of the attached supply is entered in the summary.

Page 30:

For all NCIMS HACCP listings, including aseptic, ~~and/or~~ retort milk plants and/or fermented high-acid, shelf-stable milk plants, complete FORM FDA 2359n-NCIMS HACCP SYSTEM

REGULATORY AGENCY REVIEW REPORT, which includes an evaluation of the following: (Refer to Section K. #19 for an example.)

Page 32:

2. PREPARATION OF THE "INTERSTATE MILK SHIPPER'S REPORT"

a. Individual Shipper of Raw Milk for Pasteurization, Ultra-Pasteurization, Aseptic Processing and Packaging, ~~or~~ Retort processed after Packaging or Fermented High-Acid, Shelf-Stable Processing and Packaging.

This shipper is commonly referred to as a BTU. Following the computation of the Sanitation Compliance Rating on FORM FDA 2359k- STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~OR~~ RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING and Part I of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. The earliest rating date shall be the date of the first day of the rating. (Refer to Section K. #s 16 and 17 for examples.)

b. Receiving Station or Transfer Station

Following the computation of the Sanitation Compliance Rating on FORM FDA 2359k STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~OR~~ RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING, FORM FDA 2359L-STATUS OF MILK PLANTS, and Parts I, II and III of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. The earliest rating date shall be the date of the first day of the rating. When receiving and/or transfer stations wish a separate listing and receive raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging from one (1) or more rated and listed BTUs for trans-shipment, the procedures to be followed shall be that of Section H. PUBLICATION OF THE "INTERSTATE MILK SHIPPER's REPORT, 2., c.2) or 2., c.3).

Page 33:

Following the computation of the Sanitation Compliance Rating on FORM FDA 2359k STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~OR~~ RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING, FORM FDA 2359L-STATUS OF MILK PLANTS, and Parts I, II and III of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data shall be transferred to FORM

FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. The earliest rating date shall be the date of the first day of the rating of the dairy farms (BTU) or milk plant, whichever is earliest in time

….…..…

Following the computation of the Sanitation Compliance Rating on FORM FDA 2359k STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~OR~~ RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING, FORM FDA 2359L-STATUS OF MILK PLANTS, and Parts I, II and III of FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2), the resultant data shall be transferred to FORM FDA 2359i-INTERSTATE MILK SHIPPER's REPORT. The earliest rating date and the Raw Milk Sanitation Compliance Rating shall be computed by the following method:

Page 35:

4. PREPARATION OF THE "INTERSTATE MILK SHIPPER'S REPORT" FOR ASEPTIC PROCESSING AND PACKAGING PROGRAM, ~~AND/OR~~ RETORT PROCESSED AFTER PACKAGING PROGRAM AND/OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING PROGRAM LISTINGS

Page 36:

The provisions of this Section apply to milk plants and receiving stations listed under the NCIMS Aseptic Processing and Packaging Program, ~~and/or~~ Retort Processed after Packaging Program, and/or Fermented High-Acid, Shelf-Stable Processing and Packaging Program listing procedure, except that FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) and/or FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures, respectively, shall be submitted with FORM FDA 2359i for each NCIMS aseptic milk plant and/or retort milk plant listing to the appropriate PHS/FDA Milk Specialist or PHS/FDA MST for TPCs for quality assurance review.

Page 39:

J. EXAMPLES OF RATING, NCIMS HACCP LISTING, ASEPTIC PROCESSING AND PACKAGING PROGRAM, ~~AND~~ RETORT PROCESSED AFTER PACKAGING PROGRAM, AND FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING PROGRAM LISTING FORMS AND SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK

AND/OR MILK PRODUCTS MANUFACTURERS CERTIFICATION/LISTING FORMS

…….

6. FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~OR~~ RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING……

…….

14. *Insert new* FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures……

Re-number the remaining forms accordingly.

Page ~~40~~ 45:

6. FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, ~~OR~~ RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING

Page ~~56~~ 57:

Insert new FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures

Re-number following forms accordingly.

Page 59:

K. EXAMPLES OF HOW TO PROPERLY COMPLETE RATING, NCIMS HACCP LISTING, ASEPTIC PROCESSING AND PACKAGING PROGRAM, ~~AND~~ RETORT PROCESSED AFTER PACKAGING PROGRAM, AND FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING PROGRAM ~~listing~~ LISTING FORMS AND SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS MANUFACTURERS CERTIFICATION/LISTING FORMS

Page 60:

13. FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, OR RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING ……..
……

~~25.~~ 24. *Insert new* FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures……

Re-number remaining forms accordingly.

Page 73:

13. FORM FDA 2359k-STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, OR RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING

Page 74:

Continuation of the "STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, OR RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING"

Page 89:

Insert new example of completed 24. FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures

Re-number remaining forms accordingly.

Page 89:

~~24~~ 25. FORM FDA 2359j-MILK SANITATION RATING REPORT-SECTION B. REPORT OF ENFORCEMENT METHODS (PAGE 2) (EXAMPLE: ASEPTIC AND/OR RETORT MILK PLANT AND/OR FERMENTED HIGH-ACID, SHELF-STABLE MILK PLANT)

Page 93:

NOTE: A single dairy farm BTU shall be prorated by significant interpretation violation(s) not noted on previous inspection reports. For each Item that is identified as being misinterpreted, the value to be taken off from a possible 100 points corresponds to the weight value identified per Item on FORM FDA 2359k- STATUS OF RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, OR RETORT PROCESSED AFTER PACKAGING OR FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING

Page 100:

For Example:

= # of three (3) or six (6) month periods with an inspection conducted 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, aseptic milk plants, ~~and~~ retort milk plants and fermented high-acid, shelf-stable milk plants inspected at least once every six (6) months.

Page 101:

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

Page 103:

a. During any consecutive six (6) months, at least four (4) samples of raw milk, after receipt by the milk plant, including aseptic, ~~and~~ retort and fermented high-acid, shelf-stable milk plants, shall be collected, prior to pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable 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.

Page 104:

d. Assays of Vitamin A, D, and/or A and D fortified milk and/or milk products, including aseptically processed and packaged low-acid milk and/or milk products, ~~and~~ retort processed after packaging low-acid milk and/or milk products, and fermented high-acid, shelf-stable milk and/or milk products conducted at least annually in an IMS Listed Laboratory. Credit for vitamin-fortified milk and/or milk products is not given unless vitamin analysis is completed, and records are available. Each vitamin fortified product is evaluated separately. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods for vitamins.)

Document: 2017 PROCEDURES
Pages: iv, 1, 2, 3, 5, 13, 21, 24, 25, 28, 35, 38, 39, 40, 42, 43, 44, 49, 51, 54, 55, 61, 72

Make the following changes to the 2017 PROCEDURES:
Page iv:

AQFPSS (Aseptic-Qualified Filler and Product Sterilizer System)
FHA (Fermented High-Acid)

Page 1:

A. **PRODUCTS COVERED**

Agreements adopted by the NCIMS shall apply to Grade "A" raw milk and/or milk products for pasteurization, heat-treated products, pasteurized, ultra-pasteurized, aseptically processed and packaged low-acid milk and/or milk products, and/or retort processed after packaged low-acid milk and/or milk products, fermented high-acid, shelf-stable milk and/or milk products, condensed and dry milk products, whey and whey products, and single-service containers and/or closures for milk and/or milk products produced under the NCIMS program.

Page 2:

B. **AREA RATING:** An area rating, if used, shall apply to raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~and~~ retort processed after packaging and fermented high-acid, shelf-stable processing and packaging. An area rating consists of more than one (1) producer group operating under the supervision of a single Regulatory Agency and which is rated as a single entity. An individual dairy farm shall only be included in one (1) IMS Listing.
……

D. **BULK TANK UNIT (BTU):** A dairy farm or group of dairy farms from which raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~and/or~~ retort processed after packaging and/or fermented high-acid, shelf-stable processing and packaging is collected under the routine supervision of one (1) Regulatory Agency and rated as a single entity and given a Sanitation Compliance and Enforcement Rating. An individual dairy farm shall only be included in one (1) IMS Listing.

C. **ASEPTIC-QUALIFIED FILLER AND PRODUCT STERILIZER SYSTEM (AQFPSS):** A filler and product sterilizer and associated equipment which are used for aseptic processing and packaging as defined in 21 CFR 113.3(a). This system will be described within filings for aseptic low acid products that have been filed with and reviewed by the Food Processing Evaluation Team in FDA/CFSAN's Office of Food Safety. The aseptic-qualified filler (which includes the package sterilizer) is operated as described within the Form FDA 2541g filing submission. The aseptic-qualified product sterilizer is operated in a manner that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of non-health significance capable of reproducing in the food under conditions of ambient storage. The scope of the AQFPSS includes

the filler and product sterilizer described within the Form FDA 2541g filing submission and any other equipment or processes which will be defined in written documentation provided by the Process Authority that are critical to maintain the safety of the product.

Re-letter remaining DEFINITIONS accordingly.

Page 3:

~~L.~~ M. **IMS LISTED SHIPPER:** An interstate milk shipper (BTU, receiving station, transfer station, or milk plant), which has been certified by a Rating Agency as having attained the Sanitation Compliance and Enforcement Ratings necessary for inclusion on 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 and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers (MMSR). For milk plants that produce aseptically processed and packaged Grade "A" low-acid milk and/or milk products, ~~and/or~~ retort processed after packaged Grade "A" low-acid milk and/or milk products and/or fermented high-acid, shelf-stable processed and packaged Grade "A" milk and/or milk products, prior to the milk plant participating in the NCIMS Aseptic Processing and Packaging Program and/or Retort Processed after Packaging Program and/or Fermented High-Acid, Shelf-Stable Processing and Packaging Program, respectively, the Regulatory Agency's regulatory and Rating Agency's 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 and/or Retort Processed after Packaging Program and/or the Fermented High-Acid, Shelf-Stable Processing and Packaging Program.

~~M.~~ N. **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 and/or dried milk and/or milk products and/or Grade "A" condensed and/or dry whey and/or whey products may be rated separately from the same milk plant producing other Grade "A" milk and/or milk products, provided each listing holds a separate permit. Milk plants that produce aseptically processed and packaged Grade "A" low-acid milk and/or milk products, and/or retort processed after packaged Grade "A" low-acid milk and/or milk products, and or fermented high-acid, shelf-stable processed and packaged Grade "A" milk and/or milk products shall be rated separately from plants that produce ~~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" low-acid milk and/or milk products and/or retort processed after packaged Grade "A" low-acid milk and/or milk products and/or fermented high-acid, shelf-stable 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 remaining DEFINITIONS accordingly.

Page 5:

~~W.~~X. **MILK PLANT:** A milk plant is any place, premises, or establishment where milk and/or milk products are collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed and packaged, retort processed after packaged, fermented-high, acid-shelf stable processed and packaged, condensed, dried, packaged, or prepared for distribution.

Page 13:

8. PHS/FDA 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 or retort milk plants, the PHS/FDA Milk Specialist and/or PHS/FDA MST personnel for TPCs 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, ~~or~~ the NCIMS Retort Processed after Packaging Program or the Fermented High-Acid Processing and Packaging Program, respectively. ……..

Page 21:

C.) Withdrawal of Listed Rating

When check rating data indicates that the Sanitation Compliance Rating of a milk plant, receiving station and/or transfer station requires a withdrawal of their listed rating, the Rating Agency, upon written recommendation of PHS/FDA, shall immediately withdraw the current listed rating of the milk shipper and notify such milk shipper, PHS/FDA, and all known receiving States and/or TPCs 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 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 Rating Agency. Such letter shall be dated within five (5) working days following the date of the official notification by PHS/FDA. A withdrawal of a listed rating is also required if an aseptic, ~~or~~ retort, or fermented high-acid, shelf-stable milk plant has any ~~Aseptic~~ Critical Listing Element ~~(ACLE)~~ (CLE) identified as not being in compliance on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) or on FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures following the procedures cited above.

Page 24:

b. Milk plants, including HACCP, and/or aseptic processing and packaging, ~~and/or~~ retort processed after packaging, and/or fermented high-acid, shelf-stable processing and packaging, and/or single-service containers and closures manufacturers, if appropriate; and
……..

b. Five (5) milk plants. Milk plants of varying sizes using, vat, HTST and HHST pasteurization; ultra-pasteurization; aseptic processing and packaging; ~~and/or~~ retort processed after packaging; and/or fermented high-acid, shelf-stable 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) milk plants.

Page 25:

6. To conduct ratings of aseptic processing and packaging milk plants, ~~and/or~~ retort processed after packaging milk plants~~,~~ and/or fermented high-acid, shelf-stable processing and processing 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, ~~or~~ the NCIMS Retort Processed after Packaging Program or the Fermented High-Acid, Shelf-Stable Processing and Packaging Program, respectively.

……..

b. Three (3) milk plants. Milk plants of varying sizes using, vat, HTST and HHST pasteurization; ultra-pasteurization; aseptic processing and packaging; ~~and/or~~ retort processed after packaging; and/or fermented high-acid, shelf-stable processing and packaging, if applicable, should be included in these evaluations.

Page 28:

9. A SSO may delegate the inspection/evaluation of bulk milk hauler/samplers, who collect samples of raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging or fermented high-acid, shelf-stable processing and packaging from individual dairy farms, and/or the inspection of dairy plant samplers and industry plant samplers to other qualified State or TPC Regulatory Agency personnel or certified industry personnel as outlined in Section 5 of the *Grade "A" PMO*.

Page 35:

Insert after 3 and renumber 4.
4. If a fermented high-acid, shelf-stable milk plant has any CLE identified by a SRO, PHS/FDA Milk Specialist, or PHS/FDA MST personnel as not being in compliance on FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures, the IMS listing shall be immediately denied or withdrawn.
Renumber remaining items.

Page 38-39:

2. Products Covered Under HACCP Listings

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

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1. **AUDIT:** An evaluation of the entire milk plant, receiving station, or transfer station facility, and NCIMS HACCP System to ensure compliance with the NCIMS HACCP System and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants, ~~and~~ the Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants or the Aseptic-Qualified Processing and Packaging System (AQFPSS) for fermented high-acid, shelf-stable processing and packaging milk plants, respectively

…….

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 NCIMS HACCP System and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants, ~~and~~ Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants and/or the Aseptic Qualified Filler and Product Sterilizer System (AQFPSS) for fermented high-acid, shelf-stable milk plants, respectively.

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7. **LISTING AUDIT:** An evaluation conducted by a Milk Sanitation Rating Officer (SRO) of the entire milk plant, receiving station or transfer station facility to ensure compliance with the NCIMS voluntary HACCP Program and other NCIMS regulatory requirements, with the exception of the Aseptic Processing and Packaging System (APPS) for aseptic processing and packaging milk plants, ~~and~~ the Retort Processed after Packaging System (RPPS) for retort processed after packaging milk plants or the Aseptic-Qualified Processing and Packaging System (AQFPSS) for fermented high-acid, shelf-stable processing and packaging milk plants, respectively.

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8. PHS/FDA Audits of HACCP Listings

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, ~~and/or~~ retort processed after packaging milk plants and/or fermented high-acid, shelf-stable processed and packaged milk plants, the PHS/FDA Milk Specialist and/or PHS/FDA MST personnel for

TPCs shall have completed a training course that is acceptable to the NCIMS and PHS/FDA addressing the procedures for conducting audits and the implementation of the NCIMS Aseptic Processing and Packaging Program, ~~and/or~~ the NCIMS Retort Processed after Packaging Program and/or the NCIMS Fermented High-Acid, Shelf-Stable Processing and Packaging Program, respectively. ……

Page 43:

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 HACCP listing audits as described in the MMSR. These audits shall be used in the overall Regulatory/Rating Agency Program Evaluation. Provided, that for NCIMS HACCP listed milk plants producing aseptically processed and packaged Grade "A" low-acid milk and/or milk products, ~~and/or~~ retort processed after packaging Grade "A" low-acid milk and/or milk products and/or Grade "A" fermented high-acid, shelf-stable milk and/or milk products, PHS/FDA HACCP audits shall be conducted using the procedures identified in the NCIMS Aseptic Processing and Packaging Program, ~~or~~ the NCIMS Retort Processed after Packaging Program or the NCIMS Fermented High-Acid, Shelf-Stable Processing and Packaging Program, respectively, related to the inspection/auditing and regulation of the APPS, ~~and~~ RPPS, or AQFPSS, respectively, as described in the Grade "A" PMO and MMSR, along with the completion of FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) and/or FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures, respectively.

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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 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" low-acid milk and/or milk products, ~~and/or~~ retort processed after packaging Grade "A" low-acid milk and/or milk products and/or Grade "A" fermented high-acid, shelf-stable milk and/or milk products, FORM FDA 2359p-NCIMS Aseptic PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) and/or FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained

by fermentation using live and active cultures, respectively, shall also be completed and submitted to PHS/FDA.

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3.) A HACCP ~~aseptic~~ listing that includes an aseptically processed and packaged Grade "A" low-acid milk and/or milk products plant and/or a ~~HACCP retort listing that includes a~~ retort processed after packaging Grade "A" low-acid milk and/or milk products plant and/or a Grade "A" fermented shelf-stable milk and/or milk products plant shall be requested to be withdrawn when any ~~ACLE~~ Critical Listing Element is identified as not being in compliance on FORM FDA 2359p-NCIMS ASEPTIC PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) or FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures.

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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" low-acid milk and/or milk products, ~~and/or~~ retort processed after packaging Grade "A" low-acid milk and/or milk products and/or Grade "A" fermented high-acid, shelf-stable milk and/or milk products, FORM FDA 2359p-NCIMS Aseptic PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) and/or FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures shall be completed as a part of all HACCP aseptic, ~~and/or HACCP~~ retort and/or fermented high-acid, shelf-stable listing audits.

Page 54-55:

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 appropriate PHS/FDA Milk Specialist for quality assurance review. Provided that for NCIMS HACCP listed milk plants producing aseptically processed and packaged Grade "A" low-acid milk and/or milk products, ~~and/or~~ retort processed after packaging Grade "A" low-acid milk and/or milk products and/or Grade "A" fermented high-acid, shelf-stable milk and/or milk products, FORM FDA 2359p-NCIMS Aseptic PROCESSING AND PACKAGING PROGRAM AND/OR RETORT PROCESSED AFTER PACKAGING PROGRAM CRITICAL LISTING ELEMENTS (Low-Acid (pH greater than 4.6) Aseptic and Retort Milk and/or Milk Products) and/or FORM FDA 2359q-NCIMS ASEPTIC PROGRAM COMMITTEE - CRITICAL LISTING ELEMENTS for Grade "A" fermented high-acid, shelf-stable milk and/or milk products - pH of 4.6 or below obtained by fermentation using live and active cultures shall also be completed and submitted for quality assurance review.

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f. NCIMS Aseptic/Retort Program Personnel

Before a milk plant may be regulated under the requirements of the NCIMS Aseptic Processing and Packaging Program, ~~and/or~~ the Retort Processed after Packaging Program and/or the Fermented High-Acid, Shelf-Stable Processing and Packaging Program, all relevant TPC regulatory and rating personnel shall successfully complete the mandatory NCIMS Aseptic Processing and Packaging Program, ~~or~~ Retort Processed after Packaging Program or Fermented High-Acid, Shelf-Stable Processing and Packaging Program, respectively, training developed and offered by the NCIMS Aseptic Program Committee.

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- All required regulatory inspections and related enforcement;
- All required pasteurization system equipment testing;
- All required sampling and analysis of Grade "A" raw, pasteurized, ultra-pasteurized, aseptically processed and packaged milk and/or milk products, ~~and/or~~ retort processed after packaging milk and/or milk products and/or fermented high-acid, shelf-stable processed and packaged milk and/or milk products; and milk containers, if applicable;
- All ratings/listings of shippers of Grade "A" milk and/or milk products; and
- Laboratory certification/approval program activities required for compliance with all applicable NCIMS Grade "A" Milk Safety Program requirements.

Document: 2017 EML
Pages: 4

Make the following changes to the 2017 EML:

Page 4:

10. OFFICIALLY DESIGNATED LABORATORY: An officially designated laboratory is a commercial laboratory authorized to do official work by the Regulatory Agency, or a milk industry laboratory officially designated by the Regulatory Agency or Milk Laboratory Control Agency for the examination of producer samples of Grade "A" raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, ~~or~~ retort processed after packaging, or fermented high-acid, shelf-stable processing and packaging; and bulk milk pickup tanker samples of raw milk and/or all raw milk supplies that have not been transported in bulk milk pickup tankers for drug residues.

Proposal: 118
Document: 2017 PMO
Pages: xii, xiv, 36-39, 50, 51-55, 59, 283, 385-388, 403

Make the following changes to the 2017 PMO:

Page xii: add new table of contents listing X. under Appendix H

Page xiv:

APPENDIX Q. ~~OPERATION OF AUTOMATIC MILKING INSTALLATIONS FOR THE PRODUCTION OF GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-~~

STANDARDS FOR GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING

ITEM 1r. ABMORMAL MILK

Lactating animals which show evidence of the secretion of milk with abnormalities in one (1) or more quarters, based upon bacteriological, chemical or physical examination, shall be milked last or with separate equipment and the milk shall be discarded. AMIs shall have the capability to identify and discard milk from animals that are producing milk with abnormalities. Lactating animals producing contaminated milk, that is, lactating animals which have been treated with, have consumed chemical, medicinal or radioactive agents, which are capable of being secreted in the milk and which, in the judgment of the Regulatory Agency, may be deleterious to human health, shall be milked last or with separate equipment and the milk disposed of as the Regulatory Agency may direct. ~~(For applicability to Automatic Milking Installations (AMIs), refer to Appendix Q. of this *Ordinance*.)~~

PUBLIC HEALTH REASON

The health of lactating animals is a very important consideration because a number of diseases of lactating animals, including salmonellosis, staphylococcal infection and streptococcal infection, may be transmitted to man through the medium of milk. The organisms of most of these diseases may get into the milk either directly from the udder or indirectly through infected body discharges which may drop, splash or be blown into the milk.

Bovine mastitis is an inflammatory and, generally, highly communicable disease of the bovine udder. Usually, the inciting organism is a streptococcus of bovine origin (type B), but a staphylococcus or other infectious agent often causes the disease. Occasionally lactating animal's udders become infected with hemolytic streptococci of human origin, which may result in milk-borne epidemics of scarlet fever or septic sore throat. The toxins of staphylococci and possibly other organisms in milk may cause severe gastroenteritis. Some of these toxins are not destroyed by pasteurization.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Milk from lactating animals being treated with medicinal agents, which are capable of being secreted in the milk, is not offered for sale for such a period as is recommended by the attending veterinarian or as indicated on the package label of the medicinal agent.
2. Milk from lactating animals treated with or exposed to insecticides, not approved for use on dairy animals by the EPA, is not offered for sale.

3. The Regulatory Agency requires such additional tests for the detection of milk with abnormalities, as they deem necessary.
4. Bloody, stringy, off-colored milk, or milk that is abnormal to sight or odor, is so handled and disposed of as to preclude the infection of other lactating animals and the contamination of milk utensils.
5. AMIs shall have the capability to identify and discard milk from animals that are producing milk with abnormalities. Monitoring and controlling functions related to the identification and discarding of milk with abnormalities, shall comply with the criteria set forth in Appendix H. of this *Ordinance*.
~~5~~ 6. Lactating animals secreting milk with abnormalities are milked last or in separate equipment, which effectively prevents the contamination of the wholesome supply. Milking equipment used on animals with abnormalities in their milk is maintained clean to reduce the possibility of re- infecting or cross infection of the dairy animals.
~~6.~~7. Equipment, utensils and containers used for the handling of milk with abnormalities are not used for the handling of milk to be offered for sale, unless they are first cleaned and effectively sanitized.
8. Milk without abnormalities may be diverted for other uses and the parts of the milking system that came into contact with this milk are not required to be cleaned and sanitized prior to use for milk to be offered for sale.
~~7~~9. Processed animal waste derivatives, used as a feed ingredient for any portion of the total ration of the lactating dairy animal, have been:

a. Properly processed in accordance with at least those requirements contained in the Model Regulations for Processed Animal Wastes developed by the Association of American Feed Control Officials; and

b. Do not contain levels of deleterious substances, harmful pathogenic organisms or other toxic substances, which are secreted in the milk at any level, which may be deleterious to human health.

~~8~~10. Unprocessed poultry litter and unprocessed recycled animal body discharges are not fed to lactating dairy animals.

ITEM 2r. MILKING BARN, STABLE OR PARLOR-CONSTRUCTION

A milking barn, stable or parlor shall be provided on all dairy farms in which the milking herd shall be housed during milking time operations. ~~(For applicability to AMIs, refer to Appendix Q. of this *Ordinance*.)~~ The areas used for milking purposes shall:

1. Have floors constructed of concrete or equally impervious materials. Provided, convalescent (maternity) pens located in milking areas of stanchion-type barns may be used when they comply with the guidelines specified in Appendix C., III. of this *Ordinance*.
2. Have walls and ceilings, which are smooth, painted or finished in an approved manner; in good repair; and ceiling dust-tight.
3. Have separate stalls or pens for horses, calves and bulls, and not be overcrowded.
4. Be provided with natural and/or artificial light, well distributed, for day and/or night milking.
5. Provide sufficient air space and air circulation to prevent condensation and excessive odors. In the case of AMI milking unit rooms, all ventilation air shall come from outside the cattle housing area.

PUBLIC HEALTH REASON

When milking is done elsewhere than in a suitable place provided for this purpose, the milk may become contaminated. Floors constructed of concrete or other impervious materials can be kept clean more easily than floors constructed of wood, earth or similar materials and are; therefore, more apt to be kept clean. Painted or properly finished walls and ceilings encourage cleanliness. Tight ceilings reduce the likelihood of dust and extraneous material getting into the milk. Adequate lighting makes it more probable that the barn will be clean and that the lactating animals will be milked in a sanitary manner.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. A milking barn, stable or parlor is provided on all dairy farms.
2. Gutters, floors and feed troughs are constructed of good quality concrete or equally impervious material. Floors shall be easily cleaned, brushed surfaces permitted; be graded to drain; maintained in good repair; and free of excessive breaks or worn areas that may create pools.
3. Gravity flow manure channels in milking barns, if used, shall be constructed in accordance with the specifications of Appendix C., II. of this *Ordinance* or acceptable to the Regulatory Agency.
4. Stall barns, when used with gutter grates over manure storage pits, are designed and constructed in accordance with the specifications of Appendix C., IV. of this *Ordinance* or acceptable to the Regulatory Agency.
5. Walls and ceilings are finished with wood, tile, smooth-surfaced concrete, cement plaster, brick or other equivalent materials with light colored surfaces. Walls, partitions, doors, shelves, windows and ceilings shall be kept in good repair; and surfaces shall be refinished whenever wear or discoloration is evident.

   Whenever feed is stored overhead, ceilings shall be constructed to prevent the sifting of chaff and dust into the milking barn, stable or parlor. If a hay opening is provided from a loft, which is open into the milking portion of the barn, such openings shall be provided with a dust-tight door, which shall be kept closed during milking operations.
6. Bull pens, maternity, calf and horse stalls are partitioned from the milking portion of the barn. Such portions of the barn that are not separated by tight partitions shall comply with all the requirements of this Item.
7. Overcrowding is not evidenced by the presence of calves, lactating animals or other barnyard animals in walks or feed alleys. Inadequate ventilation and excessive odors may also be evidence of an overcrowded barn.
8. The milking barn is provided with natural and/or artificial light to ~~insure~~ ensure that all surfaces and particularly the working areas will be plainly visible. The equivalent of at least ten (10) footcandles (110 lux) of light in all working areas shall be provided.
9. Air circulation is sufficient to minimize odors and to prevent condensation upon walls and ceilings. For AMI milking unit rooms, the ventilation air shall come from outside the cattle housing area.

10. A dust-tight partition, provided with doors that are kept closed, except when in actual use, shall separate the milking portion of the barn from any feed room or silo in which feed is ground or mixed, or in which sweet feed is stored.

When conditions warrant, the Regulatory Agency may approve a barn without four walls extending from floor to roof, or a shed-type barn provided the requirement of Item 3r, prohibiting animals and fowl from entering the barn is satisfied.

ITEM 3r. MILKING BARN, STABLE OR PARLOR-CLEANLINESS

The interior shall be kept clean. Floors, walls, ceilings, windows, pipelines and equipment shall be free of filth and/or litter and shall be clean. Swine and fowl shall be kept out of the milking area. Feed shall be stored in a manner that will not increase the dust content of the air or interfere with the cleaning of the floor. ~~(For applicability to AMIs, refer to Appendix Q. of this *Ordinance*.)~~ Surcingles, or belly straps, milk stools and antikickers shall be kept clean and stored above the floor.

PUBLIC HEALTH REASON

A clean interior reduces the chances of contamination of the milk or milk pails during milking. The presence of other animals increases the potential for the spread of disease. Clean milk stools and surcingles reduce the likelihood of contamination of the milker's hands between the milking of one (1) lactating animal and the milking of another.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. The interior of the milking barn, stable or parlor is kept clean.
2. Leftover feed in feed mangers appears fresh and is not wet or soggy.
3. The bedding material, if used, does not contain more manure than has accumulated since the previous milking.
4. Outside surfaces of ~~pipeline systems~~ <u>all milking and clean-in-place (CIP) equipment</u> located in the milking barn, stable or parlor are reasonably clean.
5. Gutter cleaners are reasonably clean.
6. All pens, calf stalls and bull pens, if not separated from the milking barn, stable or parlor, are clean.
7. Swine and fowl are kept out of the milking area.
8. Milk stools are not padded and are constructed to be easily cleaned. Milk stools, surcingles and antikickers are kept clean and are stored above the floor in a clean place in the milking barn, stable, parlor or milkhouse, when not in use.
9. Gravity flow manure channels in milking barns, if used, shall be maintained in accordance with Appendix C., II. of this *Ordinance*.
10. Stall barns, when used with gutter grates over manure storage pits, are operated and maintained in accordance with the specifications of Appendix C., IV. of this *Ordinance*.

In milking barns in which water under pressure is not available, the floor may be brushed-dry and limed. In the latter event, care should be exercised to prevent caking of the lime. When

lime or phosphate is used, it shall be spread evenly on the floor as a thin coating. If clean floors are not maintained by this method, the Regulatory Agency should require cleaning with water.

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ITEM 9r. UTENSILS AND EQUIPMENT -CONSTRUCTION

~~14. AMIs shall comply with all applicable Grade "A" PMO requirements and/or 3-A Standards.~~

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ITEM 12r. UTENSILS AND EQUIPMENT-STORAGE

All containers, utensils and equipment used in the handling, storage or transportation of milk, unless stored in sanitizing solutions, shall be stored to assure complete drainage and shall be protected from contamination prior to use. Provided, that pipeline milking equipment such as milker claws, inflations, weigh jars, meters, milk hoses, milk receivers, tubular coolers, plate coolers~~,~~ ~~and~~ milk pumps and AMI milking equipment which are designed for CIP cleaning and other equipment~~, as accepted by FDA,~~ which meets these criteria, may be stored in the milking barn or parlor, provided this equipment is designed, installed and operated to protect the product and solution-contact surfaces from contamination at all times.

PUBLIC HEALTH REASON

Careless storage of milk containers, utensils and equipment, which previously have been properly treated, is apt to result in recontamination of such utensils, thus rendering them unsafe.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. All milk containers, utensils and equipment, including milking machine vacuum hoses, are stored in the milkhouse in a sanitizing solution, or on racks, until used. Pipeline milking equipment such as milker claws, inflations, weight jars, milk hoses, milk receivers, tubular coolers, plate coolers ~~and~~ milk pumps and AMI milking equipment which are designed for CIP cleaning and other equipment~~, as accepted by FDA,~~ which meets these criteria, may be CIP cleaned, sanitized and stored in the milking barn or parlor, provided this equipment is designed, installed and operated to protect the product and solution contact surfaces from contamination at all times. ~~Some of the parameters~~ Parameters to be considered in determining protection are:
    a. Proper location of equipment;
    b. Proper drainage of equipment; and
    c. Adequate and properly located lighting and ventilation.
        i. Provided, AMI milking unit rooms shall have positive air ventilation systems in operation whenever the milking system is being cleaned and/or sanitized.

2. The milking barn or parlor shall be used only for milking. Concentrates may be fed in the barn during milking but the barn shall not be used for the housing of animals. When manual cleaning of product-contact surfaces is necessary, the cleaning shall be done in the milkhouse. Provided, in the case of a milking parlor that opens directly into an enclosed housing area, through a covered holding area, the holding area may be seasonally enclosed when:

a. There are no manure pit openings in the parlor, holding area or in the housing area close enough to affect the milking parlor.

b. The cattle holding and housing areas are maintained in good repair and reasonably clean.

c. With respect to dust, odors, rodents and insects, the entire area meets milking parlor standards and the parlor is free of evidence of birds.

In addition, construction and cleanliness items identified above shall be evaluated in the appropriate *Ordinance* Sections.

3. Means are provided to effect complete drainage of equipment when such equipment cannot be stored to drain freely.

4. Clean cans or other containers are stored in the milkhouse within a reasonable time after delivery to the dairy farm.

5. Strainer pads, parchment papers, gaskets and similar single-service articles are stored in a suitable container or cabinet, in a location convenient to their use, and protected against contamination.

ITEM 13r. MILKING-FLANKS, UDDERS AND TEATS

Milking shall be done in the milking barn, stable or parlor. The flanks, udders, bellies and tails of all milking lactating animals shall be free from visible dirt. All brushing shall be completed prior to milking. The udders and teats of all milking lactating animals shall be clean and dry before milking. Teats shall be treated with a sanitizing solution just prior to the time of milking and shall be dry before milking. Wet hand milking is prohibited.

PUBLIC HEALTH REASON

If milking is done elsewhere other than in a suitable place provided for this purpose, the milk may become contaminated. Cleanliness of the lactating animals is one of the most important factors affecting the bacterial count of the milk. Under usual farm conditions, lactating animals contaminate their udders by standing in polluted water or by lying down in the pasture or cowyard. Unless the udders and teats are clean and dry before milking, particles of filth or contaminated water are apt to drop or be drawn into the milk. Such contamination of the milk is particularly dangerous because manure may contain the organisms of brucellosis and tuberculosis, and polluted water may contain the organisms of typhoid fever and other intestinal diseases. Application of sanitizing solutions to the teats, followed by thorough drying just prior to the time of milking, has the advantage of giving an additional margin of safety with reference to such disease organisms as they are not removed by ordinary cleaning and it is helpful in the control of mastitis.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Milking is done in a milking barn, stable or parlor.
2. Brushing is completed prior to milking.
3. Flanks, bellies, tails and udders are clipped as often as necessary to facilitate cleaning of these areas and are free from dirt. The hair on the udders shall be of such length that it is not incorporated with the teat in the inflation during milking.
4. Udders and teats of all milking animals are clean and dry before milking. Teats shall be cleaned, treated with a sanitizing solution and dry just prior to milking. Provided that the sanitizing of teats shall not be required if the udder is dry and the teats have been thoroughly cleaned (not dry wiped) and dried (manually wiped dry) prior to milking. The determination of what constitutes a dry udder and cleaned and dried teats shall be made by the Regulatory Agency.

NOTE: Additional alternative udder preparation methods, including those used on AMIs, may also be used once they have been evaluated by FDA and found acceptable. A copy of the FDA acceptance will be available for distribution to regulatory agencies, FDA and other interested parties. Verification of an AMI's control functions responsible for proper teat preparation shall comply with the criteria set forth in Appendix H. of this *Ordinance.*

5. Wet hand milking is prohibited.

ITEM 14r. PROTECTION FROM CONTAMINATION

Milking and milkhouse operations, equipment and facilities shall be located and conducted to prevent any contamination of milk, containers, utensils and equipment. Milk shall not be strained, poured, transferred or stored unless it is properly protected from contamination. After sanitization, all containers, utensils and equipment shall be handled in such a manner as to prevent the contamination of any milk product-contact surface.
Vehicles used to transport milk from the dairy farm to the milk plant, receiving station or transfer station shall be constructed and operated to protect their contents from sun, freezing and contamination. Such vehicles shall be kept clean, inside and out, and any substance capable of contaminating the milk shall not be transported with the milk.

PUBLIC HEALTH REASON

Because of the nature of milk and its susceptibility to contamination by disease producing bacteria and other contaminants, every effort shall be made to provide adequate protection for the milk at all times. This shall include the proper placement of equipment so that work areas in the milking barn and milkhouse are not overcrowded. The quality of any air that is used for the agitation or movement of milk or is directed at a milk product-contact surface shall be such that it will not contaminate the milk.
The effect of sanitization of equipment can be nullified if the equipment is not protected after sanitizing.
To protect milk during transportation, delivery vehicles shall be properly constructed and operated.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Equipment and operations are so located within the milking barn and milkhouse as to prevent overcrowding and contamination of cleaned and sanitized containers, utensils and equipment by splash, condensation or manual contact.

2. During the teat preparation process of an AMI, the teat cups (inflations) shall be adequately shielded to prevent contamination.

3. ~~2.~~ During milking and milkhouse operations, pipelines and equipment, used to contain or conduct milk, shall be effectively separated from tanks/silos and/or circuits containing cleaning and/or sanitizing solutions. In addition, AMIs shall provide separation between milk with abnormalities and milk intended for sale. This can be accomplished by:

a. Physically disconnecting all connection points between tanks/silos and/or circuits containing cleaning and/or sanitizing solutions from pipelines and equipment used to contain or conduct milk; or

b. Separation of all connection points between such circuits by at least two (2) automatically controlled valves with a drainable opening to the atmosphere between the valves; or by a single-bodied double seat mixproof valve, with a drainable opening to the atmosphere between the seats, if:

(1) The drainable opening to the atmosphere (vent) is equal to the largest pipeline connected to the mixproof valve or the following exception:

i) If the cross sectional area of the vent opening is less than that of the largest pipe diameter for the double seat valve, the maximum pressure in the space between the two (2) valve seats for the double seat valve shall be equivalent to or less than the maximum pressure in the space between two (2) blocking seats of two (2) automatically controlled compression type valves (three (3)-way valve to the drain and a two (2)-way valve separating product lines from cleaning and sanitizing solution lines.)

(2) Both valves, and valve seats in the case of single-bodied double seat valves, are position detectable and capable of providing an electronic signal when not properly seated in the blocked position. (Refer to Appendix H., I., Position Detection Devices of this *Ordinance*.)

(3) The valve vent, including piping between blocking valves, is not cleaned until milk has been removed or isolated, except in the case of a properly designed and operated system. This drainable opening to the atmosphere may be cleaned while milk is isolated by one (1) of the blocking valves. A properly designed and operated system shall incorporate the following:

i) During CIP, ~~a valve actuation of~~ the valve blocking the cleaning/sanitizing solution ~~blocking valve~~ may be ~~used~~ pulsed open for cleaning the valve vent, including piping between blocking valves, provided the blocking valves are fail-safe and the vent is self-draining and free from restrictions. Other means of preventing ~~there shall not be~~ pressurization of cleaning solutions on ~~the exterior of~~ the valve isolating milk may be individually evaluated and found to be acceptable by FDA and the Regulatory Agency. ~~that can equal or exceed the pressure of the milk being isolated, and~~

ii) During CIP with a valve actuation for cleaning the valve vent, including piping between blocking valves, the position detection of the valve isolating milk from the valve vent, including piping between blocking valves, and the position detection of the vent open to the atmosphere, shall be monitored and interlocked with the pump or source of liquid pressure, such that if it is determined they are not properly positioned, the pump or source of liquid pressure shall be immediately de-energized.

(4) These valves, or valve seats in the case of single-bodied double seat valves, are part of an automatic fail-safe system that shall prevent the contamination of milk with cleaning and/or sanitizing solutions. Automatic fail-safe systems shall be unique to each particular installation but are normally based on the premise that both blocking valve seats are properly seated in the blocked position before the CIP cleaning system can be activated for the cleaning circuit containing this valve arrangement, except as provided in (7) below.
(5) The system shall not have manual override capability, except for testing and inspection.
(6) Controls for the fail-safe system are tested and secured as directed by the Regulatory Agency. ~~in order to prevent unauthorized changes.~~ Testing verification procedures shall comply with the criteria set forth in Appendix H. of this *Ordinance*.
(7) The vent, including piping between blocking valves, is not cleaned until milk has been removed or isolated, except in the case of a properly designed and operated single- bodied double seat valve, in which case, the vent, including piping between blocking valves, may be cleaned while milk is present in one (1) of the valve housings. A properly designed and operated single-bodied double-seat valve shall incorporate the following:

i) There shall not be any impingement of cleaning liquid on the opposite valve seat gasket during seat lifting, even in the case of damaged or missing gaskets; and

ii) The pressure in the critical seat area of the valve vent cavity, even in the case of damaged or missing gaskets, shall be demonstrated to be atmospheric or less at all times; and

iii) During a seat-lift operation, the position of the seat opposite to the seat being lifted shall be monitored by a position detection device that is interlocked with the cleaning pump or source of the CIP cleaning solution pressure such that if this opposite seat is determined to be other than fully closed, the cleaning pump or source of the CIP cleaning solution pressure shall be immediately de-energized; and

iv) The single-bodied double seat valve vent cavity cleaning option shall have an Automated Fail-Safe Control System and the Control System shall comply with applicable provisions of Appendix H. Pasteurization Equipment and Procedures, Section VI. Criteria for the Evaluation of Computerized Systems for Grade "A" Public Health Controls of this *Ordinance*.

(8) Variations from the above specifications may be individually evaluated and found to also be acceptable if the level of protection is not compromised.

Page 59:

ITEM 18r. RAW MILK COOLING

Raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be cooled to 10ºC (50ºF) or less within four (4) hours ~~or less, of the commencement of the first milking, and to 7ºC (45ºF) or less, two (2) hours or after the completion of milking.~~ after starting the milking operation. The milk shall then be cooled within two (2) more hours to 7ºC (45ºF) or less. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10ºC (50ºF).

PUBLIC HEALTH REASON

Milk produced by disease-free lactating animals and under clean conditions usually contains relatively few bacteria immediately after milking. These can multiply to enormous numbers in a few hours unless the milk is cooled. However, when the milk is cooled quickly to 7ºC (45ºF) or less, there is only a slow increase in the numbers of bacteria.
Usually, the bacteria in milk are harmless, and if this were always true there would be no reason to cool milk, except to delay souring. There is; however, no way for the dairy operator or regulating officer to be absolutely sure that no disease bacteria have entered the milk, even though observance of the other Items of this *Ordinance* will greatly reduce this likelihood. The likelihood of transmitting disease is much increased when the milk contains large numbers of disease bacteria. Therefore, it is extremely important for milk to be cooled quickly, so that small numbers of bacteria, which may have entered the milk, will not multiply.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be cooled to 10ºC (50ºF) or less within four (4) hours ~~or less, of the commencement of the first milking, and to 7ºC (45ºF) or less, two (2) hours or after the completion of milking.~~ after starting the milking operation. The milk shall then be cooled within two (2) more hours to 7ºC (45ºF) or less. The start of the milking operation is the moment when milk is first transferred to an empty, clean and sanitized farm bulk milk tank, silo or direct load milk tank truck. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10ºC (50ºF).

Page 283: Add new section X. to Appendix H.

X. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR AUTOMATIC MILKING INSTALLATIONS (AMIs) FOR GRADE "A" PUBLIC HEALTH CONTROLS

BACKGROUND

AMIs have computerized systems that are programmed for monitoring and/or controlling various sensors, instrumentation and the operational state of various devices such as pumps and valves. The following criteria are to be used for the evaluation of AMI computerized systems requirements within Items 1r, 13r and 14r of this *Ordinance*.

CRITERIA

1. A verification of all computerized system's control functions responsible for properly detecting and diverting abnormal milk; proper teat preparation; and the fail-safe valve system(s) providing separation between milk with abnormalities and milk intended for sale; and between cleaning/sanitizing solutions and milk intended for sale shall be conducted and documented at the

commissioning of the computer system and at additional frequencies as deemed necessary by the Regulatory Agency.

2. This verification means the visual observation by Regulatory Agency personnel; or documentation indicating the testing that was completed by the AMI manufacturer; or other means accepted by the Regulatory Agency.

3. A manufacturer's written or electronic documentation addressing the computerized system's monitoring and controlling functions shall explain the devices controlled, the sensors or instruments monitored, and testing procedures. This document will be available to regulatory agencies, FDA and other interested parties upon request.

Page 385 – 388:

APPENDIX Q. ~~OPERATION OF AUTOMATIC MILKING INSTALLATIONS FOR THE PRODUCTION OF GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING~~ [RESERVED]

~~This Appendix is intended to clarify how AMIs are to be constructed, installed, perform, monitored, maintained, etc. to be considered in compliance with this *Ordinance*. It is formatted to follow the Items as outlined in Section 7. of this *Ordinance*. Both requirements and recommendations are provided.~~

~~GENERAL REQUIREMENTS FOR AMI COMPUTER SYSTEMS~~

~~AMIs have computer systems that are programmed for monitoring and/or controlling various sensors, instrumentation and the operational state of various devices such as pumps and valves; have data collection, storage and reporting systems; and have communication network capabilities for multiple uses and locations. While electronic and computer systems can furnish a wide range of process verification and anomaly reporting, these are criteria only for compliance with Items 1r, 13r and 14r of this Appendix.~~

~~The dairy farm shall have an identified representative(s) that has been trained by the AMI manufacturer or AMI manufacturer's designated representative to make program changes to the AMI system.~~

~~A manufacturer's written or electronic documentation addressing the computer system's monitoring and controlling functions related to Items 1r, 13r, and 14r of this Appendix shall explain the devices controlled, the sensors or instruments monitored, and testing procedures. A document shall bear the name of the identified representative of the dairy farm and shall be available for review at the dairy farm upon request by the Regulatory Agency, Rating Agency and/or FDA.~~

~~This documentation shall address Items 1r, 13r, and 14r of this Appendix:~~

1. The software version used, the devices controlled or monitored and their locations, and the sensors or instruments monitored and their locations;
2. The testing procedures for all of the computer system's controlled and monitoring devices;
3. The procedure for any changes or maintenance to the computers, devices, instrumentation, sensors hardware, etc. and
4. Instructions on how to access the information available on the computer system.

NOTE: Controls for the devices are verified as directed by the Regulatory Agency.

The data supporting the electronic reports shall be stored in a database or data archival system. Written or electronic record(s) shall be maintained at the dairy farm identifying changes and verifying compliance with this *Ordinance*. This record shall contain the name of the identified dairy farm representative assigned to administer the computer system and these record(s) shall be available for review at the dairy farm upon request by the Regulatory Agency, Rating Agency and/or FDA.

A verification of all computer system's controlled functions shall be conducted and documented at the commissioning of the computer system and at additional frequencies as deemed necessary by the Regulatory Agency. Computer system controlled functions should be reviewed and verified by the Regulatory Agency during routine dairy farm inspections and by the Rating Agency and FDA.

ITEM 1r. ABMORMAL MILK

AMIs shall have the capability to identify and discard milk from animals that are producing milk with abnormalities. Odor is currently evaluated on a farm bulk milk tank/silo basis and shall not be any different for a herd using AMI technology.

The dairy farm shall have a documented procedure in place describing how abnormal milk is properly detected and diverted; and that equipment used for the milking of healthy animals has not become contaminated. The procedure shall also document that a physical change to the AMI system has occurred.

A verification of all computer system's controlled functions responsible for properly detecting and diverting abnormal milk, shall be conducted and documented at the commissioning of the computer system. This verification means the visual observation by Regulatory Agency personnel; or documentation indicating the testing that was completed by an AMI manufacturer's designated representative; or other means accepted by the Regulatory Agency. Written or electronic information for all required actions shall be maintained at the dairy farm and shall be made available upon request to the Regulatory Agency, Rating Agency and/or FDA.

Animals producing milk with abnormalities shall be diverted to a holding pen to be milked immediately prior to the milking system being cleaned and sanitized, or the animal(s) are identified through an appropriate identification system so that their milk will be automatically excluded from the milk offered for sale, provided that the parts of the milking system that came into contact with the milk with abnormalities are immediately cleaned and sanitized.

ITEM 2r. MILKING BARN, STABLE OR PARLOR- CONSTRUCTION

~~The AMI milker box shall be treated the same as any other milking parlor. The goal is a clean environment in which to milk animals. All ventilation air shall come from outside the cattle housing area. The AMI should be located to provide a clean access for all personnel.~~

~~ITEM 3r. MILKING BARN, STABLE OR PARLOR-CLEANLINESS~~

~~The AMI milker box shall be kept as clean as any milking and equipment cleaning area. It is recommended that the milking platform be regularly flushed with water to remove any manure that may have accumulated.~~

~~ITEM 9r. UTINSILS AND EQUIPMENT-CONSTRUCTION~~

~~AMIs are the same as any other milking system from a sanitary construction and installation standpoint and shall meet the same standards as a conventional milking system in respect to construction, installation, inspectability, the fit and finish of the milk product-contact surfaces, etc.~~

~~ITEM 10r. UTENSILS AND EQUIPMENT-CLEANING~~

~~AMIs are a continuous milking system and shall be shut down to clean at an interval sufficient to prevent the milking system from building up with soils. It is recommended that this interval not to exceed eight (8) hours.~~

~~ITEM 11r. UTENSILS AND EQUIPMENT-SANITIZATION~~

~~AMIs shall be sanitized after each cleaning and/or before each use, as is the case with any other milking system.~~

~~ITEM 12r. UTENSILS AND EQUIPMENT-STORAGE~~

~~AMIs shall have positive air ventilation systems in operation whenever the milking system is being cleaned and/or sanitized. The air for this ventilation system shall come from outside the cattle housing area and shall be as clean and dry as practical. This positive air ventilation system shall also run during milking if needed to minimize odors, moisture and/or for pest control.~~

~~ITEM 13r. MILKING FLANKS-FLANKS, UDDERS AND TEATS~~

~~AMI manufacturers shall submit data to FDA to show that the teat prepping system employed in their milking system is equivalent to Item 13r., **ADMINISTRATIVE PROCEDURES** #4 of this *Ordinance*: "Teats shall be treated with a sanitizing solution just prior to the time of milking and shall be dry before milking." Each AMI installer shall provide the dairy producer and the Regulatory Agency with a copy of this FDA acceptance, including a detailed description of the accepted equivalent procedure. Each dairy producer shall keep a copy of the accepted teat prep protocol along with the appropriate AMI manufacturer's teat prep protocol verification procedures on file at the dairy farm.~~

~~A verification of all computer system's controlled functions responsible for proper teat preparation shall be conducted and documented at the commissioning of the computer system. This verification means the visual observation by Regulatory Agency personnel; or documentation indicating the testing that was completed by an AMI manufacturer's designated representative; or other means~~

~~accepted by the Regulatory Agency. Written or electronic information for all required actions shall be maintained at the dairy farm and shall be made available upon request to the Regulatory Agency, Rating Agency and/or FDA.~~

~~ITEM 14r. PROTECTION FROM CONTAMINATION~~

~~The teat cups (inflations) of the milking cluster shall be adequately shielded, or variations may be individually evaluated and found to also be acceptable by FDA and the Regulatory Agency, during the teat prepping process to assure that contaminants shall not enter through the teat cups and get into the milk.~~

~~AMIs are designed to automatically shift from milking to cleaning/sanitizing positions; therefore, adequate separation of milk and CIP solution shall be provided to minimize the risk of cross-contamination of milk with cleaning and/or sanitizing solutions. A fail-safe valve system providing protection equivalent to an inter-wired block-and-bleed valve arrangement, as referenced in Item 14r of this *Ordinance*, shall be located as needed to prevent cross- contamination. Separation shall be provided between milk with abnormalities and milk intended for sale, and between cleaning/sanitizing solutions and milk intended for sale.~~

~~Each dairy producer shall keep a copy of the AMI manufacturer's testing verification procedures for the fail-safe valve systems on file at the dairy farm.~~

~~AMIs, which have a wash line extending into the wash vat that is continuously connected to the milking system, shall have a valving arrangement that provides for an air break equal to the diameter of the wash line.~~

~~ITEM 18r. RAW MILK COOLING~~

~~For AMIs the raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be cooled to 10ºC (50ºF) within four (4) hours or less after starting the milking operation and the milk shall be cooled within two (2) more hours to 7ºC (45ºF). The milk in the farm bulk milk tank/silo shall not exceed 7ºC (45ºF) after that time. Farm bulk milk tank/silo recording thermometers are recommended if not already required by this *Ordinance*.~~

Page 403:

Automatic Milking Installations (AMIs), definition..... 2~~, 36, 385~~

Proposal: 203
Document: 2017 PMO
Pages: 19, 147

Make the following changes to the 2017 PMO:

To modify the 2017 PMO, Section 4 Labeling, page 19

8. Date of shipment;
~~9.Name of supervising Regulatory Agency at the point of origin of shipment;~~

~~10~~.9. Whether the contents are raw, pasteurized, or in the case of cream, lowfat or skim milk, whether it has been heat-treated;…….

Renumber remaining bullets

And to Modify the 2017 PMO, Appendix B., Section IV, 7. Labeling page 147

h. Date of shipment;
~~i. Name of supervising Regulatory Agency at the point of origin of shipment;~~
~~j.~~i. Whether the contents are raw, pasteurized, or in the case of cream, lowfat or skim milk, whether it has been heat-treated;……

Re-letter remaining bullets

Proposal: 206
Document: 2017 PMO
Pages: 29, 30, 35, 337

Make the following changes to the 2017 PMO:

Page 29:

Samples shall be analyzed at an appropriate official or officially designated laboratory. All sampling procedures, including the use of approved in-line samplers and approved aseptic samplers for milk tank trucks or for farm bulk milk tanks and/or silos, and required laboratory examinations shall be in substantial compliance with the FDA/NCIMS 2400 Forms. 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 Association of Official Analytical Chemists* (*AOAC) INTERNATIONAL* (*OMA*) may also be referenced when the FDA/NCIMS 2400 Forms are unclear, however, the FDA/NCIMS 2400 Forms shall have primacy when conflicting information is present. Such procedures, including the certification of sample collectors and examinations shall be evaluated in accordance with the *Procedures.*

Page 30:

LABORATORY TECHNIQUES: Procedures for the collection, including the use of approved in-line samplers and approved aseptic samplers for milk tank trucks or for farm bulk milk tanks and/or silos, and the holding of samples; the selection and preparation of apparatus, media and reagents; and the analytical procedures, incubation, reading and reporting of results, shall be in substantial compliance with the FDA/NCIMS 2400 Forms~~, *SMEDP* and *OMA*~~. *SMEDP* and *OMA* may also be referenced when the FDA/NCIMS 2400 Forms are unclear, however, the FDA/NCIMS 2400 Forms shall have primacy when conflicting information is present. The procedures shall be those specified therein for:

Page 35 (footnote):

*** Results of the analysis of milk and/or milk products which are weighed in order to be analyzed shall be reported in # per gm. (Refer to FDA/NCIMS 2400 Forms, or, if unclear, the current edition of the *SMEDP*.)

Page 337:

Procedures for obtaining samples and for the laboratory examination of these products are contained in the FDA/NCIMS 2400 Forms, or, if unclear, 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:

FDA DID NOT CONCUR WITH THIS PROPOSAL AS CITED IN THEIR LETTER TO THE NCIMS CHAIR DATED AUGUST 20, 2019

FDA originally non-concurred with this Proposal because the Proposal is fundamentally flawed and cannot be fixed with minor editorial corrections. FDA understands this proposal was well-intentioned to resolve confusion created by inconsistencies between the FDA/NCIMS 2400 form and other conference documents. However, as written the text on page 29 and 30 can be interpreted to mean that all sampling procedures, including the use of approved in-line samplers and approved aseptic samplers for milk tank trucks or for farm bulk milk tanks and/or silos shall be in substantial compliance with FDA/NCIMS 2400 Forms. It would be further interpreted that if there was a discrepancy between SMEDP and the FDA/NCIMS 2400 Forms, the FDA/NCIMS Forms would have primacy in resolving issues related to sampling procedures, including the use of approved in-line samplers and approved aseptic samplers for milk tank trucks or for farm bulk milk tanks and/or silos.

FDA/NCIMS 2400 Forms are specific to sample analysis and laboratory techniques, not sampling procedures. The PMO, Appendix B. and the SMEDP establish sampling procedure requirements. In addition, FDA Forms 2399 and 2399a are used when evaluating sampling procedures, not the FDA/NCIMS 2400 Forms.

During the October 23-24, 2019 NCIMS Executive Board meeting, FDA and the Executive Board did not reach mutual concurrence with Proposal 206; therefore Proposal 206 in accordance with Section X-Application of Conference Agreements, A-Implementation of Changes 4, of the *Procedures* will be referred to the next Conference for discussion

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Proposal: 207
Document: 2017 PMO
Pages: 30

Make the following changes to the 2017 PMO:

Page 30:

LABORATORY TECHNIQUES: Procedures for the collection, including the use of approved in-line samplers and approved aseptic samplers for milk tank trucks or for farm bulk milk tanks and/or silos, and the holding of samples; the selection and preparation of apparatus, media and reagents; and the analytical procedures, incubation, reading and reporting of results, shall be in substantial compliance with the FDA/NCIMS 2400 Forms, *SMEDP* and *OMA*. The procedures shall be those specified therein for:

1. Bacterial count at 32ºC ~~(Standard Plate Count (SPC), 3M™ Petrifilm™ Aerobic Count (PAC) or 3M™ Petrifilm™ Rapid Aerobic Count (RAC) methods).~~ (Refer to M-a-98, latest revision, for the list of approved tests for specific milk and/or milk products ~~for which these tests are approved~~.)
2. Alternate methods, for bacterial counts at 32°C ~~(Plate Loop Count (PLC), Spiral Plate Count (SPLC), Foss BactoScan FC (BSC), bioMerieux TEMPO® Aerobic Count (TAC), Charm® Peel Plate® Aerobic Count (PPAC) and Bentley BactoCount IBC (BCC) and Bentley BactoCount IBCm (BCMC) methods).~~ (Refer to M-a-98, latest revision, for the list of approved tests for specific milk and/or milk products ~~for which these tests are approved~~.)
3. Coliform count at 32ºC ~~(Coliform Plate Count (CPC), 3M™Petrifilm™ Coliform Count (PCC) and/or 3M™Petrifilm™High Sensitivity Coliform Count (HSCC), bioMerieux TEMPO CC Coliform Count (TCC), Charm® Peel Plate Total Coliform Count (PPCC), Charm® Peel Plate® E. coli and Total Coliform (PPEC), Charm® Peel Plate® Total Coliform High Volume Sensitivity (PPCCHV) and/or Charm® Peel Plate E. coli and Total Coliform High Volume Sensitivity (PPECHV) methods).~~ (Refer to M-a-98, latest revision, for the list of approved tests for specific milk and/or milk products ~~for which these tests are approved~~.)
4. A viable bacterial count of nonfat dry milk ~~shall be made in accordance with the procedures in *SMEDP* for the SPC, PPAC or PAC of DryMilk, except agar plates shall be incubated for 72 hours.~~ at 32°C. (Refer to M-a-98, latest revision, for the list of approved tests for specific milk and/or milk products.)

Proposal: 208
Document: 2017 PMO
Pages: 30, 74, 76, 107, 116, 213

Make the following changes to the 2017 PMO:

SECTION 6. THE EXAMINATION OF MILK AND/OR MILK PRODUCTS

Page 29-30

In addition, all milk plants fortifying milk and/or milk products with vitamins shall keep volume control records. These volume control records shall cross reference the form and amount of vitamin D, vitamin A and/or vitamins A and D used with the amount of milk and/or milk products produced and indicate a percent of expected use, plus or minus. These volume control records shall be:

1. Identified with the name and location of the milk plant or their milk plant code, dated and the signature or initials of the person performing the activity;

2. Reviewed, dated and signed or initialed ~~by or under the oversight of a preventive controls qualified individual (PCQI)~~;
3. Onsite and shall be reviewed by the Regulatory Agency during each regulatory inspection for at least the previous three (3) months or from the last regulatory inspection, whichever is longer. Electronic records are considered to be onsite if they are accessible from an onsite location; and
4. Retained for at least two (2) years after the date they were created. Offsite storage of these volume control records is permitted if such records can be retrieved and provided onsite within twenty-four (24) hours of a request for official review.

ITEM 12p. CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT

Page 74

Otherwise, storage tanks shall be cleaned when emptied and shall be emptied at least every seventy-two (72) hours. Records shall be available to verify that milk storage in these tanks does not exceed seventy-two (72) hours. These records shall be:

a. Identified with the name and location of the milk plant or their milk plant code, dated and the signature or initials of the person performing the activity;
b. Reviewed, dated and signed or initialed ~~by or under the oversight of a PCQI~~;
c. Onsite and shall be reviewed by the Regulatory Agency during each regulatory inspection for at least the previous three (3) months or from the last regulatory inspection, whichever is longer. Electronic records are considered to be onsite if they are accessible from an onsite location; and
d. Retained for at least two (2) years after the date they were created. Offsite storage of these cleaning records is permitted if such records can be retrieved and provided onsite within twenty-four (24) hours of a request for official review.

Page 76

c. Cleaning charts and electronically stored records required by this Section shall be:
(i) Identified with the name and location of the milk plant or their milk plant code, dated and the signature or initials of the person performing the activity;
(ii) Reviewed, dated and signed or initialed ~~by or under the oversight of a PCQI~~;
(iii) Shall be onsite and shall be reviewed by the Regulatory Agency during each regulatory inspection for at least the previous three (3) months or from the last regulatory inspection, whichever is longer. Electronic records are considered to be onsite if they are accessible from an onsite location; and
(iv) Retained for at least two (2) years after the date they were created. Offsite storage of these cleaning records is permitted if such records can be retrieved and provided onsite within twenty-four (24) hours of a request for official review.

Page 107

ITEM 16.(D) PASTEURIZATION RECORDS, EQUIPMENT TEST AND EXAMINATIONS

1. **PASTEURIZATION RECORDS:**

All temperature and flow rate pasteurization recording charts or alternative records, acceptable to FDA in place of charts, shall be:

a. Reviewed, dated and signed or initialed ~~by or under the oversight of a PCQI~~;

b. Onsite and shall be reviewed by the Regulatory Agency during each regulatory inspection for at least the previous three (3) months or from the last regulatory inspection, whichever is longer. Electronic records are considered to be onsite if they are accessible from an onsite location; and

c. Retained for at least two (2) years after the date they were created. Offsite storage of these pasteurization records is permitted if such records can be retrieved and provided onsite within twenty-four (24) hours of a request for official review.

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 also be entered on the charts or other records acceptable to FDA in place of charts as applicable:

ITEM 17p. COOLING OF MILK AND/OR MILK PRODUCTS

Page 116

7. Each refrigerated room in which milk and/or milk products are stored, is equipped with an accurate indicating thermometer, temperature-measuring device, or temperature-recording device that complies with the applicable specifications of Appendix H. of this *Ordinance*. Such indicating thermometer, temperature-measuring device, or temperature-recording device shall be located in the warmest zone of the refrigerated room.

Page 213

1. **Cleaning of Evaporators and Condensers:** Some evaporators are designed so that the milk or milk product is exposed to large surface areas for a long period of time at temperatures conducive to the growth of microorganisms.

Pipelines and/or equipment designed for automated mechanical cleaning of evaporators should meet the following requirements:

a. A pH recording device should be installed in the return solution line to record the pH and time, which the line or equipment is exposed during the cleaning and sanitizing operation.

b. These pH recording charts shall be:

(1) Identified with the name and location of the milk plant or their milk plant code, dated and the signature or initials of the person performing the activity;

(2) Reviewed, dated and signed or initialed ~~by a PCQI~~;

(3) Onsite and shall be reviewed and initialed by the Regulatory Agency to verify the time of exposure to the cleaning solutions and their pH during each regulatory inspection for at least the previous three (3) months or from the last regulatory inspection, whichever is longer. Electronic records are considered to be onsite if they are accessible from an onsite location; and

(4) Retained for at least two (2) years after the date they were created. Offsite storage of these pH records is permitted if such records can be retrieved and provided onsite within twenty-four (24) hours of a request for official review.

Proposal: 106
Document: 2017 PMO
Pages: 74

Make the following changes to the 2017 PMO:

Otherwise, storage tanks shall be cleaned when emptied and shall be emptied at least every seventy-two (72) hours. The seventy-two (72) hour time period starts when milk first enters a cleaned and sanitized storage tank. Records shall be available to document that milk storage in these tanks does not exceed seventy-two (72) hours.

Proposal: 122
Document: 2017 PMO
Pages: 78, 337

Make the following changes to the 2017 PMO:

STANDARDS FOR GRADE "A" PASTEURIZED, ULTRA-PASTEURIZED, ASEPTICALLY PROCESSED AND PACKAGED LOW-ACID MILK AND/OR MILK PRODUCTS, AND RETORT PROCESSED AFTER PACKAGED LOW-ACID MILK AND/OR MILK PRODUCTS

ITEM 12p. CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT …

ADMINISTRATIVE PROCEDURES …

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6. a. The residual bacteria count of multi-use containers ~~and closures~~ shall be conducted as outlined in Appendix J. of this *Ordinance*. The residual bacteria count of multi-use containers, used for packaging pasteurized milk and/or milk products, shall not exceed one (1) colony per milliliter (1/mL) of capacity, when the rinse test is used, or fifty (50) colonies per fifty (50) square centimeters (cm^2) (one (1) colony per square centimeter) of product-contact surface, when the swab test is used~~,~~. For the sample set containing four (4) multi-use containers, taken at random on a given day, to be in compliance with the bacterial standards of Appendix J. of this *Ordinance* as cited above the sample set shall not have two (2) or more ~~in three (3)~~ out of the four (4) samples making up the sample set exceeding the bacterial standard ~~taken at random on a given day~~. ~~Coliform organisms shall be undetectable in all multi-use containers.~~ All multi-use containers making up the sample set shall be free of coliform organisms.

b. The residual bacteria count of single-service containers and closures, used for packaging pasteurized milk and/or 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 fifty (50) cm^2 (one (1) colony per square centimeter) of product-contact surface, when the swab test is used~~,~~. For the sample set containing four (4) single-service containers and/or closures, taken at random on a given day,

to be in compliance with the bacterial standards of Appendix J. of this *Ordinance* as cited above the sample set shall not have two (2) or more ~~in three (3)~~ out of the four (4) samples making up the sample set exceeding the bacterial standard ~~taken at random on a given day~~. ~~Coliform organisms shall be undetectable in all single-service containers and/or closures.~~ All single-service containers and/or closures making up the sample set shall be free of coliform organisms.

c. When single-service containers and/or closures are fabricated in another plant that conforms to the Standards of Appendix J. of this *Ordinance* and the Regulatory Agency has information that they do comply, the Regulatory Agency may accept the containers and/or closures as being in conformance without additional testing. If there is reason to believe that containers and/or closures do not conform to the bacteriological standards, additional testing may be required. If containers and/or closures 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 with applied closures, as defined in Appendix J. of this *Ordinance* from each manufacturing line, as defined in Appendix J. of this *Ordinance*, 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 Milk Laboratory Control Agency specifically for the examinations required under Appendix J. of this *Ordinance*. …

APPENDIX J-STANDARDS FOR THE FABRICATION OF SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS …

C. BACTERIAL STANDARDS AND EXAMINATION OF SINGLE-SERVICE CONTAINERS AND/OR CLOSURES …

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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 fifty (50) cm^2 (one (1) per square centimeter) of product-contact surface. For the sample set containing four (4) single-service containers and/or closures, taken at random on a given day, to be in compliance with the bacterial standards of Appendix J. of this *Ordinance* as cited above shall not have two (2) or more ~~in three (3)~~ out of the four (4) samples making up the sample set exceeding the bacterial standard ~~taken at random on a given day~~. All single-service containers and closures making up the sample set shall be free of coliform organisms.

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ITEM 16p. PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, AND RETORT PROCESSED AFTER PACKAGING

Pasteurization shall be performed as defined in Section 1., Pasteurization and Item 16p of this *Ordinance*. Aseptic processing and packaging and retort processed after packaging shall be performed in accordance with the applicable requirements of 21 CFR Parts 108, 113 and 117. (Refer to Appendix L. of this *Ordinance*.)

In all cases, except for the specific exemptions provided for in **ADMINISTRATIVE PROCEDURES** #3, pasteurization of raw milk and/or milk product shall be performed before the raw milk and/or milk product enters the reverse osmosis (RO), ultra-filtration (UF), evaporator or condensing equipment and shall be performed in the milk plant where the processing is done. All condensed milk and/or milk products transported to a milk plant for drying shall be re-pasteurized at the milk plant at which it is dried. If condensed whey containing at least forty percent (40%) total solids, has been partially crystallized by cooling, it may be transported to a separate milk plant for drying without re-pasteurization, provided the following conditions are complied with:

1. The condensed, partially crystallized whey is cooled and maintained at 7^{o}C (45^{o}F) or less.
2. Milk tank trucks, dedicated to hauling pasteurized product, shall be used to transport the condensed, partially crystallized whey and shall be washed and sanitized immediately prior to filling and then sealed after filling until unloading.
3. Separate unloading pumps and pipelines shall be provided and used only for the unloading of the condensed, partially crystallized whey. Such pumps and pipelines shall be cleaned and sanitized as a separate cleaning circuit.

PUBLIC HEALTH REASON

Health officials unanimously agree upon the public health value of pasteurization. Long experience conclusively shows its value in the prevention of disease that may be transmitted through milk. Pasteurization is the only practical, commercial measure, which if properly applied to all milk, will destroy all milkborne disease organisms. Examination of lactating animals and milk handlers, while desirable and of great value can be done only at intervals and; therefore, it is possible for pathogenic bacteria to enter the milk for varying periods before the disease condition is discovered. Disease bacteria may also enter milk accidentally from other sources, such as flies, contaminated water, utensils, etc. It has been demonstrated that the time - temperature combinations specified by this *Ordinance*, if applied to every particle of milk and/or milk product will devitalize all milkborne pathogens. Compilations of outbreaks of milkborne disease by the USPHS/FDA, over many years, indicate that the risk of contracting disease from raw milk is approximately fifty (50) times as great as from milk that has been “pasteurized”. 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/or milk products when certain staphylococci are present, as from udder infections, and when the milk and/or milk product is not properly refrigerated before pasteurization. Such toxins may cause severe illness. Aseptic processing and packaging and retort processed after packaging have 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.

ADMINISTRATIVE PROCEDURES

The pasteurization portion of this Item is deemed to be satisfied when:

1. Every particle of milk and/or milk product is heated in properly designed and operated equipment that meets the requirements of this Item and Appendix H. of this *Ordinance*, to one of the temperatures specified in the following table and held continuously at or above that temperature for at least the time specified:

Table 3. Pasteurization Temperature vs. Time

Batch (Vat) Pasteurization	
Temperature	**Time**
63ºC (145ºF)*	30 minutes
Continuous Flow (HTST and HHST) Pasteurization	
Temperature	**Time**
72ºC (161ºF)*	15 seconds
89ºC (191ºF)	1.0 second
90ºC (194ºF)	0.5 seconds
94ºC (201ºF)	0.1 seconds
96ºC (204ºF)	0.05 seconds
100ºC (212ºF)	0.01 seconds

*If the fat content of the milk product is ten percent (10%) or greater, or a total solids of 18% or greater, or if it contains added sweeteners, the specified temperature shall be increased by 3ºC (5ºF).

Provided, that eggnog shall be heated to at least the following temperature and time specifications:

Table 3. Pasteurization Temperature vs. Time	
Batch (Vat) Pasteurization	
Temperature	**Time**
69ºC (155ºF)	30 minutes
Continuous Flow (HTST) Pasteurization	
Temperature	**Time**
80ºC (175ºF)	25 seconds
83ºC (180ºF)	15 seconds

Provided further, that nothing shall be construed as barring any other process found equivalent to pasteurization for milk and/or milk products, which has been recognized by FDA as provided in Section 403 (h)(3) of the *FFD&CA*.

2. All milk and/or milk products, i.e., milk solids, whey, nonfat dry milk, condensed milk, cream, skim milk, etc., eggs, egg products, cocoa, cocoa products, emulsifiers, stabilizers, vitamins and liquid sweeteners shall be added prior to pasteurization. Provided, ingredients which may be added

after pasteurization are those flavoring ingredients and other ingredients which have been found to be safe and suitable and which include:

a. Ingredients permitted by the CFR standards of identity when considering a standardized milk and/or milk product;

b. Fresh fruits and vegetables added to cultured milk and/or milk products provided the resultant equilibrium pH level (4.6 or below when measured at 24°C (75°F)) of the finished product is reached without undue delay and is maintained during the shelf life of the product.

c. Ingredients subjected to prior heating or other technology, which has been demonstrated to FDA to be sufficient to destroy or remove pathogenic microorganisms;

d. Ingredients having a a_w of 0.85 or less;

e. Ingredients having a high acid content (pH level of 4.6 or below when measured at 24°C (75°F)) or high alkalinity (pH level greater than 11 when measured at 24°C (75°F));

f. Roasted nuts;

g. Dry sugars and salts;

h. Flavor extracts having a high alcohol content;

i. Safe and suitable bacterial cultures and enzymes; and

j. Ingredients, which have been found to be safe and suitable by FDA.

All such additions shall be made in a sanitary manner, which prevents the contamination of the added ingredient or the milk and/or milk product.

3. All milk and/or milk products shall be pasteurized, prior to the entrance into RO, UF, evaporator or condensing equipment, and shall be performed in the milk plant where the processing is done, except that:

a. If the product is whey, pasteurization is not required, provided:

(1) The product is acid whey (pH less than 4.7); or

(2) It is processed in RO or UF equipment at temperatures at or below 7ºC (45ºF).

b. If the product is raw milk for pasteurization, the product may be concentrated by the use of RO or UF membrane filtration without pasteurization, prior to the entrance into the equipment, provided the following sampling, testing, design, installation and operational criteria are met:

(1) Prior to processing, all raw milk supplies are sampled and tested for antibiotic residues in accordance with the provisions of Appendix N. of this *Ordinance*;

(2) The RO or UF filtration system is designed and operated to assure that milk and/or milk product temperature is maintained at or below 18.3ºC (65ºF) throughout the process. Provided that the product temperature may rise above 18.3ºC (65ºF) for a period of not more than fifteen (15) minutes, further provided that should the product temperature rise above 21.1ºC (70ºF), the product shall be either immediately diverted to the system's balance tank until the product is again below 18.3ºC (65ºF) or diverted to exit the system entirely. Diverted product that has exited the system shall be either discarded, immediately cooled to below 7°C (45°F), or immediately pasteurized;

(3) The RO or UF system shall be equipped with temperature monitoring and recording devices that ~~comply with the applicable specifications outlined in Appendix H. of this *Ordinance*~~ are acceptable to the Regulatory Agency. At a minimum, milk and/or milk product temperature shall be monitored and recorded prior to entering the system, prior to entering each stage of the modules in series that contains cooling, and the retentate stream prior to any final cooler and upon exiting the system; and

(4) If the RO or UF system is not designed, installed and operated in accordance with the above noted criteria, the raw milk and/or milk product shall be pasteurized prior to entering the RO or UF system.

4. Milk and/or milk products for pasteurization may be processed by micro-filtration (MF) systems prior to pasteurization for the sole purpose of the removal of micro-organisms, provided that:

a. Prior to processing, all raw milk supplies are sampled and tested for antibiotic residues in accordance with the provisions of Appendix N. of this *Ordinance*; and

b. If there is a continuous, circulating retentate loop with a feed and bleed system, the following design, installation and operational criteria shall be complied with:

(1) The MF system is designed and operated to assure that milk and/or milk product temperature in the circulating retentate loop is maintained at or below 18.3ºC (65ºF), or at or above 51.7°C (125°F) throughout the process. Provided that the product temperature may rise above 18.3ºC (65ºF) or fall below 51.7°C (125°F) for a period of not more than fifteen (15) minutes, further provided that should the product temperature rise above 21.1ºC (70ºF) or fall below 48.9°C (120°F), the product shall be either immediately diverted to the system's balance tank until the product is again below 18.3ºC (65ºF) or above 51.7°C (125°F), or be diverted to exit the system entirely. Diverted product that has exited the system shall be either discarded, immediately cooled to below 7°C (45°F), or immediately pasteurized;

(2) The MF system shall be equipped with temperature monitoring and recording devices that ~~comply with the applicable specifications outlined in Appendix H of this Ordinance~~ are acceptable to the Regulatory Agency. At a minimum, milk and/or milk product temperature shall be monitored and recorded prior to entering the MF system and within the circulating retentate loop of each module just prior to the circulation pump; and

(3) The permeate from the MF system is either immediately cooled to below 7°C (45°F), or immediately pasteurized.

5. All condensed milk and/or milk products transported to a milk plant for drying shall be re-pasteurized at the milk plant where it is dried.

6. If condensed whey containing at least forty percent (40%) total solids, has been partially crystallized by cooling, it may be transported to a separate milk plant for drying without re-pasteurization, provided the following conditions are complied with:

a. The condensed, partially crystallized whey is cooled and maintained at 7ºC (45ºF) or less.

b. Milk tank trucks used to transport the condensed, partially crystallized whey shall be washed and sanitized immediately prior to filling and are sealed after filling until unloading.

c. Separate unloading pumps and pipelines shall be provided and used only for the unloading of the condensed, partially crystallized whey. Such pumps and pipelines shall be cleaned and sanitized as a separate cleaning circuit.

7. The design and operation of pasteurization equipment and all appurtenances thereto shall comply with the applicable specifications and operational procedures of Item 16p, Subitems (A), (B), (C) and (D) of this *Ordinance*.

ITEM 16p.(A) BATCH PASTEURIZATION

All indicating and recording thermometers used in connection with the batch pasteurization of milk and/or milk products shall comply with the applicable specifications set forth in Appendix H. of this *Ordinance*. Specifications for test thermometers and other test equipment appear in Appendix I. of this *Ordinance*.

PUBLIC HEALTH REASON

Unless the temperature-control instruments and devices used on pasteurization equipment are accurate within known limits, there can be no assurance that the proper pasteurization temperature is being applied. Pasteurization shall be performed in equipment, which is properly designed and operated and which insures that every particle of milk and/or milk product will be held continuously at the proper temperature for the specified period of time.

Recording thermometers are the only known means for furnishing the Regulatory Agency with a record of the time and temperature of pasteurization. Experience has shown that recording thermometers, due to their mechanical complexity, are not entirely reliable. Therefore, mercury indicating thermometers or equivalent, which are much more reliable, are needed to provide a check on the recording thermometer and assurance that proper temperatures are being applied. The recording thermometer shows the temperature of the milk and/or milk product immediately surrounding its bulb, but cannot indicate the temperature of the milk and/or milk product in other portions of the batch pasteurizer. Similarly, it shows the holding time in manual-discharge vats, but not in automatic-discharge systems. The pasteurizer shall; therefore, be so designed and so operated and, where necessary, provided with such automatic controls, as to assure that every portion of the milk and/or milk product will be subjected to the proper temperature for the required length of time.

Unless the outlet valve and connections to the vats are properly designed and operated, cold pockets of milk and/or milk product may be held in the outlet valve or pipeline and raw or incompletely pasteurized milk and/or milk product may leak into the outlet line during the filling, heating or holding period.

Tests have shown that when foam is present on milk and/or milk product in vats or pockets during pasteurization, the temperature of the foam may be well below the pasteurization temperature. In such cases, pathogenic organisms that may be in the foam will not be killed. Experience indicates that some foam is present at some time in all vats, particularly at certain seasons. Furthermore, in filling vats, milk and/or milk product frequently is splashed on the surfaces and fixtures above the milk and/or milk product level, as well as on the underside of the vat cover. Droplets of this splash may drop back into the body of the milk and/or milk product, and since they may not have been at pasteurization temperature for the required time, they may contain pathogenic organisms. Heating the air above the milk and/or milk product, above pasteurization temperature, remedies these conditions. When air heating is not provided, its need may frequently be demonstrated by swabbing milk and/or milk product from the upper vat walls and from the underside of the cover, at the end of the holding period, and running phosphatase tests on the swab samples.

Many milk plant operators have reported that the use of airspace heaters, especially with partly filled vats with un-insulated lids, makes it easier to maintain the milk and/or milk product at a uniform and sufficiently high temperature. It also helps to prevent the growth of thermophilic organisms and promotes easier cleaning.

Obviously, if the design and construction of pasteurization vats and pocket covers do not prevent leakage, condensation and the entrance of water and dust, the milk and/or milk product may become contaminated with material containing disease bacteria. Keeping the covers closed during operation will decrease the chance of contaminants such as dust, insects, drip and splash from entering the milk and/or milk product.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. **TIME AND TEMPERATURE CONTROLS FOR BATCH PASTEURIZERS**

a. **Temperature Difference:** The pasteurizer shall be so designed that the simultaneous temperature difference between the milk and/or milk product, at the center of the coldest milk and/or milk product and the warmest milk and/or milk product in the vat, will not exceed 0.5ºC (1ºF) at any time during the holding period. The vat shall be provided with adequate agitation, operating throughout the holding period. No batch of milk and/or milk product shall be pasteurized unless it covers a sufficient area of the agitator to insure adequate agitation.

b. **Location and Required Readings of Indicating and Recording Thermometers:** Each batch pasteurizer shall be equipped with both an indicating and a recording thermometer. The thermometers shall not read less than the required pasteurization temperature throughout the required holding period. The milk plant operator shall check the temperature shown by the recording thermometer against the temperature shown by the indicating thermometer at the start of the holding period. This comparison shall be noted on the recording thermometer chart. The recording thermometer shall not read higher than the indicating thermometer. No batch of milk and/or milk product shall be pasteurized unless it is sufficient to cover the bulbs of both the indicating and the recording thermometer.

c. **Assurance of Minimum Holding Periods:** Batch pasteurizers shall be so operated that every particle of milk and/or milk product will be held at not less than the minimum pasteurization temperature continuously for at least thirty (30) minutes. When milk and/or milk products are raised to pasteurization temperature in the vat, and cooling is begun in the vat simultaneously with or before the opening of the outlet valve, the recording chart shall show at least thirty (30) minutes, at not less than minimum pasteurization temperature. When milk and/or milk products are preheated to pasteurization temperature before entering the vat, the recording chart shall show a holding period of at least thirty (30) minutes, at not less than the minimum pasteurization temperature plus the time of filling from the level of the recording thermometer bulb. When cooling is begun in the batch pasteurizer, after opening the outlet valve, or is done entirely outside the batch pasteurizer, the recording chart shall show at least thirty (30) minutes at not less than the minimum pasteurization temperature plus the time of emptying to the level of the recording thermometer bulb.

When the recording time interval on the recording chart at the pasteurization temperature includes filling and/or emptying time, such intervals shall be indicated on the recording chart, by the operator, by removing the recording thermometer bulb from the milk and/or milk product for a sufficient time to depress the pen; or by turning cold water into the vat jacket at the end of the holding period; or by inscribing the holding time on the recording chart. The filling time and the emptying time for each batch pasteurizer, so operated, shall be determined

by the Regulatory Agency, initially and after any change, which may affect these times. No milk and/or milk product shall be added to the batch pasteurizer after the start of the holding period.

2. **AIRSPACE HEATING**

a. Means shall be provided and used in batch pasteurizers to keep the atmosphere above the milk and/or milk product at a temperature not less than 3ºC (5ºF) higher than the minimum required temperature of pasteurization, during the holding period. (Refer to Appendix H. of this *Ordinance*.)

b. Each batch pasteurizer shall be equipped with an airspace thermometer. The surface of the milk and/or milk product shall be at least 25 millimeters (1 inch) below the bottom of the thermometer bulb when the vat is in operation.

c. The temperature shown by the airspace thermometer shall be recorded on the recording thermometer chart at the start of the holding period and at the end of the holding period, at a given time or reference point as indicated on the recording chart.

3. **INLET AND OUTLET VALVES AND CONNECTIONS**

The following definitions shall apply to inlet and outlet valves and connections:

a. **"Valve Stop"** shall mean a guide which permits turning the valve plug to, but not beyond, the fully closed position.

b. **"The Fully Open Position"** shall mean that position of the valve seat that permits the maximum flow into or out of the pasteurizer.

c. **"The Closed Position"** shall mean any position of the valve seat that stops the flow of milk into or out of the pasteurizer.

d. **"The Fully Closed Position"** shall mean that closed position of the valve seat which requires the maximum movement of the valve to reach the fully open position.

e. **"The Just-Closed Position"** shall mean that closed position of a plug-type valve in which the flow into or out of the ~~holder~~ pasteurizer is barely stopped, or any position within 2 millimeters (0.078 of an inch) thereof as measured along the maximum circumference of the valve seat.

f. **"Leakage"** shall mean the entrance of unpasteurized milk and/or milk product into a batch pasteurizer during the holding or emptying period, or the entrance of unpasteurized milk and/or milk product into any pasteurized milk and/or milk product line at any time.

g. "**Leak-Protector Valve**" shall mean a valve provided with a leak-diverting device, which when the valve is in any closed position, shall prevent leakage of milk and/or milk product past the valve.

h. **"Close-Coupled Valve"** shall mean a valve, the seat of which is either flush with the inner wall of the pasteurizer or so closely coupled that no milk and/or milk product in the valve is more than 0.5ºC (1ºF) colder than the milk and/or milk product at the center of the pasteurizer at any time during the holding period.

A close-coupled valve, which is not truly flush, shall be considered as satisfying this requirement when:

(1) The vat outlet is so flared that the smallest diameter of the large end of the flare is not less than the diameter of the outlet line, plus the depth of the flare; and

(2) The greatest distance from the valve seat to the small end of the flare is not greater than the diameter of the outlet line; and

(3) In the case of batch pasteurizers, the outlet and the agitator are so placed as to insure that milk and/or milk product currents will be swept into the outlet.

4. **DESIGN AND INSTALLATION OF VALVES AND CONNECTIONS**

All valves and connections shall comply with the following requirements:

a. Valves and pipeline connections shall meet the requirements of Item 10p of this *Ordinance*.

b. All pipelines and fittings shall be so constructed and so located that leakage shall not occur.

c. To prevent clogging, and to promote drainage, all leak-protection grooves in plug-type outlet valves shall be at least 5 millimeters (0.187 of an inch wide) and at least 2.3 millimeters (0.094 of an inch) deep at the center. Mating grooves shall provide these dimensions throughout their combined length, whenever the valve is in, or approximately in, the fully closed position. All single leak grooves, and all mating leak grooves when mated, shall extend throughout the entire depth of the seat, so as to divert leakage occurring at all points throughout the depth of the seat and so as to prevent air binding. Washers or other parts shall not obstruct leak-protector grooves.

d. A stop shall be provided on all plug-type outlet valves in order to guide the operator in closing the valve so that unpasteurized milk and/or milk product may not inadvertently be permitted to enter the outlet line. The stop shall be so designed that the plug will be irreversible when the plug is provided with any grooves or their equivalent, unless duplicate, diametrically opposite grooves are also provided. Stops shall be so designed that the operator cannot turn the valve beyond the stop position, either by raising the plug or by any other means.

e. Outlet valves, in addition to the requirements listed above, shall be so designed as to prevent the accumulation of unpasteurized milk and/or milk product in the milk and/or milk product passages of the valve when the valve is in any closed position.

f. All outlets from vat pasteurizers shall be equipped with close-coupled leak-protector valves or be otherwise similarly protected during filling, holding and emptying periods.

g. All leak-protector grooved outlet valves shall be installed in the proper position to insure the function of the leak-protector groves and the drainage of the leak-detector valve.

h. All outlet valves shall be kept fully closed during filling, heating, and holding periods.

i. Close-coupled vat pasteurizer outlet valve bodies and plugs shall be made of stainless steel or of other materials that have heat transfer properties at least equal to stainless steel.

j. All inlet pipelines are disconnected during the holding and emptying periods, and all outlet pipelines are disconnected during the filling and holding periods.

5. **RECORDING THERMOMETER CHARTS**

All recording thermometer charts shall comply with all the applicable requirements of Item 16p.(D)1. of this *Ordinance*.

ITEM 16p.(B) ~~HIGH-TEMPERATURE-SHORT-TIME (HTST)~~ CONTINUOUS-FLOW PASTEURIZATION

PUBLIC HEALTH REASON

(Refer to the Public Health Reason under Item 16p and 16p(A). of this *Ordinance*.)

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. **INDICATING THERMOMETERS AND RECORDER/CONTROLLER INSTRUMENTS**

All indicating thermometers and recorder/controller instruments and devices used in connection with the ~~HTST~~, continuous-flow pasteurization of milk and/or milk products shall comply with the applicable specifications set forth in Appendix H. of this *Ordinance*.

2. **AUTOMATIC MILK CONTROLLER**

Each ~~HTST,~~ continuous-flow pasteurization system shall be equipped with an automatic milk flow control of the diversion type, which complies with the following definition, specifications and performance requirements:

a. **Automatic Milk and/or Milk Product-Flow Controls:** ~~The term "automatic milk or milk product-flow controls" shall mean those safety devices which control the flow of milk or milk product in relation to the temperature of the milk or milk product or heating medium and/or pressure, vacuum or other auxiliary equipment. Milk or milk product-flow controls shall not be considered as part of the temperature control equipment. Milk or milk product flow controls shall be of the flow-diversion type, which automatically cause the diversion of the milk or milk product in response to a sub-legal pasteurization temperature. At sub-legal temperatures, FDDs return the milk or milk product to the raw milk or milk product side of the heating system continuously until legal pasteurization temperatures are obtained, at which time, the device restores forward-flow through the pasteurizer.~~

(1) Milk and/or milk product controls must have a Flow Diversion Device (FDD) which automatically causes the diversion of the milk and/or milk product in response to a sub legal pasteurization condition.

(2) The controls shall include logic to meet the applicable requirements of Item 16p.(B), Item 16p.(C) and Appendix H. of this *Ordinance* and perform the applicable tests listed in Item 16p.(D)2. and Appendix I. of this *Ordinance*.

(3) The controls vendor shall provide to the Regulatory Agency documentation including a user manual with testing procedures and instructions necessary to supplement those in this *Ordinance*.

b. **FDDs:** All FDDs used in continuous pasteurizers shall comply with the following or equally satisfactory specifications:

(1) The forward-flow of milk and/or milk product below the minimum pasteurization temperature shall be prevented by requiring the motive pump(s) to be de-energized when the milk and/or milk product is below the pasteurization temperature and the valve is not in the fully diverted position; or by any other equally satisfactory means. For the detection of the FDD and valve seat positions, refer to Appendix H., I., Position Detection Devices of this *Ordinance*.

(2) When a packing gland is used to prevent leakage around the actuating stem, it shall be impossible to tighten the stem-packing nut to such an extent as to prevent the valve from assuming the fully diverted position.

(3) A leak-escape shall be installed on the forward-flow side of the valve seat. However, when backpressure is exerted on the forward-flow side of the valve seat, while the milk and/or milk product-flow is being diverted, the leak-escape should lie between two valve seats or between two portions of the same seat, one upstream and the other downstream

from the leak-escape. The leak-escape shall be designed and installed to discharge all leakage to the outside, or to the constant-level tank through a line separate from the diversion line. Provided, that when leakage is discharged to the constant-level tank, a sight glass shall be installed in the leak-escape line to provide a visual means of leak detection.

(4) The closure of the forward-flow seat shall be sufficiently tight so that leakage past it shall not exceed the capacity of the leak-escape device, as evidenced when the forward-flow line is disconnected; and, in order that proper seating may not be disturbed, the length of the connecting rod shall not be adjustable by the user.

(5) The FDD shall be so designed and installed that failure of the primary motivating power shall automatically divert the flow of milk and/or milk product.

(6) The FDD shall be located downstream from the ~~holder~~ holding tube. The flow-control sensor shall be located in the milk and/or milk product line not more than 46 centimeters (18 inches) upstream from the inlet of the FDD.

(7) The FDD may be located downstream from the regenerator and/or cooler section, provided, that ~~when the FDD is located downstream from the regenerator and/or cooler section, the FDD shall be automatically prevented from assuming the forward-flow position until all 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 the definition of Pasteurization of this *Ordinance*.~~ the system complies with the criteria for downstream FDDs in Appendix H. of this *Ordinance*.

(8) The pipeline from the diversion port of the FDD shall be self-draining and shall be free of restrictions or valves; unless such restrictions are noticeable and valves are so designed that stoppage of the diversion line cannot occur. ~~In the case of continuous flow pasteurization systems, which have the FDD located downstream from the regenerator and/or cooler and are inter-wired or are computer controlled to thoroughly clean the system, including the divert pipeline before the re-starting of production, a cooling section, which is not self-draining, may be present in the divert pipeline.~~

(9) When ~~it is~~ used, the pipeline from the leak-detector port of the FDD shall be self-draining and shall be free of restrictions or valves.

(10) For the timing pump a one (1) second maximum "off" time delay is allowed to maintain the flow-promoting device in the "on" position through the travel time of the FDD.

(11) If the area between the divert and leak-detect valve seats is not self-draining when the FDD is in the diverted position, a delay of at least one (1) second and not more than five (5) seconds is required between the movement of the divert and leak-detect valves when the FDD assumes the forward-flow position. Except that, the delay may be longer than five (5) seconds if~~:~~ the timing system is a magnetic flow meter based timing system~~;~~ or if the holding time in diverted-flow through an unrestricted divert valve line is longer than the required pasteurization time as specified in the definition of Pasteurization of this *Ordinance*.~~; and except that, no time delay is required in pasteurization systems in which the FDD is located downstream from the pasteurized regenerator and in which all forward-flow product-contact surfaces of the FDD are sanitized, or sterilized during the normal start-up process.~~

(12) In the case of HHST pasteurizing systems utilizing temperatures and holding times to meet the definition of ultra-pasteurization (UP) of this *Ordinance*, the FDD may be located downstream of the regenerator and/or cooler section. Said FDD may alternatively be a system of the "Steam-Block Type" as described in Appendix H. of this *Ordinance*. ~~This FDD system shall allow for the flow of water and/or milk or milk product to the constant-level tank through appropriate valves and coolers during sterilization and when diverted.~~

(13) When switching to the "CIP" position, the FDD shall move to the divert position and shall remain in the diverted-flow position for at least ten (10) minutes, regardless of temperature, and for HTST pasteurization systems the booster pump cannot run during this ten (10) minute time delay.

c. **Milk and/or Milk Product-Flow Controller Instrumentation:** The following requirements shall be met with respect to the instrumentation of the milk and/or milk product-flow controller:

(1) The thermal-limit-controller, with sensor located at the outlet of the holding tube, shall be set and sealed so that forward-flow of milk and/or milk product cannot start unless the temperature at the controller sensor is above the required pasteurization temperature as defined in the definition of Pasteurization of this *Ordinance* for the milk and/or milk product~~,~~ and the process used, nor continue ~~during descending temperatures~~ when the temperature is below the required pasteurization temperature. ~~The~~ A seal shall be applied by the Regulatory Agency after testing, and shall not be removed without immediately notifying the Regulatory Agency. The pasteurization system shall be so designed that no milk and/or milk product can ~~be bypassed around~~ bypass the controller sensor. The controller sensor ~~that~~ shall not be removed from its proper position during the pasteurization process. The cut-in and cut-out milk and/or milk product temperatures, as shown by the indicating thermometer, shall be determined at the beginning of each day's operation and entered ~~upon~~ on the recorder chart daily by the milk plant operator.

(2) ~~In the case of pasteurization systems, with the FDD located downstream from the regenerator and/or cooler section, additional temperature controllers and timers shall be inter-wired 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 pasteurization temperature, continuously and simultaneously for at least the required pasteurization time as defined in the definition of Pasteurization of this *Ordinance*. 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 pasteurization temperature. Provided, that for~~ For pasteurization systems used for the processing of milk and/or milk products labeled as UP, it is not necessary to set and seal the thermal-limit controller at or above 138ºC (280ºF). Also, provided that these systems shall meet all the public health control requirements for HHST pasteurization systems, and that the recorder-controller chart shows that the UP milk and/or milk product has been processed at a minimum temperature of 138ºC (280ºF), and has been verified by the Regulatory Agency to have a calculated holding time of at least two (2) seconds. ~~The~~ A seal, if required, shall be applied by the Regulatory Agency after the equipment has been tested, and shall not be re- moved without immediately notifying the Regulatory Agency. The system shall be so designed

that no milk and/or milk product can be bypassed around the control sensors, which shall not be removed from their proper position during the pasteurization process. For these pasteurization systems, daily measurement by the operator of the cut-in and cut-out temperatures is not required.

(3) Manual switches for the control of pumps, homogenizers or other devices, which produce flow through the FDD, shall be wired so that the circuit is completed only when the milk and/or milk product is above the required pasteurization temperature as defined in the definition of Pasteurization of this *Ordinance* for the milk and/or milk product and the process used, or when the FDD is in the fully-diverted position.

d. **Holding Tube:**

(1) Holding tubes shall be designed to provide for the holding of every particle of the milk and/or milk product for at least the pasteurization time required in the definition of Pasteurization of this *Ordinance* for the milk and/or milk product and the process used.

(2) The holding tube shall be so designed that the simultaneous temperature difference between the hottest and coldest milk and/or milk product, in any cross section of flow, at any time during the holding period, will not be greater than 0.5ºC (1ºF). This requirement may be assumed to have been satisfied, without testing, in ~~tubular holders~~ holding tubes of 17.8 centimeters (7 inches) or smaller diameter that are free of any fittings through which the milk and/or milk product may not be thoroughly swept.

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

(4) The holding tube shall be arranged to have a continuously upward slope in the direction of flow of not less than 2.1 centimeters per meter (0.25 inch per foot).

(5) 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.

(6) The holding tube shall be so designed that no portion between the inlet and the recorder-controller temperature sensor is heated.

The following Items apply to HHST pasteurization systems:

(7) The holding time for HHST pasteurization systems shall be determined from the pumping rate rather than by the salt conductivity test, because of the short holding tube. The holding tube length shall be such that the fastest flowing particle~~,~~ of any milk and/or milk product~~,~~ will not traverse the holding tube in less than the required holding time. Since laminar flow~~,~~ (the fastest flowing particle travels twice as fast as the average flowing particle)~~,~~ can occur in the holding tube during pasteurization of high-viscosity milk and/or milk products, holding tube lengths ~~are~~ shall be calculated as twice the length required to hold the average flow for the required holding time ~~standard~~.

(8) With the direct steam heating processes, the holding time is reduced because the milk and/or milk product volume increases as the steam condenses to water during heating in the injector. This surplus water is evaporated as the pasteurized milk and/or milk product is cooled in the vacuum chamber. For example, with a 66ºC (120ºF) increase by steam ~~injection~~ addition, 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 pasteurizer, does not reflect this volume increase in the holding tube. However, this volume increase, i.e., holding time decrease, shall be considered in the calculations.

(9) For those HHST pasteurization systems capable of operating with less than 518 kPa (75 psig) pressure in the holding tube, a pressure limit indicator/pressure switch shall be interwired so that the FDD will move to the divert position if the milk and/or milk product pressure falls below a prescribed value. For operating temperatures between 89°C (191ºF) and 100ºC (212ºF) the instrument shall be set at 69 kPa (10 psi). To prevent vaporization in the holding tube, which may substantially reduce residence times, HHST pasteurization systems operating above 100°C (212ºF), the instrument shall be set at 69 kPa (10 psi) above the boiling pressure of the product, at its maximum temperature in the holding tube.

(10) With the steam injection process, a differential pressure limit indicator across the injector is needed to keep the heated milk and/or milk product in the liquid phase and to ensure adequate isolation of the injection chamber. The instrument shall 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. **Indicating and Recording Thermometers:**

(1) An indicating thermometer shall be located as near as practicable to the temperature sensor of the recorder/controller, but may be located a short distance upstream from the latter where milk and/or milk product between the two (2) thermometers does not differ significantly in temperature.

(2) The temperature shown by the recorder/controller shall be checked daily by the milk plant operator against the temperature shown by the indicating thermometer. Readings shall be recorded on the chart. The recorder/controller shall be adjusted to read no higher than the indicating thermometer.

(3) The recorder/controller charts shall comply with the applicable provisions of Item 16p.(D)1. of this *Ordinance*.

f. **Flow-Promoting Devices:**

(1) The pump or pumps and other equipment, which may produce flow through the holding tube, shall be located upstream from the holding tube, provided that pumps and other flow-promoting devices, may be located downstream from the holding tube, if means are provided to eliminate negative pressure between the holding tube and the inlet to such equipment. When vacuum equipment is located downstream from the holding tube, an effective vacuum breaker, plus an automatic means of preventing a negative pressure in the line between ~~the~~ a FDD located at the end of the holding tube and the vacuum chamber, shall be acceptable.

(2) The speed of pumps or other flow-promoting devices, governing the rate of flow through the holding tube, shall be so controlled as to insure the holding of every particle of milk and/or milk product for at least the pasteurization time required as defined in the definition of Pasteurization of this *Ordinance* for the milk and/or milk product and the process used. In all cases, the motor shall be connected to the timing pump 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 holding 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 also 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~~ holding time shall be ~~of the~~ controlled by a positive-displacement type timing pump or ~~shall comply with the specifications for~~ a magnetic flow meter based timing ~~systems~~ system as outlined in Appendix H. of this *Ordinance*. Timing pumps and homogenizers, when used as a timing pump, shall not have by-pass lines connected from their outlet pipelines to their inlet pipelines during processing if an additional flow-promoting or vacuum producing device is located within the system.

When a homogenizer is used in conjunction with a timing pump, and both are located upstream of the holding tube, it shall be either:

i) Of larger capacity than the timing pump: In which case, an unrestricted, open, recirculation line shall be used to connect the outlet pipeline from the homogenizer to its inlet line. The recirculation line shall be of at least the same or larger diameter than the inlet pipeline feeding milk and/or milk product to the homogenizer. A check-valve, allowing flow from the outlet line to the inlet line, may be used in the recirculating line, provided it is of the type which provides a cross-sectional area at least as large as the recirculating line.

ii) Of smaller capacity than the timing pump: In which case, a relief line and valve shall be used. Such relief line shall be located after the timing pump and before the inlet to the homogenizer and shall return milk and/or milk product to the constant-level tank or to the outlet of the constant-level tank, upstream of any booster pump or other flow-promoting device.

NOTE: For those systems that do not homogenize all milk and/or milk products and wish to utilize a by-pass line to by-pass the homogenizer while processing such milk and/or milk product, the by-pass line shall be connected with valves that are so designed that both lines cannot be open at the same time. This may be accomplished with three (3) way plug valves with properly designed and operating pins or other automatic, failsafe valves that accomplish the same objective.

(3) The holding time shall be taken to mean the flow time of the fastest particle of milk and/or milk product at or above the required pasteurization temperature as defined in the definition of Pasteurization of this *Ordinance* for the milk and/or milk product and the process used, throughout the holding tube section; i.e., that portion of the system that is outside of the influence of the heating medium, slopes continuously upward in the downstream direction and is located upstream from the FDD. Tests for the holding time shall be made when all equipment and devices are operated and adjusted to provide for maximum flow. When a homogenizer is located upstream from the holding tube, the holding time shall be determined with the homogenizer in operation with no pressure on the homogenizer valves.

For those systems which do not homogenize all milk and/or milk products and utilize by-pass lines as outlined in f.(2) i) above, the holding time shall be tested in both flow patterns and the fastest time used. The holding time shall be tested during both forward and

diverted-flow. If it is necessary to lengthen the holding time during diverted-flow, an identifiable restriction may be placed in the vertical portion of the diversion pipeline.
(4) When vacuum equipment is located downstream from the holding tube, the holding time shall be tested with the timing pump operating at maximum flow and the vacuum equipment adjusted to provide for the maximum vacuum.
(5) The holding time shall be tested ~~in both forward and diverted flow~~ by the Regulatory Agency initially; semiannually thereafter; after any alteration or replacement that may affect the holding time; and whenever the seal of the speed setting has been broken. For pasteurization systems utilizing a timing pump, the holding time shall be tested in both forward and diverted flow.

g. **Heating by Direct ~~Addition~~ Injection 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 that could lead to some milk and/or milk product particles being processed below pasteurization temperature. When culinary steam is injected directly into milk and/or milk product, as the means of terminal heating to achieve pasteurization temperature, the steam injector shall be designed, installed and operated to comply with the following or equally satisfactory specifications:
(1) The milk and/or milk product and steam flows shall be isolated from pressure fluctuations inside the injection chamber. One (1) method of isolation is to insert supplementary orifices on the milk and/or milk product inlet and the heated milk and/or milk product outlet of each injector. The two (2) supplementary orifices shall be sized for at least a 69 kPa (10 psi) milk and/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 product or be carried in the steam supply. Any two-phase flow caused by the non-condensable gases would displace the 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 product in the holding tube as free as possible of non-condensable gases.

h. **Prevention of Milk and/or Milk Product Adulteration with Added Water:**
(1) When culinary steam is introduced directly into the milk and/or milk product, downstream from the FDD, means shall be provided to preclude the addition of steam to the milk and/or milk product, unless the FDD is in the forward-flow position. This provision may be satisfied by the use of an automatic steam control valve with a temperature sensor located downstream from the steam inlet, or by the use of an automatic solenoid valve installed in the steam line and so wired through the FDD controls, so that steam cannot flow unless the FDD is in the forward-flow position.
(2) When culinary steam is introduced directly into the milk and/or milk product, automatic means, i.e., a stand-alone and/or programmable logic controller (PLC)-based ratio control

system, shall be provided to maintain a proper temperature differential between incoming and outgoing milk and/or milk product to preclude dilution with water.

(3) 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 backup and overflow of water from the vacuum condenser to 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, which is automatically actuated by a control, which will shut off the in-flowing water, if for example, the condensate pump stops and the water level rises above a predetermined point in the vacuum condenser. This valve may be actuated by water, air or electricity and shall be so designed that failure of the primary motivating power shall automatically stop the flow of water into the vacuum condenser.

ITEM 16p.(C) PASTEURIZERS EMPLOYING REGENERATIVE HEATING

PUBLIC HEALTH REASON

To prevent contamination of the pasteurized milk and/or milk product in regenerators, the raw milk and/or milk product shall always be under less pressure than the pasteurized milk and/or milk product or the heat-transfer medium. ~~In the case of milk or milk product-to-milk or milk product regenerators, this~~ This requirement is necessary to prevent contamination of the pasteurized milk and/or milk product by the raw milk and/or milk product ~~if~~ should flaws ~~should~~ develop in the metal or in the gasketed joints separating the raw and pasteurized milk and/or milk product.

ADMINISTRATIVE PROCEDURES

This Item is deemed satisfied when:

MILK AND/OR MILK PRODUCT-TO-MILK AND/OR MILK PRODUCT REGENERATIVE HEATING

Pasteurizers employing milk and/or milk product-to-milk and/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 milk and/or milk product in the regenerator will automatically be under greater pressure than raw milk and/or milk product in the regenerator at all times.
2. The pasteurized milk and/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 and/or milk product level, downstream from the constant-level tank, and shall be open to the atmosphere at this or a higher elevation.
3. The overflow of the top rim of the constant-level tank shall always be lower than the lowest milk and/or milk product level in the regenerator.
4. No pump or flow-promoting device which can affect the proper pressure relationships within the regenerator shall be located between the pasteurized milk and/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 and/or milk product inlet to the regenerator and the constant-level tank, unless it is designed and installed to operate only when milk and/or milk product is flowing through the pasteurized milk and/or milk product side of the regenerator and when the pressure of the pasteurized milk and/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, if present, is in operation;
b. The FDD is in forward-flow position; and
c. The pasteurized milk and/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 and/or milk product inlet to the regenerator and the pasteurized milk and/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.

6. The motor, casing and impeller of the booster pump shall be identified for those systems that rely on a pressure switch, located only on the pasteurized side, and such records maintained as directed by the Regulatory Agency.

7. All electric wiring interconnections for the booster pump should be in permanent conduit, except that rubber covered cable may be used for final connections, with no electrical connections to defeat the purpose of any provisions of this *Ordinance*.

8. ~~All~~ When the raw milk and/or milk product pump(s) are shut down, all raw milk and/or milk product in the raw regenerator(s) shall automatically drain freely into the constant-level tank or to the floor. ~~when the raw milk or milk product pump(s) are shut down and the raw milk or milk product connection(s) at the regenerator(s) is disconnected.~~

9. When vacuum equipment is located downstream from the FDD, means shall be provided to prevent the lowering of the pasteurized milk and/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 milk and/or milk product inlet to the regenerator.

~~10. In the case of pasteurization systems, with the FDD located downstream from the re- generator 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 shall 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 the definition of Pasteurization of this *Ordinance*.~~

10. When culinary steam is introduced directly into milk and/or milk product to achieve pasteurization 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 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.

~~12. When the differential pressure controller is installed and wired to control the FDD as described in paragraph 10 of this Section, the raw milk or milk product booster pump may be permitted to run at all times. Provided, that the timing pump is in operation.~~

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

OPTION I: Milk and/or milk product-to-water-to-milk and/or milk product regenerators, with both the milk and/or milk product and the heat-transfer water in the raw milk and/or milk product section, closed to the atmosphere, shall comply with the following or equally satisfactory specifications:

1. Regenerators of this type shall be so designed, installed and operated that the heat-transfer-medium side of the regenerator, in the raw milk and/or milk product section, will automatically be under greater pressure than the raw milk and/or milk product side at all times.
2. The heat-transfer water shall be a safe water and the heat-transfer water shall be in a covered tank, which is open to the atmosphere at an elevation higher, by at least 30.5 centimeters (12 inches), than any raw milk and/or milk product level downstream from the constant-level tank. The heat-transfer water between its outlet from the regenerator and the nearest point downstream open to the atmosphere shall rise to a vertical elevation of at least 30.5 centimeters (12 inches) above any raw milk and/or milk product in the system and shall be open to the atmosphere at this or a higher elevation.
3. The heat-transfer water circuit shall be full of water at the beginning of the run and all loss of water from the circuit shall be automatically and immediately replenished whenever raw milk and/or milk product is present in the regenerator.
4. The overflow of the top rim of the constant-level tank shall always be lower than the lowest milk and/or milk product level in the raw milk and/or milk product section of the regenerator. The regenerator shall be designed and installed so that all raw milk and/or milk product shall drain freely back to the upstream supply tank when the raw milk and/or milk product pumps are shut down and the raw milk and/or milk product line is disconnected from the regenerator outlet.
5. No pump shall be located between the raw milk and/or milk product inlet to the regenerator and the constant-level tank, unless it is designed and installed to operate only when water is flowing through the heat-transfer section of the regenerator and when the pressure of the heat-transfer water is higher than the pressure of the raw milk and/or milk product. This may be accomplished by wiring the booster pump so that it cannot operate unless:
   a. The heat-transfer water pump is in operation; and
   b. The heat-transfer water pressure exceeds, by at least 6.9 kPa (1 psi), the raw milk and/or milk product pressure in the regenerator. A differential pressure controller shall be installed at the raw milk and/or milk product inlet and the heat-transfer water outlet of the regenerator. The raw milk and/or milk product booster pump shall be wired so that it cannot operate unless the differential pressure is met. The accuracy of the required differential pressure controller shall be checked by the Regulatory Agency on installation; quarterly thereafter; and following repair or replacement.

OPTION II: Pasteurizers with the FDD located downstream of the regenerator and/or cooling section and with milk and/or milk product-to-water-to-milk and/or milk product regenerators ~~may also be~~ constructed, installed and operated such that the pasteurized milk and/or milk product in the regenerator will be under greater pressure than the heat-transfer-medium in the pasteurized milk and/or milk product ~~side~~ section of the regenerator, shall comply with the following or equally satisfactory specifications:

1. A differential pressure controller shall be used to monitor pressures of the pasteurized milk and/or milk product and the heat-transfer-medium. One (1) pressure sensor shall be installed at the pasteurized milk and/or milk product outlet of the regenerator and the other pressure sensor shall be installed at the heat-transfer-medium inlet of the pasteurized milk and/or milk product ~~side~~ section of the regenerator. This controller or recorder-controller shall divert the FDD whenever the lowest pressure of pasteurized milk and/or milk product in the regenerator fails to exceed the highest pressure of the heat-transfer-medium in the pasteurized milk and/or milk product side of the regenerator by at least 6.9 kPa (1 psi). Forward-flow of milk and/or milk product shall be automatically prevented until all milk and/or milk product-contact surfaces between the holding tube and the FDD have been held at or above the required pasteurization temperature continuously and simultaneously for at least the pasteurization time.
2. The heat-transfer-medium pump shall be wired so that it cannot operate unless the timing pump and/or other flow promoting devices ~~is~~ are in operation.

NOTE: Refer to Appendix H. of this *Ordinance* for further discussion concerning methods of achieving the required pressure relationships within the regenerator.

ITEM 16p.(D) PASTEURIZATION RECORDS, EQUIPMENT TESTS AND EXAMINATIONS

1. **PASTEURIZATION RECORDS:**

All temperature and flow rate pasteurization recording charts or alternative records, acceptable to FDA and the Regulatory Agency, in place of charts, shall be:

a. Reviewed, dated and signed or initialed by or under the oversight of a PCQI within seven (7) working days after the records were created;
b. Onsite ~~and shall be reviewed~~ for review by the Regulatory Agency during each regulatory inspection for at least the previous three (3) months or from the last regulatory inspection, whichever is longer. Electronic records are considered to be onsite if they are accessible from an onsite location; and
c. Retained for at least two (2) years after the date they were created. Offsite storage of these pasteurization records is permitted if such records can be retrieved and provided onsite within twenty-four (24) hours of a request for official review.

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 also be entered on the charts or ~~other~~ alternative records acceptable to FDA and the Regulatory Agency in place of charts as applicable:

a. **Batch Pasteurizers:**

(1) Date;
(2) Number or location of recording thermometer when more than one is used;
(3) A continuous record of the product temperature;
(4) Extent of holding period, including filling and emptying times when required;
(5) Reading of the airspace thermometer, at the start of the holding period and at the end of the holding period, at a given time or reference point as indicated on the chart; provided, if the airspace thermometer is a digital combination airspace/recording thermometer, which provides a continuous recording of the airspace temperature and has been calibrated by the Regulatory Agency in accordance with Appendix I., Test 4 of this *Ordinance*, the recording of the airspace temperature on the chart shall only be required at the start of the holding period;
(6) Reading of indicating thermometer, at the start of the holding period, at a given time or reference point as indicated on the chart;
(7) Quarterly, the time accuracy of the recording thermometer, as determined by the Regulatory Agency, or in the case of milk plants regulated under the NCIMS voluntary HACCP Program, a qualified industry person acceptable to the Regulatory Agency;
(8) Amount and name of the pasteurized milk and/or milk product, represented by each batch or run on the chart;
(9) Record of unusual occurrences;
(10) Signature or initials of the operator; and
(11) Name of the milk plant.

b. **HTST and HHST Pasteurizers:** Recording thermometer charts shall contain all the information specified in Subitem a. above, except (4), and (5), and in addition, shall include the following:
(1) A record of the time during which the FDD is in the forward-flow position;
(2) The cut-in and cut-out milk and/ or milk product temperatures, as shown by the indicating thermometer and recorded daily by the operator, at the beginning of the run (HTST only), and initialed quarterly by the Regulatory Agency, or in the case of milk plants regulated under the NCIMS voluntary HACCP Program, a qualified industry person acceptable to the Regulatory Agency; and
(3) Number ~~through~~ (6) from above shall also be recorded immediately after a chart has been changed.

NOTE: The temperature shown on the recording thermometer chart shall be used to determine that the required temperature for milk and/or milk products containing higher fat and/or sweeteners has been achieved.

c. **Continuous-Flow Pasteurization Systems 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), (6), and (7), and in addition, shall include the following:
(1) A continuous record of the status of the high and low-flow/loss of signal alarms; and
(2) A continuous record of the flow rate.

d. **Electronic Data Collection, Storage and Reporting:** Electronic collection, storage and reporting of required pasteurization 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. of this *Ordinance*.

……

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APPENDIX H. CONTINUOUS FLOW PASTEURIZATION SYSTEMS (EQUIPMENT AND PROCEDURES) AND OTHER EQUIPMENT

I. ~~HTST~~ CONTINUOUS FLOW PASTEURIZATION

OPERATION OF HTST PASTEURIZATION SYSTEMS

HTST pasteurization is important to the dairy industry because of the operating efficiencies that it affords. Properly operated, these units allow a high volume of production in a minimum of processing space.

The ability of HTST pasteurizers to assure a safe, finished milk and/or milk product hinges on the reliability of the time-temperature-pressure relationships that must prevail whenever the system is in operation. It is important that the milk plant operator understand the HTST process in order to maintain proper surveillance over the equipment. ~~The~~ A basic pattern is described below:

1. Cold raw milk and/or milk product, in a constant-level supply tank, is drawn into the regenerator section of the HTST pasteurizer.

NOTE: Some operators prefer to bypass the raw ~~regenerator~~ regenerator(s) when starting. Under this system, cold raw milk and/or milk product is drawn directly through the timing pump, step 3, and into the heater section. The remaining steps are performed without exception. This bypass arrangement facilitates and speeds up the starting operation. After forward-flow has been established at the FDD, the bypass, which may be manually or automatically controlled, is not used and the raw milk and/or milk product flows through the regenerator. ~~A second start-up technique involves the use of sanitizing solution at 77ºC (170ºF). This is passed through the complete unit and followed immediately by milk or milk product. Dilution of the first milk or milk product does occur; however, care shall be taken to prevent this from being packaged.~~

2. In the regenerator section, the cold raw milk and/or milk product is warmed by hot pasteurized milk and/or milk product flowing in a counter current direction on the opposite sides of thin stainless steel surfaces.

3. The raw milk and/or milk product, still under suction, passes through a positive-displacement-timing pump that delivers it under pressure through the rest of the HTST pasteurization system.
4. The raw milk and/or milk product is pumped through the heater section, where hot water or steam on opposite sides of thin stainless steel surfaces heats the milk and/or milk product to a temperature at or above ~~72°C (161°F).~~ the minimum pasteurization temperature required for that product.
5. The milk and/or milk product, at pasteurization temperature, and under pressure, flows through the holding tube where it is held for at least fifteen (15) seconds. The maximum velocity of the milk and/or milk product through the holding tube is governed by the speed of the timing pump, the diameter and length of the holding tube and surface friction.
6. After passing the sensing bulbs of the indicating thermometer and recorder/controller, the milk and/or milk product passes into the FDD, which automatically assumes a forward-flow position, if the milk and/or milk product passes the recorder/controller bulb at the preset cut-in temperature~~, i.e., 72°C (161°F)~~.
7. Improperly heated milk and/or milk product flows through the diverted-flow line back to the constant-level tank.
8. Properly heated milk and/or milk product flows through the forward-flow line to the pasteurized milk and/or milk product regenerator section where it serves to warm the cold raw milk and/or milk product and, in turn, is cooled.
9. The warm milk and/or milk product passes through the cooling section, where coolant, on the sides of thin stainless steel surfaces opposite the pasteurized milk and/or milk product, reduces its temperature to 4.5°C (40°F) and below.
10. The cold pasteurized milk and/or milk product then passes to a storage tank or vat to await packaging.

HTST PASTEURIZERS EMPLOYING MILK AND/OR MILK PRODUCT-TO-MILK OR MILK PRODUCT REGENERATORS WITH BOTH SIDES CLOSED TO THE ATOMSPHERE

Section 7., Item 16p(C) of this *Ordinance* establishes standards for regenerators. These standards insure that the raw milk and/or milk product will always be under less pressure than pasteurized milk and/or milk product in order to prevent contamination of the pasteurized milk and/or milk product in the event flaws should develop in the metal or joints separating it from the raw milk and/or milk product. An explanation of regenerator specifications is given below.
During normal operation, i.e., while the timing pump is operating, raw milk and/or milk product will be drawn through the regenerator at sub-atmospheric pressure. The pasteurized milk and/or milk product in the milk and/or milk product-to-milk and/or milk product regenerator will be above atmospheric pressure. The required pressure differential will be assured when there is no flow promoting device downstream from the pasteurized milk and/or milk product side of the regenerator to draw the pasteurized milk and/or milk product through the regenerator, and the pasteurized milk and/or milk product downstream from the regenerator rises to at least 30.5 centimeters (12 inches) elevation above the highest raw milk and/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(C), **ADMINISTRATIVE PROCEDURES** #2 of this *Ordinance*.

During a shutdown, i.e., when the timing pump stops, the raw milk and/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(C), **ADMINISTRATIVE PROCEDURES** #8 of this *Ordinance*, the raw milk and/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 and/or milk product level in the constant-level tank. However, under these conditions, as long as any raw milk and/or milk product remains in the regenerator, it will be at sub-atmospheric pressure.

During shutdown, the pasteurized milk and/or milk product in the regenerator is maintained at atmospheric pressure or above by meeting the elevation requirement of Item 16p(C), **ADMINISTRATIVE PROCEDURES** #2 of this *Ordinance*. Pressure greater than atmospheric is maintained when the level of pasteurized milk and/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 and/or milk product through the FDD would lower the pasteurized milk and/or milk product level, during pump shutdowns, thus tending to reduce the pressure on the pasteurized milk and/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 and/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(C), **ADMINISTRATIVE PROCEDURES** #2 and #3 of this *Ordinance*; however, will insure a proper pressure differential in the regenerator.

At the beginning of a run, from the time raw milk and/or milk product or water is drawn through the regenerator, until the pasteurized milk and/or milk product or water has risen to the elevation specified in Item 16p(C), **ADMINISTRATIVE PROCEDURES** #2 of this *Ordinance*, the pasteurized milk and/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 and/or milk product side of the regenerator will be greater than the sub-atmospheric pressure on the raw milk and/or milk product side. This will be assured by compliance with Item 16p(C), **ADMINISTRATIVE PROCEDURES** #2 and #3 of this *Ordinance*, as long as any raw milk and/or milk product remains in the regenerator.

When a raw milk and/or milk product booster pump is incorporated into the HTST pasteurization system, Item 16p(C), **ADMINISTRATIVE PROCEDURES** #5 of this *Ordinance* requires, in part, that automatic means shall be provided to assure, at all times, the required pressure differential between raw and pasteurized milk and/or milk product in the regenerator, before the booster pump can operate.

For some systems, it will be necessary to bypass the raw regenerator during start-up and when the FDD is in the diverted-flow position. Care shall be taken in the design of such bypass systems to assure that a dead-end does not exist. A dead-end could allow milk and/or milk product to remain at ambient temperature for long periods of time and allow bacterial growth in the milk and/or milk product. Caution shall also be observed with such bypass systems and any valves used in them so that raw milk and/or milk product will not be trapped, under pressure in the raw regenerator plates, and not have free drainage back to the constant-level tank when shutdown occurs.

THE USE OF SEPARATORS WITHIN HTST SYSTEMS

Separators in HTST pasteurization systems shall be installed and operated in such a manner that they will not adversely affect the regenerator pressures, create a negative pressure on the FDD during operation or cause milk and/or milk product flow through the holding tube during times when such flow would compromise a required public health safe guard.

1. A separator may be located between the outlet of a raw regenerator and the timing pump or between raw regenerator sections if the separator is automatically valved-out of the system, and separator stuffing pump(s) are de-energized, when:
   a. The timing pump is not in operation; or
   b. A dual stem FDD is in the inspect position; or
   c. In a system with a dual stem FDD, in which the separator is located between sections of a raw regenerator, during the first ten (10) minutes of a required ten (10) minute time delay in CIP mode and during any period of diverted-flow; or
   d. The pressures in any raw regenerator sections, located after the separator, are out of compliance with the pressure requirements of this *Ordinance*.

NOTE: The second section of a split raw regenerator shall automatically drain freely to the constant-level tank or to the floor in the event of a shut down.

2. A separator may not be located between the timing pump and the FDD.
3. A separator may be located on the pasteurized side of the FDD if:
   a. A properly installed atmospheric break is located between the FDD and the inlet of the separator;
   b. All milk and/or milk product rises to at least 30.5 centimeters (12 inches) higher than the highest raw milk and/or milk product in the system and is open to the atmosphere at some point between the outlet of the separator and the inlet of any pasteurized side regenerator;
   c. All milk and/or milk product rises to at least 30.5 centimeters (12 inches) higher than the highest raw milk and/or milk product in the system and is open to the atmosphere at some point between the outlet of any pasteurized side regenerator and the inlet of a separator; and
   d. The separator is automatically valved-out of the system, and the separator stuffing pump is de-energized:
      (1) When a dual stem FDD is in the first ten (10) minutes of a required ten (10) minute delay in CIP mode;
      (2) When the FDD is diverted in product or inspect mode;
      (3) When the timing pump is not in operation; and
      (4) When the temperature is below the required pasteurization temperature and the FDD is not in the fully diverted-position.
4. The following criteria apply to installations where a separator shall be valved-out:
   a. A valve shall be located to isolate the product supply line from the separator;
   b. A valve shall be located to prevent all flow exiting the separator from being returned to the pasteurization system downstream of the separator; and
   c. The valves are required to move in order to accomplish the two (2) criteria listed above and shall move to the valved-out position, and any separator stuffing pumps shall be de-energized, upon loss of air or power.

5. The following criteria applies to installations where a separator is located on the raw side of a HTST system and a cream or skim balance tank(s) is not being utilized for the collection of either the cream or skim that exits the HTST system:

a. A fail-safe (spring-to-close upon loss of air or power), block-and-bleed valve or valve arrangement shall be installed on the cream or skim line downstream from the separator and prior to any pump(s) or cream or skim storage tank(s), and shall be at least 30.5 centimeters (12 inches) below the required opening to the atmosphere on the pasteurized side of the HTST regenerator. This fail-safe valve or valve arrangement shall be closed whenever the separator is required to be automatically valved-out of the system and the separator stuffer pump is de-energized.

b. If a computer or programmable controller is used to provide any of these required functions, it shall comply with the applicable Section(s) of Appendix H., VI. of this *Ordinance*.

c. If not installed in compliance with a. and b. above, the height of the cream or skim storage tank shall be considered when determining the highest raw product in the HTST system.

THE USE OF LIQUID INGREDIENT INJECTION WITHIN HTST SYSTEMS

Milk and/or milk product flavoring slurries, condensed milk and/or milk products, and cream or skim for standardization and similar ingredients may be injected at a point after the last regenerator and before the timing pump, if all of the following conditions are met:

1. The slurry injection valve(s) is (are) closed and the slurry pump is de-energized:
   a. When the FDD is in the "Inspect" mode;
   b. When the timing pump, if present, is not in operation; ~~and~~
   c. When the temperature is below the required minimum legal pasteurization temperature and the FDD is not in the fully diverted position.~~;~~ and
   d. For MFMBTS, when the flow requirements are not satisfied (high flow, low flow or loss of signal) and the FDD is not in the fully diverted position.

   NOTE: The slurry pump may remain energized provided:

   1. A spring-to-close and air-to-open blocking valve is located between the slurry injection pump and the slurry injection valve(s) described in 2 below.
   2. All valves shall be inter-wired to assure they fully isolate the slurry pump from the pasteurization system when the FDD is not in the forward-flow position or whenever any flow-promoting device(s), which is (are) upstream of the FDD and (are) capable of generating flow through the FDD, is (are) not in operation.

2. ~~3~~The slurry injection valve(s) is (are) of the fail-safe type, spring-to-close and air-to-open, and are "block-and-bleed" design with a full port open to the atmosphere or a single-bodied double

seat mixproof valve design between the HTST isolation seat and the slurry pump when slurry is not being injected.
3. ~~4~~ The slurry piping between the slurry pump and the injection point may rise to a height that is higher than the overflow level of the slurry supply tank(s) but is at least 30.5 centimeters (12 inches) lower than the required opening to the atmosphere on the pasteurized side.
4. ~~2~~ The slurry supply tank has an overflow that is at least twice the diameter of the largest inlet pipe, or all inlet pipes are disconnected and the openings capped during operation of the slurry pump.
5. ~~3~~ There is a check-valve in the flow stream of the milk and/or milk product line from the last regenerator, typically after the separator, upstream of the injection point valve.
6. ~~4~~ For a milk and/or milk product flavoring slurry that contains milk and/or milk products the tanks and/or vessels used to blend and hold the slurry shall be completely emptied and cleaned after each four (4) hours of operation or less, unless the slurry is stored at a temperature of 7ºC (45ºF) or less, or at a temperature of 66ºC (150ºF) or greater and maintained thereat until the time of injection.
7. ~~5~~ If computers or programmable controllers are used to provide any of these required functions, they shall meet the applicable portion of Appendix H., VI. of this *Ordinance*.
8. ~~6~~ Appropriate test procedures shall be provided to evaluate the required inter-wiring and function.

NOTE:
1. This Section describes one (1) method that has been reviewed and accepted for this purpose. It does not preclude other methods that may be reviewed and found acceptable.
2. In order to help assure compliance with Section 2. Adulteration of this *Ordinance*, a Regulatory Agency may require that the milk plant close the slurry valve and de-energize the slurry pump during times when the system is recycling milk and/or milk product, such as in recycle mode, diverted-flow, or the first ten (10) minutes of the CIP cycle. If a computer is used to accomplish this, it does not need to meet Appendix H., VI. of this *Ordinance*.

PRESSURE RELIEF VALVES LOCATED DOWNSTREAM FROM THE HOLDING TUBE WITHIN HTST PASTEURIZATION SYSTEMS

The pressures in the pasteurized side of the regenerator shall 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 pressure relief valve on the pasteurized side of the FDD will meet this criterion if the pressure relief valve is fail-safe, 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(C) of this *Ordinance*. Any leakage from this pressure relief valve shall 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 latter 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.

POSITION DETECTION DEVICES

Where the position detectability of FDDs and valve seats is required this may be accomplished by mechanical or electronic means, such as mechanical limit switches (micro-switches) or electronic proximity switches. These switches shall be capable of providing an electrical signal when the valve seat is in the fully closed position, provided further that the position detection capability is fully testable.

Position detection devices (PDDs) shall be repeatable and capable of detecting valve seat movement of less than 3.18 mm (1/8 (0.125) of an inch) at all times.

MAGNETIC FLOW METER BASED TIMING SYSTEMS WITHIN CONTINUOUS FLOW PASTEURIZATION SYSTEMS

Many pasteurization systems use magnetic flow meter based timing systems (MFMBTS). The flow through these timing systems is developed by a combination of flow promoting devices including booster and stuffer pumps, separators and clarifiers, homogenizers and positive displacement pumps.

Section 7., Item 16p.(B)2(f) of this *Ordinance* provides for their use, provided they meet the following specifications for design, installation and use.

Components: Magnetic flow meter based timing systems shall consist of the following components:

1. A magnetic flow meter which has been reviewed by FDA or one (1) which meets the following criteria for accuracy and reliability:

   a. Self-diagnostic circuitry that provides constant monitoring of all sensing, input and conditioning circuits. The diagnostic circuitry shall be capable of detecting "open" circuits, "short" circuits, poor connections and faulty components. Upon the detection of a failure of any component, the magnetic flow meter read-out shall blank or become unreadable.

   b. The electro-magnetic compatibility of the magnetic flow meter shall be documented and available to the Regulatory Agency. The magnetic flow meter shall be tested to determine the effects of electrostatic discharge, power fluctuation, conductive emission and susceptibility, and radiative emission and susceptibility.

   c. The effect of exposure to specific environmental conditions shall be documented. The magnetic flow meter shall be tested to determine the effects of low and high temperatures, thermal shock, humidity, physical shock and salt fog.

   d. The magnetic flow meter converter or transmitter and flow sensor, for those magnetic flow meters in which flow sensor sealing is required, shall be constructed so that they can be sealed by the Regulatory Agency.

   e. The calibration of the magnetic flow meter shall be protected against unauthorized changes.

   f. The magnetic flow meter shall be protected against unauthorized converter or transmitter replacement. If flow tubes are replaced, the Regulatory Agency shall be notified and such replacement shall be regarded as a replacement of the magnetic flow meter and subject to Regulatory Agency inspection and all applicable tests under Appendix I. of this *Ordinance*.

   g. The flow tube shall be encased in appropriate material and constructed in such a manner that the final assembly complies with the conditions cited within Item 11p of this *Ordinance*.

   h. **Calibration:** The calibration shall be based on multiple points for the entire range of the magnetic flow meter for MFMBTS application. The magnetic flow meter shall be tested

against a traceable NIST standard. The procedure(s) used for the magnetic flow meter calibration is documented and available to the Regulatory Agency.

i. **Accuracy:** At mid-range, six (6) consecutive flow measurements are taken at the same low setting. From these six (6) measurements, the standard deviation is calculated. The standard deviation for these measurements shall be less than 0.5%. Compliance of the magnetic flow meter would be determined through the actual installation field-testing of the magnetic flow meter.

2. Suitable converters for conversion of electric and/or air signals to the proper mode for the operation of the system.

3. A suitable flow recorder capable of recording flow at the flow alarm set point and also at least 19 liters (5 gallons) per minute higher than the flow alarm setting. The flow recorder shall have an event pen that shall indicate the status of the flow alarm with respect to flow rate.

4. A flow alarm, with an adjustable set point, shall be installed within the system which shall automatically cause the FDD to ~~be~~ move~~d~~ to the divert position whenever excessive flow rate causes the milk and/or milk product holding time to be less than the legal holding time for the pasteurization process being used. The flow alarm shall be tested by the Regulatory Agency in accordance with the procedures of Appendix I., Test 11, 2.A. and B. of this *Ordinance* at the frequency specified. The flow alarm adjustment shall be sealed.

NOTE: Test 11, 2.A is not applicable to HHST pasteurization systems.

5. A low-flow or loss-of-signal alarm shall be installed with the system, which shall automatically cause the FDD to ~~be~~ move~~d~~ to the divert position whenever there is a low-flow or loss-of-signal from the magnetic flow meter. The low-flow or loss-of-signal provision shall be tested by the Regulatory Agency in accordance with Appendix I., Test 11, 2.C. of this *Ordinance* at the frequency specified. The low-flow or loss-of-signal provision shall be sealed.

6. For HTST pasteurization systems, when the legal flow rate has been reestablished, following an excessive flow rate, a time delay shall be instituted, which shall prevent the FDD from assuming the forward-flow position for at least a minimum of fifteen (15) or twenty-five (25) seconds depending upon the product being pasteurized and the temperature being utilized. The time delay shall be tested and sealed by the Regulatory Agency.

For HHST pasteurization systems, when the legal ~~holding time~~ flow rate has been reestablished, following an excessive flow rate, a time delay at least as long as the legal ~~flow rate~~ holding time shall be instituted, which shall prevent the FDD from assuming the forward-flow position until at least the legal holding time within the holding tube has been reestablished. In the case of HHST systems with the FDD located after the final cooler, this time delay shall be built into the sequence logic that requires all conditions for legal pasteurization to be satisfied and that legal pasteurization temperature exists from the holding tube to the FDD, before the FDD can assume the forward-flow position.

7. For HTST systems, a sanitary check valve or normally closed automatically controlled sanitary valve shall be installed with the magnetic flow meter to prevent a positive pressure in the raw milk and/or milk product side of the regenerator whenever a power failure, shutdown or flow-diversion occurs.

NOTE: This provision is not applicable to HHST pasteurization systems.

~~8. For HTST systems, when a regenerator is used with large systems, it will be necessary to bypass the regenerator during start-up and when the FDD is in the diverted-flow position. Care shall be taken in the design of such bypass systems to assure that a dead-end does not exist. A dead-end could allow milk or milk product to remain at ambient temperature for long periods of time and allow bacterial growth in the milk or milk product. Caution shall also be observed with such bypass systems and any valves used in them so that raw milk or milk product will not be trapped, under pressure in the raw regenerator plates, and not have free drainage back to the constant-level tank when shutdown occurs.~~

~~**NOTE:** This provision is not applicable to HHST pasteurization systems.~~

~~9. When switching to the "CIP" position, the FDD shall move to the divert position and shall remain in the diverted-flow position for at least ten (10) minutes, regardless of temperature, and for HTST pasteurization systems the booster pump cannot run during this ten (10) minute time delay.~~

~~10~~ 8. All MFMBTS pasteurization systems shall be designed, installed and operated so that all applicable tests required by Section 7., Item 16p(D) of this *Ordinance* can be performed by the Regulatory Agency, at the frequency specified. (Refer to Appendix I. of this *Ordinance*.) 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.

~~11~~ 9. Except for those requirements directly related to the physical presence of the timing pump, all other requirements of the most recent edition of this *Ordinance* are applicable.

Placement of Components: Individual components in a MFMBTS shall comply with the following placement conditions:

1. The magnetic flow meter shall be placed after the last raw product regenerator outlet and upstream of the holding tube. There shall be no intervening flow-promoting components between the magnetic flow meter and the holding tube.

2. For HTST pasteurization systems, when a sanitary check valve or normally closed automatically controlled sanitary valve, as described in #7 above, is used with a variable or constant speed flow promoting device, it shall be located downstream of the last regenerator outlet and upstream of the holding tube.

NOTE: This provision is not applicable to HHST pasteurization systems.

3. All flow-promoting devices, which are upstream of the FDD and which are capable of generating flow through the FDD, shall be properly interwired with the FDD so that they may run and produce flow through the system at sub-legal temperatures, only when the FDD is in the fully diverted position and in "Product" run mode, or "CIP" mode after the ten (10) minute time delay has timed out. Such flow promoting devices shall be de-energized in "Inspect" mode. Separators or clarifiers that continue to run, after they are de-energized shall be automatically valved-out of the system, with fail-safe valves, so that they are incapable of producing flow.

4. There shall not be any product entering or leaving the pasteurization system, i.e., cream or skim milk from a separator or other product components, between the magnetic flow meter and the holding tube.
5. The magnetic flow meter shall be so installed that the milk and/or milk product has contact with both electrodes at all times when there is flow through the system. This is most easily accomplished by mounting the flow tube of the magnetic flow meter in a vertical position with the direction of flow from the bottom to the top. However, horizontal mounting is acceptable when other precautions are taken to assure that both electrodes are in contact with the product and the horizontal line shall remain full of liquid during operation. Magnetic flow meters shall not be mounted on a horizontal line that may be only partially full and thereby trap air.
~~7~~6. The magnetic flow meter shall be piped in such a manner that at least ten (10) pipe diameters of straight pipe exists, upstream and downstream from the center of the magnetic flow meter, before any elbow or change of direction takes place. Except that other piping configurations upstream and downstream of the magnetic flow meter may also be used if they have been reviewed and found acceptable to FDA and the Regulatory Agency.

THE USE OF VACUUM BREAKERS ON HTST CONTINUOUS FLOW PASTEURIZATION SYSTEMS

Vacuum breakers are ~~often~~ used on HTST continuous flow pasteurization systems to help maintain proper pressure relationships in milk-to-milk regenerator sections, or to prevent a negative pressure between the FDD and any downstream flow-promoting device. The use of vacuum breakers on HTST continuous flow pasteurization systems is allowed provided the following conditions are met:

1. Vacuum breakers shall open to the atmosphere when subject to a negative pressure.
2. The pasteurized milk and 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 and/or milk product level, downstream from the constant-level tank, and shall be open to the atmosphere at this or a higher elevation.

Spring-to-close vacuum breakers are not allowed.

THE USE OF FDD LOCATED DOWNSTREAM OF REGENERATORS AND COOLER SECTIONS

The FDD may be located downstream from the regenerator and/or cooler section, provided that the following criteria are met:

1. The FDD shall be automatically prevented from assuming the forward-flow position until all 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 the definition of Pasteurization of this Ordinance.

2. Additional temperature controllers and timers shall be inter-wired with the thermal-limit-controller, and the control system shall be set and sealed so that forward-flow of milk and/or

milk product cannot start until all 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 the definition of Pasteurization of this Ordinance. 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 pasteurization temperature. For these pasteurization systems, daily measurement by the operator of the cut-in and cut-out temperatures is not required.

In addition, for continuous flow pasteurization systems which have the FDD located downstream from the regenerator and/or cooler, the following apply:

1. When the pasteurization system is inter-wired or computer controlled to thoroughly clean the system, including the divert pipeline before the re-starting of production, a cooling section, which is not self-draining, may be present in the divert pipeline.

2. In pasteurization systems in which all forward-flow product-contact surfaces of the FDD are sanitized, or sterilized during the normal start-up process the time delay in 16p(B)2.b.11 is not required.

3. The requirements of paragraphs (2), (3), (5), (7) and (8) of Section 16p(C) MILK AND/OR MILK PRODUCT-TO-MILK AND/OR MILK PRODUCT REGENERATIVE HEATING may be eliminated. Provided, that a differential pressure controller is used to monitor the highest pressure in the raw milk and/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 and/or milk product is automatically prevented and shall not start again until all milk and/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 the definition of Pasteurization of this Ordinance.

4. When the differential pressure controller is installed and wired to control the FDD as described in paragraph 3. of this Section, the raw milk and/or milk product booster pump may be permitted to run at all times. Provided, that the timing pump, if present, is in operation.

No changes page 236-237

Page 238 – Figure 33, please relabel "Timing Pump" as "Product Pump":

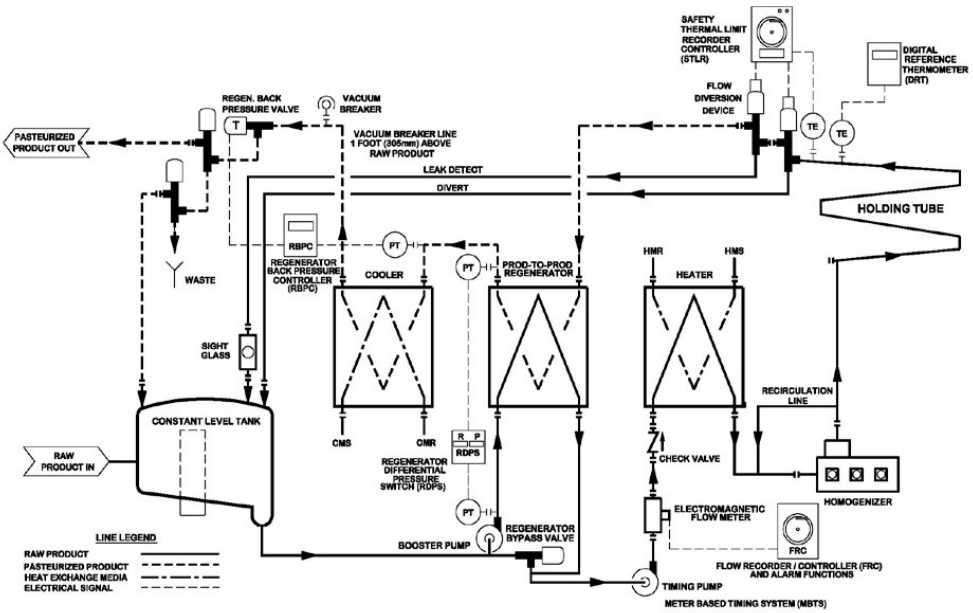

Figure 33. HTST Pasteurizer with a Booster Pump, Meter Based Timing System and a Homogenizer with a Bypass Line

Page 239 – Figure 36 - please size schematic to same dimensions as the other figures and relabel "Timing Pump" as "Product Pump":

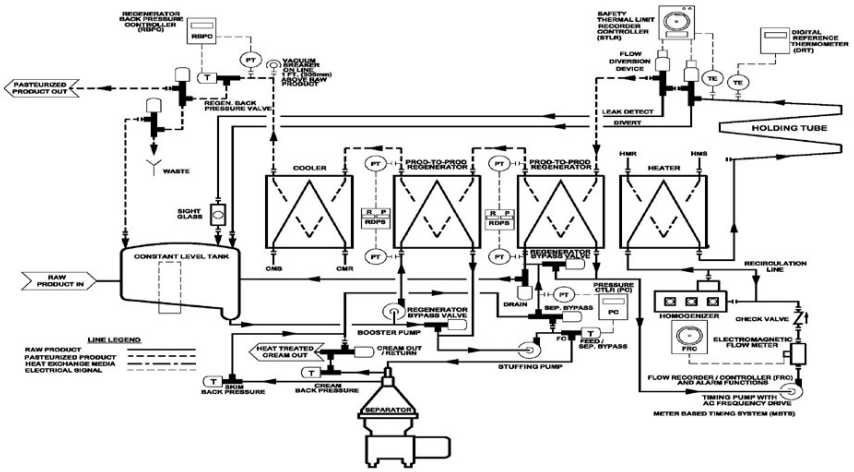

Figure 36. HTST Pasteurizer with a Separator Between the Raw Regenerator and the Heater Section with a Meter Based Timing System and a Regenerator Bypass

Page 241 – Figure 39 – please relabel "Timing Pump" as "Product Pump":

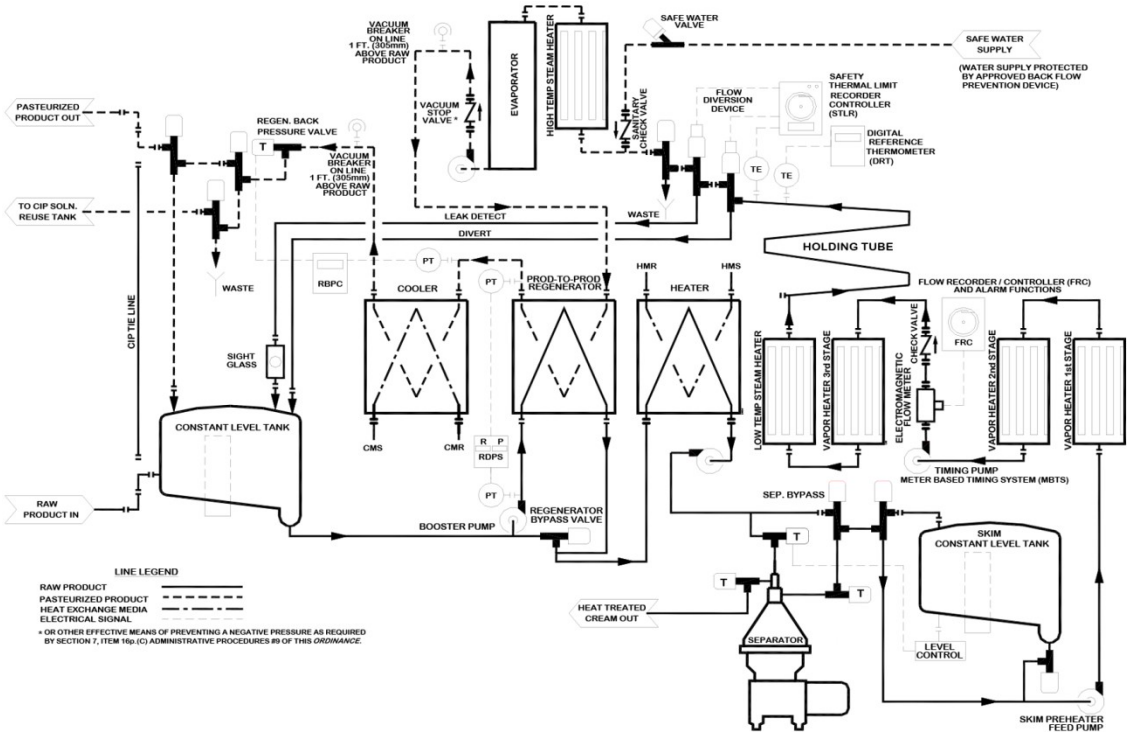

Figure 39. HTST Pasteurizer with a Regenerator, Separator, Skim Surge Tank and a Meter Based Timing System Located Upstream from an Evaporator Pump

Page 242 – Figures 41 and 42 – Please enhance the dotted control lines so they are legible:

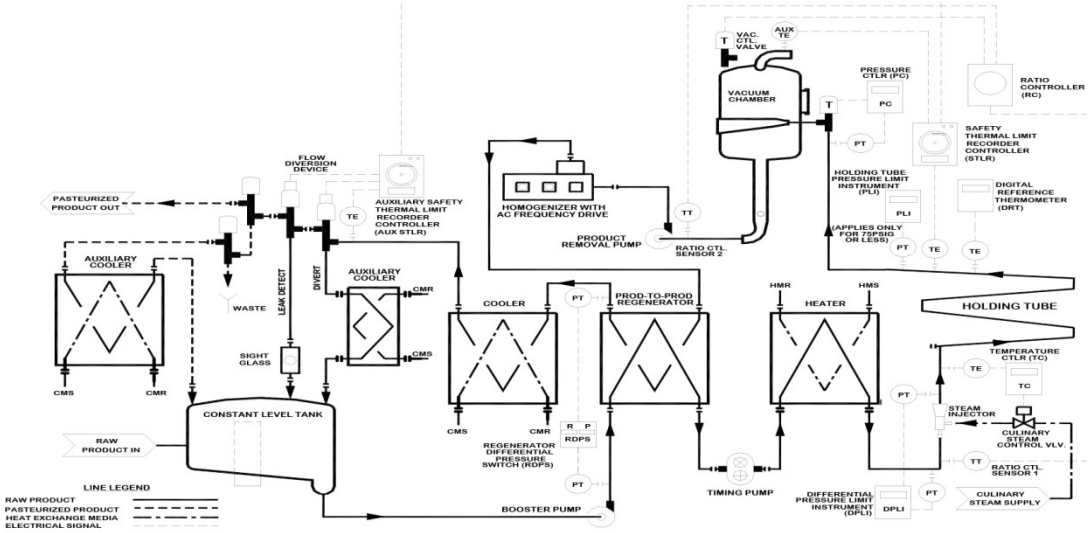

Figure 41. HHST Pasteurizer Utilizing Steam Injection Heating, Vacuum Flash Cooling and a Flow-Diversion Device Located Downstream of the Cooler Section Pump

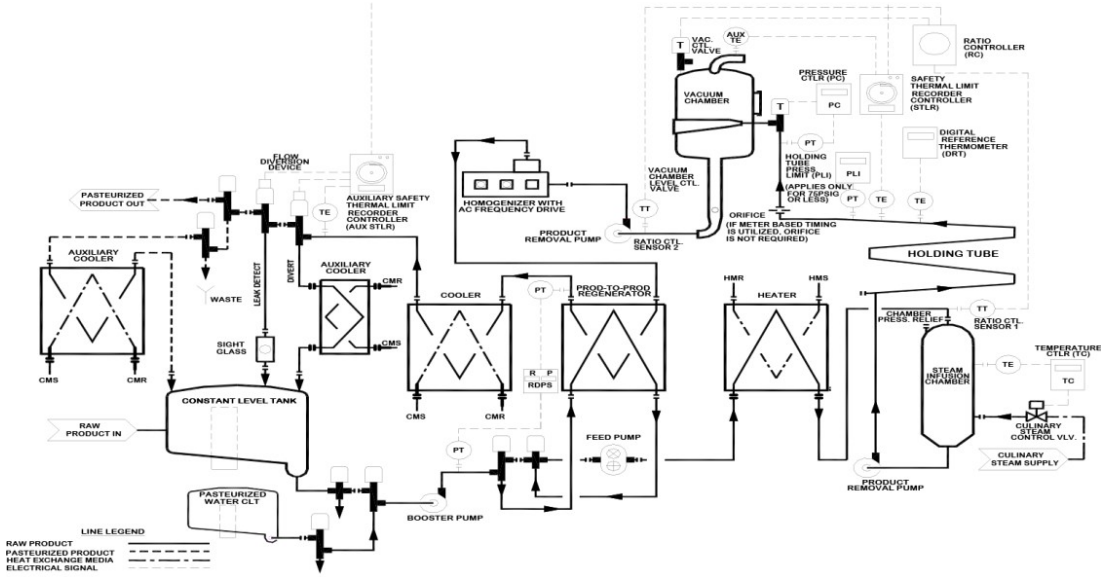

Figure 42. HHST Pasteurizer Utilizing Direct Culinary Steam Infusion and Vacuum Flash Cooling with a Homogenizer Located Downstream

Page 243 – 244:

…….

II. AIR FOR DRYING EQUIPMENT AND AIR UNDER PRESSURE – DIRECT CONTACT WITH MILK/OR MILK PRODUCTS AND MILK PRODUCT-CONTACT SURFACES

AIR FOR DRYING EQUIPMENT

Filter Media: Intake air filter media shall consist of fiberglass with a downstream backing dense enough to prevent fiberglass break off from passing through, cotton flannel, wool flannel, spun metal, activated carbon, activated alumina, non-woven fabric, absorbent cotton fiber, electrostatic, or other suitable materials which, under conditions of intended use, are non-toxic and non-shedding and which do not release toxic volatiles or other contaminants to the air, or volatiles which impart any flavor or odor to the milk and/ or milk product. Chemical bonding materials contained in the media shall be non-toxic, non-volatile and insoluble under all conditions of use. Disposable media are not intended to be cleaned and re-used. Electronic air cleaners using electrostatic precipitation principles to collect particulate matter may be used in spray drying systems only as a pre-filter.

Filter Performance: The air supply system and/or ducting shall be such that the air supply is caused to pass through suitable air filters, properly installed, before coming in contact with milk product-contact surfaces of the drying system. Supply air filters for air, ~~which~~ that will be heated before it comes in contact with the milk and/or milk product~~,~~ shall be ~~of a design~~ designed~~, selected~~ to operate at a face velocity, and installed in a manner which will allow the filter manufacturer's rating to be 90 percent (90%) or higher, when tested in accordance with the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) Synthetic Dust Arrestance test.[1] Supply air filters for air~~, which~~ that will not be heated before it comes in contact with the milk or milk product~~,~~ shall be ~~of a design~~ designed~~, selected~~ to operate at a face velocity~~,~~ and be installed in a manner which will allow the filter manufacturer's rating to be 85 percent (85%) or higher when tested in accordance with the ASHRAE Atmospheric Dust Spot Method.[1]

……..

No changes page 245 – 250

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III. CULINARY STEAM-MILK AND/OR MILK PRODUCTS

The following methods and procedures will provide steam of culinary quality for use in the processing of milk and/or milk products.

SOURCE OF BOILER FEED WATER

Potable water or water supplies, acceptable to the Regulatory Agency, shall be used.

FEED WATER TREATMENT

Feed water may be treated, if necessary, for proper boiler care and operation. Boiler feed water treatment and control shall be under the supervision of trained personnel or a firm specializing in industrial water conditioning. Such personnel shall be informed that the steam is to be used for culinary purposes. Pretreatment of feed waters for boilers or steam generating systems to reduce water hardness, before entering the boiler or steam generator by ion exchange or other acceptable procedures, is preferable to the addition of conditioning compounds to boiler waters. Only compounds complying with 21 CFR 173.310 may be used to prevent corrosion and scale in boilers, or to facilitate sludge removal.

Greater amounts shall not be used of the boiler water treatment compounds than the minimum necessary for controlling boiler scale or other boiler water treatment purposes. No greater amount of steam shall be used for the treatment and/or pasteurization of milk and/or milk products than necessary.

It should be noted that tannin, which is also frequently added to boiler water to facilitate sludge removal during boiler blow-down, has been reported to give rise to odor problems, and should be used with caution.

Boiler compounds containing cyclohexylamine, morpholine, octadecylamine, diethylamino-ethanol, trisodium nitrilotriacetae, and hydrazine shall not be permitted for use in steam in contact with milk and/or milk products.

…….

No changes page 252 – 253

Page 254 – 255:

IV. THERMOMETER SPECIFICATIONS

INDICATING THERMOMETERS FOR BATCH PSTEURIZERS

…….

Scale: Shall have a span of not less than fourteen (14) Celsius degrees (twenty-five (25) Fahrenheit degrees), including the pasteurization temperature, ± 2.5°C (± 5°F); graduated in 0.5°C (1ºF) divisions, with not more than nine (9) Celsius degrees (sixteen (16) Fahrenheit degrees) per 2.54 centimeters (1 inch) of span; and protected against damage at 105°C (220°F). Provided, that on batch pasteurizers used solely for thirty (30) minute pasteurization of milk and/or milk products at temperatures above 71°C (160°F), indicating thermometers with 1°C (2°F) scale graduations, with not more than six (6) Celsius degrees (twenty-eight (28) Fahrenheit degrees) per 2.54 centimeters (1 inch) of scale, may be used.

Accuracy: Within ± 0.2°C (± 0.5°F), through the specified scale span. Provided, that on batch pasteurizers used solely for thirty (30) minute pasteurization of milk and/or milk products at temperatures above 71°C (160°F), indicating thermometers shall be accurate to within ±.5°C (± 1°F). (Refer to Appendix I., Test 1 of this *Ordinance*.)

Submerged Stem Fitting: A pressure-tight seat against the inside wall of the holder; no threads exposed to milk and/or milk products; and the location of this seat to conform to the 3-A Sanitary Standard for a wall-type fitting or other equivalent sanitary fitting.
Bulb: Corning normal or equally suitable thermometric glass.

Page 256

INDICATING THERMOMETERS LOCATED ON PASTEURIZATION PIPELINES

…….

Accuracy: Within ± 0.2°C (± 0.5°F), throughout the specified scale span. (Refer to Appendix I., Test 1 of this *Ordinance*.)
Stem Fittings: A pressure-tight seat against the inside wall of the fittings; no threads exposed to milk and/or milk products. The probe is to be designed so that the sensitive area is discernible from the remainder of the stem. The overall probe length to be such that the sensitive area is positioned in the milk and/or milk product flow path when properly installed.
…….

No change page 257

Page 258-261

TEMPERATURE-RECORDING DEVICES FOR BATCH PASTEURIZERS

1. UTILIZING TEMPERATURES LESS THAN 71°C (160°F)

Case: Moisture proof under normal operating conditions in milk plants.
Chart Scale: Shall have a span of not less than eleven (11) Celsius degrees (twenty (20) Fahrenheit degrees), including pasteurization temperature, ± 2.5°C (± 5°F); and graduated in temperature-scale divisions of 0.5°C (1°F), spaced not less than 1.6 millimeter (0.0625 of an inch) apart between 60°C (140°F) and 69°C (155°F). Provided, that temperature-scale divisions of 0.5°C (1°F), spaced not less than 1 millimeter (0.040 of an inch) apart, are permitted when the ink line is thin enough to be easily distinguished from the printed line; graduated in time-scale divisions of not more than ten (10) minutes; and having a chord of straight-line length of not less than 6.3 millimeters (0.25 of an inch), between 63°C (145°F) and 66°C (150°F).
Temperature Accuracy: Within ± 0.5°C (± 1° F), between 60°C (140°F) and 69°C (155°F). (Refer to Appendix I., Test 2 of this *Ordinance*.)
Time Accuracy: The recorded elapsed time, as indicated by the chart rotation, shall not exceed the true elapsed time, as compared to an accurate watch, over a period of at least thirty (30) minutes at pasteurization temperature. Temperature-recording devices for batch pasteurizers may be equipped with spring operated or electrically operated clocks. (Refer to Appendix I., Test 3 of this *Ordinance*.)
Pen-Arm Setting Device: Easily accessible and simple to adjust. ~~for mercury-actuated recording thermometer. (Refer to Appendix I., Test 4 of this *Ordinance*.)~~
Temperature Sensing Device:

1. **Mercury Actuated:** Bulb, tube, and spring, protected against damage at a temperature of 105°C (220°F).
2. **Digital:**
   a. No more than 0.5ºC (1.0 ºF) drift over three (3) months use on a batch pasteurizer compared to a certified temperature source.
   b. Self-diagnostic circuitry, which provides constant monitoring of all sensing, input and conditioning circuits. The diagnostic circuitry should be capable of detecting "open" circuits, "short" circuits, poor connections and faulty components. Upon detection of failure of any component, the device shall blank, become unreadable or go visibly out of range.
   c. The electromagnetic compatibility of this device for this use shall be documented and available to the Regulatory Agency. The device shall be tested to determine the effects of electrostatic discharge, power fluctuation, conductive emission and susceptibility, and radiative emission and susceptibility. The device shall comply with the requirements for performance level characteristics of industrial devices.
   d. The effect of exposure to specific environmental conditions shall be documented. The device shall be tested to determine the effects of low and high temperatures, thermal shock, humidity, physical shock and salt fog.
   e. Both the probe and the display case shall be constructed so that they may be sealed by the Regulatory Agency.
   f. Calibration of the device shall be protected against unauthorized changes.
   g. The device shall be protected against unauthorized component or sensing element replacement. Replacement of any component or sensing element shall be regarded as a replacement of the indicating thermometer and subject to Regulatory Agency inspection and all application tests under Appendix I. of this *Ordinance*.
   h. The sensing element shall be encased in appropriate material constructed in such a way that the final assembly meets the conditions of Item 11p of this *Ordinance*.

Submerged Stem Fitting: A pressure-tight seat against the inside wall of the holder; no threads exposed to milk and/or milk products; and the distance from the underside of the ferrule to the sensitive portion of the bulb to be not less than 76 millimeters (3 inches).

Chart Speed: A circular chart shall make one (1) revolution in not more than twelve (12) hours. Two (2) charts shall be used if operations extend beyond twelve (12) hours in one (1) day. Circular charts shall be graduated for a maximum record of twelve (12) hours. Strip charts may show a continuous recording over a twenty-four (24) hour period.

Chart Support Drive: The rotating chart support drive shall be provided with a pin to puncture the chart in a manner to prevent its fraudulent rotation.

2. **UTILIZING TEMPERATURE GREATER THAN 71°C (160°F)**

Batch pasteurizers used solely for thirty (30) minute pasteurization of milk and/or milk products at temperature above 71°C (160°F) may use temperature-recording devices that comply with 1., with the following options:

Chart Scale: Graduated in temperature scale divisions of 1°C (2°F), spaced not less than 1 millimeter (.040 of an inch) apart between 65°C (150°F) and 77°C (170°F); graduated in timescale

divisions of not more than fifteen (15) minutes; and having a chord of straight-line length of not less than 6.3 millimeters (0.25 of an inch) between 71°C (160°F) and 77°C (170°F).
Temperature Accuracy: Within ± 1°C (± 2° F), between 71°C (160°F) and 77°C (170°F).
Digital Temperature Sensing Device: No more than 1°C (2°F) drift over three (3) months use on a batch pasteurizer compared to a certified temperature source.
Chart Speed: A circular chart shall make one (1) revolution in not more than twenty-four (24) hours and shall be graduated for a maximum record of twenty-four (24) hours.

RECORDER/CONTROLLERS FOR CONTINUOUS PASTEURIZERS

Case: Moisture proof under normal operating conditions in milk plants.
Chart Scale: Shall have a span of not less than seventeen (17) Celsius degrees (thirty (30) Fahrenheit degrees), including the temperature at which diversion is set, ± 7°C (± 12°F); graduated in temperature scale divisions of 0.5°C (1°F), spaced not less than 1.6 millimeter (0.0625 of an inch) apart at the diversion temperature, ± 0.5°C (± 1°F). Provided, that temperature-scale divisions of 0.5°C (1°F), spaced not less than 1 millimeter (0.040 of an inch) apart, are permitted when the ink line is thin enough to be easily distinguished from the printed line; graduated in time-scale divisions of not more than fifteen (15) minutes; and having an equivalent fifteen (15) minute chord or straight-line length of not less than 6.3 millimeters (0.25 of an inch) at the diversion temperature, ± 0.5°C (± 1°F).
Temperature Accuracy: Within ± 0.5°C (± 1°F), at the temperature, ± 3°C (± 5°F), at which the controller is set to divert. (Refer to Appendix I., Test 2 of this *Ordinance*.)
Power Operated: All recorder/controllers for continuous pasteurization shall be electrically operated.
Pen-Arm Setting Device: Easily accessible and simple to adjust for mercury-actuated recording thermometer. (Refer to Appendix I., Test 4 of this *Ordinance*.)
Pen and Chart Paper: Pen designed to give a line not over .07 millimeters (0.025 of an inch) wide and easy to maintain.
Temperature Sensing Device:
1. **Mercury Actuated:** Bulb, tube and spring protected against damage at a temperature of 105°C (220°F). Provided, that the recorder/controller temperature sensing devices, used on HHST pasteurization systems, shall be protected against damage at temperatures of 149°C (300°F).
2. **Digital:**
   a. No more than 0.5°C (1.0°F) drift over three (3) months use ~~on a HTST pasteurization system~~ compared to a certified temperature source.
   b. Self-diagnostic circuitry, which provides constant monitoring of all sensing, input and conditioning circuits. The diagnostic circuitry should be capable of detecting "open" circuits, "short" circuits, poor connections and faulty components. Upon detection of failure of any component, the device shall blank or become unreadable.
   c. The electromagnetic compatibility of this device for this use shall be documented and available to the Regulatory Agency. The device shall be tested to determine the effects of electrostatic discharge, power fluctuation, conductive emission and susceptibility, and radiative emission and susceptibility. The device shall comply with the requirements for performance level characteristics of industrial devices.

d. The effect of exposure to specific environmental conditions shall be documented. The device shall be tested to determine the effects of low and high temperatures, thermal shock, humidity, physical shock and salt fog.
e. Both the probe and the display case shall be constructed so that they may be sealed by the Regulatory Agency.
f. Calibration of the device shall be protected against unauthorized changes.
g. The device shall be protected against unauthorized component or sensing element replacement. Replacement of any component or sensing element shall be regarded as a replacement of the indicating thermometer and subject to Regulatory Agency inspection and all applicable tests under Appendix I. of this *Ordinance*.
h. The sensing element shall be encased in appropriate material constructed in such a way that the final assembly meets the conditions of Item 11p of this *Ordinance*.
i. The device shall be tested from the sensing probe through the final output.

Stem Fitting: A pressure-tight seat against the inside wall of the pipe; no threads exposed to milk and/or milk products; and the distance from the underside of the ferrule to the sensitive portion of the bulb is to be not less than 76 millimeters (3 inches).

No changes page 262 -277

Page 278:

VII. CRITERIA FOR STEAM-BLOCK TYPE FDD SYSTEMS

1. Steam-Block Type FDD Systems shall have two (2) steam-block zones between the pasteurizer and the surge tank(s)/filler(s). There shall be a continuous visible bleed of steam or condensate to the drain from each steam-block zone.
2. The steam-block zones shall be temperature - monitored and shall alarm when the temperature ~~falls below 121°C (250°F)~~ indicates there is liquid present in the steam-block.
3. The Primary Divert Valve and other critical valves shall be position detectable and fail-safe and be alarmed to provide protection when needed.

NOTE: For the detection of the FDD and valve seat positions, refer to Appendix H., I., Position Detection Devices of this *Ordinance*.

4. The Steam-Block Type FDD System shall not move to the forward-flow position until all conditions required of the HHST pasteurizing system are met and shall divert under the same conditions as a standard FDD.
5. When the Steam-Block Type FDD System is in a divert condition, a loss of temperature alarm in a steam-block zone shall cause a full port opening to drain in that steam-block zone.
6. Should both steam-block zones fail when the Steam-Block Type FDD is in diverted flow, the resulting compromised milk and/or milk product shall not be distributed for sale.
7. Computer controls shall meet the requirements of this Appendix.

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VIII. MILK AND/OR MILK PRODUCTS HACCP CCP MODELS FOR PASTEURIZATION EQUIPMENT

Milk plants regulated under the NCIMS voluntary HACCP Program, shall manage pasteurization under the HACCP Plan as a CCP…….

No changes page 280 – 283

Proposal: 108
Document: 2017 PMO
Pages: 102

Make the following changes to the 2017 PMO:

Page 102:

When a homogenizer is used in conjunction with a timing pump, and both are located upstream of the holding tube, it shall be ~~either~~ one of the following:

i) Of larger capacity than the timing pump: In which case, an unrestricted, open, recirculation line shall be used to connect the outlet pipeline from the homogenizer to its inlet line. The recirculation line shall be of at least the same or larger diameter than the inlet pipeline feeding milk or milk product to the homogenizer. A check-valve, allowing flow from the outlet line to the inlet line, may be used in the recirculating line, provided it is of the type which provides a cross-sectional area at least as large as the recirculating line.

ii) Of smaller capacity than and located after the timing pump: In which case, a relief line and valve shall be used. Such relief line shall be located after the timing pump and before the inlet to the homogenizer and shall return milk or milk product to the constant-level tank or to the outlet of the constant-level tank, upstream of any booster pump or other flow-promoting device.

iii. Of smaller capacity than and located before the timing pump when used to homogenize some but not all of the milk and/or milk product: In which case the unhomogenized milk and/or milk product shall mix with the homogenized milk and/or milk product before the timing pump and an unrestricted, open, homogenizer by-pass line shall be used to connect the unhomogenized milk and/or milk product line with the homogenized milk and/or milk product line. The homogenizer by-pass line shall be at least the same or larger diameter than the inlet pipeline feeding the timing pump.

NOTE: For those systems that do not homogenize all milk or milk products and wish to utilize a by-pass line to completely by-pass the homogenizer while processing such milk or milk product, the by-pass line shall be connected with valves that are so designed that both lines cannot be open at the same time. This may be accomplished with three (3)-way plug valves with properly designed and operating pins or other automatic, fail-safe valves that accomplish the same objective. Milk and/or milk products cannot be labeled “homogenized” if some or all

of the milk and/or milk product bypasses the homogenizer as described in this note or f.2.iii above.

Proposal: 109
Document: 2017 PMO
Pages: 108

Make the following changes to the 2017 PMO:

(11) Name and location of the milk plant or their milk plant code.

Proposal: 111
Document: 2017 PMO
Pages: 113, and 115

Make the following changes to the 2017 PMO:

Modify the 2017 PMO Item 17p #~~3~~1-5 page 113:

1. All yogurt products at all milkfat levels, cultured in the cup after filling (cup-set) and subsequently moved out of the culturing room when reaching a pH of 4.80 or below and a pH of 4.6 or below within the following twenty-four (24) hours and cooled to 7°C (45°F) or less within ninety-six (96) hours of being moved out of the culturing room **;

~~1~~2. Cultured sour cream at all milkfat levels with a pH of 4.70 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**;
~~2~~3. Acidified sour cream at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**;
~~3~~4. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling, with a pH of 4.60 or below within twenty-four (24) hours of filling* and cooled to 7°C (45°F) or less within ninety-six (96) hours of filling**;
~~4~~5. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**;
~~5~~6. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and:

a. Filled at 63°C (145°F) or above* for containers of four (4) ounces (118 ml) or larger, cooled to 15°C (59°F) or less within ten (10) hours of filling**, and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**, or

b. Filled at 69°C (155°F) or above* for containers of 2.9 ounces (85.6 ml), cooled to 15°C (59°F) or less within ten (10) hours of filling**, and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**, or

c. The addition of potassium sorbate at a minimum concentration of 0.06% and filled at 13ºC (55°F) or less*, cooled to 10ºC (50°F) or less within twenty-four (24) hours of filling**, and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**, or

d. The addition of one (1) of the specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, filled at 13ºC (55°F) or less*, cooled to 10ºC (50°F) or less with twenty-four (24) hours of filling**, and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**.

Modify the 2017 PMO Item 17p 5 page 115:

5. All pasteurized milk and milk products, except the following, shall be stored at a temperature of 7°C (45ºF) or less and be maintained thereat following filling or until further processed:

a. All yogurt products at all milkfat levels, cultured in the cup after filling (cup-set) and subsequently moved out of the culturing room when reaching a pH of 4.80 or below and a pH of 4.6 or below within the following twenty-four (24) hours* and cooled to 7°C (45°F) or less within ninety-six (96) hours of being moved out of the culturing room **;

~~a~~b**.** Cultured sour cream at all milkfat levels with a pH of 4.70 or below* and cooled to 7°C (45°F) or less within one hundred sixty-eight (168) hours of filling**;
~~b~~c. Acidified sour cream at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within one hundred sixty-eight (168) hours of filling**;
~~c~~d. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling, with a pH of 4.60 or below within twenty-four (24) hours of filling* and cooled to 7°C (45°F) or less within ninety-six (96) hours of filling**;
~~d~~e. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**; and
~~e~~f. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and:
(1) Filled at 63°C (145°F) or above* for containers of four (4) ounces (118 ml) or larger,

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Proposal: 211
Document: 2017 PMO
Pages: 138-148

Make the following changes to the 2017 PMO:

APPENDIX B. MILK SAMPLING, HAULING AND TRANSPORTATION

Milk sampling, hauling, and transport are integral parts of a modern dairy industry. Hauling, sampling and transport can be categorized into three (3) separate functions: Dairy or Industry Plant Samplers, Bulk Milk Hauling and Sampling and Milk Transport from one (1) milk handing facility to another.

I. MILK SAMPLING AND HAULING PROCEDURES

The dairy plant sampler is a person responsible for the collection of official samples for regulatory purposes outlined in Section 6. of this *Ordinance.* These persons are employees of the Regulatory Agency and are evaluated at least once every twenty-four (24) month period by a SSO or a properly

delegated Sampling Surveillance Regulatory Official (dSSO). These individuals are evaluated using FORM FDA 2399-MILK SAMPLE COLLECTOR EVALUATION REPORT (Dairy Plant Sampling – Raw and Pasteurized Milk), which is derived from the most current edition of *SMEDP*. (Refer to Appendix M. of this *Ordinance*.) Dairy plant samplers that are also SSOs or dSSOs are not required to be evaluated for sampling collection procedures at least once every twenty-four (24) month period.

The bulk milk hauler/sampler is a person responsible for the collection of official "Universal" samples for regulatory purposes as outlined in Section 6.; and/or Appendix N. of this *Ordinance*, including those that are related to reinstatement/clearing samples at dairy farms, if acceptable to the Regulatory Agency, and may transport raw milk from a dairy farm and/or raw milk products to or from a milk plant, receiving station or transfer station and has in their possession a permit from any Regulatory Agency to sample such raw milk and/or milk products. The bulk milk hauler/sampler occupies a unique position making this individual a critical factor in the current structure of milk marketing. As a weigher and sampler, they stand as the official, and frequently the only judge of milk volumes bought and sold. As a milk receiver, the operating habits directly affect the quality and safety of milk committed to their care. When the obligations include the collection and delivery of samples for laboratory analysis, the bulk milk hauler/sampler becomes a vital part of the quality control and regulatory programs affecting producer dairies. Section 3. of this *Ordinance* requires that Regulatory Agencies establish criteria for issuing permits to bulk milk hauler/samplers. These individuals are evaluated at least once every twenty-four (24) month period by a SSO or dSSO using FORM FDA 2399a-BULK MILK HAULER/SAMPLER REPORT. (Refer to Appendix M. of this *Ordinance*.)

The industry plant sampler or bulk milk hauler/sampler is a person responsible for the collection of official "Universal" samples that are related to samples collected from direct loaded milk tank trucks, if acceptable to the Regulatory Agency; and/or the collection of Appendix N. samples for regulatory purposes at a milk plant, receiving station, or transfer station as outlined in Section 6. and/or Appendix N. of this *Ordinance*. Industry plant samplers are employees of the dairy plant, receiving station or transfer station and are evaluated at least once every twenty-four (24) month period by a SSO or dSSO. These industry plant samplers are evaluated using FORM FDA 2399-MILK SAMPLE COLLECTOR EVALUATION REPORT (Dairy Plant Sampling – Raw and Pasteurized Milk) when collecting Appendix N. samples and FORM FDA 2399a when collecting official "Universal" samples from direct loaded milk tank trucks at a milk plant, receiving station or transfer station. (Refer to Appendix M. of this *Ordinance*.)

NOTE: For the purposes of determining the inspection frequency for bulk milk hauler/samplers, industry plant samplers and dairy plant samplers, the interval shall include the designated twenty-four (24) month period plus the remaining days of the month in which the inspection is due.

The milk tank truck driver is any person who transports raw or pasteurized milk or milk products to or from a milk plant, receiving station or transfer station. Any transportation of a direct farm pickup requires the milk tank truck driver to have responsibility for accompanying official samples.

The criteria for permitting these individuals should embrace at least the following:

TRAINING: To understand the importance of bulk milk collection and the techniques of sampling, including the use of an approved in-line sampler and approved aseptic samplers for milk

tank trucks or for farm bulk milk tanks and/or silos, all bulk milk hauler/samplers and industry plant samplers shall be told why, and instructed how, in the proper procedures of picking up milk and the collection of samples. The Regulatory Agency, dairy field person, route supervisors or any appropriate person whose techniques and practices are known to meet the requirements can conduct this training. If the Regulatory Agency does not conduct the training, the training shall be approved by or conducted under the supervision of the Regulatory Agency. Training also frequently takes the form of classroom sessions in which the trainer describes pickup practices, demonstrates sampling and care of samples and affords the candidate the opportunity for guided practice in these techniques. Basic considerations of sanitation and personal cleanliness, which are important to the protection of milk quality, are discussed here. Officials administering weights and measures may participate in these programs and provide instruction in the measuring of milk and the keeping of required records.

An examination, approved by the Regulatory Agency, shall be administered at the conclusion of this program. Candidates failing the exam, a score of less than seventy percent (70%), shall be denied permits or licenses until indicated deficiencies are corrected. The examination should be adequate enough to determine if a bulk milk hauler/sampler is competent. The exam shall be composed of a minimum of twenty (20) total questions broken down into the following areas:

1. Six (6) questions relating to sanitation and personal cleanliness;
2. Six (6) questions relating to sampling and weighing procedures;
3. Four (4) questions relating to equipment, including proper use, care, cleaning, etc.; and
4. Four (4) questions relating to proper record keeping requirements.

Regularly scheduled refresher short courses by the regulatory agents and officials administering weights and measures ~~would~~ should be held annually to assist in maintaining and increasing the efficiency of the bulk milk hauler/sampler. Appropriate training should also be provided to industry plant samplers with regularly scheduled refresher short courses.

QUALIFICATIONS:

1. **Experience:** Experience may include a required period of observation during which the candidate accompanies a bulk milk hauler/sampler in the performance of their duties.
2. **Personal References:** Permit applications should be supported by suitable references testifying to the character and integrity of the candidate.

EVALUATION OF BULK MILK HAULER/SAMPLER PROCEDURES: The routine inspection of bulk milk hauling/sampling procedures provides the Regulatory Agency with an opportunity to check both the condition of the bulk milk hauler/sampler's equipment and the degree of conformance with required practices.

The bulk milk hauler/sampler's technique is best determined when the regulatory agent is able to observe the bulk milk hauler/sampler at one (1) or more farms. Each bulk milk hauler/sampler shall be inspected by the Regulatory Agency prior to the issuance of a permit and at least once every twenty-four (24) months thereafter as referenced in Section 5. of this *Ordinance*. The bulk milk hauler/sampler shall hold a valid permit prior to the collection of official samples. Regulatory Agencies may use inspections from any Regulatory Agency as a means of maintaining record requirements and enforcement.

NOTE: The option to utilize inspections of bulk haulers/samplers conducted by other Regulatory Agencies, as cited above, shall not be applicable to a TPC authorized under the ICP.

The procedures for sampling and the care of samples should be in compliance with the current edition of *SMEDP*.
Specific Items to be evaluated in determining compliance include:

1. **Personal Appearance:** Bulk milk hauler/samplers shall practice good hygiene; shall maintain a neat and clean appearance; and not use tobacco in the milkhouse.
2. **Equipment Requirements:**
   a. Sample rack and ~~compartment~~ sample storage case to hold all samples collected.
   b. Refrigerant to hold temperature of milk samples (e.g. ice and water mixture) between 0ºC-4.5ºC (32ºF- 40°F).
   c. Sample dipper or other approved aseptic sampling devices of sanitary design and material approved by the Regulatory Agency; clean and in good repair.
   d. Single use sample containers; properly stored.
   e. Calibrated pocket thermometer; certified for accuracy every six (6) months; accuracy ±1°C (2°F).
   f. Approved chemical sanitizing agent (Refer to Sanitation Definition YY, Item 11r and Appendix F.) and properly constructed sample dipper container in accordance with Item 9r.
   g. An accurate device for timing milk agitation.
   h. Applicable sanitizer test kit for the type of sanitizer being used for sanitizing the bulk tank outlet valve and sampling instrument.
   i. Single-service sanitary towels shall be provided for bulk tanks with a measuring rod.
3. **Milk Quality Checks:**
   a. Examine the milk by sight and smell for any off odor or any other abnormalities that would class the milk as not being acceptable. Reject if necessary.
   b. Wash hands thoroughly and dry with a clean individual sanitary towel or other approved hand-drying device immediately prior to measuring and/or sampling the milk.
   c. Record milk temperature, collection time (optionally, in military time (24 hour clock)), date of pick-up and bulk milk hauler/sampler's name and license or permit number on the farm weight ticket; monthly the hauler/sampler shall check the accuracy of the thermometer on each bulk tank and record results when used as a test thermometer. Accuracy of required recording thermometers shall be checked monthly against a standardized thermometer and recorded. Pocket thermometer shall be sanitized for ~~30 seconds~~ the appropriate time specified for type of sanitizer being used or a minimum of one minute before use.

   NOTE: The collection time shall be defined as when the bulk milk hauler/sampler completes collection of the "Universal" sample. If a "Universal" sample is not collected of the milk that is transferred to a direct loaded milk tank truck at the dairy farm, the collection time recorded on the farm weigh ticket shall be defined as when the milk tank truck is picked up from the dairy farm.

4. **Milk Measurements:**

a. The measurement of the milk shall be taken before agitation. If the agitator is running upon arrival at the milkhouse, the measurement can be taken only after the surface of the milk has been quiescent.

b. Carefully insert the measuring rod, after it has been wiped dry with a clean individual sanitary towel, into the tank. Repeat this procedure until two (2) identical measurements are taken. Record measurements on the farm weight ticket.

c. Do not contaminate the milk during measurement.

Universal Sampling System: When bulk milk hauler/samplers collect raw milk samples, the "universal sampling system" shall be employed, whereby samples are collected every time milk is picked up at the dairy farm. This "universal sampling system" shall also be employed whenever industry plant samplers are authorized by the Regulatory Agency to collect samples from direct loaded milk tank trucks at a milk plant, receiving station or transfer station. This system permits the Regulatory Agency, at its discretion, at any given time and without notification to the industry, to analyze samples collected by the bulk milk hauler/sampler and/or industry plant sampler, respectively. The use of the "universal sample" puts more validity and faith in samples collected by industry personnel. The following are sampling procedures:

a. Pick-up and handling practices are conducted to prevent contamination of milk contact surfaces.

b. The milk shall be agitated a sufficient time to obtain a homogeneous blend. Follow the Regulatory Agency's and/or manufacturer's guidelines or when using an approved aseptic sampling device, follow the specified protocol and Standard Operating Procedure (SOP) (For informational purposes only; refer to the FDA issued M-I) for that device.

c. While the farm bulk milk tank and/or silo is being agitated, bring the sample container, dipper, dipper container and sanitizing agent for the outlet valve, or single-service sampling tubes into the milkhouse aseptically. Remove the cap from the farm bulk milk tank and/or silo outlet valve and examine the valve outlet for milk deposits or foreign matter**.** If milk deposits or foreign matter are present, or the bulk tank cap is not present then rinse and sanitize. Protect the hose cap from contamination when removing it from the transfer hose and during storage.

d. The sample may only be collected after the milk has been properly agitated or when using an approved aseptic sampling device, follow the specified protocol and SOP for that device. Remove the dipper or sampling device from the sanitizing solution or sterile container and rinse at least twice in the milk.

e. After washing hands with soap and drying, ~~C~~ collect a representative sample or samples from the farm bulk milk tank and/or silo by using a sample dipper or other approved aseptic sampling device. (For informational purposes only**:** Refer ~~to Section IV. Requirements for Using an Approved Aseptic Sampler for Farm Bulk Milk Tanks and Silos of Appendix B. of this *Ordinance* for the specific protocol for the use of approved aseptic sampling devices.)~~ to the M-I that is appropriate for the aseptic or inline sampler being used.) When transferring milk from the sampling equipment, caution should be used to assure that milk is not spilled back into the farm bulk milk tank and/or silo. Do not fill the sampling container more than three-quarters (¾) full. Close the cover on the sample container.

f. The sample dipper shall be rinsed free of milk and placed in its carrying container, if provided**.**

g. Close the cover or lid of the farm bulk milk tank.

h. The producer sample shall be identified with the producer's ~~number~~ identification, temperature, date~~,~~ and time at the point of collection.

i. A temperature control sample (TC) shall be taken at the first stop of each load. This sample shall be labeled with collection time (optionally, in military time (24 hour clock)), date, temperature and producer and bulk milk hauler/sampler identification.

j. Place the sample or samples immediately into the sample storage case. Refer to item 2a and 2b.

5. **Pump Out Procedures:**

a. Once the measurement and sampling procedures are completed, with the agitator still running, open the outlet valve and start the pump. Turn off the agitator when the level of milk ~~is below the level that will cause over-agitation~~ has reached the agitator blade (s).

b. When the milk has been removed from the tank, disconnect the hose from the outlet valve and cap the hose.

c. Observe the inside surfaces of the bulk tank for foreign matter or extraneous material and record any objectionable observations on the farm weight ticket.

d. With the outlet valve open, thoroughly rinse the entire inside surface of the tank with warm water.

6. **Sampling Responsibilities:**

a. All sample containers and single-service sampling tubes used for sampling shall comply with all the requirements that are in the current edition of *SMEDP*. Samples shall be cooled to and held between 0°C (32°F) and 4.5°C (40°F) during transit to the laboratory.

b. Means shall be provided to properly protect the samples in the sample case. Keep refrigerant at an acceptable level.

c. Racks/floaters shall be provided so that the samples are properly cooled ~~in an ice bath~~ and protected in the sample storage case.

d. Adequate insulation of the sample ~~container box~~ storage case or ice chest shall be provided to maintain the proper temperature of the samples throughout the year.

The SSO conducts periodic evaluations of sampling procedures. This program will promote uniformity and compliance of sample collection procedures.

II. REQUIREMENTS FOR USING AN APPROVED ASEPTIC IN-LINE SAMPLER (For informational purposes only: Refer to M-I-06-6)

~~A protocol specific to each milk producer who direct loads milk tank trucks (through by-passing the use of farm bulk milk tanks or silos) while utilizing an approved in-line sampler shall be developed by the Regulatory Agency in cooperation with the sampling equipment manufacturer, the milk buyer, the milk producer and FDA. As a minimum, the protocol should include the following:~~

A protocol for utilizing an in-line sampler system shall be approved by the Regulatory Agency in co-operation with the sampling equipment manufacturer, the milk producer and FDA. A copy of the approved aseptic in-line sampling system's SOP shall be on file and posted for use at the location where the sampling system is utilized.
As a minimum, the protocol (SOP) shall include the following:

1. A description of how the milk sample is to be collected, identified, handled and stored.

2. A description of the means used to refrigerate the sample collection device and milk sample collection container throughout the milk sample collection period.
3. A means to monitor ~~the sampler device temperature and~~ milk sample temperature, and the milk temperature.
4. A description of how and when the sampler is to be cleaned and sanitized, if not of a single use design.
5. A listing of the licensed bulk milk hauler/samplers who have been trained to maintain, operate, clean and sanitize the sample collection device as well as to collect, identify, handle and store the milk sample.
6. A description of the method and means that will be used to determine weight of the milk on the milk tank truck.

III. REQUIREMENTS FOR USING AN APPROVED ASEPTIC SAMPLER FOR MILK TANK TRUCKS (For informational purposes only: Refer to M-I-06-12, M-I-16-17)

A protocol (SOP) specific to each milk plant and milk tank truck(s) in which industry plant samplers utilize an approved aseptic sampler shall be developed by the Regulatory Agency in cooperation with the sampling equipment manufacturer, the milk plant and FDA. As a minimum, the protocol (SOP) shall include the following:

1. A description of how the milk sample is to be collected, identified, handled and stored.
   a. The aseptic sampler fitting shall be installed according to the manufacturer's recommendations and in a manner that is compatible with its intended use.
   b. The aseptic sampler septum shall be installed according to the manufacturer's instructions.
   c. Transfer of milk is achieved using a SOP specific to the aseptic sampler.
   d. An appropriate device, i.e., a syringe, shall be used to transfer the milk.
2. A description of how and when the aseptic sampler is to be cleaned and sanitized, if not of a single use design, as per the manufacturer's instructions.
3. A listing of the industry plant samplers who have been trained to maintain, operate, clean and sanitize the aseptic sampler as well as to collect, identify, handle and store the milk sample.

A copy of the approved aseptic sampler's SOP shall be on file at the location where the aseptic sampler is utilized.

IV. REQUIREMENTS FOR USING AN APPROVED ASEPTIC SAMPLER FOR FARM BULK MILK TANKS AND/OR SILOS (For informational purposes only: Refer to M-I-06-6, M-I-06-12 or M-I-12-4)

~~A protocol specific to each milk producer in which the milk producer, who transports milk only from his/her own dairy farm, or bulk milk hauler/samplers utilize an approved aseptic sampler sampling system shall be developed approved by the Regulatory Agency in cooperation with the sampling equipment manufacturer, the milk producer and FDA.~~

A protocol specific to obtaining a sample directly from a farm bulk milk tank / silo prior to loading the milk for transport utilizing an aseptic sampler shall be approved by the Regulatory Agency in cooperation with the sampling equipment manufacturer, the milk producer and FDA. As a minimum, the protocol shall include the following:

1. A description of how the milk sample is to be collected, identified, handled and stored.
   a. The aseptic ~~sampler fitting~~ sampler shall be installed according to the manufacturer's recommendations and in a manner that is compatible with its intended use. ~~and does not create a dead end~~.
   ~~b. The aseptic sampler septum shall be installed according to the manufacturer's instructions.~~
   ~~c.~~ b. Transfer of milk is achieved using a SOP specific to the aseptic sampler.
2. A description of how and when the aseptic sampler is to be cleaned and sanitized, if not of a single use design, as per the manufacturer's instructions.
3. A listing of the milk producer, who transports milk only from his/her own dairy farm, and/or licensed bulk milk hauler/samplers who have been trained to maintain, operate, clean and sanitize the aseptic sampling device as well as collect, identify, handle and store the milk sample.
4. A copy of the approved aseptic sampler SOP shall be on file and posted for use at the location where the sampler is utilized.

V. REQUIREMENTS FOR THE SAMPLING OF RAW SHEEP MILK THAT HAS BEEN FROZEN PRIOR TO BEING TESTED FOR APPENDIX N. DRUG RESIDUE

Raw sheep milk samples that have previously been frozen may be tested for Appendix N. drug residue provided that the sampling protocol shall be approved by the Regulatory Agency in which the dairy farm is located. The sampling protocol shall address the following items:

1. Samples shall be taken by a bulk milk hauler/sampler that is permitted by the Regulatory Agency in which the dairy farm is located.
2. The sampling protocol shall assure that representative samples are taken.
3. A storage protocol that assures that the raw sheep milk and samples are frozen within 24 hours of sample collection in accordance with the handling of the negative control as specified in the FDA/NCIMS 2400 Form for the test kit that is being used.
4. The collected raw sheep milk and samples are stored in a freezer(s) that is properly maintained and temperature monitored in accordance with the FDA/NCIMS 2400 Form General Requirements.
5. Samples delivered to the testing laboratory for testing within sixty (60) days of the freezing of the raw sheep milk.
6. An appropriate sample chain-of-custody shall be utilized to assure sample identification and handling.
7. Copies of the approved sampling protocol shall be on file with the Regulatory Agency and shall be available at the dairy farm, receiving milk plant and the laboratory performing the testing. If a copy of the sampling protocol is not available at the dairy farm, receiving milk plant or laboratory performing the testing, a copy shall be made available within twenty-four (24) hours of being requested by the Regulatory Agency.

NOTE: If the sampling protocol has not been approved by the Regulatory Agency; is not being followed; the sampling protocol has been modified without the Regulatory Agency's approval; or the dairy farm, receiving milk plant or laboratory performing the testing does not obtain a copy within twenty-four (24) hours of being requested by the Regulatory Agency it shall be considered an Appendix N. violation for the dairy farm and/or receiving milk plant.

VI. REQUIREMENTS FOR SANITIZING SAMPLING COCKS AND IN-LINE SAMPLE POINTS

1. Sampling cocks: prepare a sanitizing solution containing 200 mg/L (200ppm) of available chlorine such as hypochlorite or another equivalent strength sanitizer. Submerge the sampling cock by fitting a bag of the sanitizer solution around it. While holding the tip of the bag of sanitizing solution tightly around the body of the sampling valve, flush the sanitizer in and out of the sampling cock for at least one minute. Then purge the sampling cock valve with at least 2 liters (about ½ gallon) of milk before collecting the regulatory sample.

2. In-line sample points~~:~~ (refer to the M-I that is appropriate for the aseptic or in-line sampler being used).

VII ~~VI~~. MILK TANK TRUCK PERMITTING AND INSPECTION

Milk tank trucks shall be evaluated every twenty-four (24) months plus the remaining days of the month in which the inspection is due using the requirements established in Sections 3. and 5. of this *Ordinance* using FORM FDA 2399b-MILK TANK TRUCK INSPECTION REPORT. (Refer to Appendix M. of this *Ordinance*.)

PERMITTING: Each milk tank truck shall ~~bear a permit~~ be permitted for the purpose of transporting milk and/or milk products. (Refer to Section 3. of this *Ordinance*.) The permit shall be issued to the owner of each milk tank truck by an authorized Regulatory Agency. The permit identification and Regulatory Agency issuing the permit shall be displayed on the milk tank truck.

RECIPROCITY: Each permit shall be recognized by other Regulatory Agencies under the reciprocal agreements of the NCIMS and supporting documents of this *Ordinance.* A milk tank truck need only bear one (1) permit from an appropriate Regulatory Agency. A milk tank truck may be inspected at any time when deemed appropriate by the Regulatory Agency. Absent proof of a current permit and current inspection, when the milk tank truck is inspected by a Regulatory Agency other than the permitting agency, an inspection fee may be charged to the owner of the milk tank truck. This is necessary to allow a milk tank truck to pickup and deliver in several jurisdictions without the need for more than one (1) permit. A Regulatory Agency may have the option of inspecting any milk tank truck at any time when milk and milk products are transported in or out of a particular jurisdiction. It is the responsibility of the milk tank truck owner or operator to maintain a current proof of inspection to avoid a re-inspection fee. Disputes concerning reciprocal agreements on milk tank truck inspection between Regulatory Agencies may be tendered to the Chair of the NCIMS or the Chair's designee for resolution.

INSPECTION: Each milk tank truck shall be inspected at least once every twenty-four (24) months plus the remaining days of the month in which the inspection is due by a Regulatory Agency. (Refer to Section 5. of this *Ordinance.*) A copy of the current inspection report shall accompany the milk tank truck at all times, or the tank shall bear an affixed label, which identifies the Regulatory Agency with the month and year of inspection. The affixed label shall be located near the tank outlet valve or on the front left side of the milk tank truck bulkhead.

When significant defects or violations are encountered by a Regulatory Agency, a copy of the report shall be forwarded to the permitting Regulatory Agency and also carried on the milk tank truck until the violations are corrected.

Milk tank truck inspections shall be conducted in a suitable location, i.e., a dairy plant, receiving or transfer station or milk tank truck cleaning facility. Inspections may not require entry of confined spaces as defined by the Occupational Safety and Health Administration (OSHA) standards. When significant cleaning, construction or repair defects are noted, the milk tank truck shall be removed from service until proper confined entry safety requirements can be satisfied to determine cleaning or repairs needed. Cleaning or repairs may be verified by a qualified individual to the satisfaction of the Regulatory Agency.

Inspection reports completed by Regulatory Agencies other than the permitting agency shall be forwarded to the permitting agency for verification of inspection as required in the **PERMITTING** Section of this Appendix. The permitting agency may use these reports to satisfy permit requirements.

MILK TANK TRUCK STANDARDS: All Items of FORM FDA 2399b-MILK TANK TRUCK INSPECTION REPORT fall into the categories of "Compliance", "Non- Compliance" or "Not Applicable" (NA) as determined during the inspection. The following Items relate to FORM FDA 2399b: (Refer to Appendix M. of this *Ordinance*.)

1. **Samples and Sampling Equipment:** (When provided)
   a. Sample containers shall be stored to preclude contamination.
   b. The sample box shall be in good repair and kept clean.
   c. Sample transfer instrument shall be cleaned and sanitized to insure that proper samples are collected.
   d. The properly constructed sample transfer instrument container (refer to item 9r) is provided and adequate means for maintaining sanitizer solutions is on hand.
   e. The samples are properly stored to preclude contamination.
   f. The sample storage compartment shall be clean.
   g. Samples are maintained at an acceptable temperature 0ºC-4.5ºC (32ºF-40ºF) and a temperature control sample is provided.
   h. An approved thermometer is available for use by the sampler. The accuracy of the thermometer is checked each six (6) months with the results and date recorded on the carrying case.
2. **Product Temperature 7ºC (45ºF) or Less:**
   a. The product temperature shall meet all the requirements of Section 7., Items 18r-Raw Milk Cooling and 17p-Cooling of Milk and Milk Products of this *Ordinance*.
   b. Product that remains in external transfer systems that exceeds 7ºC (45ºF) is discarded. This includes pumps, hoses, air elimination equipment or metering systems.
3. **Equipment Construction, Cleaning, Sanitizing and Repair:** Items a. through l. on FORM FDA 2399b shall be evaluated according to the following criteria:
   a. Construction and Repair Requirements
      (1) The milk tank truck and all appurtenances shall meet applicable requirements of Section 7., Item 10p-Sanitary Piping and Item 11p-Construction and Repair of Containers and Equipment of this *Ordinance*. Equipment manufactured in conformity with 3-A Sanitary Standards, complies with sanitary design and construction requirements of this *Ordinance.*

(2) The interior of the milk tank trucks shall be constructed of smooth, non-absorbent, corrosion-resistant, non-toxic material; and it shall be maintained in good repair.

(3) The appurtenances of the milk tank truck includes aseptic samplers, if applicable, hoses, pumps and fittings, shall be constructed of smooth, non-toxic cleanable material; and shall be maintained in good repair. Where flexibility is required, the fluid transfer system shall be free draining and so supported to maintain uniform slope and alignment. They shall be easily disassembled and accessible for inspection.

(4) The cabinet portion(s) of the tank, used for the storage of appurtenances and sampling equipment, where applicable, shall be constructed to preclude contamination by dust, dirt; be clean; and in good repair.

(5) The milk tank truck dome lid assembly, vent and dust cover shall be designed to protect the tank and milk from contamination.

b. Cleaning and Sanitizing Requirements

(1) The milk tank truck and all of its appurtenances shall be cleaned and sanitized in accordance with applicable requirements of Section 7., Item 12p-Cleaning and Sanitizing of Containers and Equipment of this *Ordinance.*

(2) The milk tank truck shall be cleaned and sanitized prior to its first use. When the time elapsed after cleaning and sanitizing, and before its first use, exceeds ninety-six (96) hours the tank shall be re-sanitized.

NOTE: First use shall be defined as when milk is first transferred into the milk tank truck and the time is documented.

(3) It is allowable to pickup multiple loads continuously within a twenty-four (24) hour period, provided the milk tank truck is washed after each ~~day's used~~ twenty-four hour period. If a tanker has been exposed to an antibiotic or other contaminant, it shall be immediately cleaned and sanitized prior to its next use.

4. **Exterior Condition of Tank:** The exterior of the milk tank truck is properly constructed and in good repair. Defects and damage that would adversely affect products contained in the milk tank truck are pointed out on FORM FDA 2399b-MILK TANK TRUCK INSPECTION REPORT and corrective actions are prescribed. Cleanliness of the milk tank truck exterior is evaluated with consideration for existing weather and environmental conditions.

5. **Wash and Sanitize Record:**

a. The bulk milk hauler/sampler shall be responsible for assuring that the milk tank truck has been properly cleaned and sanitized at a permitted milk plant, receiving station, transfer station, or milk tank truck cleaning facility. A milk tank truck without proper cleaning and sanitizing documentation shall not be loaded or unloaded until the proper cleaning and sanitization can be verified.

NOTE: The option to use non-IMS listed milk tank truck cleaning facilities, as cited in a. above, shall not be applicable to a TPC authorized under the ICP.

b. A cleaning and sanitizing tag shall be affixed to the outlet valve of the milk tank truck until the milk tank truck is next washed and sanitized. When the milk tank truck is washed and sanitized, the previous cleaning and sanitizing tag shall be removed and stored at the location where the milk tank truck was washed for a period of not less than fifteen (15) days.

c. The following information shall be recorded on the cleaning and sanitization tag:
(1) Identification of the milk tank truck.
(2) Date and time (optionally, in military time (24 hour clock)) of day the milk tank truck was cleaned and sanitized.
(3) Location where the milk tank truck was cleaned and sanitized.
(4) Signature(s) or initials of the person (s) who cleaned all appurtenances, and sanitized the milk tank truck.

d. The maintenance of all information on the cleaning and sanitizing tag shall be the responsibility of the bulk milk hauler/sampler or the milk tank truck operator.

e. States shall submit to the NCIMS Executive Secretary an updated list of all currently permitted non-IMS listed milk tank truck cleaning facilities. The list is to be submitted for publication on the NCIMS web site.

6. **Location of Last Cleaning/Sanitizing:**
The location of the last cleaning and sanitizing shall be verified by the Regulatory Agency during any milk tank truck inspection and recorded on the Milk Tank Truck Inspection Form.

7. **Labeling:** The maintenance of all pertinent information on all shipping documents, shipping invoices, bills of lading or weight tickets is the responsibility of the bulk milk hauler/ sampler. A milk tank truck transporting raw, heat-treated or pasteurized milk and milk products to a milk plant from another milk plant, receiving station or transfer station is required to be marked with the name and address of the milk plant or hauler and the milk tank truck shall be under a proper seal. All shipping documents shall contain the following information as outlined in Section 4. Labeling of this *Ordinance*:

a. Shipper's name, address and permit number. Each milk tank truck load of milk shall include the IMS BTU identification number(s) or the IMS Listed Milk Plant Number, for farm groups listed with a milk plant, on the farm weight ticket or manifest;

b. Permit identification of the hauler, if not an employee of the shipper;

c. Point of origin of shipment;

d. Milk tank truck identification number;

e. Name of product;

f. Weight of product;

g. Temperature of product when loaded;

h. Date of shipment;

i. Name of supervising Regulatory Agency at the point of origin of shipment;

j. Whether the contents are raw, pasteurized, or in the case of cream, lowfat or skim milk, whether it has been heat-treated;

k. Seal number on inlet, outlet, wash connections and vents; and

l. Grade of product.

All information contained on the above described documents shall be verified by the Regulatory Agency and recorded on the appropriate inspection sheet for any bulk milk tank trucks under inspection.

8. **Vehicle and Milk Tank Truck Properly Identified:** It shall be the responsibility of the milk tank truck owner or operator to insure the proper and legible identification of the milk tank truck(s) in their possession.

9. **Previous Inspection Sheet or Affixed Label Available:** When a milk tank truck transports milk and milk products from one (1) regulatory jurisdiction to another it is not necessary to inspect each milk tank truck upon each arrival. Milk tank truck owners and operators shall carry proof of

most recent inspection from a recognized Regulatory Agency. A milk tank truck may be inspected at any time or at the discretion of any Regulatory Agency responsible for the milk supply.
10. **Sample Chain-of-Custody:** When samples for official laboratory analysis are transported by any individual where the sample chain-of-custody must be established, the driver may be required to carry a valid permit or shall be evaluated biennially for the collection of samples for official laboratory analysis. The criteria from Section I. Evaluation of Bulk Milk Hauler/ Sampler Procedures, Item 7-Sampling Responsibilities of this Appendix shall be used as the basis for the evaluation. As an alternative, a sample case sealed as required by the Regulatory Agency may be accepted.

FDA DID NOT CONCUR WITH THIS PROPOSAL AS CITED IN THEIR LETTER TO THE NCIMS CHAIR DATED ~~TBD~~ AUGUST 20, 2019

FDA originally non-concurred with proposals 210 and 211 because they did not give clear direction to FDA of how the text in the Proposals shall be added to the PMO. Proposal 210 inserted a new Section V into Appendix B. of the PMO titled "REQUIREMENTS FOR USING AN APPROVED ON-TANKER FARM BULK TANK ASEPTIC SAMPLER FOR MULTIPLE AND/OR SINGLE FARM PICKUPS." Proposal 211 inserted a new Section VI into Appendix B. of the PMO titled "REQUIREMENTS FOR USING AN APPROVED ON-TANKER FARM BULK TANK ASEPTIC SAMPLER FOR MULTIPLE AND/OR SINGLE FARM PICKUPS" and changed the existing Section VI to Section VII. The result of the two proposals as passed is that there are two sections titled "Section V" in Appendix B.

During the October 23-24, 2019 Executive Board meeting, FDA and the Executive Board reached mutual concurrence with Proposals 210 and 211. This provides for the renumbering of Appendix B., Section VI – VIII as follows, and make the corresponding changes to the PMO TABLE OF CONTENTS:

V. REQUIREMENTS FOR USING AN APPROVED ON-TANKER FARM BULK MILK TANK ASEPTIC SAMPLER FOR MULTIPLE AND/OR SINGLE FARM PICKUPS

VI. REQUIREMENTS FOR SANITIZING SAMPLING COCKS AND IN-LINE SAMPLE POINTS

VII. REQUIREMENTS FOR THE SAMPLING OF RAW SHEEP MILK THAT HAS BEEN FROZEN PRIOR TO BEING TESTED FOR APPENDIX N. DRUG RESIDUE.

VIII. MILK TANK TRUCK PERMITTING AND INSPECTION

Proposal: 210
Document: 2017 PMO
Pages: 143 and 144

Make the following changes to the 2017 PMO:

It is proposed that the following new section V, be inserted into Appendix B. of the PMO

V. REQUIREMENTS FOR USING AN APPROVED ON-TANKER FARM BULK MILK

1. A protocol specific to the use of an on-tanker farm bulk milk tank aseptic sampler which may be used for the acquisition of official milk samples from multiple and/or single farm pickups shall be approved by the Regulatory Agency in cooperation with the sampling equipment manufacturer and FDA. At a minimum, the protocol (SOP) shall include the following:
   a. A description of how the milk sample is to be collected, identified, handled and stored.
   b. A description of the means used to maintain the sample at the required temperature (between 0.0 (32F) to 4.5 (40F) degrees Celsius, as per this Appendix) during the sample collection period.
   c. A description of the process used to obtain the temperature of milk being loaded from the farm bulk milk tank.
   d. A description of how and when the sampler is to be cleaned and sanitized if not of a single use design.
   e. A description of the method and the means used to ensure the representative nature of and integrity of the milk sample acquired from every farm bulk milk tank.
   f. A description of the method and means that will be used to determine weight of the milk in the farm bulk milk tank.
2. The on-tanker farm bulk milk tank sampler shall be installed in consultation with the Regulatory Agency, according to the manufacturer's recommendations and in a manner that is compatible with its' intended use.
3. The State Regulatory Agency shall be provided a list of the licensed bulk milk hauler/samplers who have been trained to maintain and operate the aseptic sampler as well as to collect, identify, handle and store the milk sample.
4. A copy of the approved on-tanker farm bulk milk tank aseptic sampler SOP shall be on file on the tanker.

FDA DID NOT CONCUR WITH THIS PROPOSAL AS CITED IN THEIR LETTER TO THE NCIMS CHAIR DATED AUGUST 20, 2019

FDA originally non-concurred with proposals 210 and 211 because they did not give clear direction to FDA of how the text in the Proposals shall be added to the PMO. Proposal 210 inserted a new Section V into Appendix B. of the PMO titled "REQUIREMENTS FOR USING AN APPROVED ON-TANKER FARM BULK TANK ASEPTIC SAMPLER FOR MULTIPLE AND/OR SINGLE FARM PICKUPS." Proposal 211 inserted a new Section VI into Appendix B. of the PMO titled "REQUIREMENTS FOR USING AN APPROVED ON-TANKER FARM BULK TANK ASEPTIC SAMPLER FOR MULTIPLE AND/OR SINGLE FARM PICKUPS" and changed the existing Section VI to Section VII. The result of the two proposals as passed is that there are two sections titled "Section V" in Appendix B.

During the October 23-24, 2019 Executive Board meeting, FDA and the Executive Board reached mutual concurrence with Proposals 210 and 211. This provides for the renumbering of Appendix B., Section VI – VIII as follows, and make the corresponding changes to the PMO TABLE OF CONTENTS:

V. REQUIREMENTS FOR USING AN APPROVED ON-TANKER FARM BULK MILK TANK ASEPTIC SAMPLER FOR MULTIPLE AND/OR SINGLE FARM PICKUPS

VI. REQUIREMENTS FOR SANITIZING SAMPLING COCKS AND IN-LINE SAMPLE POINTS

VII. REQUIREMENTS FOR THE SAMPLING OF RAW SHEEP MILK THAT HAS BEEN FROZEN PRIOR TO BEING TESTED FOR APPENDIX N. DRUG RESIDUE.

VIII. MILK TANK TRUCK PERMITTING AND INSPECTION

Proposal: 113
Document: 2017 PMO
Pages: 182, 183, & 184

Make the following changes to the 2017 PMO:

2017 PMO Appendix D. page 182:

6. An automatic flow control system or valve, accurate within the expected pressure range, shall be installed to restrict flow ~~to the maximum design flow of the treatment unit~~ so that the entire volume of water receives the minimum dose required above.

2017 PMO Appendix D. page 183

6. An automatic flow control system or valve, accurate within the expected pressure range, shall be installed to restrict flow ~~to the maximum design flow of the treatment unit~~ so that the entire volume of water receives the minimum dose required above.

2017 PMO Appendix H. page 282

4. An automatic flow control system or valve, accurate within the expected pressure range, shall be installed to restrict flow ~~to the maximum design flow of the treatment unit~~ so that all particles receive the minimum dose listed above.

Proposal: 120
Document: 2017 PMO

Pages: 301

Make the following changes to the 2017 PMO:

9.2 DIFFERENTIAL PRESSURE CONTROLLER

Application: Test 9.2.1 applies to all differential pressure controllers used to control the operation of booster pumps within HTST pasteurization systems or used to control the operation of FDDs ~~on~~ using plate type or double/triple tube type heat exchangers in ~~HHST and HTST~~ continuous-flow pasteurization systems with the FDD located downstream of the pasteurized regenerator section(s) and/or the final cooler section.
Test 9.2.2 applies only to HTST pasteurization systems with the FDD located immediately following the holding tube.
Test 9.2.3 applies to the testing of plate type and double tube/triple tube type heat exchangers in continuous-flow pasteurization systems in which the differential pressure controller is used to control the operation of the FDD.

Proposal: 301
Document: 2017 PMO
Pages: 346, 347, 350 FORM FDA 2359m

Make the following changes to the 2017 PMO Appendix K. HACCP PROGRAM:

Page 346

PREREQUISITE AND OTHER PROGRAMS: …

In addition to PPs, other programs may be necessary to assure the HACCP system is operating as intended. ~~Prerequisite and other programs shall at a minimum provide compliance with 21 CFR 117 (Subpart A, B and F).~~

Page 347:
HAZARD ANALYSIS: …
The Hazard Analysis shall at a minimum provide compliance with ~~21 CFR 117 (Subpart C. (117.130 Hazard Analysis))~~ Appendix T. Hazard Analysis.

Pages 349:
CORRECTIVE ACTIONS: …

3. All corrective actions taken in accordance with this Section shall be fully documented in records that are subject to verification. Corrective actions and corrections shall at a minimum provide compliance with ~~21 CFR 117 (Subpart C. (117.150 Corrective Actions and Corrections))~~ Appendix T. Corrective Actions.

Pages 350:

b. The calibration of CCP process-monitoring instruments, and the performance of any periodic end-product and in-process testing, ~~in accordance with 1.a.(3)ii) and 1.a.(3)iii) of~~

~~this Section,~~ shall be documented in records that are subject to the record keeping requirements in ~~this~~ Appendix T.

VERIFICATION AND VALIDATION

1. **Verification …**
Verifications shall at a minimum provide compliance with ~~21 CFR 117 (Subpart C. (117.155 and 117.165 Verification of Implementation and Effectiveness)).~~ Appendix T. Verification.
…
Page 350:
3. **Validation of the Hazard Analysis: …**
A QI(s) trained in accordance with the training requirements of this Appendix shall perform the validation. Validation shall at a minimum provide compliance with ~~21 CFR 117 (Subpart C. (117.160))~~ Appendix T. Validation. …

*Make the following changes to FORM FDA 2359M MILK PLANT, RECEIVING STATION OR TRANSFER STATION NCIMS HACCP SYSTEM AUDIT REPORT:***…**

Section 8 HACCP SYSTEM RECORDS …
G. Requirements in ~~21 CFR 117 Subpart F~~ Appendix T. are addressed…
Section 9 HACCP SYSTEM PREREQUISITE PROGRAMS …
A. Required PP written, Implemented, and in Substantial Compliance by firm …
9. Requirements in ~~21 CFR 117 S ubpart A&B F~~ Appendix T. are addressed.

Proposal: 308
Document: 2017 PROCEDURES
Pages: 52, 54

Make the following changes to the 2017 PROCEDURES:

PROCEDURES

SECTION VIII. PROCEDURES GOVERNING THE CERTIFICATION OF MILK PLANT, RECEIVING STATION AND TRANSFER STATION NCIMS HACCP SYSTEMS FOR IMS LISTED SHIPPERS…

Page 41

2. HACCP Training

Section IV., A. 2. shall apply as written. In addition the following HACCP training requirements shall apply:

a. HACCP training for industry, Regulatory, SROs, and PHS/FDA personnel will be based on the current Hazard Analysis and Critical Control Point Principles and Application Guidelines of the U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF), the current PHS/FDA HACCP recommendations, and the requirements of Appendix K. of the Grade "A" PMO.

Page 51

E. QUALIFICATIONS AND CERTIFICATIONS…

4. HACCP Listing Personnel

   HACCP listings shall be made by qualified SROs who:

   a. Have been certified by PHS/FDA as a SRO and hold a valid certification of qualification to perform HACCP listing audits.

   b. Have completed ~~attended~~ at least one (1) abbreviated approved training course in the auditing of milk plant HACCP Systems and NCIMS listing for the period of qualification.

   c. Have, during the three (3) year period for which certified, participated in at least one (1) Milk Seminar and, in addition, attended at least one (1) training course on "Special Problems in Milk Protection" or other training course judged by the PHS/FDA to be equivalent.

   d. ~~a.~~ Do not have direct responsibility for the routine regulatory audits of the shipper to be listed.

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

   a. Candidate Background

      1.) Training and Experience

         A.) The Candidate shall provide a statement describing their background and experience that qualifies them to perform this work.
         B.) Candidates are encouraged to gain practical milk plant experience in the application of HACCP and in conducting milk plant NCIMS HACCP audits by working with SROs that are certified to perform NCIMS HACCP Listings audits whenever practical.
         C.) The Candidate shall complete a basic HACCP training course that is acceptable to the NCIMS and PHS/FDA; NCIMS HACCP Orientation; as well as training in general auditing requirements for the auditing of milk plants, receiving stations and transfer stations under the NCIMS HACCP Program. The NCIMS HACCP Orientation and training in general auditing requirements for auditing milk plants, receiving stations and transfer stations at a minimum consists of the Appendix T.

training from the PHS/FDA Milk Specialists and the abbreviated training course approved and supplied by the HACCP Implementation Committee.
D.) Candidate shall be a certified SRO for milk plants.

b. Original Certification Process

1.) Knowledge of HACCP and NCIMS HACCP Auditing Standards and Requirements

A standardized PHS/FDA Milk Specialist, qualified to conduct HACCP Audits, shall accompany the Candidate during the course of one (1) mock-listing audit conducted separate from an official HACCP listing audit. The Candidate may be certified to conduct HACCP listings after successfully completing one (1) mock-listing audit, with the certification valid for three (3) years. In the case of an original HACCP certification, the date of expiration of the other SRO certification shall be automatically extended to correspond with the original HACCP certification expiration date.

2.) Knowledge of HACCP and NCIMS HACCP Auditing Standards and Requirements

The PHS/FDA Milk Specialist shall accompany the Candidate during the mock-listing audit and shall evaluate the Candidate's HACCP knowledge and NCIMS HACCP auditing skills. Particular attention shall be given to the Candidate's observations, evaluation, and decision-making skills related to planning and conducting the mock-listing audit, identifying and recording the findings, communicating with industry representatives, and arriving at a listing audit determination. The PHS/FDA Milk Specialist shall categorize the Candidate's HACCP knowledge and NCIMS HACCP auditing skills into one (1) of the following three (3) categories:

A.) The Candidate's work is acceptable; or
B.) The Candidate's work is acceptable with written recommendations identifying areas that need improvement; or
C.) The Candidate is not certified.

NOTE: The cause shall be documented and provided to the Candidate and the Rating Agency.

c. Continuous Certification

After the initial successful HACCP Certification, subsequent certification of a SRO to make NCIMS HACCP Listing Audits shall be valid for three (3) years unless revoked for cause.

1.) Milk Plant Technical Knowledge

The Candidate shall continue to meet the requirements for certification of a SRO for milk plants.

During the three (3) year certification period, the SRO, certified to conduct NCIMS HACCP listings, shall complete the minimum training requirements established to maintain proficiency regarding the NCIMS voluntary HACCP Program including having attended at least one (1) training course in the auditing of milk plant HACCP Systems and NCIMS listing for the period of qualification. The NCIMS HACCP Implementation Committee has developed and accepted for this required training ~~both a comprehensive multi-day course presented by members of the NCIMS HACCP Implementation Committee and~~ an abbreviated approved training course of individual instruction that may be presented to individuals or small groups by any of the HACCP Certified FDA Milk Specialists.

Small group training with practical exercises and other appropriate training that may include written examinations shall be used to evaluate the SROs technical knowledge for continuing certification.

2.) Knowledge of HACCP and NCIMS HACCP Auditing Standards and Requirements

During the three (3) year certification period, a PHS/FDA Milk Specialist shall accompany the SRO during the course of at least one (1) recertification listing audit. The recertification listing 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 Milk Specialist and SRO. This decision shall be made prior to the beginning of the recertification listing audit. In the absence of an agreement, the recertification listing audit shall be conducted during a mock listing audit. The standardizing official (PHS/FDA Milk Specialist) shall accompany as a "silent observer" during this recertification listing audit. The PHS/FDA Milk Specialist shall evaluate the SROs HACCP knowledge and NCIMS HACCP auditing skills. Particular attention shall be given to the SROs observations, evaluation, and decision-making skills related to planning and conducting the listing or mock-listing audit, identifying and recording the findings, communicating with industry representatives, and arriving at an audit listing or mock-listing audit determination. The PHS/FDA Milk Specialist will categorize the SROs HACCP knowledge and NCIMS HACCP auditing skills into one (1) of the following three (3) categories:

A.) The SRO is recertified to conduct NCIMS HACCP Listing Audits; or
B.) The SRO is recertified with written recommendations identifying areas that need improvement; or
C.) The SRO is not recertified.

NOTE: The cause shall be documented and provided to the SRO and the Rating Agency.

Make the following changes to the 2017 PMO:

Page 352

Appendix K. HACCP PROGRAM

IV. TRAINING AND STANDARDIZATION

HACCP training for industry and regulatory personnel will be based on the current "Hazard Analysis and Critical Control Point Principles and Application Guidelines" of NACMCF, the current FDA HACCP recommendations, and the regulatory requirements of this Appendix and related Sections of this *Ordinance*.

Regulatory Agency personnel responsible for the evaluation, licensing and regulatory audits of facilities using the NCIMS voluntary HACCP Program shall have equivalent training to the training required to perform traditional NCIMS functions. They shall also have specialized training in conducting HACCP System audits.

Industry, Regulatory, Rating and FDA personnel should be trained together.

HACCP TRAINING:

1. **Core Curriculum:** The Dairy HACCP Core Curriculum consists of:
   a. Basic HACCP training; plus
   b. An orientation to the requirements of the NCIMS voluntary HACCP Program.

Basic HACCP training consists of instruction in the application of the NACMCF Principles of HACCP to Food Safety. This training includes practical exercises in conducting a hazard analysis and evaluating potential hazards; in writing a HACCP Plan; and in the validation of the plan. It should be taught by experienced instructors.

The orientation component ideally is coupled with the basic HACCP training, but can be taught separately. The content of the orientation will be conducted under the guidance of the NCIMS. It is intended to familiarize industry and regulatory personnel with specific dairy HACCP concerns and the regulatory requirements under the NCIMS voluntary HACCP Program. It is to be taught by instructors experienced in the application of HACCP under the NCIMS voluntary HACCP Program.

The industry individual(s) performing the functions identified in this Appendix requiring training or listed in Part 2 of this Section shall have successfully completed appropriate training in the application of HACCP principles to milk and milk product processing at least equivalent to that received under the Dairy HACCP Core Curriculum. Alternatively, job experience may qualify an individual to perform these functions if the experience has provided knowledge at least equivalent to that provided through the standardized curriculum.

2. **Industry Personnel:** Only industry individuals who have met the requirements of Part 1 of this Section shall be responsible for the following functions:
   a. Developing PPs;
   b. Developing the hazard analysis, including delineating control measures, as required;

c. Developing a HACCP Plan that is appropriate for the specific milk plant, receiving station or transfer station, in order to meet these requirements;
d. Validating and modifying the HACCP Plan in accordance with the corrective action procedures and the validation activities as specified; and
e. Performing required HACCP Plan records reviews.

3. **Regulatory Personnel:** Regulatory personnel performing HACCP audits shall have successfully completed appropriate training in the application of HACCP or Food Safety Plan principles for milk and milk product processing at least equivalent to that received under the Dairy HACCP Core Curriculum. Specialized Appendix T. training combined with the abbreviated approved training course in the auditing of milk plant HACCP Systems offered by FDA is acceptable in meeting the training requirement.

Proposal: 215
Document: 2017 PMO
Pages: 359,360, 361, 362, 363, 364

Make the following changes to the 2017 PMO:

p.359

APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

I. INDUSTRY RESPONSIBILITIES

MONITORING AND SURVEILLANCE:

Industry shall screen all bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers regardless of final use, for Beta lactam drug residues. Additionally, other drug residues shall be tested for by employing a random sampling program on bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers raw milk supplies when the Commissioner of the FDA determines that a potential problem exists as cited in Section 6. of this *Ordinance*. The random bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers sampling and testing program shall represent and include, during any consecutive six (6) months, at least four (4) samples 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. Samples collected under this random sampling and testing program shall be analyzed as specified by FDA. (Refer to Section 6. of this *Ordinance*.)
The bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling. These bulk milk pickup tanker samples may be collected using an approved aseptic sampler. The sample shall be representative. Bulk milk pickup tanker testing shall be completed prior to processing the milk. ~~Bulk milk pickup tanker samples confirmed positive for drug residues using approved test methods and/or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required shall be retained as determined necessary by the Regulatory Agency.~~ Bulk milk pickup

tanker samples shall be confirmed positive for drug residues using approved test methods, as cited in M-a-85, latest revision, unless there are less than two approved test methods for detecting a particular drug or drug family. In this case, verified screening positive results using test methods not evaluated by FDA and accepted by the NCIMS** without additional confirmation required are acceptable. These samples shall be retained as determined necessary by the Regulatory Agency.

All raw milk supplies that have not been transported in bulk milk pickup tankers shall be sampled prior to processing the milk. The sample(s) shall be representative of each farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. Testing of all raw milk supplies that have not been transported in bulk milk pickup tankers shall be completed prior to processing the milk.

NOTE: On-farm producer/processors that plan to store or ship their raw sheep milk frozen, shall sample their raw sheep milk prior to freezing. The sample shall be obtained by a bulk milk hauler/sampler permitted by the Regulatory Agency where the dairy farm is located. The raw sheep milk sample shall then be tested in a certified laboratory or screening facility. If this is the on-farm producer/processor's only raw sheep milk supply, this testing would suffice for the required Appendix N. testing for all raw milk supplies that have not been transported in bulk milk pickup tankers, which are required to be completed prior to processing the milk. In the case of sheep milk dairy farms, the raw milk sample may be frozen in accordance with a sample protocol approved by the Regulatory Agency in which the dairy farm is located as specified in Appendix B. of this *Ordinance* and transported to a certified laboratory for testing. The test results, or raw milk samples, shall clearly distinguish the lot number of the frozen raw sheep milk and accompany the frozen raw sheep milk to the plant.
All presumptive positive test results for drug residues using approved test methods or verified screening positive test results using test methods not evaluated by FDA and accepted by the NCIMS** from analysis conducted on commingled raw milk tanks, bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers or farm raw milk tanks/silos (only milk offered for sale) samples shall be reported to the Regulatory Agency in which the testing was conducted. Bulk milk pickup tanker and/or all raw milk supplies that have not been transported in bulk milk pickup tankers samples confirmed positive for drug residues using approved test methods or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS** without additional confirmation required shall be retained or disposed of as determined by the Regulatory Agency.

All presumptive positive test results using approved test methods for drug residues on finished milk and/or milk products shall be reported to the Regulatory Agency in which the testing was conducted.

Industry plant samplers shall be evaluated according to the requirements specified in Section 6. and at the frequency addressed in Section 5. of this *Ordinance*.

REPORTING AND FARM TRACE BACK:

When a bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers is found to be presumptive positive for drug residues using approved test methods or verified screening positive for drug residues using test methods not evaluated by FDA

and accepted by the NCIMS**, the Regulatory Agency in which the testing was conducted, shall be immediately notified of the results and the ultimate disposition of the raw milk.

The producer samples from the bulk milk pickup tanker, found to be confirmed positive for drug residues using approved test methods or verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS** without additional confirmation required shall be individually tested to determine the farm of origin. The samples shall be tested as directed by the Regulatory Agency.

When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc., is (are) used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, is (are) found to be confirmed positive for drug residues using approved test methods or verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS** without additional confirmation required the farm of origin of the drug residue has consequently already been determined and further testing is not required to determine the farm of origin.

Upon official notification to the Regulatory Agency and milk producer of a violative individual producer's milk, further farm pickups by bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and/or farm use of the violative individual producer's milk shall be immediately discontinued, until such time, that subsequent tests, using the same or equivalent (M-I-96-10, latest revision) test method as used when the producer was initially found to be violative and are no longer positive for drug residues.

NOTE: Further farm pickups refer to milk still in farm bulk milk tank(s) and/or silo(s) or milk that is in the process of being loaded onto a bulk milk pickup tanker.

RECORD REQUIREMENTS:

Results of all testing may be recorded in any format acceptable to the Regulatory Agency that includes at least the following information:

1. Identity of the person doing the test;

2. Identity of the bulk milk pickup tanker or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. used for the storage of all raw milk supplies that have not been transported in bulk milk pickup tankers being tested*;

3. Date/time the test was performed (Time, Day, Month and Year);
4. Identity of the test performed/lot #/any and all controls (+/-);
5. Results of the test;
6. Follow-up testing if the initial test was positive/any and all controls (+/-);
7. Site where test was performed, and
8. Prior test documentation shall be provided for a presumptive positive load using approved test methods or a verified screening positive load using test methods not evaluated by FDA and accepted by the NCIMS.

***** Include the BTU number(s) of the dairy farms present on the bulk milk pickup tanker and/ or all raw milk supplies that have not been transported in bulk milk pickup tankers with the above information.
Records of all sample test results shall be maintained for a minimum of six (6) months by the industry at the location where the test methods were run, and/or another location as directed by the Regulatory Agency and as agreed to by industry. For the laboratory survey, two (2) years of records shall be available at the facility at the time of the survey.

** One (1) year after two (2) test methods are found acceptable by FDA and the NCIMS for detecting a particular drug or drug family, other than Beta lactams, as cited in M-a-85, latest revision, Option one (1) or two (2) in Section VI of this Appendix shall be used for confirmation.

II. REGULATORY AGENCY RESPONSIBILITIES

Upon receipt of notification from industry of a bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers which contains milk from another Regulatory Agency's jurisdiction, is found to be presumptive positive for drug residues using approved test methods or verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS******, it is the responsibility of the receiving Regulatory Agency to notify the Regulatory Agency(ies) from which the milk originated.

MONITORING AND SURVEILLANCE:

Regulatory Agencies shall monitor industry surveillance activities during either routine or unannounced, on-site quarterly inspections to collect samples from bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers and to review industry records of their sampling program. Samples should be collected and analyzed from at least ten percent (10%) of the bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers scheduled to arrive on the day of the inspection. The test method used shall be appropriate for the drug being analyzed and shall be capable of detecting the same drugs at the same concentrations as the test method being used by industry. Alternately, the Regulatory Agency or Laboratory Evaluation Officer (LEO) may take known samples with them on the audit visit and observe the Industry Analyst (IA) test the samples. Receiving locations that choose to certify all receiving IAs, certified under the provisions of the NCIMS Laboratory Certification Program, are exempt from the sample collection requirements of this Section. Receiving locations where all approved receiving IAs and Industry Supervisors (ISs) successfully participate in a biennial on-site evaluation and annual spilt sample comparisons by LEOs are also exempt from the sample collection requirements of this Section.

A review shall include, but not be limited to, the following:

1. Is the program an appropriate routine monitoring program for the detection of drug residues?
2. Is the program utilizing appropriate test methods?
3. Is each producer's milk represented in a testing program for drug residues and tested at the frequency prescribed in Section I. of this Appendix for drug residues?

4. Is the program assuring timely notification to the appropriate Regulatory Agency of positive results, the ultimate disposition of the bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers and of the trace back to the farm of origin?
5. Is the dairy farm pickup and/or use of the violative individual producer's milk suspended until subsequent testing, using the same or equivalent (M-I-96-10, latest revision) test method as used when the producer was initially found to be violative, establishes the milk is no longer positive for drug residues?

To satisfy these requirements:

a. There shall be a documented agreement between the Regulatory Agency and industry that specifies how this notification is to take place. This notification shall be "timely" for example by telephone or fax and supported in writing.

b. The ultimate disposition should either be prearranged in a documented agreement between the Regulatory Agency and the industry, or physically supervised by the Regulatory Agency. The milk should be disposed of in accordance with provisions of M-I-06-5 or an FDA and Regulatory Agency reviewed and accepted specified drug residue milk diversion protocol for use as animal feed.

c. All screening test positive (confirmed) loads using an approved test method shall be broken down (producer trace back) using the same or an equivalent test method (M-I-96-10, latest revision). Confirmation tests (load and producer trace back/permit enforcement action) shall be performed by an Official Laboratory, Officially Designated Laboratory or Certified Industry Supervisor (CIS). Positive producers shall be handled in accordance with this Appendix.

d. All verified screening test positive loads using test methods not evaluated by FDA and accepted by the NCIMS** without additional confirmation required shall be broken down (producer trace back) using the same test method. Producer trace back shall be performed as cited in a prior documented agreement with the Regulatory Agency. (Refer to Section VI. of this Appendix.) Verified screening positive producers shall be handled in accordance with this Appendix.

e. When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is (are) used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, is (are) found to be confirmed positive for drug residues using approved test methods, the farm of origin of the drug residue has consequently already been determined and further testing is not required to determine the farm of origin. Confirmation tests shall be performed by an Official Laboratory, Officially Designated Laboratory or CIS. Positive producers shall be handled in accordance with this Appendix.

f. When a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. is (are) used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers, is (are) found to be verified screening positive for drug residues using test methods not evaluated by FDA and accepted by the NCIMS** without additional confirmation required the farm of origin of the drug residue has consequently already been determined and further testing is not required to determine the farm of origin. Producer trace back shall be performed as cited in a prior documented agreement with the Regulatory Agency. (Refer to Section VI. of this Appendix.) Verified screening positive producers shall be handled in accordance with this Appendix.

g. The suspension and discontinuance of farm bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers is the responsibility of the industry, under the direction and supervision of the Regulatory Agency. At the discretion of the Regulatory Agency, records shall be maintained by industry and/or the Regulatory Agency that:

(1) Establish the identity of the producer for raw milk supplies that have not been transported in bulk milk pickup tankers that tested positive or the producer and the identity of the load that tested positive; and

(2) Establish that milk is not picked up or used from the drug residue positive producer until the Regulatory Agency has fulfilled their obligations under Section II. of this Appendix, as applicable, based on ~~the test method utilized~~ using the same or equivalent (M-I-96-10, latest revision**)** test method as used when the producer was initially found to be violative and has cleared the milk for pick up and/or use.

Sufficient records shall be reviewed to assure that all bulk milk pickup tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers are sampled before additional commingling at the milk receiving facility and the results were made available to the appropriate BTU(s).

The Regulatory Agency shall also perform routine sampling and testing for drug residues determined to be necessary as outlined in Section 6. of this *Ordinance*.

ENFORCEMENT:

If testing reveals milk positive for drug residues, the milk shall be disposed of in a manner that removes it from the human or animal food chain, except where acceptably reconditioned under FDA Compliance Policy Guide (CPG 7126.20). The Regulatory Agency shall determine the producer(s) responsible for the violation.

Permit Suspension and the Prevention of the Sale of Milk: Any time milk is found to test as a confirmed positive using an approved test method, the Regulatory Agency shall immediately suspend the producer's Grade "A" permit or equally effective measures shall be taken to prevent the sale of milk containing drug residues. Upon official notification to the Regulatory Agency and milk producer of a confirmed positive, future farm pickups by bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and/or farm use of the violative individual producer's milk are prohibited until subsequent testing, using the same or equivalent (M-I-96-10, latest revision) test method as used when the producer was initially found to be violative, reveals the milk is free of drug residue. Any bulk milk pickup tanker(s) previously received at a milk plant, receiving station, or transfer station, or is in-transit prior to the official notification to the Regulatory Agency and milk producer, shall not be deemed violative provided the bulk milk pickup tanker(s) tests negative in accordance with this Appendix.

NOTE: Further farm pickups refer to milk still in farm bulk milk tank(s) and/or silo(s) or milk that is in the process of being loaded onto a bulk milk pickup tanker.

Prevention of the Sale of Milk: Any time milk is found to test as a verified screening positive for a drug residue using test methods not evaluated by FDA and accepted by the NCIMS** without

additional confirmation required the Regulatory Agency shall immediately take effective measures to prevent the sale of the milk containing drug residues.

Penalties for Confirmed Positive Milk: The penalty shall be for the value of all milk on the contaminated load and/or raw milk supply that has not been transported in bulk milk pickup tankers plus any costs associated with the disposition of the contaminated load or raw milk supply that has not been transported in bulk milk pickup tankers. The Regulatory Agency may accept certification from the violative producer's milk marketing cooperative or purchaser of milk as satisfying the penalty requirements.

Reinstatement: When the permit has been suspended as required, the Grade "A" producer's permit may be reinstated, or other action taken, to allow the sale of milk for human food, when a representative sample taken from the producer's milk, prior to commingling with any other milk, is no longer positive for drug residue~~.~~ using the same or equivalent (M-I-96-10, latest revision) test method as used when the producer was initially found to be violative.

Follow-Up: Whenever a drug residue test is confirmed positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS**, an investigation shall be made to determine the cause. The farm inspection is completed by the Regulatory Agency or its agent to determine the cause of the residue and actions taken to prevent future violations including:

1. On-farm changes in procedures necessary to prevent future occurrences as recommended by the Regulatory Agency.
2. Discussion and education on the Drug Residue Avoidance Control measures outlined in Appendix C. of this *Ordinance.*

Permit Revocation: After a third violation for a drug residue using approved test methods in a twelve (12) month period, the Regulatory Agency shall initiate administrative procedures pursuant to the revocation of the producer's Grade "A" permit under the authority of Section 3. of this *Ordinance*, due to repeated violations.

REGULATORY AGENCY RECORDS:

In regard to the industry reporting a confirmed positive using an approved test method or verified screening positive using test methods not evaluated by FDA and accepted by the NCIMS** tanker and/or a raw milk supply that has not been transported in bulk milk pickup tankers result, the Regulatory Agency's records shall indicate the following:

1. What were the Regulatory Agency's directions?
2. When was the Regulatory Agency notified? By whom?
3. What was the identity of the load or farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. when used for a milk plant's raw milk supply(ies) that has (have) not been transported in bulk milk pickup tankers?
4. What screening and/or confirmatory test method(s) were used and who were the analyst(s)?
5. What was the disposition of the adulterated milk?
6. Which producer(s) was responsible?

7. Record of negative test results, using the same or equivalent (M-I-96-10, latest revision) test method as used when the producer was initially found to be violative, prior to subsequent milk pickup from the violative producer(s).

** One (1) year after two (2) test methods are found acceptable by FDA and the NCIMS for detecting a particular drug or drug family, other than Beta lactams, as cited in M-a-85, latest revision, Option one (1) or two (2) in Section VI of this Appendix shall be used for confirmation.

Document: 2017 METHODS
Pages: 7

Make the following changes to the 2017 MMSR:

Page 7

B. RATING METHODS FOR RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING

1. DRUG RESIDUE COMPLIANCE - PROCEDURE FOR DETERMINING BTU OR ATTACHED SUPPLY COMPLIANCE WITH APPENDIX N. OF THE GRADE "A" PMO

During an Interstate Milk Shippers' (IMS) rating or check rating, it is necessary to determine compliance of the BTU or attached supply with the requirements of Appendix N. of the *Grade "A" PMO*. The following criteria are to be used in making that determination. If the BTU or attached supply is not in substantial compliance, a rating or check rating is not to be completed and the Rating Agency shall immediately withdraw the IMS certification.

a. Record Review

Determine from records that are stored in a manner acceptable to the Rating Agency that all milk pick-up tankers are screened daily, prior to processing, for *Beta lactams* with an approved test method. As necessary, determine that all dairy farms are randomly tested four (4) times in any consecutive six (6) months for other drug residues, if directed by Section 6. of the *Grade "A" PMO*.

Compliance with the above Item would be satisfied in the following manner:

1.) Records indicating that milk was always shipped to an IMS listed shipper shall suffice for actual test results.
2.) If milk is shipped to a non-listed milk plant, receiving station and/or transfer station, records indicating actual testing shall be provided or available for review. When the Regulatory Agency has determined adequate documentation for compliance with this Section exists, the Rating Agency may accept this documentation. SROs may at their discretion request records on the testing of loads of milk that are sent to non-listed milk plants, receiving stations and/or transfer

stations. If records are requested, the SRO should choose and request to review records for no more than fifteen (15) days, unless these selected records show a problem.

b. Regulatory Notification and Disposition

If a load sample or individual dairy farm sample is positive for a drug residue, determine if the Regulatory Agency was immediately notified, including the method of proper disposition to keep the contaminated milk out of the food chain.

c. Reinstatement

Determine if the violative dairy farm was not allowed to ship milk until the milk no longer tested positive, using the same or equivalent (M-I-96-10, latest revision) test method as used when the producer was initially found to be violative for drug residues.

Proposal: 216
Document: 2017 PMO
Pages: 362, 363

Make the following changes to the 2017 PMO:

Appendix N., page 362.

To satisfy these requirements:

a. There shall be a documented agreement between the Regulatory Agency and industry that specifies how this notification is to take place. This notification shall be "timely" for example by telephone or fax and supported in writing.

b. The ultimate disposition should either be prearranged in a documented agreement between the Regulatory Agency and the industry, or physically supervised by the Regulatory Agency. ~~The milk should be disposed of in accordance with the provisions of FDA Compliance Policy Guide (CPG 7126.20 675.200 "Diversion of Adulterated Food to Acceptable Animal Feed Use" current revision) of M-I-06-5 or an FDA and Regulatory Agency reviewed and accepted specified drug residue milk diversion protocol for use as animal feed.~~

Appendix N., page 363.

ENFORCEMENT:

If testing reveals milk positive for drug residues, the milk shall be disposed of in a manner that removes it from the human or animal food chain, except where acceptably reconditioned under FDA Compliance Policy Guide (CPG ~~7126.20~~ 675.200 "Diversion of Adulterated Food to Acceptable Animal Feed Use" current revision). The Regulatory Agency shall determine the producer(s) responsible for the violation.

Proposal: 304
Document: 2017 PROCEDURES
Pages: v, 10, 38, 65, 74

Make the following changes to the 2017 PROCEDURES:

2017 PROCEDURES

ABBREVIATIONS AND ACRONYMS

Page v:

SAP (Strategic Action Plan)
SCC (Somatic Cell Count) …

SECTION IV. OVERSIGHT AND RESPONSIBILITIES

A. **PHS/FDA RESPONSIBILITIES** …

B.) Milk Hauling and Transportation:

1.) The issuing of milk tank truck permits,
2.) Milk tank truck inspection (adequacy and frequency),
3.) Actions taken against those milk tank trucks or milk transportation companies not in compliance,
4.) Forwarding results of milk tank truck inspections, performed on milk tank trucks permitted by another Regulatory Agency, to that Regulatory Agency in a timely manner,
5.) Follow-up actions taken when a violative milk tank truck inspection report is received from another Regulatory Agency regarding a milk tank truck permitted by this Regulatory Agency,
6.) Inspection, enforcement and permitting program for unattached milk tank truck cleaning facilities, and
7.) Adequacy of associated records.

7.) The Minimum State Program Evaluation Requirements and Criteria cited in M-I-03-12 (Supplement 1) shall be used to determine if a Regulatory/Rating Agency Program is "in compliance" or "not in compliance" with the requirements of the *Grade "A" PMO* and *Procedures*.

1.) The Regulatory/Rating Agency Program shall be determined to be "in compliance" if:

A.) There are not any public health weaknesses identified that could realistically lead to a potential health hazard; and

B.) There has not been a departure from FDA and the NCIMS program requirements as indicated by:

1.) None of the Minimum State Program Evaluation Requirements and Criteria cited in M-I-03-12 (Supplement 1) that automatically trigger a Strategic Action Plan (SAP) to be jointly developed by FDA and the State or TPC, respectively, if the percent Compliance falls below the identified level are identified; and
2.) The identification of other program requirements not meeting the minimum criteria do not indicate the development and implementation of a SAP.

2.) The Regulatory/Rating Agency Program shall be determined to be "not in compliance" if:

A.) There is a public health weakness(es) identified that could realistically lead to a potential health hazard; and
B.) There is a departure from FDA and the NCIMS program requirements as indicated by:

1.) One (1) or more of the Minimum State Program Evaluation Requirements and Criteria cited in M-I-03-12 (Supplement 1) that automatically trigger a Strategic Action Plan (SAP) to be jointly developed by FDA and the State or TPC, respectively, if the percent Compliance falls below the identified level is/are identified; and
a.2.) The identification of other program requirements not meeting the minimum criteria indicate the development and implementation of a SAP.

b. Any State or TPC in "substantial non-compliance" as determined by PHS/FDA shall be referred to the NCIMS Executive Board for determination of listing on a separate page on the *IMS List*. The State or TPC, upon notification of PHS/FDA and the NCIMS Executive Board shall have an opportunity to address the NCIMS Executive Board to explain why they believe they should not be so listed. If such listing is required, annual evaluations shall be conducted until substantial compliance, as determined by PHS/FDA, is achieved. Any State or TPC "not in substantial compliance" a second consecutive year shall be notified by PHS/FDA and provided an opportunity for a hearing by the NCIMS Executive Board. The NCIMS Executive Board, as a result of the hearing, may determine that the State or TPC shall not be an active participant in future NCIMS Conferences until substantial compliance is achieved.

c. If the next triennial written program evaluation meets the criteria cited in b.~~2.)~~ above, the Regulatory/Rating Agency Program shall be determined "in substantial non-compliance" with the requirements of the *Grade "A" PMO* and *Procedures*.

d. If two (2) consecutive triennial written Regulatory/Rating Agency Program evaluations are conducted and completed/issued within the established required time frames for the reports and both are classified as being "in compliance" with the requirements of the *Grade "A" PMO* and *Procedures*, the PHS FDA Milk Specialist and/or PHS/FDA MST personnel

for TPCs shall inform the State or TPC, respectively, of their option to have their Regulatory/Rating Agency Program evaluation conducted every five (5) years instead of every three (3) years. If the State or TPC elects to have this five (5) year option that shall be documented in writing to their appropriate PHS/FDA Milk Specialist or PHS/FDA MST for TPCs.

4. Laboratory Evaluations ….

Page 38:

SECTION VII. PROCEDURES GOVERNING A STATE's OR THIRD OR THIRD-PARTY CERTIFIER's PARTICIPATION IN THE COOPERATIVE PROGRAM FOR THE CERTIFICATION OF IMS LISTED SHIPPERS

REGULATORY/RATING AGENCY PROGRAM EVALUATIONS

A. PHS/FDA shall evaluate the inspection, supervisory, and rating work of Regulatory and Rating Agencies triennially to determine whether milk regulations are being interpreted and enforced in accordance with the provisions of the *Grade "A" PMO*. (Refer to Section IV., A., 3.)

B. Any State or TPC in "substantial non-compliance" as determined by PHS/FDA shall be referred to the NCIMS Executive Board for determination of listing on a separate page ~~in~~ on the *IMS List*. The State or TPC upon notification of PHS/FDA and the NCIMS Executive Board shall have an opportunity to address the NCIMS Executive Board to explain why they believe they shall not be so listed. If such listing is required, annual evaluations shall be conducted until substantial compliance as determined by PHS/FDA is achieved. Any State or TPC "not in substantial compliance" a second consecutive year shall be notified by PHS/FDA and provided an opportunity for a hearing by the NCIMS Executive Board. The NCIMS Executive Board, as a result of the hearing, may determine that the State or TPC shall not be an active participant in future NCIMS Conferences until substantial compliance is achieved.

SECTION VIII. PROCEDURS GOVERNING THE CERTIFICATION OF MILK PLANT, RECEIVING STATION AND TRANSFER STATION NCIMS HACCP SYSTEMS FOR IMS LISTED SHIPPERS…

SECTION IX. PROCEDURES GOVERNING THE NCIMS VOLUNTARY INTERNATIONAL CERTIFICATION PROGRAM …

E. COMPLIANCE WITH THE NCIMS VOLUNTARY INTERNATIONAL CERTIFICATION PROGRAM

1. Third Party Certifier (TPC) …

Reasons for the removal of a TPC from the NCIMS voluntary ICP and subsequent withdrawal of MCs and certified laboratories from the *IMS List* include, but are not limited to, the following: …

Page 65:

c. When there is evidence, found during PHS/FDA check ratings or a triennial Regulatory/Rating Agency Program Evaluation, that the TPC is in "substantial non-compliance" with the applicable requirements set forth in the documents of the NCIMS Grade "A" Milk Safety Program, the TPC shall be referred to the NCIMS Executive Board in accordance with Section IV, A. 3.~~b~~d. of this document. The TPC and MC(s) listed by the TPC can be subject to withdrawal by PHS/FDA MST and/or LPET from the *IMS List*. …

APPENDIX A. OFFICIAL AGREEMENTS UTILIZED IN THE NCIMS VOLUNTARY INTERNATIONAL CERTIFICATION PROGRAM …

MEMORANDUM OF AGREEMENT (MOA) …

3.) **Term of the Memorandum Of Agreement (MOA)** …

Page 74:

d. When there is evidence, found during PHS/FDA check ratings or a triennial Regulatory/Rating Agency Program Evaluation, that the TPC is in "substantial non-compliance" with the applicable requirements set forth in the documents of the NCIMS Grade "A" Milk Safety Program, the TPC shall be referred to the NCIMS Executive Board in accordance with Section IV, A. 3.~~b~~d. of the *Procedures*. The TPC and MC(s) listed by the TPC can be subject to withdrawal by PHS/FDA MST and/or LPET from the *IMS List.* …

Document: 2017 BYLAWS OF THE NCIMS
Pages: 84

Make the following changes to the 2017 BYLAWS OF THE NATIONAL CONFERENCE ON ITERSTATE MILK SHIPMENTS:

BYLAWS OF THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS

ARTICLE I ------ DUTIES OF THE BOARD …

Page 84:

SECTION 14. The Board shall, after written notification of PHS/FDA recommendations, within 120 days, rule on the matter of "substantial non-compliance" with

Regulatory/Rating Agency Program Evaluations, including Regulatory, Rating and Laboratory as required by Section IV., A. 3.~~b~~d. and VII., B. of the *Procedures*.

Proposal: 303
Document: 2017 PROCEDURES
Pages: 12 & 13

Make the following changes to the 2017 PROCEDURES:

Procedure for Issuing Interpretations of the *Grade "A" PMO* and Related Documents (M-a's)

1. PHS/FDA is requested or determines the necessity to issue an M-a.
2. PHS/FDA develops the draft M-a, with a proposed implementation date, after seeking input from appropriate sources.
3. PHS/FDA disseminates the draft M-a to all Regulatory and Rating Agencies and the Executive Board with provisions for a thirty (30) day written comment period from the date of dissemination. The date the draft M-a was actually distributed by PHS/FDA to all Regulatory and Rating Agencies and the Executive Board shall be the date of dissemination from which all timelines are calculated. When calculating the timelines, the date of dissemination is not counted as one (1) of the days.
4. All comments shall be submitted to the Executive Secretary, NCIMS Executive Board.
5. The Executive Secretary shall forward comments to PHS/FDA MST and the Executive Board within fifteen (15) days of the end of the comment period.
6. The NCIMS Executive Board may, within seventy-five (75) days of the dissemination of the draft M-a, with the majority of the Board consenting, request PHS/FDA to consider modifying the draft M-a as provided by the Board.
7. Within one hundred and five (105) days of the dissemination of the draft M-a, PHS/FDA shall provide to the NCIMS Executive Secretary sufficient copies of each draft M-a for submission to the NCIMS voting delegates for their approval or disapproval. After receipt from PHS/FDA of the draft M-a, the NCIMS Executive Secretary shall forward within fifteen (15) days a copy of the draft M-a to the current NCIMS voting delegates, along with a ballot and instructions for returning their vote. The Executive Secretary shall include a copy of the comments and the minutes covering the discussion between PHS/FDA and the Executive Board. All ballots shall contain a date fifteen (15) days from the date the ballot was mailed or sent (if by other means) by which time, the ballot shall be received by the NCIMS Executive Secretary to be counted.
8. The NCIMS Executive Secretary may use any available method for delivering copies of each draft M-a and the voting ballots including, but not limited to: (i) the mail; (ii) private carriers; (iii) facsimile; (iv) email; or (v) other electronic means. The Executive Secretary has fifteen (15) days from the end of the voting period to forward the results (votes per State) to PHS/FDA.
9. An M-a shall not become effective unless it receives the approval from a simple majority of the returned ballots of the NCIMS voting delegates.

10. PHS/FDA shall, at the next duly convened Conference, submit a Proposal, incorporating the requirements of any M-a, issued between Conferences, into the appropriate document(s).

NOTE: In the event of a public health emergency, PHS/FDA shall exercise its authority to protect the public health under the provisions of the *FFD&CA* and the Public Health Service Act. Federal regulations that impact the regulation of the Grade "A" dairy industry are not subject to this "Procedure for Issuing Interpretations".

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 developed jointly by PHS/FDA and the NCIMS Executive Board.

Procedure for Issuing Memorandums of Information (M-I's) Related to Answers to Questions Received from the Field (Milk Seminars, FDA Training Courses, Workshops, etc.)

1. PHS/FDA develops the draft M-I, with proposed answers to questions that were received from the field (milk seminars, FDA training courses, workshops, etc.).
2. PHS/FDA will provide the draft M-I to the NCIMS Document Review Committee for review.
3. The NCIMS Document Review Committee will provide comments to PHS/FDA within forty-five (45) days of receiving the draft M-I.
4. Within forty-five (45) days PHS/FDA will provide responses to all comments received from the NCIMS Documents Review Committee.
5. The NCIMS Documents Review Committee and PHS/FDA will have thirty (30) days to mutually resolve outstanding issues/concerns.
6. If an issue/concern is not resolved and/or the NCIMS Documents Review Committee identifies a specific question and answer that the committee has determined goes beyond providing guidance/information on what FDA's current thinking is on a specific subject/scenario/situation and has been determined to be more interpretive in nature, then the specific question and answer will be removed from the draft M-I.
7. PHS/FDA will finalize the mutually agreed upon M-I and distribute the memorandum to the NCIMS Executive Board, FDA Milk Specialists, Regulatory/Rating Agencies, Laboratory Evaluation Officers and Milk Sanitation Rating Officers.

Proposal: 305
Document: 2017 PROCEDURES
Pages: 15

Make the following changes to the 2017 PROCEDURES:

B. STATE, TPC, AND SSC RESPONSIBILITIES

1. Ratings of Milk Shippers and Single-Service Containers and/or Closures Manufacturer Certification Listings …

Page 15

d. When a certified interstate milk shipper's supply, raw or pasteurized, changes status because of degrading, permit revocation, ~~significant change in the number of dairy farms,~~ or change in the Sanitation Compliance or Enforcement Rating to less than ninety percent (90%), the shipping State or TPC shall immediately notify in writing all known receiving States and/or TPCs and the appropriate PHS/FDA Milk Specialist or PHS/FDA MST for TPCs.

Proposal: 205
Document: 2017 PROCEDURES
Pages: 27 and 29

Make the following changes to the 2017 PROCEDURES:

Modify the 2017 Procedures Manual Section V. Qualifications and Certifications. Page 27

6. Recertification: A certified SSO shall continue to hold a valid certificate of qualification as a SRO, LEO, or in the case of a State or TPC Regulatory Supervisor, hold a valid certificate as a SSO. The SSO shall be recertified once each three (3) years which includes the remaining days of the month in which the certification expires, by PHS/FDA personnel in an independent side-by-side comparison of sampling procedure observations using the items listed on the appropriate inspection or evaluation report form. The SSO and PHS/FDA personnel shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed on at least the following number of bulk milk hauler/samplers and/or plant samplers, applicable to the category for which the SSO is being recertified, at dairy facilities:

Modify the 2017 Procedures Manual Section V. Qualifications and Certifications. Page 29
c. Recertification: A certified dSSO shall be recertified once each three (3) years which includes the remaining days of the month in which the certification expires, by a PHS/FDA certified SSO in an independent side-by-side comparison of sampling procedure observations using the items listed on the appropriate inspection or evaluation report form. The dSSO and SSO shall be in agreement at least eighty percent (80%) of the time on each listed item. Comparison evaluations shall be performed on at least the following number of bulk milk hauler/samplers and/or plant samplers, applicable to the category for which the dSSO is being recertified, at dairy facilities:

Proposal: 307
Document: 2017 PROCEDURES
Pages: 85

Make the following changes to the 2017 PROCEDURES:

Modify the 2017 Procedures, page 85, Article II---Duties of the Chair, Section 3

SECTION 3. The Chair, with the approval of the Board, shall appoint qualified Conference registrants to Standing Committees, including the Appendix N. Modification Committee, Constitution and Bylaws, Documents Review Committee, HACCP Implementation Committee, Laboratory, Methods of Making Sanitation Ratings, Liaison, Single-Service Container and Closure, Technical Engineering Review, Scientific Advisory, Hauling Procedures, Other Species and International Certification Program Committees, and Councils as is necessary to carry out the mission of the Conference. From among the members of each Standing Committee, the Conference Chair, with the approval of the Board, shall appoint a Committee Chair and Committee Vice-Chair as outlined in Article IV, Section 13, of the *Constitution*.

Proposal: 223
Document: 2017 EML
Pages: 6, 7, 8, 9, 10, 11, 17, 20, 21, & 22

Make the following changes to the 2017 EML:

Page 6:

SECTION 2: LABORATORY EVALUATION PROGRAMS

Reports of on-site surveys of Official Milk Laboratories and CIS facilities shall be sent within sixty (60) days of the initial, biennial/triennial anniversary or supplemental date of the laboratory ~~evaluation~~ survey to the Official Milk Laboratory/CIS facility, the appropriate FDA ~~Regional Office~~ Milk Specialist responsible for the state in which the laboratory/facility resides and the FDA/LPET. Reports to the Official Milk Laboratories/CIS facilities shall include the narrative report and may include copies of the completed FDA/NCIMS 2400 Forms. Reports to the appropriate FDA ~~Regional Office~~ Milk Specialist shall be sent electronically and shall include the narrative report only. Reports to the FDA/LPET shall be sent electronically and shall include the narrative report and completed FDA Summary Template only (see pages 48 – 49).

Pages 6 & 7:

CERTIFICATION/APPROVAL OF MILK LABORATORY ANALYSTS

Certification of milk laboratory analysts by the FDA/LPET or LEO shall be based on the following criteria:

1. Evaluations of State Central Milk Laboratories shall be scheduled and performed by their triennial expiration date. The on-site survey may be conducted up to 60 days prior to the triennial expiration date. State central milk laboratories shall submit requests, ...

2. Evaluations of other milk laboratories within a state shall be scheduled and performed by their biennial expiration date. The on-site survey may be conducted up to 60 days prior to the biennial expiration date. Milk laboratories within a state shall submit requests, ...

Page 8:

Copies of notices of changes of certification or revocation of certification shall be sent to the laboratory or facility involved, the Regulatory Agency, the Rating Agency, the appropriate FDA ~~Regional Office~~ Milk Specialist responsible for the state in which the laboratory/facility resides and the FDA/LPET. For FDA/LPET notification, changes in certification shall be indicated on the completed FDA summary template and shall be submitted electronically.

Page 9:

When a certified analyst or CIS leaves an accredited laboratory, the laboratory/facility manager shall notify the FDA/LPET or LEO immediately since the loss of a certified analyst may result in the loss of certification for one or more procedures, or may result in the loss of the laboratory's/facility's accreditation. For example, a laboratory having only one certified analyst or CIS shall lose accreditation. Official examinations cannot be conducted at non-accredited laboratories/facilities. When a laboratory or CIS facility loses its accreditation because of lack of certified analysts or CISs, or for some other reason, the FDA/LPET or LEO shall immediately notify the milk laboratory involved, the Milk Control Agency, the respective Regulatory/Rating Agency, any other Regulatory/Rating Agencies that oversees locations where known customers of that laboratory are located, the appropriate FDA ~~Regional Office~~ Milk Specialist responsible for the state in which the laboratory/facility resides and the FDA/LPET, by a letter of notification to be dated within five (5) working days of the loss of accreditation. For any FDA/LPET notification, changes in accreditation shall be indicated on the completed FDA summary template and shall be submitted electronically.

Laboratories requesting withdrawal of accreditation shall notify the LEO in writing. Upon receipt of the written request, the LEO shall immediately notify the respective Regulatory/Rating Agency, any other Regulatory/Rating Agencies that oversees locations where known customers of that laboratory are located, the appropriate FDA ~~Regional Office~~ Milk Specialist responsible for the state in which the laboratory/facility resides and the FDA/LPET by a letter of notification to be dated within five (5) working days of receipt of the written request. Upon notice of withdrawal of accreditation, the certificate, if issued, shall be returned to the issuing State LEO within ninety (90) days. For FDA/LPET notification, changes in accreditation shall be indicated on the completed FDA summary template and shall be submitted electronically.

State Central Milk Laboratories requesting withdrawal of accreditation shall notify the FDA/LPET in writing and shall notify the appropriate FDA ~~Regional Office~~ Milk Specialist responsible for the state in which the laboratory/facility resides in writing within five (5) working days of FDA/LPET's receipt of the written request.

Pages 10 & 11:

When a screening facility loses its approval because of the lack of approved ISs or IAs, or for some other reason, the LEO shall immediately notify the screening facility involved, the respective Regulatory/Rating Agency, any other Regulatory/Rating Agencies that oversees locations where known customers of that laboratory are located, the appropriate FDA ~~Regional Office~~ Milk Specialist responsible for the state in which the facility resides and the FDA/LPET, by a letter of notification to be dated within five (5) working days of receipt of the loss of approval. For FDA/LPET notification, changes in approval shall be indicated on the completed FDA summary template and shall be submitted by email.

Screening facilities requesting withdrawal of approval shall notify the LEO in writing. Upon receipt of the written request, the LEO shall immediately notify the Milk Control Agency, the respective Regulatory/Rating Agency, other Regulatory/Rating Agencies that oversees locations where known customers of that laboratory are located, the appropriate FDA ~~Regional Office~~ Milk Specialist responsible for the state in which the laboratory/facility resides and the FDA/LPET by a letter of notification to be dated within five (5) working days of receipt of the written request. For FDA/LPET notification, changes in approval shall be indicated on the completed FDA summary template and shall be submitted by email.

Page 17:

Copies of the proficiency testing report, including tabulation of analyst results, shall be sent within four (4) months of the split sample examination date to the participating laboratory, the appropriate FDA ~~Regional Office~~ Milk Specialist responsible for the state in which the laboratory/facility resides, and the FDA/LPET.

Page 20:

Copies of the PT report, including tabulation of laboratory results, shall be sent within four (4) months of the split sample examination date to the participating laboratory, the appropriate FDA ~~Regional Office~~ Milk Specialist responsible for the state in which the laboratory/facility resides, and the FDA/LPET.

Page 21:

2. The individual shall submit an acceptable written report(s) of the milk laboratory initial check on-site survey(s) to the FDA/LPET within sixty (60) days of the evaluation. Reports to the appropriate FDA ~~Regional Office~~ Milk Specialist responsible for the state in which the laboratory/facility resides shall be sent electronically and shall include the narrative report only. Reports to the FDA/LPET shall be sent electronically and shall include the narrative report and completed FDA Summary Template only (see pages 48 – 49).

Page 22:

2. The individual shall submit an acceptable written report(s) of the milk laboratory check on-site survey(s) to the FDA/LPET within sixty (60) days of the survey(s). Reports to the appropriate

FDA ~~Regional Office~~ Milk Specialist responsible for the state in which the laboratory/facility resides shall be sent electronically and shall include the narrative report only. Reports to the FDA/LPET shall be sent electronically and shall include the narrative report and completed FDA Summary Template only (see pages 48 – 49).

7. The individual shall not fail, without cause, to attend an FDA ~~Regional~~ Milk Seminar once within their three (3) year certification period. ~~If a region holds an FDA Regional Milk Seminar, then LEOs in that region are obligated to attend. If another region holds their milk seminar in the same year, the LEO may opt to attend that regional milk seminar in lieu of attending the seminar held in their region and still meet the requirement.~~

Proposal: 306
Document: 2017 PROCEDURES
Pages: 29

Make the following changes to the 2017 PROCEDURES:

H. **MILK LABORATORY EVALUATION PERSONNEL**

Milk laboratory evaluations may be made upon the request of that State's or TPC's Regulatory Agency and shall be made by certified LEOs who:

1. Have been certified and approved by PHS/FDA as a LEO per the requirements and criteria listed in the most recent edition of the *EML*. (Refer to Section 4 of the *EML*)
2. Holds a valid certificate or provisional endorsement of qualification.
3. Shall not fail, without cause, to attend once within their three (3) year period of certification, the PHS/FDA Milk Seminar~~, when offered~~, and, in addition, attend at least one (1) Milk Laboratory Evaluation Officer's Workshop or other training courses judged by PHS/FDA LPET to be equivalent.

Proposal: 228
Document: FDA/NCIMS 2400 FORMS

Make the following changes to the FDA/NCIMS 2400 FORM:

As listed on M-a-98 Table 4. Modified Colitag should be included under the Presence/Absence methods for Coliform detection. In addition, Modified Colitag should be included in the 2400m Dairy Waters form.

Proposal: 229
Document: FDA/NCIMS 2400 FORMS

Make the following changes to the FDA/NCIMS 2400 FORM:

As listed on M-a-98 Table 4. Modified Colitag should be included under the MPN methods for Coliform detection. In addition, Modified Colitag should be included in the 2400m Dairy Waters form.

Proposal: 230
Document: FDA/NCIMS 2400 FORMS

Make the following changes to the FDA/NCIMS 2400 FORM:

Modify FORM FDA/NCIMS 2400l Disintegration Methods, Part – PLATING, Item 14a.

14. Controls – For Each Group of Samples (See SPC item 6)
a. Check sterility of agars, Petri dishes, dilution buffer ~~and swabs~~ , forceps and pipets.

Proposal: 234
Document: FDA/NCIMS 2400 FORMS

Make the following changes to the FDA/NCIMS 2400 FORM:

FORM FDA/NCIMS 2400 Cultural Procedures – General Requirements
Rev. 11/17

3. Temperature Measuring Devices

f. Automatic temperature recording instruments other than those described in section 3e that meet the requirements of 3c, if used, compared weekly against an accurate thermometer; record results.

Proposal: 238
Document: FDA/NCIMS 2400 FORMS
Pages: 11

Make the following changes to the FDA/NCIMS 2400 FORM:

From Cultural Procedures, Page 11:

22. Mechanical Dilution Bottle Shaker [~~Not~~ If approved for use in this program]

~~23. Microwave Oven [Not for melting media]~~

From Standard Plate and Coliform Count, Agar Pour Plate Methods, IMS #2 (SPC), IMS #21 (CPC), Page 4, Item 8c:

c. **Mechanical shakers may be used only if a laboratory provides validation data on a specific unit. Data must pass validation criteria**

From Petrifilm™ Aerobic & Coliform Count Methods, IMS #5 (PAC), IMS # (RAC), IMS #20 (PCC, HSCC), Page 4, Item 9c:

c. Mechanical shakers may be used only if a laboratory provides validation data on a specific unit. Data must pass validation criteria (see CP GR item 22)

From Pasteurized Milk Containers, Closures and Packaging, IMS #22 (PMC), Page 5:

MATERIALS

21. See Items 4 & 5
22. Sodium Hexa-metaphosphate Solution, 10% (if calcium alginate swabs used, SPC & CPC only), sterile
23. Shaking Machine, optional (See SPC item 8.c or PAC item 9.c)

Proposal: 239
Document: FDA/NCIMS 2400 FORMS

Make the following changes to the FDA/NCIMS 2400 FORM:

PHOSPHATASE TEST - CHARM® PASLITE® - ALKALINE PHOSPHATASE TEST USING CHARM II 6000/6600 AND LUMINOMETER/LUMINATOR/NOVALUM®/NOVALUM II X®
IMS #29

[Unless otherwise stated all tolerances are ±5%]

SAMPLES

1. Laboratory Requirements (see Cultural Procedures [CP] items 33 & 34) _____
[See current version of M-a-98 to determine if this test method has been approved for use on the specific dairy product being tested]

a. Product Groups/Descriptions _____

1. Fluid white milks - including skim through whole fat milk _____

2. Unflavored liquid dairy products – including half and half, cream, light cream, whipping cream (products that can be accurately pipetted) _____

3. Flavored liquid dairy products (Liquid products that can be accurately pipetted, containing flavor additives and/or thickening agents including flavored milks, and etc.) _____

4. Solid/semisolid dairy products - thick dairy products not able to be pipetted, solid and/or powdered additives, including e.g.; heavy cream ≥ 36% milkfat _____

APPARATUS

2. CP, items 1-32 (as necessary) _____

a. Unless otherwise stated, "shake vigorously" refers to standard microbiological mixing, i.e., 25 times in a 1 foot arc in 7 sec or vortex for 10 sec at maximum setting (subsamples/controls in an appropriate container for vortexing) _____

3. Instrument Used: _____

a. Charm II 6000/6600: _____ _____
b. Luminometer: _____ _____
c. Luminator: _____ _____
d. NovaLUM: _____ _____
e. **NovaLUM II X**_____ _____

4. Incubator Block for 13 x 100 mm Test Tubes or 2 mL Microtubes _____

a. Thermostatically-controlled at 35±1ºC _____

b. Check temperature by electronic display or by thermometer in small well in block or by liquid immersion; maintain records _____

5. Pipettors and Pipets _____

a. Fixed volume or electronic, 100 µL _____

b. Calibration checked as specified in CP item 6.e; maintain records _____

c. Disposable, 10 mL (ASTM) pipet with 0.1 mL graduations _____

6. Reagent Dispenser _____

a. Fixed volume or electronic, 1.0 mL _____

b. Calibration checked (CP item 6.e) with 10 mL Class A graduated cylinder; maintain records _____

7. Test Tubes or Microtubes and Adapter _____

a. Test tubes for Charm II 6600/Charm II 6000 systems, disposable borosilicate glass 13 x 100 mm, dirt and scratch free _____

b. Microtubes - for Luminometer/Luminator/NovaLUM**/NovaLUM II X 2** mL screw cap _____

c. Microtube adapter for Luminometer/Luminator/NovaLUM**/NovaLUM II X 2** _____

8. 6000/6600 or Luminometer/Luminator/NovaLUM/NovaLUM II X 2 Analyzer _____

a. Operating instructions available _____

b. Calibrated for applicable product groups, item 1.a _____

9. Water Bath, Circulating, 34±1°C and 63±1°C (or 66±1ºC if fat > 10%), or 13 x 100 Test Tube Dry Well Heater Blocks acceptable (Confirmation Procedure) _____

10. Centrifuge - Charm II Heraeus® (3,400 RPM), Minifuge, or Equivalent (1,200 - 2,000 g) _____

11. Handling and Storage _____

a. Kit contains Reagent AP, Stopping Solution, Alkaline Phosphatase Calibrator Tablets and Positive Control _____

Kit: Lot #: _____ Rcd. Date: _____ Exp. Date: _____ _____

1. For solid/semisolid dairy products, Diluent AP _____

Diluent AP: Lot #: _____ Exp. Date: _____ _____

b. Store reagents at 0.0-4.5ºC until expiration date _____

c. Stopping Solution may be stored at room temperature. If stored at room temperature, laboratory expiration date is 2 months from first date of room temperature storage. Stopping solution must be at 18-24ºC at time of use _____

1. For the Charm 6600 and Luminometers without temperature probes, the stopping solution may be stored in a water bath or other means to maintain within 1ºC of the temperature used during calibration _____

d. Label bottles with open and expiration dates _____

CONTROLS

12. Negative Control/Sample _____

a. Product group. Prepare at least 50 mL of negative sample for use as a negative control, negative calibrator, and to rehydrate positive control and calibrators _____

1. Fluid white milk - heat a sample of product (highest fat content) to 95±1ºC for 1 min with stirring _____

2. All flavored liquid dairy products can be tested by heating a chocolate sample (highest fat content) to 95±1ºC for 1 min with stirring _____

3. All unflavored liquid dairy products can be tested by heating pasteurized light cream to 95±1ºC for 1 min with stirring _____

4. Solid/semisolid dairy products - mix or knead 5 g of product (highest fat content) with 20 mL Diluent AP until homogeneous and heat to 95±1ºC for 1 min with stirring. Cool on ice to 0.0-4.5ºC. Centrifuge for 3 min and decant supernatant for use as Negative Control/Sample _____

5. Note, if product precipitates during negative sample preparation, e.g. sheep milk, heating sample to 63ºC for 45 min is acceptable. If using 13 x 100 test tube dry well heater block at 95ºC it takes 10 min to heat product to 95ºC; once at temperature, time for 1 min; (Use TC) _____

b. Cool rapidly in an ice bath and hold at 0.0-4.5ºC _____

c. Store at 0.0-4.5ºC, the Negative Control/Sample may be used for up to 48 hours _____

d. Or, aliquot 1 mL quantities in small tubes (milk only), seal and freeze at –15ºC or colder in a non-frost-free freezer, or place in an insulated foam container in a frost-free freezer, use within 2 months _____

Lab Prep. Date: _____ Lab Exp. Date: _____ _____

13. Positive Control (for Daily Checks) _____

a. Reconstitute positive control (450 mU/L) with negative control/sample, item 12, as indicated on label, or alternatively use 350 mU/L calibrator (item 14.a.2.a) _____

b. Shake vigorously or vortex and let settle 10 min at 0.0-4.5ºC for re-suspension _____

1. For solid/semisolid dairy products only, add 1 mL of rehydrated material 13.b with 3 mL of negative control/sample (item 12.a.4) to complete preparation of positive control _____

c. Shake vigorously or vortex again and use for test _____

d. Positive controls and calibrators held at 0.0 to 4.5ºC may be used for 48 hours, milk controls may be frozen at –15ºC or lower for up to 3 weeks; thaw in refrigerator prior to us _____

e. With 6600 and C2Soft, enter either the triplicate RLU average of positive control or triplicate RLU average of 350 mU/L calibrator as the pos avg. and CP in C2Soft configuration file. Refer to C2Soft manual _____

CALIBRATION

14. With Each New Kit Lot # Check Calibration of Analyzer and Replace Microtube Adapter When Applicable _____

a. Prepare 350 mU/L, 175 mU/L, 44 mU/L (milk only), 88 mU/L (flavored and unflavored only) calibrators using negative control/sample, item 12 _____

1. Rehydrate a calibrator tablet with 100 µL water, mix to disperse tablet, wait 1 min and mix again _____

2. Add the specified volume of negative control/sample to each dissolved calibrator tablet to make calibrators: _____

a. Add 2.5 mL to make 350 mU/L _____

b. Add 5 mL to make 175 mU/L _____

c. Add 10 mL to make 88 mU/L (flavored and unflavored only)_____

d. Add 20 mL to make 44 mU/L (fluid white milk only) _____

3. Wait 10 min to rehydrate. Maintain at 0.0-4.5ºC. Mix before use _____

b. Calibrate instrument by testing each calibration control (350, 175, 44 (or 88) mU/L) in triplicate _____

6600 with C2Soft Software

c. For fluid white milks, unflavored or flavored liquid dairy product on the 6600 system with C2Soft software, follow the Standard Curve Calibration procedure _____

1. Program has a separate assay line for each product group, fluid white milk, flavored and unflavored liquid dairy product _____

2. In calibrate mode, enter low concentration (44 or 88 mU/L) value, followed by 3 replicate counts _____

3. Enter medium concentration (175 mU/L) value, followed by 3 replicate counts _____

4. Enter high concentration (350 mU/L) value, followed by 3 replicate counts _____

5. Calibration successful will be prompted at end of the procedure _____

d. For solid/semisolid dairy products using the 6600 system with C2Soft, follow instructions for positive average or control point setup _____

1. Count 3 replicates of 350 mU/L control _____

2. Control point is equal to average of triplicate counts _____

Luminometer/Luminator/NovaLUM/NovaLUM II X ~~2~~ System

e. For fluid white milk, unflavored or flavored liquid dairy products, determine average value for each calibrator _____

1. Set up a separate channel and calibration for each product group, fluid white milk, flavored and flavored liquid dairy products _____

2. Check calibration _____

a. Average negative control/sample tested in triplicate. Average must be less than 5 (less than 15 for flavored dairy products) _____

b. Average 44 mU/L (or 88 mU/L unflavored and flavored liquid dairy products) calibrator, must be between 32-55 mU/L (45 – 110 mU/L unflavored and flavored liquid dairy products) _____

c. Average 175 mU/L positive control, must be 145-205 mU/L _____

d. Average 350 mU/L calibrator, must be 320-400 mU/L _____

3. If conditions are not met, recalibrate according to Luminometer/Luminator/NovaLUM**/NovaLUM II X 2** calibration instructions _____

f. For solid/semisolid dairy products verify control point of 350 mU/kg _____

1. Count 3 replicates of negative control/sample and 350 mU/kg positive control _____

2. Average negative/control sample must test less than 245 mU/kg _____

3. Average 350 mU/kg positive control, must test 350±105 mU/kg_____

4. If conditions are not met, recalibrate according to Luminometer/Luminator/NovaLUM**/NovaLUM II X 2** calibration instructions _____

DAY OF USE PERFORMANCE CHECKS

15. Each Day of Use, Test a Negative Control/Sample (item 12) and Positive Control (item 13), For at Least One Product _____

a. Test beginning from item 16.b _____

b. Verify negative control/sample calibration _____

1. Fluid white milk test VALID or less than or equal to 5 mU/L, unflavored and flavored assay value VALID or less than or equal to 15 mU/L with Luminometer/Luminator/NovaLUM**/NovaLUM II X ~~2~~** or < 44 mU/L (<88 mU/L flavored and unflavored) with 6600 and C2Soft _____

2. Solid and semi-solid dairy products test VALID or less than 30% of the control point _____

c. Verify positive control calibration _____

1. Positive Control (450 mU/L) rehydrated with fluid white milk, flavored and unflavored fluid dairy products, must be 300-585 mU/L or 350mU/L calibrator must be 247-453 mU/L _____

2. Solid and semi-solid dairy products, within ± 30% of 350 mU/kg or the control point _____

d. Periodic rotation of product calibrations is recommended when multiple calibrations are used _____

TEST PROCEDURE

16. Test Procedure

_____ **[Samples kept at 0.0-4.5ºC throughout testing]**

a. Prepare sample _____

1. For fluid white milks, unflavored and flavored, mix by inverting top to bottom, then bottom to top (a complete half circle or 180 degrees) without pausing, 25 times; use within 3 min _____

2. For subsamples of fluid white milk, unflavored and flavored,

mix by shaking 25 times in 7 sec with a 1 ft movement
or vortex
for 10 sec at maximum setting; use within 3 min
_____

3. For solid/semisolid dairy products **(not including controls, items 12.b & 13)** add 1 part to 4 parts Diluent AP _____

   a. Mix or knead until homogeneous _____

   b. Centrifuge for 3 min _____

   c. Use liquid extract in item 16.c _____

b. Dispense 100 µL of Reagent AP into test tubes or microtubes (do not dispense down the sides) _____

c. Dispense 100 µL of the prepared sample (item 16.a) or mixed controls (items 12.d & 13) just <u>above</u> the Reagent AP and immediately vortex
_____

1. Use a new pipet tip for each sample, place pipet tip in sample or prepared control (no more than 1 cm), draw up and remove tip from sample/control _____

2. Touch off to side of container _____

3. Holding pipet 90º to lab bench at eye level, dry exterior of tip (if necessary) by wiping from the pipet toward the tip, be careful not to touch end of tip _____

4. Dispel 100 µL sample <u>directly</u> <u>above</u> surface of Reagent AP (do <u>not</u> dispense down side of test tube or microtube) _____

5. Depress plunger several times to completely expel sample _____

6. Mix test tubes or microtubes with a back-and-forth motion for 10 sec – or use a vortex mixer _____

d. Place the test tube/microtube in the 35±1ºC incubator for 3 min _____

e. Within 10 sec after incubation add 1 mL of room temperature (18-24ºC) Stopping Solution _____

f. Remove test tubes/microtubes from incubator, cap and shake each vigorously or vortex for 10 sec _____

g. Place test tube/microtube into analyzer within 3 min, tubes held at room temperature (Note: stability of count may be stabilized by placing tubes/microtubes in a room temperature bath) _____

1. **6600 with C2Soft Software** _____

   a. Select appropriate assay type _____

   b. Enter ID of sample and press enter _____

   c. Load sample in analyzer and press enter _____

   d. In 5 sec RLU reading will be displayed, mU/L value will appear in results or pop-up window _____

   e. For solid/semisolid dairy products, sample RLU will be compared to control point _____

2. **Luminometer/Luminator/NovaLUM/NovaLUM II X ~~2~~** _____

   a. Select appropriate AP calibrated channel _____

   b. Press Start or Enter _____

   c. In 5 sec mU/L reading will be displayed _____

h. Counting of all test tubes/microtubes must be completed in 3 min _____

i. Samples with ≥ 350 mU/L or ≥ 350 mU/kg (or for solid/semisolid dairy products, values greater than or equal to control point) of ALP activity are suspect positive and must be confirmed (item 17) _____

CONFIRMATION

17. Positive Confirmation _____

a. Prepare lab pasteurized negative control and positive control made of the same dairy product _____

b. Test controls to verify they are in range. If out of range, recalibrate channel and test controls to verify calibration _____

c. Retest suspect positive sample _____

d. Samples with ≥ 350 mU/L of ALP activity are suspect positive and must be tested for microbial, and reactivated phosphatase (items 18 & 19) _____

18. Microbial Phosphatase/Heat Stable Phosphatase _____

a. Heat 1.0 mL of suspect sample at 63±1ºC for 30 min, stirring or mixing every 10 min _____

1. For semisolid/solid dairy products dilute 1.0 g suspect sample with 4.0 mL diluent AP, mix or knead until homogeneous _____
2. If fat content is > 10%, heat at 66±1ºC for 30 min _____

b. Cool sample rapidly to 0.0-4.5ºC in an ice bath _____

c. Test positive and negative controls (item 17.a) following item 16 _____

d. Test heated sample and unheated sample (original sample) following item 16 (semisolid/solid dairy products begin at item 16.b) _____

e. Interpretation _____

1. Controls test as specified in item 15 _____

2. If heated and unheated samples have equal activity (±30%, mU/L or RLU) the sample is regarded **Not Found** for residual phosphatase, the activity originally measured is microbial _____

3. If the heated sample is more than 30% below unheated sample (mU/L or RLU), the sample contains milk phosphatase activity, either residual or reactivated _____

19. Reactivated Phosphatase _____

a. Magnesium acetate solution commercially available _____

b. Or, prepared in laboratory _____

1. Dissolve 35.4 g of Mg acetate tetra-hydrate, $Mg\ (C_2H_3O_2)_2 \cdot 4H_20$ in 25 mL deionized (DI) water, warming slightly to aid dissolution _____

2. Pour solution into 100 mL volumetric flask, rinse original container several times and add rinses to flask _____

3. After cooling to room temperature, make up to 100 mL (stable for 1 year at 0.0-4.5ºC) _____

c. Procedure _____

1. Label separate test tubes as "Blank" and "Test" _____

2. Add a 5.0 mL aliquot of sample (unheated, original sample prepared as in 12.a) to each test tube _____

a. For semisolid/solid dairy products, combine 2.5 g product and 10.0 mL Diluent AP _____

b. Mix or knead until homogeneous, and add 5.0 mL to clean test tubes labeled "Blank" and "Test" _____

3. Add 0.1 mL DI water to the sample labeled "Blank", and 0.1 mL Mg acetate solution to the sample labeled "Test" _____

4. Cap tubes, mix and heat both aliquots for 1 hour at 34±1ºC _____

5. Remove samples from water bath and cool rapidly to 0.0-4.5ºC in an ice bath _____

6. Dilute 1 mL of sample containing Mg acetate (Test) with 5 mL (1:6 dilution) of negative control product (item 12.a) and mix; label tube as "Diluted Test" _____

7. Test undiluted sample containing no Mg acetate (Blank) and diluted sample containing Mg acetate (Diluted Test) for phosphatase activity following item 16 (semisolid/solid dairy products begin at item 16.b) _____

d. Interpretation _____

1. If the diluted aliquot containing Mg acetate (Diluted Test) has equal (30%) or greater phosphatase activity than the undiluted aliquot containing no Mg (Blank), the sample is regarded as **Not Found** for residual phosphatase, and the phosphatase originally measured is of reactivated origin _____

Diluted w/Mg (Test) ≥ Undiluted (Blank) = Reactivated

2. If the diluted aliquot (Diluted Test) contains less (30% below or less) activity than the undiluted aliquot (Blank) the sample is considered **Positive** for residual phosphatase _____

Diluted w/Mg (Test) < Undiluted (Blank) = Residual

3. A false-positive for residual phosphatase may also be obtained if a reactivatable sample has been allowed to stand at elevated temperatures (20ºC) for periods of 1 hr or more before testing (SPC < 20,000/mL) _____

RECORDING, INTERPRETATION, AND REPORTING

20. Record and Interpretation _____

a. Record values _____

b. Interpret _____

1. If value obtained is < 44 mU/L for fluid white milk, < 88 mU/L for unflavored, or < 350 mU/kg for solid/semi-solid dairy products the sample is **Not Detected** (the 6600 with C2Soft software doesn't give a value but states None Found) _____
2. If value obtained is ≥ 350 mU/L or mU/kg the sample is **actionable** (for solid/semi-solid dairy products the 6600 with C2Soft software doesn't give a value but states 'Suspect')_____

21. Report _____

a. **Not Found** for residual phosphatase if: _____

1. < 350 mU/L _____
2. ≥ 350 mU/L or mU/kg but: _____

a. Meets reactivated phosphatase criteria (item 19.d.1) _____

b. Meets microbial/heat stable phosphatase criteria (item 18.e.2) _____

c. Documentation shows the product was treated in such a way that reactivated phosphatase may be present _____

b. **Positive** for residual phosphatase if: _____

1. ≥ 350 mU/L or mU/kg and: _____

   a. Meets residual phosphatase criteria (item 19.d.2) _____

   b. No microbial phosphatase present (item 18.e.3) _____

   c. No documentation to show the product could have become reactivated _____

PHOSPHATASE TEST – CHARM® FAST ALKALINE PHOSPHATASE TEST USING CHARM NOVALUM® AND NOVALUM II X®
IMS #29

[Unless otherwise stated all tolerances are ±5%]

SAMPLES

1. Laboratory Requirements (see Cultural Procedures [CP], items 33 & 34) _____

[See current version of M-a-98 to determine if this test method has been approved for use on the specific dairy product being tested]

a. Product Groups/Descriptions _____

   1. Fluid white milks - including skim through whole fat milk _____

   2. Unflavored liquid dairy products – including half and half, cream, light cream, whipping cream (products that can be accurately pipetted) _____

   3. Flavored liquid dairy products (Liquid products that can be accurately pipetted, containing flavor additives and/or thickening agents including flavored milk, and etc.) _____

APPARATUS

2. CP, items 1-32 (as necessary) _____

a. Unless otherwise stated, “shake vigorously” refers to standard microbiological mixing, i.e., 25 times in a 1 foot arc in 7 sec or vortex for 10 sec at maximum setting (subsamples/controls in an appropriate container for vortexing) _____

3. Pipettors and Pipets _____

a. Fixed volume or electronic, 100 µL _____

b. Calibration checked as specified in CP item 6.e; maintain records _____

c. Disposable, 10 mL (ASTM) pipet with 0.1 mL graduations _____

4. Microtube Adapter for NovaLUM/NovaLUM II X _____

5. NovaLUM/NovaLUM II X Analyzer _____

a. Operating instructions available _____

1. Channels configured for Fast Alkaline Phosphatase (FAP) assay for appropriate definitions _____

a. FAP MILK – 45 sec time _____
b. FAP CREAM – 90 sec time _____

c. FAP CHOC – 90 sec time _____

2. Thermoprobe connected with NovaLUM/NovaLUM II X positioned upright in Stand _____

a. Stub probe ~~Probe~~ measuring ambient room temperature~~, DO NOT IMMERSE IN WATER~~ (Ambient room temperature must be between 18-24ºC to run the test) _____

3. Microtube adapter for Luminometer/Luminator/NovaLUM/NovaLUM II X _____

6. Water Bath, Circulating, 34±1ºC and 63±1ºC (or 66±1ºC if fat > 10%), or 13 x 100 Test Tube Dry Well Heater Blocks Acceptable (Confirmation Procedure) _____

7. Centrifuge - Charm II Heraeus® (3,400 RPM), Minifuge, or Equivalent (1,200-2,000 g) _____

8. Handling and Storage _____

a. Kit contains Reagent FAP Vials and Calibrator Tablets _____

Kit: Lot #: _____ Exp Date: ___/___/___ _____

Calibrator Lot #: _____ Exp Date: ___/___/___ _____

b. Reagents stored at 0.0-4.5ºC until expiration date _____

1. FAP vials may be stored at room temperature. If stored at room temperature, laboratory expiration date is 3 weeks from first date of room temperature storage. FAP vials must be at 18-24ºC at time of use _____

~~c. Label bottles with open dates~~_____

CONTROLS

9. Negative Calibrator/Control _____

a. Product group. Prepare at least 20 mL of negative sample for use as a negative calibrator/control and to rehydrate 350mU/L positive calibrator/control _____

1. Fluid white milk - heat a sample of product (highest fat content) to 95±1ºC for 1 min with stirring _____

2. All flavored liquid dairy products can be tested on the FAP CHOC channel by heating a chocolate sample (highest fat content) to 95±1ºC for 1 min with stirring _____

a. Cool rapidly in an ice bath and hold at 0.0-4.5ºC _____
b. Centrifuge for 3 min and decant supernatant _____

3. All unflavored liquid dairy products can be tested on the FAP CREAM channel by heating pasteurized light cream to 95±1ºC for 1 min with stirring _____

4. Note: if product precipitates during negative sample preparation, e.g. sheep milk, heating sample to 63ºC for 45 min is acceptable. If using 13 x 100 test tube dry well heater block at 95ºC, it takes 10 min to heat product to 95ºC; once at temperature, time for 1 min. (Use TC) _____

b. Cool rapidly in an ice bath and hold at 0.0-4.5ºC _____

c. Store at 0.0-4.5ºC, the Negative Control/Sample may be used for up to 48 hours _____

d. Or, aliquot 1 mL quantities into small tubes (see 5.a.~~2~~1.b for product definitions), seal and freeze at –15ºC or colder in a non-frost-free freezer or in an insulated foam container in a frost-free freezer, use within 2 months _____

Lab Prep. Date: _____ Lab Exp. Date: _____

_____

10. Positive 350 mU/L Calibrator/Control _____

a. Prepare Positive Calibrator/Control _____

1. Rehydrate a calibrator tablet with 100 µL water, mix to disperse tablet, wait 1 min and mix again _____

2. Add 2.5 mL of Negative Calibrator/Control to dissolve calibrator tablet_____

3. Shake vigorously and let settle 10 min at 0.0-4.5ºC for re-suspension _____

4. Shake vigorously again and use for test _____

b. Positive calibrator/control held at 0.0-4.5ºC may be used for 48 hours _____

CALIBRATION

11. With Each New Kit Lot # Calibrate Analyzer and Replace Microtube Adapter _____

a. Prepare Negative Calibrator/Control and Positive Calibrator/Control, items 9 and 10 _____

b. Select appropriate channel for calibration and follow prompts.
Note: Previously calibrated channels will list a selection menu, select 'calibrate'; follow prompts _____

1. Test a negative calibrator/control, item 13.c _____
2. Test a positive calibrator/control, item 13.c _____

3. Instrument will make internal adjustments _____

4. Test another negative calibrator/control, item 13.c _____

5. Test another positive calibrator/control, item 13.c _____

6. If performance of negative (<15) and positive is in range (320-400), instrument will prompt calibration successful. If performance out of range, instrument will recalculate settings and prompt to perform another positive and negative calibrator/control _____

7. Repeat steps 4-6. If out of range NovaLUM will prompt a re-calibration, step 1 _____

DAY OF USE PERFORMANCE CHECKS

12. Each Day of Use, Test a Negative Control/Sample (item 9) and Positive Control (item 10), For at Least One Product _____

a. Verify FAP vial stored at room temperature. Select NovaLUM 'programmed plans', select appropriate FAP channel and select menu 3 'Control Check'. Follow Prompts _____

1. Test positive calibrator/control, item 13.c. Positive Control valid, 247-453 mU/L _____

2. Test negative calibrator/control, item 13.c. Negative Control valid or less than or equal to 15 mU/L _____

b. Periodic rotation of channels is recommended when multiple channels are used _____

TEST PROCEDURE

13. Procedure _____
[Samples kept at 0.0-4.5ºC throughout testing]

a. Prepare sample _____

1. Mix retail milk samples by inverting containers top to bottom, then bottom to top (a complete half circle or 180 degrees) without pausing, 25 times; use within 3 min _____

2. Mix negative control or subsamples of retail containers by shaking 25 times in 7 sec with a 1 ft movement or vortex at least 10 sec at maximum setting; use within 3 min. (sample(s)/control(s) must be in appropriate container to allow the use of vortexing) _____

3. For flavored dairy products (not including controls, items 9 & 10) _____

a. Add 1 mL of sample into an appropriate tube or vial (NOT FAP vial) _____

b. Centrifuge for 3 min _____

c. Use liquid extract in item 13.~~d~~c _____

b. Verify FAP vial stored at room temperature. _____

1. Pierce foil top with clean pipet tip. _____

c. Dispense 100 µL of the prepared sample (item 13.a) or mixed controls (items 9 & 10) into the FAP vial liquid and then immediately press enter on NovaLUM _____

1. Follow prompt and vortex FAP vial with sample for 5 sec at maximum setting _____

2. Follow prompt and attach microtube adapter to threaded side of vial. Then fully insert vial into NovaLUM chamber. This step must be completed while screen is flashing (30 sec) _____

d. At the end of pre-programmed time, the screen will stop flashing and count the sample. The mU/L phosphatase level will be displayed on screen. Press OK to print and prepare for next sample _____

e. Samples with ≥ 350 mU/L of ALP activity are suspect positive and must be confirmed (item 14) _____

CONFIRMATION

14. Positive Confirmation _____

a. Prepare lab pasteurized negative control and positive control made of the same dairy product _____

b. Test controls to verify they are in range. If out of range, recalibrate channel and test controls to verify calibration _____

c. Retest suspect positive sample _____

d. Samples with ≥ 350 mU/L of ALP activity are suspect positive and must be tested for microbial, and reactivated phosphatase (items 15 & 16) _____

15. Microbial Phosphatase/Heat Stable Phosphatase _____

a. Heat 1.0 mL of suspect sample at 63±1ºC for 30 min, stirring or mixing every 10 min (Use TC) _____

1. If fat content is >10%, heat at 66±1ºC for 30 min _____

b. Cool sample rapidly to 0.0-4.5ºC in an ice bath _____

c. Test positive and negative controls (item 14.a) following item 13 _____

d. Test heated sample and unheated sample (original sample) following item 13 _____

e. Interpretation _____

1. Controls test as specified in item 12 _____

2. If heated and unheated samples have equal activity (-30%,mU/L or RLU) the sample is regarded Not Found for residual phosphatase, the activity originally measured is microbial _____

3. If the heated sample is more than 30% below unheated sample (mU/L or RLU), the sample contains milk phosphatase activity, either residual or reactivated _____

16. Reactivated Phosphatase _____

a. Magnesium acetate solution commercially available _____

b. Or, prepared in laboratory _____

1. Dissolve 35.4 g of Mg acetate tetra-hydrate, Mg $(C_2H_3O_2)_2 \cdot 4H_20$ in 25 mL deionized (DI) water, warming slightly to aid dissolution _____

2. Pour solution into 100 mL volumetric flask, rinse original container several times and add rinses to flask _____

3. After cooling to room temperature, make up to 100 mL (stable for 1 year at 0.0-4.5ºC) _____

c. Procedure _____

1. Label two 13 x 100 test tubes or appropriate for volume as “Blank” and “Test” _____

2. Add a 5.0 mL aliquot of sample (unheated, original sample not prepared as in 13.a) to each test tube _____

~~2~~3. Add 0.1 mL DI water to the sample labeled "Blank", and 0.1 mL Mg acetate solution to the sample labeled "Test" _____

~~3~~4. Cap tubes, mix and heat both aliquots for 1 hour at 34±1ºC (Use

TC) _____

4~~5~~. Remove samples from water bath and cool rapidly to 0.0-4.5ºC in an ice bath _____

~~5~~6. Dilute 1 mL of sample containing Mg acetate (Test) with 5 mL (1:6 dilution) of negative control product (item 14.a) and mix, label tube as "Diluted Test" _____

~~6~~7. Test undiluted sample containing no Mg acetate (Blank) and diluted sample containing Mg acetate (Diluted Test) for phosphatase activity following item 13 _____

d. Interpretation _____

1. If the diluted aliquot containing Mg acetate (Diluted Test) has equal (±30%) or greater phosphatase activity than the undiluted aliquot containing no Mg acetate (Blank), the sample is regarded as Not Found for residual phosphatase, and the phosphatase originally measured is of **reactivated** origin _____

Diluted w/Mg (Test) ≥ Undiluted (Blank) = Reactivated

2. If the diluted aliquot (Diluted Test) contains less (30% below or less) activity than the undiluted aliquot (Blank) the sample is considered Positive for **residual phosphatase** _____

Diluted w/Mg (Test) < Undiluted (Blank) = Residual

3. A false-positive for residual phosphatase may also be obtained if a reactivatable sample has been allowed to stand at elevated temperatures (20C) for periods of 1 hour or more before testing (SPC < 20,000/mL) _____

RECORDING, INTERPRETATION, AND REPORTING

17. Recording and Interpretation _____

a. Record Values _____

b. Interpret _____

1. If value obtained is <44 mU/L for fluid white milk or <88 mU/L for flavored/unflavored the sample is Not Detected _____

2. If value obtained is ≥350 mU/L or mU/kg the sample is **actionable** _____

18. Report _____

a. **Not Found** for residual phosphatase if: _____

1. <350 mU/L _____

2. ≥350 mU/L but: _____

a. Meets reactivated phosphatase criteria (item 16.d.1) _____

b. Meets microbial phosphatase criteria (item 15.e.2) _____

c. Documentations showing the products was treated in such a way that reactivated phosphatase may be present _____

b**. Positive** for residual phosphatase if: _____

1. ≥350 mU/L or mU/g and: _____

a. Meets residual phosphatase criteria (item 16.d.2) _____

b. No microbial phosphatase present (item 15.e.3) _____

c. No documentation to show the product could have become reactivated _____

Proposal: 240
Document: FDA/NCIMS 2400 FORMS

Make the following changes to the FDA/NCIMS 2400 FORM:

APPENDIX N BULK MILK TANKER SCREENING TEST FORM

CHARM® SL (raw commingled cow, sheep, water buffalo and goat milk), IMS #9-C13
AND
Charm 3 SL3 (raw commingled cow milk), IMS #9-C15
AND
Charm BL30SEC (raw commingled cow milk), IMS ##-C##

BETA-LACTAM TESTS

[Unless otherwise stated all tolerances are ±5%]

GENERAL REQUIREMENTS

1. See Appendix N General Requirements (App. N GR) items 1-8 & 15 _____

SAMPLES

2. See App. N GR item 9 _____

APPARATUS & REAGENTS

3. Equipment _____

a. Charm Sciences Strip Incubator:
56±1°C 8 min timer - SL beta-lactam test;
56±1°C 3 min with internal timer – SL3 beta-lactam test
56±1°C Charm EZ display when message “Add milk to strip and close door”
-required for BL30SEC optional for SL and SL3 _____

1. Clean, properly maintained and located on a level surface _____

2. Check temperature daily (day of use); maintain records _____

    a. Charm EZ printout acceptable for daily temperature check (annual accuracy check required); maintain records _____

3. Temperature measuring device for each incubator (App N. GR item 3) _____

4. Lid closed (slightly sprung so that timer not active) when not running tests _____

5. Incubator Temperature: _____ _____

6. Timer if not included in incubator
Incubation Time of internal timer: _____
_____

b. ROSA® Reader, ROSA Pearl Reader (with or without ROSA Barcode option), Charm EZ or Charm Sciences equivalent with print out or download of data; manual available

Serial Number: _____ _____

1. SL beta-lactam test - ROSA Reader V1.03 or higher
(or if ROSA Pearl Reader or Charm EZ see 3.b.2) _____

a. Calibrators _____

Range(s)		Result
Low: _____	_____	_____
High: _____	_____	_____

b. Maintain records _____

2. SL3 beta-lactam test - ROSA Pearl Reader V3.00 or higher or
Charm EZ _____

a. Calibrators - Low and High for use in all assay channels _____

Range(s)		Result
Low: _____ (darker magenta)	_____	_____
High: _____ (lighter pink)	_____	_____

b. Maintain records _____

3. BL30SEC beta-lactam test -
Charm EZ reader in the incubate and read mode _____

a. Calibrators - Low and High for use in all assay channels _____

Range(s)		Result
Low: _____ (darker magenta)	_____	_____
High: _____ (lighter pink)	_____	_____

b. Maintain records _____

~~3~~4. Calibrator serial numbers match reader SN _____

~~4~~5. **Do not proceed if out of range.** Manufacturer should be contacted for corrective actions _____

~~5~~6. Printer or computer link for hardcopy download _____

c. Pipettor - 300 µL and disposable tips (see App. N GR item 7) _____

d. Or single use 300 µL ROSA-pipet with overflow bulb to accurately measure amount of sample, supplied by manufacturer **(screening only)**

_____

e. Optional Centrifuge (Not applicable to SL3 or BL30SEC beta-lactam test) - mini

or equivalent (1200-2000 x g) for frozen controls _____

4. Reagents _____

a. Test Strips (EZ Compatible for Charm EZ) _____

Lot #: _____ Exp. Date: _____ _____

QC Date: _____ By: _____ _____

b. Positive Control _____

1. Lyophilized or tablet 5 ppb Penicillin G beta-lactam tests _____

Lot #: _____ Exp Date: _____ _____

c. Negative Control _____

1. Previously negative tested raw milk (item 5.d) _____

5. Reagent stability _____

a. SL3 and BL30SEC reagents must be received within 72 hours if shipped non-refrigerated;
over 72 hours must be refrigerated. (Not applicable to the SL reagents)

_____

b. Store reagents at 0.0-4.5°C, desiccant blue, maintain no longer than manufacturer's expiration date _____

1. **Do not use if desiccant indicator is white or pink** _____

c. Positive Control - Manufacturer supplied, maintain no longer than manufacturer's expiration date _____

1. Reconstitute with Negative Control (raw milk), tested +400 or more positive, used within 48 hours when maintained at 0.0-4.5°C _____

Lab Prep. Date: _____ Lab Exp. Date: _____ _____

2. Or, aliquot within 24 hours and freeze at –15°C or colder in a

non frost-free freezer or in an insulated foam container in a frost-free freezer; use within 2 months _____

Lab Prep. Date: _____ Lab Exp. Date: _____ _____

a. Thaw slowly overnight in refrigerator or more rapidly in cold water. Mix well until sample is homogeneous _____

1. **Do not use if there is visible protein precipitation**_____

b. Store at 0.0-4.5°C and use within 24 hours; do not refreeze _____

c. For **SL ONLY**, centrifuge 3 min and cool _____

1. Test portion below fat layer without mixing _____

3. Day of use, must produce +400 or greater reading; maintain records _____

Test Value: _____ _____

Do not proceed if out of range _____

d. Negative Control - raw milk tested –600 or more negative; (SL Test Negative Control can be any of the approved species milk)_____

Sample ID: _____ Test Value: _____ _____

Date tested: _____ _____

1. Use within 72 hours when maintained at 0.0-4.5°C _____

2. Or, aliquot within 24 hours and freeze at –15°C or colder in a non

frost-free freezer or in an insulated foam container in a frost-free freezer; use within 2 months _____

Lab Prep. Date: _____ Lab Exp. Date: _____ _____

a. Thaw slowly overnight in refrigerator or more rapidly in cold water. Mix well until sample is homogeneous _____

1. **Do not use if there is visible protein precipitation**_____

b. Store at 0.0-4.5°C and use within 24 hours; do not refreeze _____

c. For SL **ONLY**, centrifuge 3 min and cool _____

1. Test portion below fat layer without mixing _____

3. Day of use must produce –600 or more negative; maintain records _____

Do not proceed if out of range _____

TECHNIQUE

6. Daily Performance and Operation Check _____

a. See App. N GR items 10.b-d _____

b. If using ROSA reader Versions 1.05 and higher, or ROSA-Pearl, use ESC 5 reader function to enter performance monitoring mode of reader; if using Charm EZ, use Menu to enter Performance Monitoring mode and “Perf Mon” to enter daily performance check; refer to manual for directions _____

c. Check Calibrators; items 3.b.1 or 3.b.2 _____

d. Positive and negative controls must give appropriate readings prior to any sample analysis (see App. N GR item 10.a) _____

e. Controls in-range when in performance monitoring mode, ROSA reader version 1.05 and higher, ROSA Pearl or Charm EZ _____

f. **Do not proceed if out of range** _____

7. Test Procedure _____

a. Set out required number of test strips and place them in a dry labeled container at room temperature, or take out strips as needed _____

1. Discard unused test strips at the end of the day _____

b. Label test strips, one for each test sample and each control. Avoid crushing sample compartment(s) _____

c. Mix milk sample(s)/control(s) 25 times in 7 sec with a 1 ft movement or vortex for 10 sec at maximum setting; use within 3 min (samples/controls must be in appropriate containers to allow the use of vortexing) _____

1. Centrifuge sheep milk sample(s)/controls that have been previously frozen; refer to 5.c.2.a-c and 5.d.2.a-c _____

d. Place strip into appropriate incubator _____

1. EZ reader in incubate and read mode displays appropriate test name and “add milk to strip and close door” when in correct temperature range, follow item 7.i _____

e. While holding strip flat, peel back plastic (to ‘peel to here’ line) to expose sample pad compartment. Avoid lifting the wick and sponge under tape _____

1. For multiple samples, complete steps 7.d-g for each sample/control, before starting test of next sample _____

2. Complete all samples within 2 min (1 min 15 sec for SL3 test) of placing first strip in incubator _____

f. Add 300 µL of mixed sample/control to corresponding strip _____

1. Using pipettor (item 3.c) with new tip for each sample/control, draw up 300 µL avoiding foam or bubbles _____

a. Remove tip from liquid _____

b. While holding the pipettor vertically, expel test portion slowly into either side well of appropriate strip _____

2. Using new manufacturer-provided ROSA-pipet (item 3.d) for each sample/control **[Screening only]** _____

a. Squeeze top bulb while holding vertically with bulb and overflow reservoir side pointing down, draw up test portion avoiding foam and bubbles. Sample should completely fill pipet shaft and overflow into the bottom half of the overflow reservoir _____

b. Remove tip from liquid _____

c. While holding the ROSA-pipet vertically, expel test portion slowly into either side well of appropriate strip. Excess portion should remain in reservoir _____

g. Re-seal plastic firmly around sample pad compartment _____

h. ROSA Reader and Charm EZ (read only mode)

1. Close lid and latch ROSA incubator to start automatic timer in the incubator. If no automatic timer in incubator, set external timer for 8 min for SL. For SL test, incubate 8 min not to exceed 9 min. For SL3 test, incubate 3 min not to exceed 3 min and 30 sec _____

2. At end of incubation visually inspect C (Control) line An absent C line, a partial C line or an indistinct C line indicates an invalid test; and the sample/control must be re-tested _____

3. Insert only valid test(s) in reader _____

a. ROSA reader set to appropriate channel

1. SLBL slow blink for SL beta-lactam test _____

2. SLBL solid (no blink) for SL3 beta-lactam test _____

3. Press ENTER, reading and interpretation appear in 5 sec, read strips within 5 min (3 min with SL3) of completion of incubation. Strips may be held vertically, sample compartment down while waiting to be read _____

b. Charm EZ automatically sets channel when color coded strip inserted _____

1. Close door; reading and interpretation appear in 5 sec, read strips within 5 min (3 min with SL3) of completion of incubation. Strips may be held vertically, sample compartment down while wait to read _____

i. Charm EZ (incubate and read mode) _____

1. Charm EZ automatically sets channel and incubator temperature when color coded strip inserted. Optionally enter sample ID _____

2. Peel strip (7.e) and add milk (7.f) _____

3. Close door to begin _____

4. Charm EZ automatically prompts for further testing when positive _____

8. Interpretation with Reader _____

a. If there is a negative or zero reading on the reader, sample is **a Negative (NF)** _____

b. If there is a positive reading on the reader, sample is **an Initial Positive** _____

9. Verification of Initial Positive Tanker Samples (see App. N GR item 11); Confirmation of Presumptive Positive Tanker Samples (see App. N GR item 12); and Traceback of Producer(s) on a Confirmed Positive Tanker (see App. N GR item 13) _____

10. Reporting (see App. N GR item 14)

Proposal: 241
Document: FDA/NCIMS 2400 FORMS

Make the following changes to the FDA/NCIMS 2400 FORM:

Change to 2400 form Cultural Procedures General Requirements– Item 29.g.

29. **Prepared Media Storage**
g. Charm Peel Plate® Storage

1. ~~Refrigerate~~ Store unopened packages of Peel Plate® plates at 0-25 ~~or below 8~~°C; if ~~frozen~~ refrigerated, allow 30 min to acclimate to room temperature before opening packages

2. Use before expiration date on package

3. After opening, return unused plates to the foil pouch with desiccant indicator, Zip-seal open end shut

4. Store opened (re-sealed) packages at 0-25 ~~or below 8~~°C

5. Check desiccant indicator of Peel Plate® plates before use. Do not use if desiccant has turned white or pink. Do not use if plates are discolored, pink, yellow or brown

Changes to 2400 form a-6

PEEL PLATE® AEROBIC AND COLIFORM PROCEDURES
IMS # 6 (PPAC), # 18 (PPCC, PPEC, PPCCHV, PPECHV <u>and Cultured Dairy CD Forms</u>)

[Unless otherwise stated all tolerances are ±5%]

SAMPLES

1. Laboratory Sample Requirements (see Cultural Procedures [CP] items 33 & 34) [For inhibitor testing requirements, refer to Section 6 of the PMO]
_____

MATERIALS AND APPARATUS

2. Peel Plate Aerobic Count (PPAC), Peel Plate Total Coliform Count (PPCC), Peel Plate E. coli & Total Coliform (PPEC), Peel Plate Total Coliform High Volume Sensitivity (PPCCHV) ~~and~~<u>,</u> Peel Plate E. coli & Total Coliform High Volume Sensitivity (PPECHV) <u>and Cultured Dairy Forms of Coliform tests (PPCCCD, PPECCD, PPCCHVCD, and PPECHVCD)</u> _____

PROCEDURE

3. Work Area _____

a. Level plating bench not in direct sunlight _____

b. Sanitize immediately before start of plating _____

4. Selecting Dilutions _____

a. PPAC _____

1. Plate two decimal dilutions per sample _____

2. Select dilutions that would be expected to yield one plate with 25-250

colonies _____

a. Raw milk is normally diluted to 1:100 and 1:1000 _____

b. Finished products are normally diluted to 1:10 and 1:100 _____

3. PPAC not performed on cultured or acidified products _____

b. PPCC or PPEC _____

1. For pasteurized fluid milk samples (except chocolate), 1 mL direct and/or decimal dilutions, as appropriate _____

2. For chocolate milk samples (other flavored milk optional), distribute 2 mL of a 1:2 dilution (1 part sample and 1 part diluent) among two (2) PPCC/PPEC plates, 1 mL per plate _____

3. For samples other than milk (item 11) distribute 10 mL of a 1:10 dilution (1 part sample and 9 parts diluent) among ten (10) PPCC/PPEC plates, 1 mL per plate or use PPCCHV/PPECHV plates (item 4.c)
_____

4. For PPCC/PPEC performed on cultured product containing active Lactic Acid Bacteria (LAB), e.g. cottage cheese, use manufacturer prepared plates for Culture Dairy, PPCCCD or PPECCD and follow item 4.b.3
_____

a. Or alternatively if using PPCC or PPEC plates, prepare ~~Prepare~~ diluent with 0.2% sodium bisulfite _____

1. Use sterile solution of sodium bisulfite available from the manufacturer, or prepare a 20% solution of sodium bisulfite and filter or heat sterilize. Keep refrigerated. Add 1 mL of sterile sodium bisulfite to 99 mL sterile dilution buffer_____

2. Alternatively, add sodium bisulfite to 99 mL dilution buffer or MS water and sterilize _____

b. Homogenize 1:10 dilution (1 part sample and 9 parts sodium bisulfite diluent) _____

1. Mix as in item 8, or _____
2. Vortex at highest setting for 10 seconds, or _____
3. Blend for 2 min, or _____
4. Stomach for 2 min _____

c. For solid products, let settle for 30 sec. Distribute supernatant (liquid portion) of homogenate among ten (10) PPCC/PPEC plates, 1 mL per plate or use PPCCHV/PPECHV/ PPCCCD or PPECCD plates _____

c. High Volume Sensitivity Coliform, PPCCHV/PPECHV/ PPCCCHVD or PPECHVCD plates _____

1. For evaporated milk, heavy and light cream, sweetened condensed milk, sour cream, and sour cream based dips and eggnog (flavored milk optional) prepare either a 1:5 minimum dilution or 1:10 dilution _____

2. For cultured product containing active LAB, e.g. cottage cheese, use manufacturer prepared plates for Culture Dairy, PPCCHVCD or PPECHVCD _____

a. Or alternatively if using PPCCHV or PPECHV plates, prepare ~~Prepare~~ diluent with sodium bisulfite as in 4.b.4.a above _____

b. Homogenize (see 4.b.4.b above) a 1:5 dilution (1 part sample and 4 parts sodium bisulfite diluent) or a 1:10 dilution (1 part sample and 9 parts diluent) _____

3. Test 1:5 dilution/homogenate (see item 4.b.4.c) by dispensing 5 mL to one plate, or test 1:10 dilution/homogenate by dispensing 5 mL to each of 2 plates (10 mL total) _____

d. For most acidified products, it is not necessary to adjust the pH due to the buffering capacity of the Peel Plate medium. The buffering capacity may be evaluated with different acidified products using Litmus paper to verify that the pH will be in the acceptable range. Document for product type and discard the plate contacted by the Litmus paper _____

1. PPCC/PPEC/ PPCCCD or PPECCD plates – pH range 6.6 to 7.2 _____

2. PPCCHV/PPECHV/ PPCCHVCD or PPECHVCD plates – pH range 6.5 to 7.5 _____

3. Refer to manufacturer's instructions for list of low pH products that may require adjustment before plating _____

5. Identifying Peel Plate Tests _____

a. Select number of samples in any series so that all will be plated within 20 min

(pref. ≤ 10 min) after diluting first sample _____

b. Label each plate with sample or control identification and dilution _____

c. Arrange plates in order before preparation of dilutions _____

CONTROLS

6. Controls (AM and PM) _____

a. Check sterility of dilution blanks, PPAC plates, and pipets/tips used for each group of samples _____

b. Expose a rehydrated PPAC plate to air during plating for 15 min _____

1. The air control plate must be the first plate set up immediately before samples are shaken and must be located such that it is in the area of the plating activity (not off to the side) _____

a. Inoculate the center of the PPAC with 1 mL dilution buffer as described in items 9.i.1 or 10.i _____

b. Pull adhesive film off and adhere to top side of plate. Leave plate open, completely exposing rehydrated surface for 15 min; use timer _____

c. After 15 min, replace adhesive film back down as described in 9.i.2 and incubate as described in item 10.i.2 _____

2. After incubation, air plate(s) shall contain ≤ 5 colonies _____

3. Take and record corrective actions for air control plate(s) with > 5 colonies _____

a. Maintain records _____

b. Include information on bench sheet, work sheet or report sheet(s) _____

DILUTING SAMPLES

7. Sample Agitation _____

a. When appropriate, wipe top of unopened containers with sterile, ethyl alcohol-saturated cloth _____

b. Before removal of any portion or sub-samples, thoroughly mix contents of each container _____

1. Mix raw sample(s) by shaking 25 times in 7 sec with a 1 ft movement (containers approx., ¾ full) _____

2. Mix retail milk samples by inverting containers top to bottom, then bottom to top (a complete half circle or 180 degrees) without pausing, 25 times _____

c. Remove test portion within 3 min of sample agitation _____

8. Dilution Agitation _____

a. Before removal of any portion, shake each dilution bottle 25 times in 7 sec with a 1 ft movement _____

b. Remove test portion within 3 min of dilution agitation _____

c. Mechanical shakers may be used only if a laboratory provides validation data on a specific unit. Data must pass validation criteria _____

PLATING

9. Sample and Dilution Measurement, Pipets _____

a. Use separate sterile pipets for the initial transfers from each container, adjust pipets in pipet container without touching the pipets _____

b. Do not drag pipet tip over exposed exterior of pipets in pipet container _____

c. Do not drag pipet across lip or neck of sample container or dilution blank _____

d. Insert pipet not more than 2.5 cm (1”) below sample surface or dilution surface (avoid foam and bubbles) _____

e. Using pipet aid, draw test portion above pipet graduation mark and remove pipet from liquid (mouth pipetting not permitted) _____

f. Adjust test volume to mark with lower side of pipet: _____

1. In contact with inside of sample container (above the sample surface) _____

2. Or, in contact with inside of dilution blank neck or area above buffer on straight-walled container _____

3. Ensure excess liquid does not adhere when pipet is removed from the sample container or dilution blank _____

g. For dilutions, dispense test portion to dilution blank (with lower side of pipet in contact with neck of dilution blank, or area above buffer on straight-walled containers) with column drain of 1-3 sec _____

h. Keeping plate flat on bench, peel back the top adhesive film to fully expose medium _____

i. Deposit 1 mL (PPAC/PPCC/PPEC/PPCCCD/PPECCD), or 5 mL (PPECHV/PPCCHV/PPCCHVCD/PPECHVCD) of sample or dilution keeping plate flat and pipet nearly vertical above center of plate _____

1. Rapidly release sample or dilution test portion holding pipet vertically just above the center of the plate with tip slightly above, but not in contact with medium, with a continuous column drain of 1-3 sec _____

a. Using pipet aid, blow out last drop of undiluted sample, away from main part of sample on plate _____

b. Gently touch off pipet _____

c. If necessary to fully wet dry medium, immediately lift plate from table and gently rotate plate to get sample across dry medium. Place plate back on table. _____

2. PPAC/PPCC/PPEC/PPCCHV/PPECHV/PPCCCD/PPECCD/ PPCCHVCD/PPECHVCD – Replace the adhesive film onto base preventing wrinkles. Apply pressure around perimeter to seal _____

j. Leave plates undisturbed for gel solidification: _____

1. 10 seconds for PPAC/PPCC/PPEC/PPCCCD/PPECCD _____

2. 1 min for PPCCHV/PPECHV/PPCCHVCD/PPECHVCD _____

k. Discard pipets into disinfectant OR dispose into biohazard bags or containers to be sterilized, (using this method of disposal does not require placing into disinfectant first) _____

10. Sample & Dilution Measurements, Pipettors [for electronic pipettors, follow manufacturer instructions] Mechanical ____ Electronic ____ _____

a. Each day before use, vigorously depress plunger 10x to redistribute lubrication and assure smooth operation (mechanical pipettors) _____

b. Before each use examine pipettor to assure that no liquid is expelled from the pipettor nose-cone (contaminated), if fouling is detected do not use until cleaned as per manufacturer recommendation _____

c. Use separate sterile tip for the initial transfers from each container _____

d. Depress plunger to first stop (mechanical pipettors) _____

e. Do not drag tip/barrel across lip or neck of sample container or dilution blank, and do not allow pipettor barrel within sample container _____

f. Insert tip approximately 0.5-1.0 mm below sample or dilution surface (avoid foam and bubbles) _____

g. With plate flat and pipettor vertical, slowly and completely release plunger on mechanical pipettor; do not lay pipettor down once sample is drawn up, use vertical rack or charging stand if necessary _____

h. Touch off lower side of tip: _____

1. To inside of sample container above the sample surface, excess liquid not adhering to tip _____

2. Or to the inside of dilution blank neck or area above buffer on straight-walled containers, excess liquid not adhering to tip _____

a. For dilutions, hold pipettor nearly vertical with lower side of tip touching neck of dilution blank (or area above buffer on straight-walled containers), dispense test portion to blank by slowly depressing plunger to stop (mechanical pipettor) _____

3. For two (2) stop pipettors, depress plunger to second stop with tip remaining in contact with dilution blank _____

i. Keeping plate flat on bench, peel back the top adhesive film (PPAC/PPCC/ PPEC/PPCCHV/PPECHV/PPCCCD/PPECCD/PPCCHVCD/PPECHVCD) to fully expose medium. Deposit 1 mL (PPAC/PPCC/PPEC/PPCCCD/PPECCD) or 5 mL

(PPECHV/PPCCHV/PPCCHVCD/PPECHVCD) of sample or dilution, keeping
plate flat and pipet nearly vertical above center of plate _____

1. Rapidly release sample or dilution portion within 1-3 seconds vertically onto the center or just above the center of the plate with tip slightly above
but not in contact with medium by slowly depressing plunger completely _____

a. If pipettor has two (2) stops, depress plunger to second stop _____

b. Do not touch off pipettor tip(s) on plates _____

c. Optionally, deposit samples with pipettor capable of making a 1:10 dilution in the tip _____

d. If necessary to fully wet dry medium, immediately lift plate from table and gently rotate plate to get sample across dry medium. Place plate back on table. _____

2. PPAC/PPCC/PPEC/PPCCHV/PPECHV/ PPCCCD/PPECCD/PPCCHVCD/PPECHVCD – Replace the adhesive film onto
base preventing wrinkles. Apply pressure around perimeter to seal _____

j. Leave plates undisturbed for gel solidification: _____

1. 10 sec for PPAC/PPCC/PPEC/PPCCCD/PPECCD _____

2. 1 min for PPCCHV/PPECHV/PPCCHVCD/PPECHVCD _____

k. Discard tips into disinfectant OR dispose into biohazard bags or containers to be sterilized (using this method of disposal does not require placing into disinfectant first) _____

11. Samples other than milk _____

a. Weigh 11 g aseptically into a 99 mL dilution blank heated to 40-45°C _____

12. Dry Milk Product Samples _____

a. Weigh 11 g aseptically into a 99 mL dilution blank heated to 40-45°C _____

b. Wet sample completely with gentle inversions _____

c. Let soak a minimum of 2 min; shake 25 times in 7 sec with a 1 foot movement,
use within 3 min of agitation _____

INCUBATION

13. Incubating Peel Plate Plates (see CP item 15) _____

a. Stack plates in horizontal position, clear side up _____

1. PPAC/PPCC/PPEC/PPCCCD/PPECCD – no more than 20 high _____

2. PPCCHV/PPECHV/PPCCHVCD/PPECHVCD – no more than 12 high _____

b. Incubate within 10 min _____

1. PPAC for 48±3 hours at 32±1°C _____

2. PPCC/PPEC/PPCCCD/PPECCD and PPCCHV/PPECHV/PPCCHVCD/PPECHVCD for 24±2 hours at 32±1°C; except when testing with bisulfite diluent, incubate 48±3 hours _____

COUNTING COLONIES

14. Counting Aids (see CP item 16) _____

a. Count colonies with aid of magnification under uniform and properly controlled artificial illumination _____

b. Hand tally (see CP item 17) _____

c. Optionally, count using approved Charm Peel Plate Counter (CPPC) _____

1. Test calibration prior to the start of and at the end of reading test plates _____

a. Store Calibrators in a clean, dry container, protected from light _____

b. Place Low calibrator in CPPC plate nest, clear side up so that plate feet seat into position. Follow prompts to count, remove and place High Calibrator to count _____

c. Low calibrator and High calibrator produce results in expected ranges _____

1. If insertion of a calibrator results in a placement error message,

remove and re-insert _____

2. If calibrators are out of range, do not proceed**;** seek technical assistance _____

2. Sort plates by type and matrix; then select test channel PPAC or PPCC/ PPEC and appropriate matrix _____

a. An administrator may create a new channel or matrix; refer to Manufacturer's instructions. _____

b. Rehydrate a fresh Peel Plate with appropriately diluted matrix (this plate is not to be incubated) and use as a background for new channel setup (refer to CPPC equipment manual). Press Background button on Admin tab and accept as the background image. _____

3. Examine each test plate visually prior to placing into the CPPC_____

a. For atypical plates; spreader colonies, confluent growth, excessive growth around edge of plate, etc., do not count with CPPC, record as appropriate using items 15 & 16 _____

4. Place Peel Plate in platform, adhesive film down and clear side up, seating feet into the CPPC plate nest _____

5. Enter Sample ID and press Count/Accept _____

6. Review the count/image _____

a. If count does not appear to agree with visual inspection, click on image to review counted colonies and to allow for a manual adjusted count _____

1. The CPPC count may be corrected by overwriting the count with the visual count. In the automatically recorded result, M

precedes the manual count and the CPPC count appears in parenthesis _____

2. Dilution factor and Peel Plate lots and expiration may also be changed on the edit table _____

b. Manual count prompt to count plate will automatically appear if large colonies, spreaders or TNTC counts are detected. Press OK and edit table appears for corrections, item 14.c.6. a. _____

c. Record count result by placing a next plate to be counted into plate nest and pressing Accept Count/Next button _____

7. Repeat steps 14.c.2-4, or 14.c.3-4 if same test and matrix. Previous count and manual edits are accepted, recorded and placed in memory _____

8. Results and images may be downloaded as .csv. and .pdf files. Results may also be printed. Refer to manufacturer's instructions _____

9. Maintain records _____

15. Counting, Recording and Computing Aerobic Count, PPAC _____

a. After incubation count all colonies on selected plates _____

b. Where impossible to count at once, store plates at 0.0-4.5°C for not longer than 24 hours (avoid as a routine practice) _____

c. Record results of sterility and control tests _____

d. Record dilutions used and number of colonies on each plate counted _____

e. When possible, select spreader colony free plates with 25-250 colonies and count all red colonies _____

1. Use higher magnification if necessary to distinguish colonies from foreign matter _____

2. Examine edge of plates for colonies _____

3. Count all colonies stained various shades of red _____

f. If consecutive plates yield 25-250 colonies, count all colonies on plates from both dilutions _____

g. Spreader colonies or plates with gel liquefaction _____

1. Count colonies on representative portion only when colonies are well distributed and area covered, repressed or liquefied colonies do not exceed 25% of plate _____

2. Do not count if repressed growth area or gel liquefaction >25% of plate area _____

3. When spreader colonies must be counted, count each dark spot within the spread growth as a single colony _____

4. Count chains/spreader colonies from separate sources as separate colonies _____

5. If 5% of plates are more than 25% liquefied or covered by spreader colonies, take immediate steps to eliminate and resolve problem _____

h. If there is no plate yielding 25-250 colonies, use plate having nearest to 250 colonies _____

i. If plates from all dilutions exceed 250 colonies, estimate see item 18.a.3. _____

j. If plates from all dilutions yield < 25 colonies each, record actual number in lowest dilution _____

k. If all plates from a sample show no colonies, record count as 0 _____

l. Multiply number of colonies (or estimated number if necessary) by the reciprocal of the dilution _____

1. If consecutive dilutions yield 25-250 colonies, compute count using formula below _____

$N = \Sigma C/[(1 \times n1) + (0.1 \times n2)]d$
Where, N = number of colonies per milliliter or gram
ΣC = sum of all colonies on all plates counted
n1 = number of plates in lower dilution counted
n2 = number of plates in next highest dilution counted
d = dilution from which the first counts were obtained

Example: 1:100 = 244 colonies 1:1,000 = 28 colonies
$N = (244 + 28)/ [(1 \times 1) + (0.1 \times 1)]0.01$

= 272/[1.1]0.01
= 272/0.011
= 24,727 [25,000 (reported)]

Note: In the NCIMS Program the denominator will always be 0.11 for 1:10 dilutions and 0.011 for 1:100 dilutions

16. Counting, Recording and Computing Total Coliform, PPEC/PPCC/PPCCCD/PPECCD and PPECHV/PPCCHV/PPCCHVCD/PPECHVCD _____

a. After incubation count all colonies on selected plates _____

b. Where impossible to count at once, store plates at 0.0-4.5°C for not longer than 24 hours (avoid as a routine practice) _____

c. Count all colonies regardless of color or size. Red colonies are coliform producing galactosidase while blue/purple and black colonies are coliform producing the enzymes galactosidase and glucuronidase. (No further confirmation is required) _____

1. Cultured products containing LAB, e.g. yogurt, may present a red background; count distinct darker red and blue/purple colonies after 24±2 or, 48±3 hours if using bisulfite diluent, as coliform _____

d. If no colonies appear on plate(s), record count as 0 _____

e. If there are 1-154 colonies on a plate, record number counted _____

f. If > 154 colonies develop on highest dilution plate, record number as > 150 _____

g. When multiple plates of a dilution are used (items 4.a.2 and 4.a.3), sum counts of the plates _____

h. Multiply number of colonies (or estimated number if necessary) by the reciprocal of the dilution _____

17. Identifying Counting Errors _____

a. Perform monthly counting for PPAC _____

1. With 3 or more analysts, use the RpSm method (see current SMEDP); maintain records _____

2. With two analysts, comparative counts agree within < 10%; maintain

records _____

3. If only one analyst, replicate counts agree within 8% of one another; maintain records _____

b. If using an approved Charm Peel Plate Counter (CPPC, item 14.c) analysts must perform monthly visual counts comparing to CPPC results (CPPC = one analyst) using a plate in the countable range _____

1. If only one analyst, count must be ≤ 10% between visual and the CPPC result; maintain records _____

2. With two or more analysts, use the RpSm method (see current SMEDP); using the CPPC result as an analyst count; maintain records _____

REPORTING

18. Reporting (see CP item 34.b.2.d) _____
[When samples are demonstrated to contain inhibitors, no bacteria counts are reported; report as positive for inhibitors or growth inhibitors (GI)]

a. Aerobic Count, PPAC _____

1. Report computed count as Peel Plate Aerobic Count/mL or /g (PPAC/mL or PPAC/g) when taken from plate(s) in the 25-250 range _____

2. Report PPAC plate counts of 0 to 24 as < 25 times the reciprocal of the dilution and report as Estimated PPAC (EPPAC) _____

3. When colonies exceed 30 per cm.sq., compute count by multiplying count in representative 1 sq.cm, or average count in 5 representative squares, x dilution factor x sq. area of plate (1 mL plate=17.4 sq. cm), and report as > computed count Estimated (EPPAC) _____

4. If computed counts from PPAC plates >250, report as Estimated PPAC (EPPAC) _____

5. If for any reason, an entire plate is not counted, the computed count is reported as Estimated (EPPAC) _____

b. Total Coliform, PPCC/PPEC/<u>PPCCCD/PPECCD</u> _____

1. Report count as Peel Plate Coliform Count/mL or /g (PPCC/PPEC/<u>PPCCCD/PPECCD</u> /mL
or ~~PPCC/PPEC/mL~~ /g) when taken from plate(s) in the 1-154 range
_____

a. For chocolate milk 1:2 dilutions plated in duplicate, sum results and report as coliform/mL (PPCC or PPEC or PPCCCD or PPECCD/mL) _____

2. If no colonies appear on coliform plates, report as < 1 times the reciprocal of the dilution and report as Estimated (EPPEC or EPPCC or EPPCCCD or EPPECCD) _____

3. Counts from coliform plates > 154 are reported as > 150 Estimated Peel Plate Coliform Count (EPPCC or EPPEC or EPPCCCD or EPPECCD)

_____

c. High Sensitivity Total Coliform, PPCCHV/PPECHV/PPCCHVCD/PPECHVCD

_____

1. Report count for 1:5 dilution in a single plate or 1:10 dilution in duplicate plates, sum results and report as coliform/mL or g (PPCCHV/PPECHV/PPCCHVCD/PPECHVCD) _____

2. If for any reason, an entire plate is not counted, the computed count is reported as Estimated (EPPCCHV/EPPECHV/EPPCCHVCD/EPPECHVCD) _____

d. Report only first two left-hand digits _____

1. If the third digit is 5 round the second number using the following rules

_____

a. When the second digit is odd round up (odd up, 135 to 140)

_____

b. When the second digit is even round down (even down, 125 to 120) _____

e. If all plates from a sample have excessive spreader colony growth or liquefiers, report as spreaders (SPR) or liquefiers (LIQ) _____

f. If a laboratory accident renders a plate uncountable, report as laboratory accident (LA)

The following errors have been identified in the 2017 PMO. These errors were not present in IMS-a-51 and likely were a direct cause of converting the 2017 PMO into a 508 compliant document. FDA will be making the following editorial corrections in the 2019 PMO.

2017 PMO
Page: 47
Correction: The word “outer” was misspelled.

> “5. Where flush toilets are used, doors to toilet rooms are tight and self-closing. All ~~out-er~~ outer openings in toilet rooms shall be screened or otherwise protected against the entrance of insects…”

2017 PMO
Page:74
Correction: The word “cleaning” was omitted.

> Otherwise, storage tanks shall be cleaned when emptied and shall be emptied at least every seventy-two (72) hours. Records shall be available to verify that milk storage in these tanks does not exceed seventy-two (72) hours. “These cleaning records shall be:”

2017 PMO
Pages: 87-88
Correction: Numbering is incorrect.

This section does not require separate raw and pasteurized CIP cleaning systems.
~~1~~ 3. This Section does not require separate raw and pasteurized CIP cleaning systems.
Pasteurized re-circulation lines, divert lines, and leak-detect lines connecting to the constant- level tank shall be designed so that there is an air gap between the termination of these pipelines and the raw milk or milk product overflow level. This air gap shall be equivalent to at least two (2) times the diameter of the largest of these pipelines. For purposes of this Section, an overflow is defined as the flood rim of the constant-level tank or any unrestricted opening below the flood rim of the constant-level tank which is large enough that it is at least equivalent to two (2) times the diameter of the largest of these pipelines.
~~2~~ 4. All milk and/or milk products that have overflowed, leaked, been spilled or improperly handled are discarded. Milk and/or milk products drained from processing equipment at the end of a run, collected from a defoamer system, and milk or milk product solids rinsed from equipment, containers or pipelines shall be repasteurized only if such milk or milk products are handled in a sanitary manner and maintained at 7ºC (45ºF) or less. When the handling and/or cooling of such milk and/or milk products are not in compliance with this requirement, they shall be discarded. Milk and/or milk products from damaged, punctured or otherwise contaminated containers or product from out-of-code containers shall not be repasteurized for Grade “A” use.
~~3~~ 5. Means are provided to prevent contamination of milk and/or milk products, containers, utensils and equipment by drippings, spillage and splash from overhead piping, platforms or mezzanines.
~~4~~ 6. The processing of foods and/or drinks other than Grade “A” milk and/or milk products are performed to preclude the contamination of such milk and/or milk products.
~~5~~ 7. No product is handled in the milk plant that may create a public health hazard. Permission to handle products other than those defined in Section 1. of this *Ordinance* or to conduct operations in equipment or rooms, other than those for which they are designated, should be provisional and subject to revocation if found objectionable.

~~6~~ 8. In no case shall pasteurized milk or milk products, be standardized with unpasteurized milk or milk products, unless the standardized milk or milk product is subsequently pasteurized.
~~7~~ 9. Reconstituted or recombined milk and milk products shall be pasteurized after reconstitution or recombining of all ingredients.
~~8~~ 10. Raw milk or milk product-to-water-to-pasteurized milk or milk product plate or double/ triple tube type heat exchangers may be used for heat-exchange purposes, other than legal pasteurization, when constructed, installed and operated in accordance with the following:

2017 PMO
Page: 119
Correction: Ordinance misspelled.

ADMINISTRATIVE PROCEDURES
This Item is deemed to be satisfied when:
1. All milk and milk products, including concentrated (condensed) milk and milk products, are bottled and packaged at the milk plant where final pasteurization is performed. Such bottling and packaging shall be done without undue delay following final pasteurization.
2. All bottling or packaging is done on approved mechanical equipment. The term "approved mechanical equipment" shall not be interpreted to exclude manually operated machinery, but is interpreted to exclude methods in which the bottling and capping devices are not integral within the same system.
3. All pipes, connections, defoaming devices and similar appurtenances shall comply with Items 10p and 11p of this ~~*Odinance*~~ Ordinance. Milk and milk products from continuous defoamers are not returned directly to the filler bowl.

2017 PMO
Page: 352
Correction: Extra number 7.

6. **Records Maintained on Computers:** The maintenance of records on computers, in accordance with the requirements cited above, is acceptable.
~~7.~~

2017 PMO
Page: 360
Correction: Missing text.

REPORTING AND FARM TRACE BACK:

Upon official notification to the Regulatory Agency and milk producer of a violative individual producer's milk, further farm pickups (further farm pickups refers to milk still in farm bulk milk tank(s) and/or silo(s) or milk that is in the process of being loaded onto a bulk milk pickup tanker) by bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and/or farm use of the violative individual producer's milk shall be immediately discontinued, until such time, that subsequent tests are no longer positive for drug residues. Any bulk milk pickup tanker(s) previously received at a milk plant, receiving station, or transfer station, or is in-transit prior to the official notification to the Regulatory Agency and milk

producer, shall not be deemed violative provided the bulk milk pickup tanker(s) test negative in accordance with Appendix N.

2017 PMO
Page: 363
Correction: Missing text.

Permit Suspension and the Prevention of the Sale of Milk: Any time milk is found to test as a confirmed positive using an approved test method, the Regulatory Agency shall immediately suspend the producer's Grade "A" permit or equally effective measures shall be taken to prevent the sale of milk containing drug residues. Upon official notification to the Regulatory Agency and milk producer of a confirmed positive, future farm pickups (future farm pickups refers to milk still in farm bulk milk tank(s) and/or silo(s) or milk that is in the process of being loaded onto a bulk milk pickup tanker) by bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and/or farm use of the violative individual producer's milk are prohibited until subsequent testing reveals the milk is free of drug residue. Any bulk milk pickup tanker(s) previously received at a milk plant, receiving station, or transfer station, or is in-transit prior to the official notification to the Regulatory Agency and milk producer, shall not be deemed violative provided the bulk milk pickup tanker(s) test negative in accordance with Appendix N.

2017 PMO
Page: 375
Correction: Missing text.

… The Regulatory Agency shall be notified of the producer trace-back results. The verified screening positive milk is removed from the human and/or animal food chain, which is managed between the user of the test method, the milk supplier and the dairy producer. Future pickups (future pickups refers to milk still in farm bulk milk tank(s) and/or silo(s) or milk that is in the process of being loaded onto a bulk milk pickup tanker) …

2017 PMO
Page: 378
Correction: Missing text.

Care shall be taken when reprocessing reclaimed milk and/or milk products so vitamin A levels do not exceed the label claims by more than 150% (3000 IU (900 mcg) per quart) and vitamin D levels do not exceed 840 IU (21 mcg) per quart.

2017 PMO
Page: 379
Correction: Missing text.

21 CFR 130.10-*Requirements for foods named by use of a nutrient content claim and a standardized term* (b)-*Nutrient addition* states: "Nutrients shall be added to the food to restore nutrient levels so that the product is not nutritionally inferior, as defined in 101.3(e)(4) of this

chapter, to the standardized food as defined in parts 131 through 169 of this chapter." The addition of nutrients shall be reflected in the ingredient statement. Therefore, vitamin A shall be added to milk and milk products from which fat has been removed; such as, reduced fat and nonfat/skim milk and milk products, in an amount necessary to replace the amount of vitamin A lost in the removal of fat.

In addition, the following forms have been updated and the updated forms will be included in the 2019 MMSR:

Page 48 – 2359i Interstate Milk Shipper's Report - (Box was added for App T. compliance)
Page 49 – back page of pg. 48 above was also updated
Page 50 – 2359i Interstate Milk Shipper's Report, Electronic Submission - (Box was added for App T.)
Page 52 – 2359m Milk Plant, Receiving Station Or Transfer Station NCIMS HACCP System Audit Report (Box 10, letter "I" – Items 1-4" were added in 2017 but wasn't updated)
Page 71 and 73 – 2359j (Page 2) and 2359k (Page 1) – Corrected mathematical errors
Page 77 – 2359i Interstate Milk Shipper's Report (Box was added for App T. and updated lab codes)
Page 78 – 2359i Interstate Milk Shipper's Report (back page of newer form was added)
Page 79 – 2359i Interstate Milk Shipper's Report, ELECTRONIC SUBMISSION (Box was added for App T. and lab codes were updated)
Page 81 – 2359m Milk Plant, Receiving Station Or Transfer Station NCIMS HACCP System Audit Report (Box 10, letter "I" – Items 1-4" were added in 2017 but wasn't updated)
Page 84 – 2359i Interstate Milk Shipper's Report (Box was added for App T. and new lab codes designations was updated)
Page 85 - 2359i Interstate Milk Shipper's Report (page #2 of form)

All Proposals that make changes to the NCIMS documents will be incorporated into the next edition of the affected document as they are updated. Copies of this memorandum are enclosed for distribution to FDA Milk Specialists, Milk Regulatory/Rating Agencies, Laboratory Evaluation Officers, and Milk Sanitation Rating Officers. This memorandum should be widely distributed to representatives of the milk industry and other interested parties and will be available on the FDA Website at www.fda.gov at a later date.

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

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